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The West Midlands ActiVe lifestyle and healthy Eating in School children (WAVES) study: a cluster randomised controlled trial testing the clinical effectiveness and cost-effectiveness of a multifaceted obesity prevention intervention programme targeted at children aged 6–7 years

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<sup>1</sup>Institute of Applied Health Research, University of Birmingham, Birmingham, UK <sup>2</sup>Institute of Cancer and Genomic Sciences, University of Birmingham, Birmingham, UK

<sup>3</sup>Edinburgh Migration, Ethnicity and Health Research Group, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK

<sup>4</sup>Faculty of Mathematics and Physical Sciences, School of Food Science and Nutrition, University of Leeds, Leeds, UK

<sup>5</sup>Clinical Trials Unit, University of Warwick, Warwick, UK

<sup>6</sup>School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Birmingham, UK

<sup>7</sup>Medical Research Council (MRC) Epidemiology Unit, Cambridge, UK

<sup>8</sup>Norwegian School of Sport Sciences, Oslo, Norway

<sup>9</sup>Birmingham Community Healthcare NHS Trust, Birmingham, UK

<sup>10</sup>Services for Education, Birmingham, UK

\*Corresponding author

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## Abstract

The West Midlands ActiVe lifestyle and healthy Eating in School children (WAVES) study: a cluster randomised controlled trial testing the clinical effectiveness and cost-effectiveness of a multifaceted obesity prevention intervention programme targeted at children aged 6–7 years

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 <sup>1</sup>Institute of Applied Health Research, University of Birmingham, Birmingham, UK
<sup>2</sup>Institute of Cancer and Genomic Sciences, University of Birmingham, Birmingham, UK
<sup>3</sup>Edinburgh Migration, Ethnicity and Health Research Group, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK
<sup>4</sup>Faculty of Mathematics and Physical Sciences, School of Food Science and Nutrition, University of Leeds, Leeds, UK
<sup>5</sup>Clinical Trials Unit, University of Warwick, Warwick, UK
<sup>6</sup>School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Birmingham, UK
<sup>7</sup>Medical Research Council (MRC) Epidemiology Unit, Cambridge, UK
<sup>8</sup>Norwegian School of Sport Sciences, Oslo, Norway
<sup>9</sup>Birmingham Community Healthcare NHS Trust, Birmingham, UK
<sup>10</sup>Services for Education, Birmingham, UK

\*Corresponding author p.adab@bham.ac.uk

**Background:** Systematic reviews suggest that school-based interventions can be effective in preventing childhood obesity, but better-designed trials are needed that consider costs, process, equity, potential harms and longer-term outcomes.

**Objective:** To assess the clinical effectiveness and cost-effectiveness of the WAVES (West Midlands ActiVe lifestyle and healthy Eating in School children) study intervention, compared with usual practice, in preventing obesity among primary school children.

**Design:** A cluster randomised controlled trial, split across two groups, which were randomised using a blocked balancing algorithm. Schools/participants could not be blinded to trial arm. Measurement staff were blind to allocation arm as far as possible.

Setting: Primary schools, West Midlands, UK.

**Participants:** Schools within a 35-mile radius of the study centre and all year 1 pupils (aged 5–6 years) were eligible. Schools with a higher proportion of pupils from minority ethnic populations were oversampled to enable subgroup analyses.

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**Interventions:** The 12-month intervention encouraged healthy eating/physical activity (PA) by (1) helping teachers to provide 30 minutes of additional daily PA, (2) promoting 'Villa Vitality' (interactive healthy lifestyles learning, in an inspirational setting), (3) running school-based healthy cooking skills/education workshops for parents and children and (4) highlighting information to families with regard to local PA opportunities.

**Main outcome measures:** The primary outcomes were the difference in body mass index z-scores (BMI-zs) between arms (adjusted for baseline body mass index) at 3 and 18 months post intervention (clinical outcome), and cost per quality-adjusted life-year (QALY) (cost-effectiveness outcome). The secondary outcomes were further anthropometric, dietary, PA and psychological measurements, and the difference in BMI-z between arms at 27 months post intervention in a subset of schools.

**Results:** Two groups of schools were randomised: 27 in 2011 (n = 650 pupils) [group 1 (G1)] and another 27 in 2012 (n = 817 pupils) [group 2 (G2)]. Primary outcome data were available at first follow-up (n = 1249 pupils) and second follow-up (n = 1145 pupils) from 53 schools. The mean difference (MD) in BMI-z between the control and intervention arms was -0.075 [95% confidence interval (CI) -0.183 to 0.033] and -0.027 (95% CI -0.137 to 0.083) at 3 and 18 months post intervention, respectively. The main analyses showed no evidence of between-arm differences for any secondary outcomes. Third follow-up included data on 467 pupils from 27 G1 schools, and showed a statistically significant difference in BMI-z (MD -0.20, 95% CI -0.40 to -0.01). The mean cost of the intervention was £266.35 per consented child (£155.53 per child receiving the intervention). The incremental cost-effectiveness ratio associated with the base case was £46,083 per QALY (best case £26,804 per QALY), suggesting that the intervention was not cost-effective.

**Limitations:** The presence of baseline primary outcome imbalance between the arms, and interschool variation in fidelity of intervention delivery.

**Conclusions:** The primary analyses show no evidence of clinical effectiveness or cost-effectiveness of the WAVES study intervention. A post hoc analysis, driven by findings at third follow-up, suggests a possible intervention effect, which could have been attenuated by baseline imbalances. There was no evidence of an intervention effect on measures of diet or PA and no evidence of harm.

**Future work:** A realist evidence synthesis could provide insights into contextual factors and strategies for future interventions. School-based interventions need to be integrated within a wider societal framework and supported by upstream interventions.

Trial registration: Current Controlled Trials ISRCTN97000586.

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# List of abbreviations

AVFC	Aston Villa Football Club	IQR	interquartile range
BMI	body mass index	MD	mean difference
BMI-z	body mass index z-score	MRC	Medical Research Council
CADET	Child And Diet Evaluation Tool	MVPA	moderate to vigorous physical activity
CD	compact disc	MW7	McCance and Widdowson's The
CEAC	cost-effectiveness acceptability curve		Composition of Foods: Seventh Summary Edition
CHU9D	Child Health Utility 9D	NBR	net benefit regression
CI	confidence interval	NDNS	National Diet and Nutrition Survey
CONSORT	Consolidated Standards of Reporting Trials	NDNS-RP	National Diet and Nutrition Survey Rolling Programme
CUA	cost–utility analysis	NICE	National Institute for Health and Care Excellence
DVD	digital versatile disc	PA	physical activity
FU1	follow-up 1	PE	physical education
FU2	follow-up 2	PedsQL	Paediatric Quality of Life Inventory
FU3	follow-up 3	QALY	quality-adjusted life-year
G1	group 1	RD	risk difference
G2	group 2	SD	standard deviation
HRQL	health-related quality of life	SE	standard error
ICC	intracluster correlation coefficient	TA	teaching assistant
ICER	incremental cost-effectiveness ratio	WTP	willingness to pay
IMD	Index of Multiple Deprivation		

## **Plain English summary**

Excess weight in children is associated with health, emotional and social problems. Schools offer an opportunity to promote healthy lifestyles.

This study tested whether or not a programme of activities could prevent excess weight gain in primary school children. Fifty-four schools in the West Midlands participated, with 1397 year 1 pupils (aged 5–6 years) being involved in study measurements. The WAVES (West Midlands ActiVe lifestyle and healthy Eating in School children) study healthy lifestyle programme was delivered over the next school year to children in 26 of the schools. The 1-year programme included:

- helping teachers to provide opportunities for an additional 30 minutes of physical activity (PA) in the school day
- participation in the 'Villa Vitality' programme (interactive learning led by Aston Villa Football Club with practical opportunities for PA and healthy eating)
- termly healthy cooking skills and education workshops for parents and children
- information to families signposting local PA opportunities.

The remaining 28 schools continued with their usual activities.

We assessed height, weight and other measures of body fat in all participating children. We also measured the children's diet, PA levels and well-being. We took these measures before programme delivery, and again 3, 18 and 27 months after the end of the programme.

Overall, we found no major difference in any measurements between children in schools with and children in schools without the WAVES study programme. The programme was not cost-effective. However, there were no safety concerns, the programme was well received by schools and families and it was perceived to have wider benefits.

# **Scientific summary**

### Background

Childhood obesity is associated with adverse health and psychosocial outcomes, which continue into adulthood. Obesity prevalence doubles during the primary school years, suggesting that this period presents an important opportunity for delivering interventions aimed at preventing obesity. Systematic reviews show some evidence that school-based multicomponent interventions could effectively reduce obesity prevalence, but methodological weaknesses in existing studies suggest a need for further trials with a stronger design, reporting longer-term outcomes. Other limitations of previous trials include a lack of detailed process and implementation measures, the infrequent consideration of differential intervention effects in subgroups, the neglect of potential harms and the absence of cost-effectiveness analyses.

## **Objectives**

- 1. How effective is the theory-based WAVES (West Midlands ActiVe lifestyle and healthy Eating in School children) intervention package, delivered at school level, in reducing adiposity in children, compared with usual practice?
- 2. For how long do any observed effects persist after active intervention has ceased?
- 3. What is the incremental cost-effectiveness ratio (ICER) of supplying the WAVES study obesity prevention intervention?
- 4. How effective is the intervention package at improving diet and increasing physical activity (PA), compared with usual practice?
- 5. What is the effect of the intervention on quality of life and body image dissatisfaction?
- 6. Does the intervention work differently by sex, ethnicity, level of deprivation or baseline weight status?

### Methods

#### Design

The WAVES study was a cluster randomised controlled study, split across two randomisation groups, with an economic evaluation.

#### Setting

State primary schools in the West Midlands, UK, including pupils from a range of backgrounds, varying in terms of ethnicity, socioeconomic status and geographical location.

#### **Participants**

Eligible schools were within 35 miles of the University of Birmingham, included children in school years 1–5 (aged 5–10 years), had a minimum class size of 17 and were not in 'special measures'. Schools with a higher proportion of pupils from minority ethnic populations (South Asian and Black African Caribbean) were oversampled (ratio 3 : 1) to enable subgroup analyses. In participating schools, all year 1 pupils (aged 5–6 years) were eligible. Parents provided consent (mainly 'opt in') and children gave verbal assent for the study measurements.

#### Baseline assessment

Baseline data were obtained at the end of year 1 (pupils aged 5–6 years) prior to randomisation. Data were collected by the direct assessment of participating children in school by trained researchers using validated instruments and standard protocols, as well as from parent questionnaires. The primary

measure was assessment of height and weight, used to derive body mass index z-score (BMI-z). Other anthropometric assessment included measures of waist circumference, skinfold thickness (at five sites) and body fat percentage by bioelectrical impedance. Dietary intake was assessed using the Child And Diet Evaluation Tool 24-hour tick list, and PA was assessed over 5 days using Actiheart® monitors (CamNtech Ltd, Papworth, UK). Psychosocial measures included quality of life (Pediatric Quality of Life inventory), social acceptance (KIDSCREEN-52) and body image dissatisfaction. Preference-based utility was assessed using the Child Health Utility 9D (CHU9D) measure (© University of Sheffield 2008). Data on pupils' date of birth, sex, ethnicity and postcode were obtained from the parent questionnaire or school records.

#### Randomisation

A blocked balancing algorithm was used to randomise participating schools to either the intervention or the comparator arm. The algorithm randomly selected one of a number of allocation designs that minimised the imbalance between a set of prespecified covariate means (percentage of pupils who were eligible for free school meals; percentage of South Asian, black African Caribbean, white or other ethnic group background; school size). The first 27 schools [group 1 (G1) schools] were randomised within the first block, and 1 year later the remaining 27 schools [group 2 (G2) schools] were randomised within the second block, conditioning the balancing algorithm for the first block allocations.

#### Intervention and comparator

The 12-month intervention, targeting the school and family environment, encouraged healthy eating and PA through four inter-related components:

- 1. Helping teachers to provide opportunities for additional moderate to vigorous physical activity (MVPA) during the school day (aiming for an additional 30 minutes per day).
- Participation in the 'Villa Vitality' programme, delivered through an iconic sport institution (Aston Villa Football Club) over 6 weeks. This programme promotes healthy lifestyles, in particular increased PA and healthy eating, and includes practical opportunities for PA and cooking skills, interactive learning and home-based activities.
- 3. Termly (three over the school year) healthy cooking workshops in school time for parents and children, focusing on healthy eating (with the key messages of increasing fruit, vegetable and fibre intake, and reducing fat and sugar intake) and practical skills.
- 4. Two information sheets to families signposting local PA opportunities.

Schools allocated to the comparator arm continued with their usual healthy lifestyle activities.

#### **Outcome measurements**

The primary outcomes were the difference in BMI-z between the trial arms at 3 and 18 months post intervention (clinical outcome), and the cost per quality-adjusted life-year (QALY) (cost-effectiveness outcome). The secondary outcomes included further anthropometric measurements; dietary, PA and psychological assessment; and difference in BMI-z between arms at 27 months post intervention in G1 schools. Outcome assessments were undertaken at 3 months (follow-up 1) and 18 months (follow-up 2) after the end of the intervention period (pupils aged 7–8 and 8–9 years). For half of the participating schools (G1 schools), children were further assessed 27 months (follow-up 3) after the end of the intervention (pupils aged 9–10 years).

#### Sample size

The sample size calculation was based on the primary outcome (BMI-z), taking into account repeated measures (estimated correlation between before and after measures = 0.9), varying cluster size (assuming mean cluster size of 25, standard deviation = 23) and probable estimates of the intracluster correlation coefficient (0–0.04). In order to detect a difference of a 0.25 BMI-z between intervention and comparator groups with 90% power, a two-sided alpha level of 0.05 and an estimated pupil dropout rate of 20%, a follow-up sample of 1000 children from 50 schools was needed. Allowing for school dropout of 8%, we recruited 54 schools to take part in the study.

## **Economic evaluation**

The cost-effectiveness of the intervention compared with no intervention was assessed from a public sector perspective using a trial-based cost-utility analysis. Costs were based on cluster-level resource use for intervention delivery, and the primary outcome was QALYs using CHU9D at 18 months post intervention. In the base case, missing data were imputed to estimate the incremental cost per QALY gain. A secondary analysis was based on cost per obesity case prevented. All costs were expressed in the year 2014. Missing data were addressed using multiple imputation methods and the uncertainty surrounding the cost-effectiveness estimates was examined through the use of the net benefit regression framework.

## Results

Twenty-seven schools (n = 650) were randomised in 2011 (G1), and another 27 (n = 817) were randomised in 2012 (G2). At first follow-up (3 months) and second follow-up (18 months) for the primary outcome, data were available for 1249 and 1145 pupils, respectively, from 53 schools. The mean difference (MD) in BMI-z between control and intervention arms was -0.075 [95% confidence interval (CI) -0.183 to 0.033] at 3 months and -0.027 (95% CI -0.137 to 0.083) at 18 months post intervention. There was no significant difference in any of the secondary outcomes between the arms for the main analyses for the first two follow-up periods.

The third follow-up (27 months) included data on 467 pupils from 27 G1 schools and showed a statistically significant difference in BMI-z in favour of the intervention group (MD –0.20, 95% CI –0.40 to –0.01, in partially adjusted models; MD –0.18, 95% CI –0.34 to –0.02, in fully adjusted models). Post hoc analysis in response to this finding showed heterogeneity between G1 and G2 schools, with a significant difference in mean BMI-z at baseline. School group-specific analyses showed an intervention effect in G1 schools, at 3 and 18 months, of a similar size to that observed at 27 months. However, there was no significant effect in G2 schools. There was no statistically significant intervention effect for the other anthropometric measures, although the direction of effect for all, apart from the sum of four skinfolds, favoured the intervention. There was no difference between groups in terms of quality of life, self-perception or body image dissatisfaction, suggesting that there was no evidence of harm from the intervention.

Subgroup analyses showed no evidence of heterogeneity of effects by sex, ethnicity, household deprivation or baseline weight status. Sensitivity analyses did not alter the findings.

## Results of economic analysis

For the primary economic analysis, the mean cost of the intervention was £155.53 per child, taking account of all of those who received the intervention, or £266.35 per child when including only those who were included in measurements. The incremental cost-effectiveness of the intervention compared with no intervention was £46,083 per QALY in the base case (including only children with measurements) or £26,804 per QALY if we assume that the sample with measurements was representative of the wider population who received the intervention. There is much uncertainty around both estimates because of the lack of significant intervention effect in terms of QALY gains. The intervention is, therefore, not cost-effective using National Institute for Health and Care Excellence-recommended willingness-to-pay threshold levels of £20,000–30,000 per QALY. It was not possible to report the secondary outcome of cost per obesity case prevented, as the primary analyses showed no evidence of effect.

## Conclusions

The primary analyses show no evidence of effectiveness of the WAVES study intervention in reducing BMI-z at 3 or 18 months. The lack of cost-effectiveness is mainly due to the lack of clinical effectiveness, which led to a high level of uncertainty around the ICERs.

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The exploratory post hoc analysis, driven by findings at third follow-up, suggests a clinically important difference in BMI-z between arms in favour of the intervention, which was sustained over 27 months in G1 schools. Baseline imbalance in the main outcome in G2 schools may have contributed to the observed group difference. This interpretation needs caution, given the absence of evidence of effectiveness in terms of behavioural outcomes.

Detailed process evaluation suggests variation in delivery and perceived impact of intervention components. The WAVES study intervention was well received and valued at various levels by schools, children and their parents. The Villa Vitality, daily PA and cooking workshop components were particularly appreciated and relatively well implemented. Given the acceptability and feasibility of delivery and the lack of evidence of harm, the last two components, which have a lower overall cost, could be taken up by schools to fulfil their mandatory functions in relation to healthy lifestyles.

### **Future work**

Schools are important settings for accessing children and their families, but are one of several levels of environments that influence behaviour. The delivery of knowledge and skills to support healthy lifestyles is one of the mandatory functions of schools and is recognised by school staff as a contributor to children's wider well-being. Future school-based interventions need to be integrated within a wider societal framework and supported by upstream interventions. This includes having supportive policies to promote social and environmental change. Interventions at multiple levels are needed to tackle the complex set of interacting factors that contribute to childhood obesity.

In terms of methodology, future cluster randomised controlled trials need to include appropriate steps to ensure a balanced allocation of intervention and control across key characteristics, to reduce the risk of chance bias.

## **Trial protocol**

The trial protocol is available at www.ncbi.nlm.nih.gov/pubmed/?term=adab+pallan+waves+protocol.

## **Trial registration**

The trial is registered as ISRCTN97000586.

### Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

## Chapter 1 Introduction

## **Epidemiology of childhood obesity**

Childhood obesity has been classed as one of the most serious public health challenges of the 21st century,<sup>1</sup> affecting around 41 million children aged < 5 years, with a projected increase to 70 million by 2025.<sup>2</sup> Children who are overweight are at a higher risk of adverse physical health,<sup>3</sup> emotional<sup>4</sup> and social<sup>5</sup> consequences during childhood. Furthermore, children who are obese, even from the age of 7 years, and irrespective of their adult weight status, are at higher risk of premature mortality in adulthood than their normal-weight counterparts.<sup>6,7</sup> There is evidence of tracking of lifestyle health behaviours from an early age, such that more than half of very overweight children become obese adults,<sup>8</sup> with a consequent increased risk of cardiometabolic and respiratory disease, as well as a higher risk of some cancers and musculoskeletal complications in adulthood.<sup>9,10</sup> This high risk of morbidity has resulted in obesity being designated a 'disease' in the USA.<sup>9</sup> The estimated cost of overweight and obesity to the UK economy was £20B (£4.2B to the UK NHS and £15.8B indirect costs) in 2007.<sup>11</sup>

In England, data from the most recent population survey showed that around one-third of children aged 2–15 years had excess weight (overweight or obese).<sup>12</sup> Annual surveillance data are also available from the National Child Measurement Programme, which undertakes measurements of height and weight in all primary school children at school entry (aged 4–5 years) and during their last year at school (aged 10–11 years). These data show that during the primary school years the proportion of children with excess weight increases from one-quarter to around one-third, and the proportion who are very overweight doubles (from 9% to 19%).<sup>13</sup> More detailed examination of these data show that certain subgroups are at higher risk. Although there is relatively little inequality in the prevalence of childhood obesity at the age of 4–5 years, during the primary school period an increasing gap in prevalence develops, with a higher increase among boys than among girls, among children of South Asian and African Caribbean ethnicity than among children of white ethnicity and among children from more deprived households than among children from less deprived households.<sup>14</sup> Longitudinal studies suggest that persistent obesity is established by the age of 11 years.<sup>15</sup>

All of the above evidence highlights the primary school age period as a critical window for preventative intervention.

### **Causes of childhood obesity**

A large number of observational studies have examined the causes of childhood obesity. A recent evidence review by the National Institute for Health and Care Excellence (NICE) summarised the modifiable behaviours that are likely to affect healthy weight maintenance and prevent weight gain in adults and children.<sup>16</sup> Although, essentially, this can be achieved by adopting healthy eating habits and increasing levels of physical activity (PA), there is no single dietary component or particular type of PA that will solely contribute to weight maintenance; rather, a combination of approaches is always needed.

Reviews of interventional studies suggest that, for weight maintenance, children should be encouraged to aim to undertake at least 60 minutes of moderate to vigorous physical activity (MVPA) over the course of each day.<sup>17</sup> In terms of the dietary components and patterns that are associated with obesity, the evidence is less consistent. Nevertheless, there is good evidence that the moderate consumption of 'Mediterranean'-style diets (higher fruit and vegetable and fibre content) and a limit on the intake of energy-dense or high-fat foods, as well as high-sugar foods and drinks, are associated with weight maintenance.<sup>16</sup> However, translating this knowledge into behaviour change is complex, as are factors influencing children's diet and PA levels.<sup>11</sup>

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### Existing research on childhood obesity prevention

Numerous systematic reviews have summarised the evidence on interventions aimed at preventing childhood obesity, the main two of which<sup>18,19</sup> [both published after the West Midlands ActiVe lifestyle and healthy Eating in School children (WAVES) trial had started] are reported in detail below.

A Cochrane review,<sup>18</sup> first published in 2001 and updated in 2005 and 2011, reviewed 55 prevention trials. These included studies in school, community, health and family settings that targeted a range of ages. Interventions were aimed at improving diet, increasing PA or a combination of the two. Studies with both short- and longer-term follow-up were included. Of the included trials, 50 were from high-income settings, including six from the UK. The majority of trials were aimed at children aged 6–12 years and were delivered in school settings. Data from a subset of 37 of the studies were combined in a meta-analysis (n = 27,946 children) and showed that, overall, these interventions were effective with a small clinical effect, reducing the body mass index z-score (BMI-z) by –0.15 units relative to the control group.

However, there was much heterogeneity in study design, types of intervention and outcome measurements, which limited the ability to draw any firm conclusions. The positive impact of interventions also varied, with some, but not all, improving diet, PA or other outcomes, and impacts being sometimes limited to just boys or just girls. Many of the included studies were of low quality, did not include sufficient sample size to assess effects on weight status and did not sufficiently report on implementation factors to allow wider adoption, and none reported on cost-effectiveness. Longer-term follow-up was also lacking. Equity of intervention, in terms of sex and ethnicity, and any adverse effects were not always assessed.

Although the review concluded that there was strong evidence of school-based interventions – particularly those targeting children aged 6–12 years – having a positive impact on weight status, there was insufficient evidence of the particular components that should be recommended or how such programmes should be implemented in a variety of settings. Commonly included intervention components that seemed to be associated with positive results included school curricula that included healthy eating and PA, increased sessions for PA in the school week, an improvement in the nutritional quality of the school food supply, supportive environments and cultures, support for teachers and parental support to encourage home activities. In terms of research needs, the review concluded that future trials need strong evaluation designs that capture process implementation, longer-term outcomes and equity of effects, and that consider potential harms and cost-effectiveness.

The second comprehensive review was undertaken by the US Agency for Healthcare Research and Quality, which included the findings of studies published up to April 2013.<sup>19,20</sup> This review included data from 147 studies, of which 115 were mainly school based, and the majority of which had been conducted in the USA within the previous 10 years. At least half of the studies reviewed demonstrated a positive effect of school-based interventions on some measure of adiposity, particularly when there was also a home component. Diet-only interventions were generally more successful than PA-only programmes. The review concluded that the evidence for an effect of school-based interventions on weight status was moderate (lower strength of evidence than the conclusions from the Cochrane review)<sup>18</sup> and that interventions were more likely to be successful if they were more intense and of longer duration, promoted environmental change as well as providing education, and targeted multiple settings (school, home and community).

Other reviews generally have similar conclusions, suggesting that interventions that target single behaviours are generally less successful,<sup>21,22</sup> whereas multicomponent interventions have more chance of having a positive impact.<sup>23,24</sup> However, conclusions are inconsistent about the duration of interventions and those intervention components that are likely to have most effect.<sup>25</sup>

In summary, although multifaceted school-based interventions have the potential to prevent weight gain and obesity in children, the results of previous studies are inconsistent and the combination of components most likely to be effective is not clear. Previous studies were not always adequately powered, the basis for
interventions was sometimes unclear, process implementation was inadequately reported and long-term outcomes were rarely assessed. A major gap is the reporting of the cost-effectiveness of interventions.

# **Aims and objectives**

In this trial, we sought to address the main methodological weaknesses identified in previous studies. The aim was to assess the clinical effectiveness and cost-effectiveness of a multifaceted, 12-month, school-based intervention aimed at preventing overweight and obesity in primary school children. The intervention was developed and refined using the framework recommended by the Medical Research Council (MRC) for complex interventions.<sup>26</sup> We included a sample size that was large enough to detect clinically significant differences in adiposity, used a range of measures of adiposity and psychosocial effects, included objective measures of PA and diet intake and incorporated a cost-effectiveness evaluation (see *Chapter 7*), a comprehensive process evaluation (see *Chapter 4*) and an assessment of longer-term effects (up to 27 months post intervention completion). As the intervention was delivered through schools, the school (cluster) was the main unit of analysis and appropriate cluster-level adjustments were made (see *Chapter 2* for a more detailed description).

The research questions were:

- 1. How effective is the theory-based WAVES study intervention package, delivered at school level, in reducing adiposity in primary school-aged children, compared with usual practice?
- 2. For how long do any observed effects persist after active intervention has ceased?
- 3. What is the incremental cost-effectiveness ratio (ICER) of supplying the WAVES study obesity prevention intervention?
- 4. How effective is the intervention package at improving diet and increasing PA, compared with usual practice?
- 5. What is the effect of the intervention on quality of life and body image dissatisfaction?
- 6. Does the intervention work differently by sex, ethnicity, level of deprivation or baseline weight status?

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# Chapter 2 Methods

# **Trial design**

The WAVES study was a cluster randomised controlled trial evaluating the clinical effectiveness and cost-effectiveness of an obesity prevention intervention programme delivered to primary school children in year 2 (aged 6–7 years). The unit of randomisation was the school. A 1 : 1 (intervention-to-control) allocation ratio was applied using a blocked balancing algorithm for the randomisation procedure.

# Participants

#### **Clusters (schools)**

All state-maintained primary schools in the West Midlands region of the UK located within a 50-km radius of the study co-ordinating centre and including school years 1–5 (school years in which measurements were scheduled to take place) were eligible for inclusion. Schools were excluded that, at the point of recruitment, were in special measures (a status applied by the Office for Standards of Education in England to schools failing to give their pupils an acceptable standard of education, and the persons responsible for leading, managing or governing the school not demonstrating the capacity to secure the necessary improvement in the school) and schools with < 17 pupils (minimum cluster size) in the relevant school year group. The sampling frame included schools from the following local education authorities: Birmingham Central, Birmingham North, Birmingham South, Coventry, Dudley, Sandwell, Shropshire, Solihull, Staffordshire, Stoke-on-Trent, Telford and Wrekin, Walsall, Warwickshire and Wolverhampton.

#### Participants (school pupils)

Within each participating school, all children in year 1 (aged 5–6 years), the school year when baseline measurements were undertaken, were eligible for inclusion.

## **Outcomes**

Schools participating in the WAVES study became involved in two groups [group 1 (G1) and group 2 (G2)], with initial involvement of each group being 12 months apart. The WAVES study had four individual participant-level data collection points split across eight measurement periods: baseline (G1 schools May–July 2011 and G2 schools April–July 2012), follow-up 1 (FU1: 3 months post intervention, G1 schools September–December 2012 and G2 schools September–December 2013), follow-up 2 (FU2: 18 months post intervention, G1 schools January to March 2014 and G2 schools January to March 2015) and follow-up 3 (FU3: 27 months post intervention, G1 schools only September–December 2015). Subject to individual verbal assent, participating individuals took part in a variety of assessments undertaken by trained researchers following standardised operating procedures. Outcome measures included in the data collection were the same at each time point, with the exception of FU3, when Actiheart® monitors (CamNtech Ltd, Papworth, UK), used to objectively measure levels of PA, were not fitted. Weighing scales were serviced and calibrated biannually, and skinfold callipers and blood pressure monitors were serviced and calibrated biannually, and skinfold callipers and blood pressure monitors were serviced and calibrated biannually. Children were asked to wear light clothing for all of the physical measurements and to remove their shoes and socks for the measurement of their height and weight.

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# Individual participant-level outcomes

#### Primary outcomes

The primary outcome is the difference in BMI-zs between control and intervention arms at first and second follow-up. (UK 1990 reference curves were used to allocate BMI-zs at all time points.<sup>27</sup>) Data required for BMI-zs were height, weight, sex and age. Height was measured in duplicate to the nearest 0.1 cm using a portable stadiometer (Leicester Height Measure, Invicta Plastics Ltd, Leicester, UK). When the readings differed by > 0.4 cm, an additional reading was taken (see *Appendix 1*). Provided that there were two height measurements within 0.4 cm of each other, a definitive height was calculated as the average of the two closest readings or, in instances of no two closest readings, the average of all three readings. Weight (see *Appendix 2*) was measured to the nearest 0.1 kg using a Tanita bioimpedance monitor (Tanita BC-420MA Class III, Tanita Corporation, Tokyo, Japan). Age was calculated in days from date of birth (obtained either directly from the parent or from school records) and date of measurement (recorded on each measurement sheet; see *Appendix 3*). Sex was obtained either directly from the parent or from school records and was verified at the point of measurement. A body mass index (BMI) value was then calculated by dividing weight in kilograms by height in metres squared. UK 1990 growth reference charts were then used to produce an age- and sex-specific BMI-z for each child from their calculated BMI value.<sup>27,28</sup>

#### Secondary outcomes

#### Waist z-score

Waist circumference was measured in duplicate to the nearest 0.1 cm using a flexible, non-stretch, cloth tape measure. When the readings differed by > 0.4 cm, an additional reading was taken (see *Appendix 4*). Provided that there were two waist circumference measurements within 0.4 cm of each other, a definitive measurement value was calculated as the average of two closest readings or, in instances of no two closest readings, the average of all three readings. UK 1990 growth reference curves were then used to produce an age- and sex-specific waist z-score from the definitive waist circumference measurement value.

#### Skinfold measurement

Skinfold thickness was measured in duplicate to the nearest 0.1 cm at five sites: biceps, suprailiac, subscapular, thigh and triceps. When the readings differed by > 0.4 cm, an additional reading was taken (see *Appendix 5*). All of the measurements were undertaken on the non-dominant side (the side of the child's non-writing hand) using Holtain Tanner/Whitehouse skinfold callipers (Holtain Ltd, Crymych, UK). Provided that there were two site-specific skinfold measurements within 0.4 cm of each other, a definitive site-specific measurement value was calculated as the average of two closest readings or, in instances of no two closest readings, the average of all three readings. The 'sum of four skinfolds' outcome is the sum of the definitive skinfold measurement values for biceps, subscapular, suprailiac and triceps.

# Bioimpedance and body fat percentage

In addition to measuring weight, the Tanita monitor uses bioelectrical impedance analysis technology to calculate body fat percentage. Age, height and sex are entered into the monitor and this information is used together with the weight measured and bioelectrical impedance (assessed through a low, safe signal, which is sent through the body from two electrodes that are built into the foot sensor pads) to calculate body fat percentage. In addition, a bioimpedance value in ohms is provided and this is also reported.

#### Dietary intake

An instrument developed by the University of Leeds for use in children aged 3–7 years, the Child And Diet Evaluation Tool (CADET), was used to asses dietary intake. The version used was slightly modified from that initially described;<sup>29</sup> details of all of the modifications are provided below. CADET provides a 24-hour record of consumption using a 115-item prospective tick list with no necessity to record quantity or weight of the food/drink item. CADET is designed for completion on a school day and, for ease of completion, intake is split into a school diary and a home diary, with seven distinct time periods in total: morning break, lunchtime, afternoon break on the school diary; and before tea/after school, evening meal/tea, after

tea/during night and the following day breakfast/before school on the home diary. In the original CADET, breakfast data were routinely collected at school.

For the WAVES study, trained researchers recorded all of the items of food and drink consumed at school by participating children during one school day. On that same day, before the end of school, children were given a home food diary for completion by a parent/carer. Detailed written instructions for completion with illustrative examples were provided in addition to an instructional digital versatile disc (DVD) that could be watched by parents/carers. The following day, a researcher visited the school to collect and evaluate the returned home food diaries. If a child had an incomplete home food diary, or when it was clear that the diary had not been completed correctly, a one-to-one dietary recall was undertaken with the child when possible. Data collected in this way were then processed through the CADET nutrient analysis programme by the Nutrition Epidemiology Group at the University of Leeds. This programme converts the tick list data for each child into macronutrient and micronutrient intakes for the 24-hour data collection period using age- and sex-specific portion sizes. Only participants with both school and home food diary data were included. In addition, it was agreed in advance that CADET records with > 50 ticks for the 24-hour time period were unlikely to have been completed correctly and, therefore, such individuals are excluded from all analyses using dietary intake outcome data.

Updated macronutrient and micronutrient information from the latest UK nutrient databank<sup>30</sup> published in 2015 [McCance and Widdowson's *The Composition of Foods*: Seventh Summary Edition (MW7)] was used in the CADET nutrient analysis programme for the WAVES study. In addition, to take account of new and deleted food categories in MW7, the weighting of databank food items that make up each CADET-listed food was updated in the CADET nutrient analysis programme in 2015 by the University of Leeds Nutritional Epidemiology Group via the following process.

- Average food consumption frequencies for 3- to 11-year-olds for food items were extracted from the food level dietary data set of the National Diet and Nutrition Survey Rolling Programme (NDNS-RP) (years 1–4: 2008–9 to 2011–12).<sup>31</sup>
- These frequencies were grouped into MW7 food categories, an example of which is shown in *Table 1*. There were five MW7 milk categories that were included in the CADET listed food 'Milk, milky drink, lassi' (CADET code a1).
- Consumption frequency proportions were calculated to determine the overall weighting as a
  percentage for each MW7 category within each CADET listed food [e.g. the percentage of whole-milk
  of the total milk drunk by children aged 3–11 was calculated to be 35% (see *Table 1*)].
- When MW7 food categories had very small frequencies of consumption, professional judgement and food industry knowledge were employed to amalgamate categories to simplify the list of MW7 foods used.
- Such judgements were cross-checked by another member of the team.

CADET code	CADET description	MW7 food category description	NDNS updated weightings (%)
a1	Milk, milky	Milk, soya, non-dairy alternative to milk, unsweetened, fortified	5
	drink, lassi	Milk shake, powder, made up with semi-skimmed milk	2
		Milk, whole, pasteurised, average	35
		Milk, semi-skimmed, pasteurised, average	56
		Milk, skimmed, pasteurised, average	2
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#### TABLE 1 An example of final weightings assigned to UK nutrient databank food items making up CADET listed foods

NDNS, National Diet and Nutrition Survey.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Adab *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK. The age- and sex-specific average food portion sizes used in the CADET nutrient analysis programme are based on mean food intakes from the 1997 National Diet and Nutrition Survey (NDNS),<sup>32</sup> which collected weighed food intake data from large nationally representative samples of children and young people. The more recent NDNSs did not collect weighed data and it was therefore felt that portion size estimates from these may be less accurate than using the 1997 data. Age- and sex-specific portions of individual foods using 1997 NDNS data had been provided to the Leeds Nutritional Epidemiology Group, together with suggested weightings to group these further into CADET listed foods by Wendy Wrieden and Karen Barton when they worked for the University of Dundee. (The same data were used to produce aggregated portion data for their 2008 publication.<sup>33</sup>) These data were used in earlier calculations of age- and sex-specific portions is programme as follows.

- All age- and sex-specific portion sizes for items included in the CADET tick list were recalculated using the original 1997 NDNS data provided by the University of Dundee.
- Despite the relatively large NDNS sample size, some age/sex groups were small, meaning that for some foods the original age- and sex-specific portion size could have been based on data from as few as one individual, which, in some instances, resulted in large portion size fluctuations across the age groups. Portion sizes were manually smoothed using portion sizes from adjacent age groups when it was felt necessary. *Table 2* shows boys' portion sizes for chicken curry before and after smoothing: the smoothed portion size for boys aged 4 years (80) was calculated from the average of the portion size for boys aged 3 and 5 years (70 and 90) because the original value appeared to be too low.
- In some cases of missing data, portion sizes from similar foods were used; for example, portion sizes that had been determined for 'nuts' (CADET code b8) were also used for 'seeds' (CADET code k22).
- For a small number of occurrences of missing data (when one or more age- and sex-specific portion size for a particular item could not be estimated from the 1997 NDNS data), recent non-weighed data from the NDNS-RP (2008–9 to 2011–12)<sup>31</sup> were used to estimate portion size. For example, age- and sex-specific portion sizes for 'beans and pulses' from the recent NDNS-RP data were used as estimated portion sizes for the CADET listed foods 'Lentils, dahl' and 'Other beans and pulses' (CADET codes k20 and k21).

Such judgements were cross-checked by another member of the team.

The food and nutrient intake data were used to calculate mean energy intake in kilojoules (kJ) and mean intake in grams of fruit and vegetables, fat and fibre (based on the Englyst method).<sup>34</sup> From the individual data for 24-hour combined fruit and vegetable intake in grams, a binary variable was created to identify children who met the current government recommendation for daily fruit and vegetable consumption of at least five portions. The '5 A Day' campaign in England<sup>35</sup> accurately defines fruit and vegetable portion sizes for adults. However, for children, although the consumption of at least five portions of a variety of fruit and vegetables is recommended, as requirements vary with age, body size and levels of PA, only a rough guide – 'the amount they can fit in the palm of their hand' – is provided in terms of the amount that constitutes a portion. More quantifiable portion size information is provided, however, by the Northern Ireland Public Health Agency,<sup>36</sup> which states that a child portion is 'roughly half an adult portion'. The number of portions consumed was, therefore, determined based on the definitions from England's '5 A Day' campaign but halving the number of grams for fresh, frozen or tinned varieties of fruit and

	Male a	Male age (years)													
Portion sizes		4	5		7	8		10	11						
Original	70	23	90	180	163	140	158	195	196						
Smoothed	70	80	90	180	163	140	158	195	196						

TABLE 2 ATTENDING OF STIDULITING DUTION SIZES TOT DUVS dUEU 4 VEDIS. CHICKET CUTV (CADET COUE IS
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vegetables as well as for dried fruit. Therefore, children were assigned one portion per 40 g of fresh, frozen or tinned fruit and vegetables or 15 g of dried fruit consumed. An additional portion was also assigned for the reporting of both fruit juice/smoothie consumption and beans/pulses consumption: multiple servings of these items still contributed only one portion to their total portion intake. Individuals for whom the number of portions determined in this way was five or more were classified as meeting the current government recommendation for children's consumption of fruit and vegetables.

Free sugar, often referred to as 'added sugar' or 'non-milk extrinsic sugar (NMES)', is not listed in the latest nutrient databank and is therefore not part of the standard output from CADET. To split the total grams of sugar provided by CADET into free and intrinsic sugar, the food items from CADET were mapped to the nearest available food in the 1997 NDNS. The total, free and intrinsic sugar amounts for the mapped NDNS foods were used to calculate free and intrinsic sugar proportions. The free sugar proportion was then applied to the total sugar amount in the recent UK nutrient bank to obtain a value in grams for free sugar. For example, if a MW7 food had a total sugar amount of 10 g per 100 g and the mapped NDNS equivalent food had a free sugar proportion of 40%, the amount of free sugar allocated within CADET to the MW7 food would be 4 g per 100 g. This was completed for all foods in the CADET nutrient analysis programme (used for the processing of the WAVES study dietary data) and a weighted average was calculated for each of the 115 food categories included in CADET. These data were used to obtain a mean non-milk extrinsic sugar intake in grams during the 24-hour period.

# Physical activity

Children wore a combined heart rate and movement sensor (Actiheart)<sup>37</sup> attached to the chest with two standard ECG electrodes initialised to record in 30-second epochs. The children were asked to wear the monitor continuously (including during sleep and any water-based activities) for 5 days (including a weekend) and to continue with their usual behaviour (see *Appendix 6*).

Free-living heart rate data were preprocessed<sup>38</sup> and combined with trunk acceleration to derive activity intensity (J/minute/kg) time series using a branched equation framework.<sup>38</sup> Heart rate data were individually calibrated using a group equation based on age, sex and sleeping heart rate derived from submaximal response to a bicycle ergometry exercise in a similarly aged population of Finnish children<sup>39</sup> using a previously described modelling methodology.<sup>40</sup>

Periods of non-wear were inferred from the combination of non-physiological heart rate and prolonged periods of zero acceleration, which were taken into account to minimise potential diurnal bias when summarising time series data into participant-level summary measures.

Total PA energy expenditure (kJ/day/kg) was summarised, along with its underlying intensity distribution in 0.25 metabolic equivalent (MET) increments (1 MET defined as 118 J/minute/kg  $\approx$ 5.8 ml O<sub>2</sub>/minute/kg).

Total movement volume was summarised as average acceleration along with its underlying movement intensity distribution using only the acceleration signal (including for the definition of non-wear). Time spent at specific movement intensities includes MVPA, defined as time spent above the acceleration threshold of 1.75 m/second<sup>2</sup> and expressed in minutes per 24 hours; sedentary time is defined as time when acceleration is  $\leq 0.075$  m/second<sup>2</sup> (includes time when sleeping) and is expressed as hours per 24 hours. From the former (time spent in at least moderate activity), a binary variable was created to classify children as either achieving or not achieving the current government minimum PA recommendation for children aged 5–18 years<sup>41</sup> of engaging in MVPA for at least 60 minutes every day.

Only children who had at least 24 hours of valid data, distributed as at least 6 hours in each quadrant of the day (morning 03.00 to 09.00, noon 09.00 to 15.00, afternoon 15.00 to 21.00, and midnight 21.00 to 03.00), were included to ensure representation of the whole 24-hour period<sup>42</sup> and to further minimise potential diurnal bias.

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# Health-related quality of life

The child (aged 5–7 years) self-report version of the Paediatric Quality of Life inventory (PedsQL),<sup>43</sup> the social acceptance domain of KIDSCREEN-52<sup>44</sup> and the Child Health Utility 9D (CHU9D) were used to assess health-related quality of life (HRQL). PedsQL is a validated questionnaire that considers physical, emotional, social and school functioning. These aspects of quality of life are considered separately; emotional, social and school functioning are combined to consider psychosocial functioning, and all four are combined to assess overall guality of life. The social acceptance domain of KIDSCREEN-52 was used to assess bullying. Although the KIDSCREEN-52 domain is validated for use only in slightly older children (aged 8 years), no alternative instrument was available that had been validated for use in children aged 5–6 years. All PedsQL scores have a minimum value of 0 and a maximum value of 100. The KIDSCREEN-52 domain has a score range of 3–15. For both instruments, higher scores indicate a better quality of life. CHU9D<sup>45,46</sup> was also administered for use in the health-economic analysis. It is a paediatric, generic, preference-based measure of HRQL. It consists of a descriptive system and a set of preference weights, giving utility values for each health state that is described by the descriptive system, thus allowing the calculation of quality-adjusted life-years (QALYs) for use in cost-utility analyses (CUAs). A description of the HRQL dimensions it assesses, and the scoring mechanism used, is provided in Chapter 7 (see Outcomes/Measuring quality-adjusted life-years). All three instruments were interviewer administered at all time points (see Appendix 7).

#### Weight status categories

The age- and sex-specific BMI-zs (previously described) were used to classify individuals into four weight status categories, based on the UK 1990 centile cut-off points for population monitoring of weight status:  $\leq$  2nd centile = underweight; > 2nd centile to < 85th centile = healthy weight;  $\geq$  85th centile to < 95th centile = overweight; and  $\geq$  95th centile = obese. Two binary weight status variables were then created: (1) 'obese' compared with 'not obese' and (2) 'obese/overweight'.

#### Blood pressure

Blood pressure was measured in duplicate using a clinically validated, automated oscillometric blood pressure monitor (BpTRU BPM-100, BPTRU Medical Devices, Conguitlam, BC, Canada) with the correct cuff size for each child. All measurements were taken on the right arm, with the child in a seated position, and children were asked to remain still and silent throughout. The first measurement was taken after a 3-minute seated rest. A second measurement was then taken after a 3-minute minimum rest interval. If an error reading occurred, or one of the first two values was outside the normal range, a third reading was taken, again after a 3-minute minimum rest interval (see Appendix 8). A definitive systolic and diastolic value was then calculated. Initially, all of the readings in which either the systolic or the diastolic value was > 20 mmHg above the 99.6th centile of the UK age- and sex-specific blood pressure reference data were excluded as implausible.<sup>47</sup> Unpaired readings, owing to an error reading being returned by the monitor for either the systolic or the diastolic blood pressure value, were then excluded. The remaining systolic and diastolic blood pressure values were then treated independently. When a value was available from only one reading, this was taken as the definitive value. When values from two readings were available, then the definitive value was taken as the average of these two values. When values were available from three readings, then the definitive value was taken as the average of the two closest values or, in instances of no two closest values, the average of all three values.

#### Body image satisfaction

Body image was assessed using the Child's Body Image Scale. This is a body image assessment tool for children and consists of seven sex-specific photo images of children who ranged from very thin to obese.<sup>48,49</sup> The instrument was interviewer administered. Each child was shown the appropriate sex-specific range of photo images. Initially, they were asked to select the image that looked most like them (underweight = 1 to obese = 7) and then the image that showed the way that they would like to look. A body image satisfaction score was then calculated by subtracting the second score (the way that they would like to look) from the first score (looked most like them). A score of '0' indicated body image satisfaction (as the child looked like they would like to look). A negative value indicated that the child would like to be fatter; a positive value indicated

that the child would like to be thinner, with greater body dissatisfaction the higher the magnitude of the value. To enable dissatisfaction to be considered irrespective of whether the direction was towards wanting to be fatter or wanting to be thinner, the negative values were converted into positive values for use in the body image satisfaction analyses.

# Additional variables used in the analysis

# Socioeconomic status

The postcode of each participant was requested at baseline and obtained either from school records or directly from the child's parent/carer. This was used to obtain the Index of Multiple Deprivation (IMD) 2010 score for the area in which each child was living at baseline, as a measure of socioeconomic status. In addition, participants were split into five deprivation groups using quintile cut-off points for England, such that group 1 comprised all of the individuals living in an area classified as being among the 20% most deprived in England and group 5 comprised those living in an area classified as being among the 20% most affluent.

# Ethnicity

Ethnic group data, using the classification recommended for use in England by the Office for National Statistics and used in the England and Wales 2011 Census,<sup>50</sup> were obtained either from school records or directly from the parent/carer of participating children. These data were then split into four ethnic groups: (1) white (including English, Welsh, Scottish, Northern Irish and British); (2) South Asian (including Bangladeshi, Indian and Pakistani); (3) black (including African and Caribbean); and (4) other ethnic group (including Irish, Gypsy or Irish Traveller, any other white background, white and black Caribbean, white and black African, white and Asian, any other mixed/multiple ethnic background, Chinese, any other Asian background, any other black/African/Caribbean background, Arab, and any other ethnic group).

# Intervention implementation level

Schools were classified into three groups (low, medium and high) based on the level of overall implementation fidelity achieved. A detailed description of the methods used is provided in *Chapter 4* (see *Methods, Assimilation of process evaluation data*). The two schools allocated to the intervention arm of the trial that did not implement any components of the intervention programme were universally allocated a score of '0' and were included in the low-implementation fidelity group for the subgroup analyses.

# **Cluster-level outcomes**

In order to inform the sampling procedure and to be of use in the fully adjusted models, school-level data were obtained from all local education authorities in the West Midlands, UK. The latest data available at the time of request were for the 2009–10 school year. The school characteristics requested included school size (number of pupils on roll), the percentage of the school population who were white, the percentage of the school population who were white, the percentage of the school population who were South Asian (including Bangladeshi, Indian and Pakistani), the percentage of the school population eligible for a free school meal (as an indicator of the socioeconomic make-up of the school population). These are subsequently referred to as baseline school characteristics. In addition, at baseline, head teachers of both control and intervention schools were requested to complete a school questionnaire. The questionnaire aimed to gather information on activities already being undertaken, facilities that were available and the general environment in relation to healthy eating and PA at each participating school (see *Appendix 9*).

# Sample size

As the planned analysis of the WAVES study included adjustment for baseline measurements, power calculations were based on repeated-measures methods using estimates of correlation between before and after measurements. Sample sizes were then inflated and compared with those required for

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individual randomisation, using the design effect, to account for the randomisation being at the cluster level and making allowance for the variation in cluster sizes.<sup>51</sup>

The important summary statistics used to inform the sample size calculations were based on estimates from an analysis of data from a previous study<sup>52</sup> involving eight schools and for which baseline and follow-up measurements by control and intervention arms were available. From these data we estimated the intracluster correlation coefficients (ICCs) and the correlation between the before and after measurements. Two outcomes were considered: (1) BMI-z (ICC = 0.01, 95% CI 0 to 0.04, estimated correlation between before and after measurements = 0.9) and (2) percentage of children overweight or obese (ICC = 0, 95% CI 0 to 0.02, estimated difference between before and after measurements = 0.7).

At the protocol stage, previous experience indicated that for schools agreeing to take part, an average number of 43 pupils would be recruited, and the planned sample size and estimation of power it would provide was based on this but also allowed for variation in cluster size [standard deviation (SD) = 23]. However, experience during the initial phase of pupil recruitment for the WAVES study suggested that the average number of pupils recruited per school would be only about 25. Funding for the trial meant that a maximum of a little over 50 schools could be recruited, and it was estimated that there would be a pupil dropout rate of 20% during the course of the study. Revised power calculations were therefore undertaken, based on a final sample size of 1000 children split among 50 clusters.

In relation to the primary outcome of BMI-z, such a sample size provides > 90% power to detect a change of 0.25 z-scores under all probable estimates for the ICC (0, 0.01 or 0.04). A change of 0.25 z-scores is equivalent to approximately 0.5 kg of body weight for a 7-year-old child and has been shown to be associated with clinically detectable benefits in obese adolescents.<sup>53</sup> It also provides > 80% power to detect a change of 0.125 z-scores under more conservative estimates of the ICC (95% CI 0 to 0.009). This sample size also provides > 80% power to detect a difference (between control and intervention schools) in the percentage of children being overweight or obese of about 7% (exact value dependent on baseline values).

All power calculations were carried out in Stata 13 (StataCorp, College Station, TX, USA) using the 'sampsi' function with the analysis of covariance method (for repeated measures) and then inflated by the appropriate design effect.

# Sequence generation

The unit of randomisation was the school. Schools that had agreed to participate in the study were randomised to either the intervention or the control arm using a blocked balancing algorithm.54,55 Essentially, this algorithm randomly selected one of a number of allocation designs that minimised the imbalance between a set of prespecified covariate means. The covariates included within this algorithm were percentage of pupils eligible for free school meals, percentage of South Asian pupils within the school, percentage of black African Caribbean pupils within the school, percentage of white pupils within the school, percentage of other ethnic group pupils within the school and number of pupils within the school. The first 27 schools (G1 schools) were randomised in the first block, and 1 year later the second 27 schools (G2 schools) were randomised in the second block, conditioning the balancing algorithm for the first block allocations. For G1 schools, the balance algorithm was implemented to balance on means. In G2 schools, some covariates exhibited a significant departure from normality and a transformation was used to improve the normality assumptions of the balance algorithm. This transformation was selected using the 'ladder of powers' function in Stata, and the transformation with the lowest chi-squared value. Covariates transformed were percentage white pupils (log), percentage other ethnic group pupils (square root) and percentage black African Caribbean pupils (square root). In this way, balance was achieved across all allocations.

# Allocation concealment mechanism

Allocation to either the control or the intervention arm of the trial was at the cluster (school) level. Randomisation for each group of participating schools took place after completion of baseline measurements, such that both schools and their participating year 1 pupils were not informed of arm allocation (to ensure concealment of allocation) until after consent to participate had been obtained.

#### Implementation

The trial co-ordinator undertook the school enrolment procedure from a weighted random sample of all eligible schools. The sampling procedure and subsequent randomisation of participating schools were undertaken by the trial statistician.

A weighted random sample of schools was used to try to ensure sufficient representation among participating schools to enable subgroup analysis by minority ethnic group. School populations were stratified by ethnic mix: white, South Asian (comprising Bangladeshi, Indian and Pakistani), black (comprising African and Caribbean) and other ethnicity (comprising all other ethnic groups). Schools were dichotomised as either being or not being in the top 80th percentile in terms of black or South Asian pupil representation in their overall school population. Schools with a higher minority ethnic population (in the top 80th percentile for black or South Asian representation) were given an increased chance of selection with a ratio of 3 : 1 to create a weighted random sample of 200 schools. Schools in this sample were ordered using a random number generator, and seven were excluded as they did not meet the eligibility criteria.

Study invitation letters (followed by telephone calls starting approximately 2 weeks later) were then sent sequentially to the head teachers of the remaining schools. It was anticipated that the relatively large number of clusters being recruited (> 50) should ensure balance across three other important factors [urban/rural location, school size and proportion of children eligible for a free school meal (as an indicator of the socioeconomic make-up of pupils in the school)], such that a range of these school characteristics would be represented. However, regular checks for response bias in terms of these factors as well as ethnic mix were undertaken by the trial statistician, as a precaution, during the school enrolment period.

In schools that had agreed to take part, all of their pupils in year 1 (aged 5–6 years) were eligible for inclusion in the study. Invitation letters, together with a detailed information leaflet about the study and a parental consent form, were sent to schools for distribution. Members of the research team visited schools to explain the study to the eligible children and to provide them and their parents with an opportunity to ask any questions that they might have. Consent for participation in the study by both schools and eligible pupils was completed before the trial statistician randomised schools to either the control or the intervention arm of the trial. Parental consent for the full set of measures (measurements and questionnaires) was gained through an opt-in consent process for both G1 and G2 schools. However, following lower than anticipated pupil recruitment for G1 schools, an additional opt-out consent was introduced for G2 schools. The opt-out consent covered a more limited set of measures (height, weight, blood pressure and all child questionnaires). It was implemented, when possible, in schools in which pupil recruitment was falling short of the anticipated mean cluster size of 25. As would be expected, this occurred more frequently in one class entry schools with only one Year 1 class in which a much higher proportion of consents was required to achieve the anticipated mean cluster size of 25 consented pupils.

# Blinding

Owing to the nature of the intervention, blinding of schools or participating pupils was not possible. Although all of the data collection staff were blind to arm allocation at baseline, for logistical reasons it was not possible to blind members of the core research team for follow-up data collection periods. However, the majority of data collection was undertaken by teams of sessional staff, with only supervision

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by a member of the core research team. The main responsibility in terms of measurements for the core research team staff was the set-up and fitting of monitors to objectively measure PA, although, on occasion, involvement of these staff in other measurements was required. The sessional staff, responsible for the majority of data collection, were not advised of arm allocation, but it is possible that the trial arm could have been revealed to them by a comment from either a member of school staff or one of the pupils from whom data were being collected. To try to assess the frequency of sessional staff becoming unblinded to arm allocation, these staff were asked to complete a questionnaire on termination of employment (for a visual representation of blinding through the progress of the study, see *Figure 7*).

# Chapter 3 Interventions

# **Control schools**

Schools had to agree to take part in the trial knowing that they had an equal chance of being randomised to either the control or the intervention arm. To encourage school agreement to participate, it was considered important (based on findings from the feasibility study) that all schools, irrespective of trial arm allocation, should receive something in addition to the experience of being involved in the trial. During the recruitment process, invited schools were advised that if allocated to the control arm of the trial, the school would be provided with some resources suitable for year 2 personal, social and health education lessons. Resources that had already been developed and did not cover the topic area of health or healthy lifestyle behaviours were identified. These were sent to all control schools at the start of the autumn term of the intervention year. The resources provided were:

- 'Your World, My World' resource from Oxfam (Oxford, UK), exploring the lives of four children from around the world (www.oxfam.org.uk/education/resources/your-world-my-world)
- 'Climate Cops' resource from Npower (Npower Ltd, Swindon, UK) a teaching toolkit on electricity and energy.

In addition, schools local to Birmingham received information about the 'Teddy Bear Hospital', a service provided by medical students at the University of Birmingham. The service involves medical students visiting schools free to provide a children's teddy bear clinic with the aim of dispelling any fears about health-care professionals and promoting relevant health and safety issues in a fun, educational manner.

The educational resources were provided to all of the control schools, but how and whether or not the materials were used was the choice of each individual school.

# **Intervention schools**

Schools that were allocated to the intervention arm of the trial were asked to deliver each component of the WAVES study multifaceted intervention programme to all children in year 2 (aged 6–7 years), irrespective of whether or not the child's parent had consented for them to be involved with the study measurements and, therefore, participate in the trial.

The WAVES study intervention was developed by combining the available research evidence with theory that was informed through qualitative research with relevant stakeholders<sup>56</sup> and guided by the MRC framework for complex interventions.<sup>57</sup> We first identified the most promising intervention strategies from systematic reviews of childhood obesity prevention studies. Among 70 included studies within eight systematic reviews, we summarised the intervention components, target behaviour and type of activity. We then conducted focus groups with a range of stakeholders (including parents and school staff) to explore those that were perceived to be the most important and feasible to implement. We considered intervention techniques (e.g. reward behaviours, role model, exposure to PA opportunities), activities (e.g. education materials, parenting classes, cooking workshops) and particular settings (e.g. school curriculum, community setting). Prioritised ideas were checked against available local resources and, with input from an expert group, the intervention package was formed. There were two broad intervention aims: (1) increasing children's PA levels through school and (2) supporting health behaviour skill development in families through activity-based learning.<sup>56</sup>

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The intervention was further refined following a feasibility study among children from eight primary schools.<sup>52</sup> The aim of the finalised intervention was to target both the home and school environment, using a variety of behaviour change strategies to increase the level of PA and improve the quality of the children's diet. Based on findings from earlier qualitative studies, the intervention was introduced to participants as a healthy lifestyle programme. The programme, delivered through school over a 12-month period, had four main components: signposting, additional daily PA programmes to be run in school, cooking workshops and Villa Vitality. A summary is provided below, followed by a more detailed description of each component.

# WAVES study intervention programme summary

# Signposting

Aim: to increase children's PA levels outside school with their family.

Method: information sheets were provided for the children to take home, highlighting facilities in the local area and simple ways to increase activity levels. Motivational messages were also included.

Intervention techniques: to provide information on when and where to perform behaviour.

Delivered by: delivered to the school by the WAVES study research team; handed out to the children by class teachers.

Timescale: G1 schools, July 2011 and September–October 2011; G2 schools, July 2012 and September–October 2012.

#### Physical activity programmes to be run in school

Aim: to encourage children to be physically active and more specifically to increase children's PA levels by 30 minutes per day during school time.

Method: teachers were asked to select the two most suitable PA programmes for their school, from four offered, to assist them in increasing their children's PA during school time.

Intervention techniques: environmental restructuring, prompt practice.

Delivered by: class teachers, teaching assistants (TAs) or lunchtime supervisors (depending on school).

Timescale: G1 schools, September 2011–July 2012; G2 schools, September 2012–July 2013.

#### Cooking workshops

Aim: to improve nutrition knowledge, cooking skills and dietary habits of children and their families (specifically, to encourage the consumption of more fruits, vegetables and high-fibre foods and reduce the consumption of high-sugar and high-fat foods).

Method: the WAVES study research team provided training and materials for school staff to enable them to deliver short lessons on healthy eating and cooking workshops for children and parents – one workshop per school term.

Intervention techniques: to provide information on the consequences of behaviour in general, model/ demonstrate behaviour, prompt practice and prompt generalisation of behaviour.

Delivered by: school staff (nominated by the school).

Timescale: one session per term, three in total throughout the school year – G1 schools, 2011–12 academic year; G2 schools, 2012–13 academic year.

Staff training: a 1-day training course run at the University of Birmingham – G1 schools, October 2011; G2 schools October 2012 (two dates offered per year). Attended by school staff who were involved in delivering the cooking workshops at each school.

# Villa Vitality

Aim: to use role models to motivate children to adopt healthy lifestyles, with a focus on nutrition and PA.

Method: children were invited to take part in a programme encouraging healthy lifestyle behaviours run by Aston Villa Football Club (AVFC), but also involving weekly challenges and a class project delivered by class teachers.

Intervention techniques: to provide information on the consequences of behaviour in general, model/ demonstrate behaviour, prompt practice and prompt generalisation of behaviour.

Delivered by: AVFC and school teachers for challenges and class projects.

Timescale: run during the spring and summer terms: G1 schools, 2011–12 academic year; G2 schools, 2012–13 academic year.

# **Detailed description of each WAVES study intervention component**

#### Signposting

The signposting component aimed to encourage families to be active over the summer and guide them to local PA opportunities. Prior to the summer holidays, the year 1 class teachers gave an information sheet to all of the children in their classes and asked them to take it home to their parents. This sheet highlighted simple ways to increase levels of PA, such as walking, cycling or visiting the park, and setting weekly achievement goals as a family (see *Appendix 10*).

During the summer holidays, members of the research team developed school-specific signposting sheets. These outlined activities available within the local area that were suitable for year 2 children, including local play areas, recreational grounds and leisure centres, as well as sports and activity clubs. Prior to printing and distribution, at the start of the autumn term (G1 schools, September 2011; G2 schools, September 2012), the signposting sheets were sent to head teachers to give them the opportunity to suggest extra items for inclusion and check that they felt that all of the items included were appropriate. Once approval of a final version had been obtained, the sheets were distributed at each school to all children [who had now moved into year 2 (aged 6–7 years)] as early as possible in the autumn term. For an example of one of the signposting sheets, with the school name and logo removed, see *Appendix 11*.

#### Physical activity programmes to be run in school

The aim of this component was to increase children's PA in school. The target was to achieve an additional 30 minutes of PA per day, over and above what they were already doing. Four different activity programmes were offered to schools, from which they were asked to select the two that they felt would most suit their school. To avoid additional time required for changing into physical education (PE) kit and, therefore, to make it easier for the activities to be slotted into the timetable, all programmes offered could be undertaken with children wearing their school uniform. All programmes also allowed for a degree of flexibility, enabling teachers to tailor delivery to suit their individual class. It was anticipated that there might be concern from teachers that the time taken out of the school day for the activity component might have a negative impact on academic education. To try to dispel this concern, teachers were advised that feedback from schools with previous experience of the programmes indicated that teaching time lost from the addition of the PA

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programmes into the timetable is regained through greater concentration and improved behaviour and attitudes towards schooling. All programme materials were delivered to class teachers by a member of the research team, who spent time introducing teachers to the resource and also took the opportunity to remind them that the aim was to increase children's activity levels by 30 minutes every day during school time. Class teachers were encouraged, if possible, to participate in the activities with their class pupils, acting as role models.

#### Programmes offered

The Wake Up Shake Up programme<sup>58</sup> (*Figure 1*) involves children following aerobic-type activity routines (5–10 minutes) to music (shown on a self-explanatory DVD). There are different routines for children to work through gradually and, in addition, they can design their own routines as they become more competent. The routines can be fitted into any part of the school day and no extra equipment is required; all of the activities are focused on different movements. The Wake Up Shake Up DVD resource is sufficiently comprehensive for teachers to get started straight away. The aerobic type routines are reasonably energetic, so it was recommended for Wake Up Shake Up to be completed either in classrooms that have a sufficiently large area for activity or in an area such as the school hall. For further information about Wake Up Shake Up, see www.wakeupshakeup.com/.

Activate<sup>59</sup> (*Figure 2*) involves progressive repeated patterns of movement to music. The programme is designed for use in the morning and just after lunch, but the activities can be used spontaneously at any time of day. Activate programmes are repeated for 2 weeks at a time and become progressively more difficult over a developmental 36-week structure. In addition, extra activity extensions can be introduced at a speed to suit the class. No extra equipment is needed; all of the activities are focused around different movements. The Activate pack was sufficiently comprehensive to allow teachers to start implementing the programme as soon as the research team delivered the materials to the school. An information pack was provided as well as a DVD and music compact disc (CD) to guide teachers through the programme. For further information about Activate, see www.valsabinpublications.com/publications/activate/.

Positive Play<sup>60</sup> (*Figure 3*) is a resource designed to be used during school playtimes. It provides staff with a wide range of games and activities, for both outdoor and indoor use, as well as guidance and recommendations for organisation. Some (but not all) activities included required equipment such as cones, bean bags, balls and hoops. It was recommended that delivery of this programme took place when possible in the school playground/playing fields or an inside space in the case of bad weather. Teachers were advised that this



FIGURE 1 Wake Up Shake Up. Reproduced with permission from Wake Up Shake Up Productions (Wadebridge, UK).



FIGURE 2 Activate. Reproduced with permission from Val Sabin Publications and Training (Northampton, UK).



FIGURE 3 Positive Play. Reproduced with permission from Val Sabin Publications and Training.

programme could be used to deliver only half of the 30-minute target of additional daily activity when used during school breaks or lunchtime. For further information about Positive Play, see www.positiveplay.co.uk/.

Take 10: Fit to Succeed<sup>61</sup> (Figure 4) is a resource that provides ideas with easy-to-follow guidance on how to incorporate 10- to 15-minute bursts of PA into a child's school day. The activities are grouped into six categories: (1) action rhymes, (2) co-ordination and manipulation challenges, (3) running and chasing games, (4) activities for small spaces, (5) aerobics and (6) skipping. The activities require minimum preparation, as clear instructions are provided in the manual (and, for some activities, a DVD). Some (but not all) of the activities required equipment such as bean bags, balls and skipping ropes. Many of these activities are suitable for use in the classroom. Bursts of activity can be formally scheduled into the timetable, for example first thing in the morning and after lunch, but they can also be used more spontaneously. They can be incorporated into different areas of the curriculum to support learning, for example during personal, social and health education, numeracy, literacy and science. The games are easy to link with, or adapt to, any topic being taught. A number of activities, such as those found in the running and chasing games and skipping section, are designed to be used in the playground or gym to encourage PA during break times. These can also be used by schools to encourage PA during lunch breaks. Teachers were advised that this programme could be used to deliver only half of the 30-minute target of additional daily activity when used during school breaks or lunchtime. As four categories of the programme include a mixture of both physically active and sedentary activities, teachers were provided with a chart for these categories (see Appendix 12), indicating those activities that were suitable for contributing towards the 30-minute daily activity target of the WAVES study PA component. There is no detailed website for Take 10: Fit to Succeed, but to access the materials for the programme see www.take10.org.uk/ (owned and published by Babcock LDP).

#### **Cooking workshops**

The aim of the cooking workshop component of the WAVES study intervention was to improve the dietary behaviours of children and their families through increased nutrition knowledge, food preparation skills and confidence in preparing healthy meals. The workshops and associated resources were developed by research nutritionists who were part of the WAVES study research team, but content and materials were sent to the relevant study co-investigator for approval. The workshops were designed to be delivered by school staff following attendance at a training day run by the WAVES study research team. It was recommended that at least two members of staff per year 2 class attended the workshop training (see *Appendix 13*). Each workshop was preceded by three or four short lessons delivered to the children in the classroom 1–2 weeks before each workshop. The aim of these lessons was to encourage children to start thinking about the key nutrition messages that would be covered in the workshop. Intervention schools



FIGURE 4 Take 10: Fit to Succeed. Reproduced with permission from Babcock LDP (Exeter, UK).

© Queen's Printer and Controller of HMSO 2018. This work was produced by Adab *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK. received a payment of £380 to cover the cost of teacher cover for the cooking workshop training and the purchasing of perishable items for the actual cooking workshops. Schools were asked to invite all parents of year 2 children to attend each cooking workshop.

For each workshop, teachers were provided with the following:

- an invitation letter to parents (see Appendix 14)
- a workshop advertising poster (see Appendices 15–17)
- lesson presentation slides and notes (see Appendices 18–27)
- a workshop session plan (see Appendices 28–30)
- workshop presentation slides and notes (see Appendices 31–33)
- parent workshop information sheets (see Appendices 34–36)
- resources required for the activities and interactive games (see Appendices 37–47).

There were three cooking workshops during the intervention year, one per term, of 60–90 minutes' duration each. Each workshop covered a different eating occasion: breakfast, lunch and snacks and simple evening meals. The same key simple nutrition messages ran across all workshops to try to reinforce the lifestyle behaviours being encouraged:

- to increase intake of fruit, vegetables and fibre
- to reduce intake of sugar and fat.

To help both children and parents follow the workshop presentations and understand the key messages covered, a 6-year-old character called Bert was created. Throughout the workshops Bert was presented to participants in a variety of different scenarios. All workshops involved an element of food preparation, but cooking facilities required were kept intentionally very minimal owing to a general lack of facilities available within UK primary schools at the time of the study. Chopping boards and knives, together with preparation equipment and serving bowls/plates, were provided by the research team, and the only equipment required for delivery was a kettle or another means of boiling water for the third, simple evening meals workshop. In addition to practising food preparation skills, the workshops also included education messages to try to improve nutrition knowledge of both children and parents and a variety of interactive games that aimed to reinforce the information being delivered. All of the workshops could be delivered in the classroom if a school did not have a more suitable location available (such as a school hall).

# Breakfast cooking workshop and classroom lessons

#### Breakfast classroom lesson content

Breakfast classroom lesson 1 covered (1) the importance of eating breakfast every day to help children concentrate at school and be physically active both during PE and during break time and lunchtime, and (2) the fact that cereals are a healthy breakfast option and that high-fibre cereals are healthier because they keep you fuller for longer, are lower in sugar, help blood sugar levels to rise steadily, help to prevent constipation and can prevent some diseases, such as heart disease and diabetes mellitus, as children get older. This was followed by an activity during which children were shown slides containing pictures of different cereals and asked whether they thought it was a cereal that it would be good to eat every day or if it was a cereal best eaten only as a treat and not every day.

Breakfast classroom lesson 2 was about bread and toast. Children were asked to think of different types of bread and which types were healthier, with a prompt to consider bread from different countries. Children were then told that brown and seeded breads are healthier because they are higher in fibre, which means that they help to keep us fuller for longer, keep blood sugar levels steady and prevent constipation. Children were then separated into groups to play 'bread snap'. Each group was given a set of cards on which there were different types of bread and these were dealt out evenly to each member of the group; each player put down one card at the same time and if two of the same card were put down, the first

player to put their hand on the pile and shout 'bread!' got to keep all of the cards in the pile. The game then started again. The player who had the most cards at the end was the winner.

Breakfast classroom lesson 3 dealt with spreads and toppings that might be consumed at breakfast time. Children were first asked about the type of milk that is healthiest and then, as a reminder to reinforce messages from the previous two lessons, to think of some healthy cereals and types of bread.

#### Breakfast workshop content

This started with a reminder of the key nutritional messages that ran through all of the workshops: to increase the intake of fruit, vegetables and fibre and decrease the intake of fat and sugar. As an icebreaker, participants were asked to think about what they usually have for breakfast and why it is important to have breakfast every day. The participants were then introduced to the first Bert scenario: that he goes to school without having breakfast and, as a result, cannot do his lessons, has no energy to play with his friends and is very hungry. This was to show participants the consequences that may result from not eating breakfast and to emphasise the importance of eating breakfast. Bert then decides to have a healthy breakfast in the morning, which is balanced and contains items from several of the food groups. This means that Bert has more energy to enjoy his day, is better able to do his lessons and is no longer hungry. Children were then asked if they could remember from the lessons on cereals and bread the types that would keep them fuller for longer. Participants were then advised that for Bert to stay fuller for longer and, therefore, to prevent snacking, he should eat some starchy food, such as a high-fibre cereal or wholemeal toast, and have a portion of fruit for his breakfast. Teachers were then asked to make sure that participants were aware that eating whole fruit is recommended and is much better than fruit juice, which contains less fibre and is higher in sugar. Fruit juice drinks should be limited to one glass per day as they contain very little fruit and do not therefore contribute to fruit portion consumption.

**Interactive game 1** The next few slides of the workshop presentation showed pictures and/or a description of different types of breakfast and participants were asked which of these they thought would keep Bert fuller for longer.

Following the game, participants were reminded that high-fibre cereals (such as wholewheat cereal biscuits, shredded wholegrain wheat biscuits, wholegrain wheat flakes with wheat bran and wholewheat malted grain squares) and bread (such as wholemeal and seeded) are good for having every day, and foods such as white bread and sugary cereals (such as sugar-frosted flakes of corn or chocolate-flavoured coated rice) are better as a treat, as they will not keep us full for very long. The workshop then moved on to sugar, and participants were asked to think about how many teaspoons of sugar they could have in a day. They were then told that the maximum recommended daily intake for children is eight heaped teaspoons.

**Interactive game 2** Bert was keen to know the amount of sugar in the food and drink that he had. The participants were split into groups and given two sets of cards: one with pictures and descriptions of different types of food and drinks and the other with pictures and descriptions of various numbers of heaped teaspoons of sugar. As a group they were asked to match each food or drink card with the correct teaspoons of sugar card.

Bert was then told that he should aim to cut down on the amount of fat in his breakfast and that he could do this by boiling or poaching eggs rather than frying them, grilling rather than frying treat foods, such as sausages, and cutting excess fat off meats.

**Interactive activity 3** Participants were split into groups. They were given a set of cards with pictures of different food and drink items that might be consumed at breakfast and another set of cards that said either 'treat' or 'every day'. They were asked to put the cards into two groups: items that would be OK for Bert to have every day and items that would be better to have only as a treat.

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The participants were then given the opportunity to create and taste a healthy breakfast. Schools had been provided with a selection of high-fibre breakfast cereals, tins of fruit in fruit juice, and raisins, and were asked to purchase skimmed milk, low-fat yoghurt and a variety of fresh fruit. Participants were split into pairs and each pair was provided with a chopping board and a plastic knife that was sufficiently strong and sharp to cut fresh fruit. Each participant was also given a disposable bowl and spoon. Participants created and then ate their own healthy breakfast from the items available and all were encouraged to include some chopped fresh fruit as part of their breakfast.

#### Lunch and snacks cooking workshop and classroom lessons

#### Lunch and snacks classroom lesson content

At the start of the 'Lunch and snacks lesson 1', children were provided with a simple explanation of what is meant by a snack (a small amount of food eaten between meals). They were then told about the advantages of healthy snacks: that they would keep them fuller until their next meal, help them to concentrate on school activities and lessons and give them energy to play with friends. Children were then taught that the best eating pattern for every day was to have three healthy meals and two healthy snacks, before they were asked to think about what snacks it would be good to have at school. The lesson finished with a 'guess the snack' activity, in which children were provided with clues for five different snacks and asked to guess the snack that was being described and draw a picture of it on an activity sheet.

'Lunch and snacks lesson 2' was about snacks after school. It reinforced the difference between a snack (a small amount of food eaten between meals) and a meal [food eaten at a regular time (breakfast, lunch and dinner) to fill you up] and the fact that three healthy meals and two healthy snacks were best for everyday consumption. Children were reminded that in the previous lunch and snack lesson they had thought about the types of fruit and vegetables that would be good to have at school and were then asked to think of some slightly bigger snacks that they could have after school to keep them full until their next meal. A slide with photographs of such snacks was then shown to the children before they had the opportunity to complete a word search puzzle containing the names of various possible healthy snacks.

The final lunch and snack lesson tried to teach children about healthy packed lunches. First, it covered the types of food/drink that a healthy packed lunch should contain: fruit and vegetables; protein, such as meat, fish or beans; a starchy food; dairy food or drinks; and a drink. Two example healthy packed lunches were then illustrated, with explanations of what each included item was providing. Having been reminded that they had already been taught that some foods were for everyday consumption and that others were best only as a treat, the children were asked to think of some lunchtime foods that they thought would be best to have as a treat. They were then shown photographs of some examples of foods best to have as a treat. The activity for this lesson was to design their own healthy packed lunch for a school trip.

# Lunch and snack workshop content

Initially, the aims of the workshop were summarised: to think about the number of snacks children should have in a day; everyday snacks and those to have only as a treat; and packed lunches for school or trips out. As part of this, teachers were asked to make sure that children and parents were aware of the key nutrition messages running through all of the lessons and workshops: to increase fruit and vegetable and fibre intake and to decrease sugar, salt and fat intake. Participants were then asked about the number of healthy meals and healthy snacks that they thought was best for everyday consumption before being advised that the answer was three meals and two snacks. It was suggested that, although snacks could be had at any time, break time in the school day might be a good opportunity to have a healthy snack to delay children's hunger, help keep their sugar levels constant and maintain their levels of concentration until lunchtime. Depending on the timing of children's evening meal, the other suggested opportunity for a snack was either after school for families who eat a bit later or, for families whose children eat a bit earlier, between their evening meal and bedtime.

Participants were then asked if they remembered Bert and were given the scenario of Bert not having a snack at break time and its consequences (being unable to do his lessons, having no energy to play and being hungry). The opposite scenario of Bert deciding to have a healthy snack at break time was then presented before participants were asked to think of some healthy snacks. Teachers were asked to reinforce the message of variation and balance, and that no food/drink was being banned but that some were more suitable for everyday consumption and others were best kept to have only as a treat. Participants were then told some of the features of a healthy snack: being low in sugar, fat and salt and providing some vitamins and minerals. Examples of both healthy snacks (dried or fresh fruit, vegetables, low-fat yoghurts, unsalted nuts) and those best consumed only as a treat (cakes, chocolates, crisps, candies, juice) were then provided. Parents were also encouraged to think about portion sizes in relation to snacks best eaten as a treat, with a piece of chocolate rather than a whole bar given as an example. Small healthy home-made sandwiches were suggested as an option for an occasion requiring a slightly bigger snack, and participants were advised that this option would be covered in more detail later in the session. The benefits of healthy snacks were then discussed, namely the fact that they are lower in sugar and fat, thus helping to keep our insides, such as our teeth and heart, healthy; that they can help us feel fuller for longer; and that the vitamins and minerals they contain help to keep us healthy; for example, the calcium in a drink of milk helps to build strong bones and teeth.

The next element of this workshop involved another scenario for Bert: that he was going on a school trip and needed to take a packed lunch with him. The teacher then covered items that could be included in a healthy packed lunch, also providing simple information on the functions of different food types: fruit and vegetables that contain vitamins and minerals that help keep our bodies healthy; protein foods, such as meat, fish, eggs and beans, which help our bodies to grow strong; starchy foods, such as rice, pasta, bread and potatoes, which provide energy and help keep us fuller for longer; dairy foods and drinks, such as low-fat cheese, milk and yoghurt, which contain calcium and help our teeth and bones to grow and stay strong; and a drink to stop you getting thirsty, such as water, milk or juice. In relation to the last item – a drink – teachers asked the children if they could remember the rule about fruit juice: that consumption should be limited to only one glass or small carton a day. Participants were then given some picture cards of different foods and asked to split the cards into treat or everyday packed lunch items.

There was then a quick recap of the session before the final food preparation activity. Participants were encouraged to have healthy snacks. They were reminded of the items that a healthy packed lunch should include and that eating healthily helps keep us fuller for longer, gives us more energy for playing and means that we can concentrate better. Participants were then provided with a wholemeal (if possible) bread tortilla, a variety of different protein and vegetable filling options and visual instructions on how to assemble a wrap. Knives and chopping boards were available for the chopping of vegetable items when required. Participants then made up a healthy wrap using the ingredients provided.

# Simple evening meal cooking workshop and classroom lessons

#### Evening meal classroom lesson content

'Evening meal lesson 1' began with the children being shown a picture of the Eatwell plate (Public Health England, in association with the Welsh Government, Food Standards Scotland and the Food Standards Agency in Northern Ireland) and asked to name some foods from each food group. Teachers were asked to highlight to the children that there are lots of different ingredients that can make up a healthy dinner, but that for a dinner to be healthy it was important for it to contain fruit and vegetables and be low in salt and sugar and lower in fat. The lessons and workshop refer to the evening meal as dinner. We are aware that dinner is usually the last meal of the day and was the term that would be used to talk about the evening meal. Children were then given the opportunity to say what they called their evening meal. To reinforce the message of what constitutes a healthy meal, which the children had already received in relation to a packed lunch, children were reminded again in relation to dinner, namely that a healthy dinner should contain vegetables and/or fruit, some form of protein, a starchy food, some sort of dairy food or drink and a drink.

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This was followed by the activity for this lesson in which children were shown slides of different meals/ snacks, which also included times, and were asked to select whether the food was for breakfast, lunch, dinner or evening meal and also whether it was for everyday consumption or for a treat.

The second lesson in preparation for the evening meal workshop was all about healthy lifestyle behaviours in general. Children were asked to think of healthy habits that they do every day before being taken through some healthy habits that broadly reinforced the messages of the WAVES study intervention programme. The healthy habits covered were having three healthy meals and two healthy snacks a day, with a reminder to make sure that, in general, they comprised everyday rather than treat foods; eating breakfast every day; consuming five portions of fruit and vegetables every day; water being the best drink, but that they could also have milk, fruit juice (but a maximum of one glass per day) or diluted squash; making sure they had 'me-sized' meals; and doing a minimum of 60 minutes of PA every day. The children were then read a story about Bert having a healthy habits day. Some bits of text were deliberately missing and the children were asked to make suggestions for words or phrases that could be used to fill in the blanks. The children were then asked to draw a picture of themselves performing one of their healthy habits.

Lesson three, in preparation for the evening meal workshop, started with teaching children some basic hygiene rules for food preparation and cooking. Children were asked to think of things that they thought it might be important for them to do before starting to cook, before being told about four rules that should be followed: (1) make sure that the cooking area is clean and tidy, (2) tie back long hair, (3) remove any jewellery and, most importantly, (4) wash their hands. The class was then asked what they would do if (1) they felt like they wanted to sneeze and (2) they wanted to go to the toilet while cooking. After some class discussion, the teachers told the children that if they felt like they wanted to sneeze they should put down any food or equipment, move away from the cooking area to sneeze and then blow their nose, wash their hands with soap and warm water and dry them before returning to the cooking area. With regard to leaving the cooking area to go to the toilet, they were told that they should remove their apron and leave it in the kitchen, go to the toilet and, again, wash their hands with soap and warm water and dry them before returning to the kitchen to put on their apron. The lesson then moved on to a discussion on food preparation. Children were given a few examples of techniques and skills that might be needed (chopped/washed/grated/chilled/peeled) and asked, first, if they could think of some more and, second, if they could think of a time when they have used any of the skills or techniques. The activity for this lesson involved the children matching pictures of people doing different cooking actions with the name of the skill being used. Each child was given a sheet with five pictures and skills (washing/mixing/peeling/grating/ chopping) on one side and a picture of a blank apron on the other for them to design their own WAVES study apron.

#### Evening meal workshop content

As for the lunch and snack workshop, this started with an introduction to the aims of the session, namely to think about portion sizes, aiming for five a day (portions of fruit and vegetables) and to plan and prepare a tasty meal. The message introduced in the lunch and snack workshop of three healthy meals and two healthy snacks being best for everyday consumption, with suggestions for the best timing for snacks, was then reinforced before moving on to the concept of 'me-sized meals'. Teachers introduced participants to the importance of having the right meal for their size and reminded them that children needed only portions that matched their age, stressing that a 5-year-old child requires smaller portions than a 10-year-old child, who requires smaller portions than an adult. Children were asked to compare the size of their fist with that of an adult's and told that a smaller fist means a smaller tummy that requires smaller portion sizes. Parents present were told that serving more food would not make their child grow any faster, but would be likely to lead to extra fat storing up in their bodies. Some healthy eating habits were then suggested: to wash your hands before eating, to eat together at the table and to turn off the television and computer games while eating. Participants were then reminded of the main food groups (fruit and vegetables/protein foods/starchy foods/dairy foods, and also a treat foods group). They were asked to think of foods they usually have at dinner and the food groups they were from. Participants then played a game of 'food group bingo', whereby participants were grouped and each group was given a

bingo card with the five food groups – about which they had just been reminded – running horizontally across the card, and the pictures of five food items from each food group running vertically below each of the food group headings. Slides with different foods were then shown for the participant groups to match them to the pictures on their bingo card and cross them off. The first group with a completed row across the page was asked to shout 'bingo!' and was the winner.

Next, participants were reintroduced to Bert. They were reminded that he was 6 years old and asked how many portions of fruit and vegetables he should be trying to eat every day, before being told that he should be aiming to eat five child-sized portions every day. Participants were then asked to think whether or not they have their five a day, and suggested ways to achieve this were having fruit and vegetables as snacks and making sure that breakfast, lunch and dinner always include at least one portion. Then another Bert scenario was presented, in which he wanted to try a healthy dinner. To avoid confusion, participants were advised that 'dinner' was being used to refer to the last meal of the day; this was followed by a discussion of different names that can be given to the evening meal. Participants were then asked to think about what Bert might mean by a healthy dinner. They were then told that Bert needs a dinner that contains fruit and/or vegetables, is based on healthy carbohydrate foods and includes some protein. The advantages of having a healthy meal were then reiterated (helps Bert to have more energy to play, be fuller for longer and grow strong). In anticipation of the food preparation part of the workshop, participants were asked to think of things that they should do before starting to prepare food or cook. The suggestions provided were the same as for the last classroom lesson (make sure the cooking area is clean and tidy/tie back long hair/remove jewellery/wash your hands). The food skills and preparation for this session was to create a healthy couscous meal including a mix of fresh vegetables and some protein. The couscous was prepared following the instructions on the packet but using a low-salt stock cube, and participants were provided with a variety of vegetable and protein items to chop and add to their bowl of couscous.

# Villa Vitality

The aim of the Villa Vitality component was the promotion of healthy lifestyle messages through an iconic sports institution and its staff. Villa Vitality is a programme run by AVFC, an English Premier League football club at the time of the study, that promotes healthy lifestyles and, in particular, increased PA and healthy eating. It aims to motivate children to lead healthy lifestyles by taking the teaching out of a classroom environment and into the engaging setting of a football club. The programme is run over 6 weeks, with a full-day visit to the AVFC ground (Villa Park) in weeks 1 and 6. In between these days, children are involved with weekly healthy lifestyle challenges, work on a class project and are visited at school by a member of AVFC staff. An overview of the programme format is provided in *Figure 5*. The activities undertaken during the programme focus on developing children's understanding of the importance of eating a healthy balanced diet and being physically active.

Day 1, the 2-hour session on day 2 and day 3 are run by AFVC staff, who also organise return transport between the school and the AVFC ground. During the 6-week period of the programme, teachers are asked to run weekly healthy lifestyle challenges with their class and also to undertake a class project. A teacher's pack (see *Appendix 48*) is provided to all teachers in advance of day 1. In addition to information on the overall programme, the teacher's pack provides details of the class project and weekly challenges, including suggestions of how these could be delivered.

#### Day 1

The first day of the programme is divided into three sections: PA, healthy eating and the launch of class projects and challenges.

The PA session is run in the AVFC Academy and involves exercise activities led by AVFC's community coaches, teaching children the importance of being physically active and highlighting ways to include PA into their daily lives. The session is not dependent on sporting ability. The first part, 'run around questions', is intended as a warm-up, but also incorporates an educational element. With the children gathered in a

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FIGURE 5 The Villa Vitality programme.

group, the coaches ask them a healthy lifestyle question, provide four possible answers and allocate the answers to different zones marked out on the Academy's indoor playing field. The children are then asked to run to the zone that they think has the correct answer. The children then regroup; the coach gives them the correct answer, explains why it is correct and then asks another healthy lifestyle question. The next part of the session is about ball skills. The coaches run a variety of different exercises in which children learn skills such as dribbling, turning and passing. For the final part of the session, the children are split into two teams for a football match that allows them to practise the skills they have been taught.

The healthy eating session is delivered by a nutritionist and aims to teach children the importance of eating a healthy balanced diet, how different types of food contribute to this and the concept of portion size and eating 'me-sized' meals. For a detailed session plan, see *Appendix 49*.

The class project and challenges session introduces children and teachers to these elements of the programme, designed for delivery by class teachers at school over the period between the 2 days spent at AVFC. For the project, prepared either together as a class or in smaller groups, children develop a song,

rap lyrics, a poem or rhyme incorporating key messages from day 1 of the Villa Vitality programme. The challenges focus on healthy lifestyle behaviours; parents are encouraged to become involved by means of an introductory letter about the challenges, which is followed by a parent information sheet relating to each challenge. There are six challenges, one for each week of the programme, and a sticker reward system is used to incentivise children to complete each challenge. All of the materials, such as introductory letters, parent information sheets and child activity sheets, are included in the teacher's pack (see *Appendix 48*). The individual challenges are:

- 1. 60 minutes of activity each day (children and parents are given information on the government recommendation for children to be active for a minimum of 60 minutes every day, the health benefits of being active and some ideas on how to achieve the 60-minute minimum target, and children are asked to keep an activity diary)
- 2. swap a snack each day (children and parents are asked to think about daily snack consumption, in terms of both quantity and types of snack consumed; they are provided with possible strategies for reducing the number of snacks consumed and given examples of healthier and less healthy snacks; and children are encouraged to swap a high-fat and/or high-salt and/or high-sugar snack for a healthier alternative and to keep a record of all substitutions made)
- 3. drink more water each day [children and parents are told that over half of the added sugar in children's diets is from the consumption of sugary drinks and told about the importance of staying hydrated throughout the day for both health and concentration; they are advised that a child needs six to eight glasses of fluid (1.2 l) every day to stay properly hydrated; children are encouraged to replace sugary drinks with water and to keep a record of the drinks consumed each day; parents are provided with tips and ideas on how to get their child to drink more water]
- 4. eat a healthy breakfast each day (the importance of eating breakfast every day for concentration is highlighted to both children and parents; they are informed that a healthy breakfast is based on a form of starchy carbohydrate, such as bread and cereals, and that wholegrain versions, which are higher in fibre, are better; breakfast is suggested as an opportunity for fruit and vegetable consumption and examples are given of ways in which this could be achieved; and children are asked to draw a picture of what they have for breakfast every day and are encouraged to make sure that it is healthy)
- 5. eat five portions of fruit and vegetables a day (parents and children are told that at least five portions is the recommended intake for fruit and vegetables and that a handful constitutes a portion; consumption of a range of different coloured fruit and vegetables is encouraged to ensure intake of a full range of vitamins and minerals; parents are provided with suggestions on how a portion can be achieved; and children are encouraged to eat at least five portions and are asked to keep a daily record of all of the fruit and vegetables that they eat)
- 6. plan, cook and eat a healthy balanced meal with your family (families are encouraged to plan a meal in advance, using the Eatwell plate (Public Health England, London, UK; http://webarchive. nationalarchives.gov.uk/20120206100416/http://nhs.uk/Livewell/Goodfood/Documents/Eatwellplate.pdf) to help them think of the different foods types to include and the proportion that each should contribute to the meal to help achieve a balanced diet; it is suggested to parents that this might be a good opportunity to allow their child to help out in the kitchen).

Children are also provided with a booklet of fun activities to take home and complete, which focuses on the key healthy lifestyle messages taught throughout the day (see *Appendix 50*).

# Day 2

This involves a 2-hour school visit by a member of the AVFC coaching staff. This is scheduled approximately 4 weeks after the children's first visit to AVFC. During the first hour the coach runs a PA session involving a series of fun team games that are designed to practise the ball skills that the children were taught in the activity session of day 1. The second hour is used to support the pupils and teachers with their Villa Vitality school project and class challenges.

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# Day 3

Day 3 is divided into three sections: PA, cooking and recording the group project on a CD.

The PA session involves children participating in 1 hour of PA, involving dance mats and aerobic routines supervised by qualified instructors.

The cooking session gives children the opportunity to prepare their own healthy lunch and snacks with an AVFC chef in the Villa Vitality programme Food Academy. In the morning, the lunch preparation is split between the two groups, with one preparing the main course (a pasta bake) and the other preparing the dessert (a fresh fruit salad). In the afternoon, each group is involved in the preparation of a healthy snack to take home (rice and vegetable salad or tuna and salad wrap). Before the start of the first cooking session, the children in both groups are taught food hygiene, including the use of aprons and hats, hand washing and the cleaning of surfaces. Once all of the children are wearing their aprons and hats, and have washed their hands, they learn how to use a knife safely for chopping, as this is a skill that they will use for the preparation of vegetables or fruit later in the session.

The recording of the group project takes place in the AVFC radio studio. Children have the opportunity to record the outcome of the group work that they have been undertaking at school to develop a song, rap lyrics, a poem or rhyme with a healthy lifestyle theme. A member of AVFC staff also undertakes a short interview with each group of children, asking them about the healthy lifestyle messages they have included. The radio studio session with each group is recorded. The recordings for each school are then made into a CD and a copy for each child is sent to the school for distribution.

# Patient and public involvement

This trial started before there was a formal requirement to involve patients and the public. Nevertheless, we involved parents, teachers and children at several levels in an informal way. One of our co-investigators is a health education consultant working with Services for Education and so advised the team on how best to engage with schools and how to ensure that the intervention and study procedures would be acceptable within a school environment. We also consulted a head teacher who advised on the wording of information letters for schools and how to encourage participation. A panel of seven parents and children advised on the cooking workshop material and lessons. A class of children from a non-participating school tried out the revised Villa Vitality programme and provided comments on how it could be improved.

# **Chapter 4** Process evaluation of intervention implementation

# Introduction

Process evaluation has become increasingly recognised as an essential component of public health intervention research; it is of particular importance for research evaluating complex interventions that have multiple components delivered externally, as implementation may vary across study sites.

The development and evaluation of the WAVES study intervention programme were guided by the framework published by the MRC in 2008.<sup>62</sup> At the point of development of the WAVES study process evaluation methods, there were a number of resources highlighting important elements for consideration, but a single agreed comprehensive framework for such evaluation was not available, reflected by the heterogeneity of process evaluation methods presented in the literature. In developing our methods we drew together key aspects of process evaluation presented in previous health promotion intervention literature<sup>63,64</sup> to produce a comprehensive approach to the process evaluation for the WAVES study, an evaluation of a complex and multifaceted intervention programme delivered by teachers and external facilitators. Although the process evaluation methods for the WAVES study were developed and undertaken prior to the publication of the more recent MRC guidance on process evaluation of complex interventions,<sup>65</sup> many of the concepts recommended by the recent framework were included.

# Methods

The first stage of development was to define the process evaluation dimensions to be included. This was achieved through the identification of specific research questions that needed to be addressed and the subsequent mapping of these questions on to different evaluation dimensions drawn from existing literature.<sup>63,64</sup> The most appropriate data collection methods to assess the defined dimensions were then identified. Methods and tools that could be used were assimilated through advice provided by experienced researchers in the field and relevant literature.<sup>66–70</sup> Multiple methods of data collection were used for each dimension to allow triangulation of the data and to provide a broad picture of intervention implementation. It was also anticipated that it would help to ensure comprehensive data availability across all of the process evaluation dimensions, even when some data sources for an intervention component were incomplete or missing. This approach also allowed for cross-checking of reporting accuracy, for example comparing a researcher observation with a teacher logbook entry for the same activity. The research questions identified, together with the mapped process evaluation dimensions and the assessment tools used, are presented in *Table 3*.

#### Information sources utilised

#### **Researcher observations**

Observations were used to collect data on the following process evaluation dimensions: adherence, exposure, participant responsiveness, quality (of delivery) and using checklists developed for each of the relevant intervention components. The observations were also used for the identification of school-specific contextual factors that may influence intervention component delivery. During the early stages of the implementation phase of the intervention (September–October 2011), the observation checklists were piloted and inter-rater reliability was tested through independent completion by two researchers having

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#### TABLE 3 Summary of research questions assessed in the WAVES study intervention process evaluation

Based on process evaluation components outlined by Baranowski and Stables' and Linnan and Steckler.°
 Based on implementation fidelity components outlined by Dane and Schneider.<sup>64</sup>

observed the same session. Any differences were discussed for clarification of what was expected for different ratings to be selected and explanatory text was added to the checklist with the aim of improving future consistency. This process was continued until high inter-rater reliability was achieved and was intermittently repeated throughout the intervention period to ensure that consistency was maintained. The details of the information collected and dimensions assessed by the observation checklists are provided in *Table 4* (see *Appendices 51–53* for example observation checklists relating to the Activate PA package, the breakfast cooking workshop and Villa Vitality session 1).

A trained member of the WAVES study research team undertook observations in all of the schools that delivered the intervention. To try to minimise impact of observer presence during school visits, the research team members were required to be familiar with the checklist content such that they could simply observe or, if appropriate, join in the activity at the time and then complete the checklist as soon as possible after leaving the session. For both activity packages selected by each school (to assist delivery of the PA component), termly observations (per class) of delivery were undertaken. For the cooking workshop

Researcher observation checklist item	Fidelity/ adherence	Reach/dose/ exposure	Recruitment	Quality	Participant responsiveness	Programme differentiation	Context
Activity observed <sup>a,b,c</sup>							√
Duration of activity <sup>a,b,c</sup>	1	1					
Method of delivery <sup>b</sup>	√						
Number of children <sup>a,b,c</sup>		1			1		
Number of parents <sup>a</sup>		1			1		
Number of staff present, number joining in, and if not why <sup>a,b,c</sup>				1			
Number of children present but not participating and why <sup>a,b,c</sup>		✓			1		
Does the leader remind the children of the benefits of the activity? <sup>b</sup>			✓	1			
Does the leader encourage the children to move energetically? <sup>b</sup>			<b>√</b>	1			
Does the leader encourage the children to participate? <sup>c</sup>			<b>√</b>	1			
How enthusiastic is the teacher? <sup>a,b,c</sup>				1			
Do the children have sufficient space? <sup>b</sup>				1			
Overall quality of delivery <sup>a,b,c</sup>				1			
Proportion of children achieving MVPA <sup>b</sup>	1						
Proportion of children enthusiastic about/enjoying session <sup>a,b,c</sup>					✓		
							continued

# **TABLE 4** Content summary of researcher-completed observation checklists used for the WAVES study intervention process evaluation

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Researcher observation checklist item	Fidelity/ adherence	Reach/dose/ exposure	Recruitment	Quality	Participant responsiveness	Programme differentiation	Context
Proportion of children getting actively involved in session <sup>a</sup>					✓		
Proportion of parents enthusiastic about/enjoying session <sup>a</sup>					✓		
Proportion of parents getting actively involved in session <sup>a</sup>					✓		
Was all of the recommended session content delivered? <sup>a,c</sup>	1	✓					
Children with special educational needs included? <sup>a,b,c</sup>	1	1					
Number of children being disruptive <sup>a,b,c</sup>							1
Are most children able to follow the instructions given? <sup>c</sup>	1						
Did language appear to be a barrier for parents? <sup>a</sup>				1	✓		1
a Cooking worksho b PA observation ch	p observation lecklist.	checklist.					

**TABLE 4** Content summary of researcher-completed observation checklists used for the WAVES study intervention process evaluation (*continued*)

component the delivery of at least one of the three workshops was observed at each school, and for the Villa Vitality component one of the three sessions was observed for all of the schools.

Completed observation checklists were not reviewed prior to subsequent school visits to ensure that the researchers were not biased by previous observations. Feedback was not provided to teachers following the observation owing to the study being a Phase IV trial, that is, endeavouring to evaluate the intervention in a real-life setting and aiming to ensure that intervention guidance from the research team was standardised across schools.

#### Evaluation questionnaires and researcher experiences

Evaluation questionnaires were used for obtaining both parent and staff feedback on different elements of the intervention. A cooking workshop parent feedback questionnaire was distributed for those in attendance at the workshops (see *Appendix 54* for an example questionnaire relating to the breakfast cooking workshop). School staff were asked to complete an evaluation for Villa Vitality session 1 (see *Appendix 55*) as well as for

the overall programme (see *Appendix 56*). The school questionnaire, completed by the head teacher or deputy head teacher in both intervention and control schools (see *Chapter 2*, *Cluster-level outcomes*, for further details), was important for the gathering of data on the wider contextual influences of the school on intervention delivery. This information, together with that from observations, was supplemented through a reflective diary for each school. After a researcher school visit, their impressions of the ethos of the school and their overall experience of the school during the visit, together with any particular factors that could be relevant to the WAVES study intervention delivery, were recorded in a school-specific diary of experiences.

## School staff logbooks

School staff were asked to complete logbooks to report on the delivery of the PA, cooking workshop and Villa Vitality components of the intervention. The logbooks collected information on the process evaluation dimensions of adherence, exposure, participant responsiveness, quality of delivery and, to some degree, programme differentiation. A separate logbook was sent to schools, ready for the start of each term in the intervention year, for the PA and cooking workshop components, and shortly before session 1 for the Villa Vitality component. The logbooks were designed to be concise and as simple to complete as possible (see *Appendices 57–59*). Completed logbooks were returned at the end of each term, with two reminder letters sent the following term to schools that had failed to return them. No feedback was given to teachers on the quality of delivery of the various intervention components, but logbooks were inspected on return to check for incomplete or incorrect completion, and any such errors were fed back to staff with the aim of improving subsequent completion. *Table 5* summarises the data collected for each logbook, together with the process evaluation dimensions assessed.

Teacher logbook item	Fidelity/ adherence	Reach/dose/ exposure	Recruitment	Quality	Participant responsiveness	Programme differentiation	Context
PA logbook (comp	leted daily)						
Time of activity	√	✓					
Duration of activity	1	√		√	√		
Reason for non-completion							1
Number of children who did not participate		1					
Additional comments	√	1	1	√	1	1	1
<b>Cooking workshop</b> Cooking workshop l	<b>o logbook (or</b> essons	ne per worksho	op)				
Number of lessons delivered prior to the workshop	1	1	1	J			
Time spent delivering the lessons	√			5			
Additional comments	✓	1	√	√	1	1	1
							continued

TABLE 5 Content summary of teacher-completed logbooks used for the WAVES study intervention process evaluation

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Teacher logbook item	Fidelity/ adherence	Reach/dose/ exposure	Recruitment	Quality	Participant responsiveness	Programme differentiation	Context
Cooking workshop							
Time spent and delivering the workshop	1			1			
Number of children who did not participate and reasons		√			1		
Number of children with at least one parent/carer present		✓	✓		√		
Number of helpers present							1
Additional comments	1	1	1	√	1	1	1
<b>Villa Vitality logbo</b> Villa Vitality days 1–2	<b>ok</b> 3						
Number of children attending the day		1					
Reasons for non-attendance						1	1
Villa Vitality project a	and weekly ch	allenges					
Time spent delivering the project/challenges	1			1			
Number of children who completed each challenge					1		
Additional comments	1	1	1	√	1	1	1

 TABLE 5
 Content summary of teacher-completed logbooks used for the WAVES study intervention process evaluation (continued)

#### Qualitative evaluation

Intervention programme experiences of school staff were explored through interviews, and focus groups were run for parents and children (separately). This qualitative approach was used to collect information relating to the adherence, participation, programme differentiation and responsiveness domains of process evaluation. The parent focus groups were also useful in determining school adherence to the programme, as they provided an indication of whether or not the school had tried to engage parents at the level requested for the relevant components of the intervention programme. The focus group method of data collection was selected for parents and children, as it was thought that such group discussion would encourage open expressions of attitudes and experiences.<sup>72</sup> It was also felt that the children would be more comfortable with a focus group environment, in which their peer group would provide support and promote confidence.<sup>73</sup> Interviews were used for school staff to ensure that school-specific teacher experiences were elicited but also for practical reasons.

Schools were purposively sampled for invitation to participate in the qualitative evaluation such that a range of primary schools varying in terms of pupil ethnic mix, size, geographic location, deprivation (assessed by the percentage of the school population eligible for a free school meal) and level of implementation fidelity achieved for intervention delivery (assessed by members of the research team involved with observations) were involved. Separate topic guides were developed for each participant group, which initially focused on the overall intervention programme before exploring the individual components separately. The topic guide for the teacher interviews and the parent and child focus group topic guides are provided in *Box 1*.

**BOX 1** Topic guides used to guide interviews with teachers and focus groups with parents and children, exploring experiences of delivering the WAVES study

#### **Topic guides**

#### Topic guide: teacher interviews

Question 1: can you tell me about your overall experience of being involved in the WAVES study intervention programme?

Question 2: can you explain your overall experience of the PA programmes?

Question 3: what did you think about the signposting sheets?

Question 4: what were your experiences of the cooking workshops?

Question 5: what were your experiences of the Villa Vitality programme?

Question 6: overall, what impact (if any) do you think the WAVES study intervention programme had on your year 2 children?

Question 7: do you think that there were components of the WAVES programme which were more beneficial than others?

Question 8: do you think that the WAVES study intervention programme could be adopted by primary schools in general?

#### Topic guide: parent focus groups

Question 1: can you tell me what you know about the WAVES study and the activities it involved?

Question 2: can you tell me about you and your child's overall experience of being involved in the WAVES study?

Question 3: as part of the WAVES study programme, schools were asked to fit in an extra 30 minutes of activity into the school day. Did you know this was happening in your child's school? How do you feel about it?

Question 4: what did you think about the signposting sheets?

Question 5: what did you think of the cooking workshops? Do you think the workshops had any impact on your family?

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**BOX 1** Topic guides used to guide interviews with teachers and focus groups with parents and children, exploring experiences of delivering the WAVES study (*continued*)

Question 6: your child's class also attended AVFC for the Villa Vitality programme. What do you think your child's experience of the Villa Vitality programme was?

Question 7: do you think there were components of the WAVES study programme that were more beneficial than others?

Question 8: do you think the WAVES study programme of activities had any effect on your child's behaviours and attitudes towards healthy lifestyle behaviours?

Question 9: what effect (if any) do you think the WAVES study programme has had on your family's lifestyle habits?

Question 10: what role (if any) do you think schools play in obesity prevention?

Topic guide: child focus groups

Question 1: can you tell us what you know about the WAVES study? What did you do as part of the WAVES study?

Question 2: what did you think of the cooking workshops in school? Did you learn anything new?

Question 3: can you tell me what you think about the WAVES study physical activities? How do they make you feel?

Question 4: what did you think about the Villa Vitality programme? What did you do at Villa Vitality?

Question 5: did you take part in the Villa Vitality challenges? What did you think of the challenges?

#### Assimilation of process evaluation data

The use of multiple data collection methods for the process evaluation of each of the intervention components resulted in a large number of data. For each of the three main intervention components (cooking workshops, PA and Villa Vitality), key information to be used from each data source to inform the individual process evaluation dimensions was identified and tabulated. This table was then populated by school as illustrated for PA in *Figure 6*. During this process, if data were available from multiple sources for a particular session, then consistency reporting checks were undertaken. This picked up a few researcher/ school staff reporting discrepancies and, in these instances, researcher reported data were used. This data collation process did not include the signposting sheets because of the uniformity of delivery of this component across schools: confirmation of signposting sheet distribution to children was confirmed for all schools.

An iterative process of score allocation (to maximise interschool consistency) was then undertaken separately for each of the three main intervention programme components. For the process evaluation dimensions of fidelity/adherence, participant responsiveness, reach/dose/exposure, recruitment and quality, two researchers independently allocated school-specific scores on a scale ranging from one (very low) to five (very high). Programme differentiation and context information contributed through its consideration during the allocation of scores to the other dimensions. Score allocation was undertaken in repeated groups of four randomly selected schools, with inter-researcher discussion between each group to reach a consensus in instances when allocated scores varied. School-specific summary scores for each intervention

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1	20	15	30	30	4	most	744	ray balant	)es	yes	20	15	30	30	4	Frequently	yes	yes	yes.		45	- 40	high	yes	4	good	- 4	yes	140	children very poslive	Teacher very enthusiastic
2	10	10	15	5	+-	4	yes	of base of base affect they did would?	yes	540	10	.10	15	ъ	(#)	Occasional IV	Yes	yes	yes		- 4	:4	high	Set	4	good	4	yes	145		Small classroom
з	10	7	15	30	5	afer	148		jes.	no	10	7	6	30	4	Occasional ly	yes :	yes	rio	Children anothing otherst	35	43	medium	yes	.4	poor	4	yes	no	Teacher didn't enjoy PA	Teacher changeover April 2012

FIGURE 6 A worked example of the tabulation of data from multiple sources by process evaluation dimension.

component and process evaluation dimension, together with an overall score, were then generated, as summarised in *Table 6*, for a school universally allocated maximum scores. As a general check for possible inconsistencies, the overall score was then used to rank schools in terms of implementation fidelity achieved, considering all dimensions, for separate review by both researchers.

This independent score allocation process was followed by a consultation with the wider WAVES study team. Five researchers familiar with the WAVES study intervention delivery were asked to use the same process of score allocation to independently score six schools. As a further consistency check, these scores were compared with those already allocated. Low levels of variation were observed, with all wider research team allocations being within one point of those allocated by the two researchers. The staff then revisited the scores with specific consideration of those for which there were minor score allocation differences. A consensus was given to reached after this discussion and the wider research team were then asked to undertake another review of the proposed final scores.

At this point, it was agreed that school-specific definitive scores had been determined and a consensus had been reached on the implementation fidelity rating of schools. Three levels of intervention implementation were defined through the ranking of schools by definitive overall score and their subsequent division into tertiles. Schools with scores ranging from 0 to 51 were classified as low, those scoring between 52 and 58 were classified as medium and those scoring between 59 and 75 were classified as high implementation. Scores by intervention component were then calculated proportionately, such that 0–17 represented low fidelity, 18–19 represented medium fidelity and 20–25 represented high fidelity.

# **Results**

Twenty-six schools were randomised to receive the intervention, but unforeseen circumstances in two meant that 24 (classes = 38) implemented the WAVES study intervention and were therefore involved in the process evaluation. With the exception of researcher observations (on account of all data collection targets being met), process evaluation data availability is summarised in *Table 7*.

#### Data cross-checking

Overall, there was general agreement between data sources when data were available from more than one source. There was some variation in PA and cooking workshop session duration reporting between logbooks and observation checklists, with the logbook reported values tending to be higher than the researcher observations. From 61 matched data points across 16 schools, a mean difference (MD) for PA of 1.3 minutes (SD 5 minutes) was observed, and from data across 19 schools there was an average cooking

	Inter	vention component		
Process evaluation dimension	PA	Cooking workshop	Villa Vitality	Process evaluation dimension score
Fidelity/adherence	5	5	5	15
Reach/dose/exposure	5	5	5	15
Recruitment	5	5	5	15
Quality	5	5	5	15
Participant responsiveness	5	5	5	15
Intervention component score	25	25	25	75°
a Overall implementation fidelity s	core.			

#### TABLE 6 Maximum possible process evaluation scores across all dimensions for each intervention component
Process evaluation data source	Returned/expected (%)
PA logbooks	
Term 1	19/37ª (51)
Term 2	24/37ª (65)
Term 3	12/37ª (32)
Cooking workshop logbooks	
Breakfast	28/38 (74)
Lunch and snacks	27/38 (71)
Evening meals	21/38 (55)
Villa Vitality logbook	25/38 (66)
Questionnaires/evaluations	
School questionnaire	23/24 <sup>b</sup> (96)
Teacher questionnaire	23/38 (61)
Cooking workshop parent evaluations	
Breakfast	23/38 (61)
Lunch and snacks	23/38 (61)
Evening meals	17/38 (45)
Villa Vitality teacher evaluations	51/76 <sup>c</sup> (67)
Qualitative data	Total number of participants
Teacher interviews	16
Parent focus groups ( $n = 8$ )	30
Children focus groups ( $n = 13$ )	61

TABLE 7 Summary of WAVES study process evaluation data availability by class (except when specified otherwise)

a One school did not deliver the PA intervention component.

b One per school, completed by head teacher or deputy head teacher.

c One evaluation requested per class for each of 2 days spent at AVFC.

workshop duration of 85 minutes compared with 60 minutes. However, after the exclusion of PA logbook data for one school where large discrepancies from matched observation data were identified, with recognition of marginal reporting errors, other data cross-checks between these two sources suggested that, in general, logbooks gave a reasonable estimate of school activity.

#### Allocated intervention implementation scores and associated levels of fidelity

Across the schools that implemented the intervention, the minimum overall intervention implementation score was 35 and the maximum score was 68 [median score 56, interquartile range (IQR) 51.0–60.8]. As previously described, schools were classified into three levels of intervention implementation fidelity (low, medium and high) by overall score, intervention component score and process evaluation dimension score. This distribution by school is illustrated in *Table 8*. There were no significant differences when implementation fidelity levels were considered across several school characteristics (outcomes are presented in *Table 9*).

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### Intervention component-specific scores

This section considers implementation fidelity separately for each of the intervention components and, to add context, integrates the outcomes with some qualitative findings from the process evaluation. Discussed findings are illustrated through direct quotations extracted from the verbatim transcriptions and are presented in *Table 10*.

# Cooking workshops

For the cooking workshops, 15 schools (63%) were classified as achieving either high (n = 11) or medium (n = 4) implementation fidelity. However, it should be noted that in four of these the external staff trained

	Overall implementa	eved		
School characteristic	Low ( <i>n</i> = 8), median (IQR)	Medium ( <i>n</i> = 8), median (IQR)	High ( <i>n</i> = 8), median (IQR)	<i>p</i> -valueª
School size (number of pupils on roll)	319 (241–473)	233 (171–351)	279 (187–417)	0.31
Free school meals eligibility (%)	25.3 (17.2–33.1)	32.9 (11.3–42.3)	29.2 (12.1–39.7)	0.91
Ethnicity (% white)	40.2 (1.6–84.0)	75.6 (65.8–82.3)	17.4 (11.1–94.0)	0.29
Ethnicity (% Asian)	32.5 (2.0–79.5)	13.0 (2.0–21.7)	37.3 (2.4–63.5)	0.40
Ethnicity (% black)	5.2 (1.1–27.8)	3.4 (1.5–6.5)	2.1 (0.2–19.6)	0.62
Ethnicity (% other ethnic group)	5.9 (3.7–14.3)	9.5 (5.3–11.4)	5.6 (2.5–18.4)	0.91
a Kruskal–Wallis test.				

#### TABLE 9 Association between overall implementation fidelity level and school characteristics

by the WAVES study research team were responsible for their delivery. For two schools this was for all three workshops, as the head teacher informed the research team that the school did not have sufficient staff capacity to run the sessions. In the other two schools the WAVES study team intervened following unsatisfactory delivery of the first cooking workshop (it was considered that children were being given misleading nutrition information).

Although a comparison of matched cooking workshop logbook and observation records (n = 39) identified a shorter duration reported in the latter, the average session length taken from this source was still at the lower limit of planned duration (60–90 minutes). Apart from this difference, there was minimal variation in reporting between these two sources.

Most schools (n = 15) delivered all three workshops. Six schools ran two workshops, but one of these delivered material from all three sessions, as they combined the lunch and dinner workshops into one session. The remaining five schools managed to deliver only one of the workshops. As requested, most schools invited parents to attend the cooking workshops but researcher observations indicate wide variation in the proportion who attended. The proportion of children for whom a parent was present ranged from 2% to 67%, with a mean attendance of 41% (SD 15%). During the qualitative element of the process evaluation, the cooking workshops were recalled well and an analysis of the data showed appreciation from parents, children and teachers (see *Table 10*, quotations 1–6).

#### Physical activity

Over half of the schools (54%, n = 13) that undertook intervention implementation were included in the low implementation fidelity group for the PA component, with only four (17%) obtaining high implementation fidelity scores. Among schools (n = 19) for which data on weekly frequency of delivery were available (taken from logbooks and teacher questionnaires), only just over half (53%, n = 10) reported achieving the daily delivery target. A further 21% (n = 4) and 16% (n = 3) reported an overall delivery frequency of three and four times per week, respectively, with the remaining two schools managing to deliver this component on only one or fewer days in an average week. If only days on which delivery of the PA component took place are included, then the daily average duration of additional activity is 17.5 minutes, falling to 12 minutes when days on which delivery did not happen are included, representing 58% and 40%, respectively, of the target duration of 30 minutes.

Fitting in the PA component was identified as a challenge during the teacher interviews, especially achieving the target duration of 30 minutes (see *Table 10*, quotation 7). Teachers who opted for the 'as and when' approach to delivery of the PA component struggled more (see *Table 10*, quotation 8) than those who tried to embed it into the daily timetable (see *Table 10*, quotation 9). This was supported by

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Quotation number Q	uotation
1	For the dinner I tried the beans and I like them. Child
2a	You can't have loads of sugar.
2b	Fibre gives you an energy boost and it gives you energy for longer not like sugars, the sugars just give you energy for 1 minute.
	Child
3	The cooking workshops are great and it's really lovely to come in and work with your child. Parent
4	It's been difficult for me cause I think most times that you've done the studies my wife's came in 'cause I'm at work so I'm a bit sort of in the dark.
	Parent
5	So well resourced, you know, you could just literally just pick up the box, I didn't even have to, you know, the lessons beforehand you didn't have to photocopy them, everything was just there for you. Female teacher
6	Well this is going to sound terrible but I've only really done the first one and we did that in spring term. The other two we are going to do this term. The reason why well autumn term we do a major production towards Christmas time which I was organising and liaising with four classes, so that took up a lot of our time and hall time as well, and then we've just recently had SATS and that took priority. Female teacher
7	I can't say we always did 30 minutes, I think we always did possible 20, you know, it's difficult as you appreciate, you've got assessment weeks, you've got different activities going on and so we did our best, yeah. I think probably 20 was more realistic.
	Female teacher
8	You try and have your routine but then you might have an assembly that goes over or it just doesn't fit in with the children the way they are, so you know, sometimes we can't do it now but we have to do it later.
	Female teacher
9	They know what they're expected to do, it starts off the day and the afternoon in a calm way. Female teacher
10	I had a really, really lots of fun there [Villa Vitality programme at AVFC]. Child
11	I think the Villa Vitality was definitely a highlight for me, and we're doing reports at the moment and a lot of the children they're writing about their favourite thing from year 2 and a lot of them have actually mentioned that
	Female teacher
12	It was fantastic and combining the sport and the nutrition was brilliant. Female teacher
13	Yeah I remember looking at this and thinking we're all on a tight budget and it's all about cost. Parent
14	Signposting I can't even remember having these. Parent
15a	I haven't had any children come to me and tell me that they've gone to any of these groups. Female teacher
15b	I'm not sure how much of an impact they had.

# TABLE 10 Illustrative quotations drawn from the qualitative element of the process evaluation

researcher observations in which higher levels of child ability and activity familiarity, together with an easier return from the activity session to classroom work, were reported for classes with regular timetabled slots for the additional PA. The diary of experiences also showed a greater tendency for a generally less structured school day and more challenging child behaviour issues among classes when a 'casual' approach to delivery was adopted by the teacher.

#### Villa Vitality

The Villa Vitality component was completed by all schools that delivered the intervention programme. As might be expected from a component for which delivery was mainly the responsibility of external staff, a high level of implementation fidelity was attained by a large proportion of the schools (71%, n = 17). There was, however, still variation in the fidelity of implementation (through differences in the teachers' approach to delivery of the weekly challenges and class project, their involvement with the sessions held at the AVFC grounds and the general level of encouragement that they provided). Five schools (21%) were classed as having low implementation fidelity, despite the limited requirement for teacher input. Positive feedback was evident from both the children's focus groups (see *Table 10*, quotation 10) and the teacher interviews (see *Table 10*, quotation 11) in relation to the Villa Vitality component. It was also seen as important by some teachers for the integration of the PA and nutrition messages of the intervention programme (see *Table 10*, quotation 12).

# Signposting

In general, recollections by parents were vague or non-existent (see *Table 10*, quotation 14) and no changes to behaviours based on this component were reported. Barriers to implementing the advice provided by the signposting sheets were sometimes discussed by parents (see *Table 10*, quotation 13). The qualitative analysis of the teacher interviews revealed uncertainty about the impact of this component (see *Table 10*, quotations 15a and b).

# Other influences over intervention delivery

The qualitative work and researcher experiences/observations identified that the degree of intervention delivery staff interest in the WAVES' study overall objective had a strong influence on the level of implementation fidelity. Higher quality of implementation – resulting from greater delivery staff engagement with the research and more effort in intervention implementation across all components – was evident when there was already a belief among staff who were responsible for delivery that healthy lifestyle behaviours form a key element of school life. Perceptions of having sufficient staff capacity to undertake the supplementary activities – and the difficulties with fitting them into an already busy class timetable – were an additional critical factor that had an impact on delivery of all main intervention components. Time available for the intervention was further negatively affected by the pressure under which teachers feel to maximise academic performance. Finally, the level of support for the intervention activities by the school as a whole but, in particular, by the head teacher, was also identified as important, with achievement of generally better implementation fidelity in more supportive schools.

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# **Chapter 5** Statistical analysis methods

n this chapter we outline the main statistical analysis methods, along with a range of sensitivity analyses that were carried out.

# Main analysis

#### Flow chart

A chart summarising the eligibility, trial arm allocation and subsequent progress of schools (cluster level) and consented pupils (participant level) is provided in *Chapter 6* (see *Figure 7*). It provides the numbers of participating schools and consented pupils, and cluster size is summarised by the median and IQR.

#### Timeline cluster diagram to assess the risk of biases

A lack of clear reporting of the recruitment process and other aspects of blinding means that it can be difficult to establish whether a cluster randomised trial suffers from recruitment or other biases. One potential tool that has been proposed to improve the reporting of these items and allow the identification of potential biases is a timeline cluster tool.<sup>74</sup> We have used this tool to demonstrate the potential risks for bias in the WAVES trial. Within this tool each of the stages of the trial is represented, in chronological order, in the diagram. An accompanying table describes these aspects of the study in more detail.

#### **Baseline characteristics summaries**

We first summarised and compared the characteristics of those who consented to the trial and those who did not. We did this for a limited number of routinely collected pupil-level baseline characteristics. To enable this, sex, ethnicity and home postcode were requested from participating schools for all eligible pupils. Home postcode was requested to enable an IMD 2010 score (as an indicator of deprivation) to be obtained for each pupil for the lower-layer super output area in which they lived. These pupil-level baseline characteristics are summarised by consented and non-consented pupils (see *Table 12*). Sex, ethnicity and IMD quintile are summarised by numbers and percentages; IMD score is summarised by its median and IQR.

The baseline characteristics of consented pupils (see *Tables 13* and *14*) and participating schools (see *Table 15*) are summarised by control and intervention arms. These baseline characteristics are summarised by numbers and percentages, by means and SDs or by medians and IQR ranges. Medians and IQRs were used for variables that exhibited non-normality. Further details are given below (see *Transformations*).

#### Analyses of outcomes

Analyses of all outcomes are by intention to treat. As randomisation is at the school (cluster) level, appropriate statistical methods to account for the clustering within schools (see *Model choice*) were used in the analysis. An analysis of outcomes is presented for the first, second and third follow-up stages at 3, 18 and 27 months post intervention completion, respectively. We report unadjusted, partially adjusted and fully adjusted results. Full details are explained below.

### Model choice

The primary aim of the study is to evaluate whether or not the BMI-z differs between arms. In statistical terms, this null hypothesis (no difference) can be tested using a mixed linear regression model, with follow-up BMI-z as the dependent variable, baseline BMI-z and treatment arm as the independent variables and school as a random effect.

Null hypotheses for secondary outcomes take a similar form to those for the primary outcome. For example, for the binary outcome of being overweight, the null hypothesis is that the proportion of children who are overweight is the same the between arms. An analysis of the secondary outcomes will, therefore, take a similar form to that described for the primary outcome. Secondary outcomes are either binary (e.g. normal

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weight vs. overweight) or continuous (e.g. energy expenditure). For binary outcomes we have used Poisson mixed regression; this has been shown to be a reliable way of estimating risk differences (RDs) for binary outcomes when covariate adjustment is needed.<sup>75,76</sup> For continuous outcomes we have used linear mixed regression, with an appropriate transformation to accommodate any non-normality when necessary.

#### **Transformations**

To accommodate any non-normality of the outcomes, data were transformed when necessary. To identify which outcome variables required a transformation, a three-step method was used. First, means and medians were calculated and compared for each outcome variable to highlight any clear skew in the data. Second, potential transformations were considered using a ladder of powers plot.<sup>77</sup> This gave a clear indication of whether a variable could be better approximated via a normal distribution before or after transformation. The transformation that visually seemed to represent the best fit via the ladder of powers was then tested to see if it improved goodness of fit. To this end, two models were fitted: one with the data in their raw form and a second with the data in their transformed form. From each model, the residual errors were calculated and plotted. The normality of the residuals was compared between the two models. From this, it was decided whether or not the transformation improved the model. If there was some ambiguity about whether or not the transformed variable improved the model, the preference was to use the untransformed variable, as it aided in the interpretation of the results. Outcomes that needed to be transformed are identified in the relevant results tables. All outcomes requiring transformation were back transformed so that the MDs and confidence intervals (CIs) are presented on the natural scale and comparable for all outcomes. To ensure consistency, outcomes were transformed for all follow-ups using the same transformation, so that if an outcome was transformed at FU1 then the same transformation was used at FU2.

#### Covariate adjustment

All of the analysis models include a random effect for school. We report a totally unadjusted for covariates result, a partially adjusted result, which is our primary analysis, and a fully adjusted result. The primary partially adjusted analysis will be adjusted for baseline value of the outcome. For binary outcomes, our partially adjusted result adjusts for an appropriate continuous variable that is used when calculating the dichotomous outcome. For example, for obese/overweight, we adjusted for baseline BMI-z; for achieving 60 minutes of at least moderate PA per 24 hours, we adjusted for the baseline minutes of activity per 24 hours that is used to calculate the dichotomous outcome; and for meeting the recommended portions of fruit and vegetables per day, we adjusted for the baseline value of the total grams of fruit and vegetables eaten.

The secondary fully adjusted analysis adjusts for both baseline school- and baseline child-level covariates. Both the baseline child- and baseline school-level covariates to be included in the adjustment were prespecified and included school-level factors that were used in the randomisation. These included school size (number of children attending the school), percentage of pupils eligible for full school meals and ethnic mix of pupils (percentage of school population white, percentage of school population black African Caribbean, percentage of school population South Asian). Pupil-level factors include sex (male/female); baseline BMI-z, ethnicity (white, South Asian, black African Caribbean; and other); deprivation, calculated from home postcode (IMD 2010 score); baseline total energy intake (kJ/day); and baseline total PA expenditure (kJ/kg/day). Age has not been adjusted for, as at each measurement time point there was very limited variation in the children's ages. We adjust for school- and pupil-level factors for both ethnicity and deprivation, as the school population was expected to differ from the consented study population.

#### Planned subgroup analyses

We examined whether or not any difference in outcomes between control and intervention arms varies by ethnicity, sex, intervention implementation fidelity, socioeconomic status and obesity levels. For ethnicity we stratified the analysis into white, South Asian and black African Caribbean groups. This stratification was based on the ethnicity of the individual children. For socioeconomic status we stratified the analysis into two groups based on the IMD quintile allocation previously described: children allocated to quintiles 1 and 2 (more deprived) were compared with those allocated to IMD quintiles 3–5

(less deprived). For fidelity, schools that delivered the intervention were allocated implementation fidelity scores for each of the three main intervention programme components, which were then summed to create an overall score for each school. Schools were then ranked by this overall score and divided into tertiles to generate three groups (lower, medium and higher) relating to the level of intervention implementation fidelity achieved. The two intervention schools that did fail to deliver any components of the intervention programme were allocated an overall implementation score of zero and included in the lower implementation fidelity group for this subgroup analysis. Finally, for obesity, we stratified the analysis into two groups and compared those children defined as obese (BMI- $z \ge 95$ th centile value for relevant age and sex using UK 1990 growth reference charts<sup>27</sup>) with those defined as not obese.

The significance of subgroup effects is assessed by tests of interactions of these covariates and the treatment effect. The study had low power to detect all but the largest differences.

#### Exploratory subgroup analyses

A more detailed explanation of why we undertook this exploratory analysis is provided in *Chapter 6*. A subgroup analysis was conducted on study randomisation 'groups'. G1 schools received the intervention in the 2011–12 school year, and G2 schools received the intervention in the 2012–13 school year. The significance of the subgroup effect was assessed by a test of interaction between group and treatment arm. In addition, we report the parameter estimate, 95% CI and *p*-value that correspond to group.

### Missing data

The primary analysis is a complete-case analysis. We report the number included in each analysis by arm, so as to allow full consideration of missing data for every result.

In a sensitivity analysis we used multiple imputation.

#### Reporting of treatment effects

When reporting results, for each continuous outcome we report mean and SD (or median and IQR when appropriate) for baseline and follow-up, along with MD, CI [95% (prespecified key variables) CI or 99% (additional secondary outcomes) CI] and *p*-value. For binary outcomes we report the number and percentage, again for baseline and follow-up, along with RD, CI and *p*-value. To obtain the RD from the Poisson model we use a marginal approach whereby we average over the risk in the control group and use the relative risk estimate from the Poisson model [along with its standard error (SE)] to construct a RD and 95% CI. All three of the follow-ups are reported in independent tables.

#### Statistical significance

The outcomes classified as key anthropometric, diet, PA and psychological variables, and subgroup comparisons at both time points, will be considered significant at the 5% level (and so 95% CIs are reported), whereas other secondary outcomes will be deemed significant at the 1% level (and so 99% CIs are reported). This difference in levels of significance gives more weight to the primary outcomes. Outcomes considered as key anthropometric, diet, PA and psychological variables were prespecified; for continuous variables these are BMI-z, height/waist z-score, sum of four skinfolds, body fat percentage, PA energy expenditure, PedsQL total score, CHU9D utility score and energy intake, and for binary outcomes these are obese, obese/overweight, eating five or more portions of fruit and vegetables and achieving 60 minutes of at least moderate PA per day.

#### Reporting of intracluster correlations

We report ICCs for all primary and secondary main analyses (unadjusted, partially adjusted and fully adjusted) at all follow-ups. We additionally report ICCs that were estimated with the absence of treatment arm in the model. For continuous outcomes we report the conventional ICC directly from the fitted model. For binary outcomes we report what is known as the conventional ICC on the natural scale, obtained from fitting a linear model to the binary outcome. We report 95% CIs for all ICCs. For all models we were able to report the CI for the ICC using the 'estat' function in Stata.

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#### Implementation

All of the analyses were carried out in Stata except the multiple imputation procedures, for which we used REALCOM-IMPUTE (Centre for Multilevel Modelling, Bristol, UK) in conjunction with MLwiN 2.35 (Centre for Multilevel Modelling, Bristol, UK).<sup>78</sup> For the analysis of continuous and binary outcomes, we used the 'meglm' command with robust SEs. We used the default estimation method used by the function that involves a mean variance adaptive Gauss–Hermite quadrature, for which the default starting values and default number of integration points in Stata were used.

#### Changes to analysis methods since protocol stage

Population-averaged models, as opposed to random-effects models (also known as marginal models), were initially specified as the method to allow for clustering. At the protocol stage we had followed guidance in which it was stated that random-effects models lack appropriate interpretation and might be biased.<sup>79</sup> However, before the analysis began, we opted to use the more conventional random-effects approach, as our perception is that this approach is much more commonly used in the analysis of cluster trials.<sup>80</sup>

We had also anticipated fitting logistic regression models to binary outcomes and reporting odds ratios. We changed this so that we could report RDs to be consistent with CONSORT (Consolidated Standards of Reporting Trials) guidelines,<sup>81</sup> and used a log link to allow the reporting of a RD.

Assessment of the baseline characteristics of randomisation groups 1 and 2 showed an imbalance in the characteristics between the arms within each group and between groups. As such, a post hoc exploratory subgroup analysis of the randomisation groups was conducted (see *Chapter 6* for more details).

# Sensitivity analyses

In addition to the general methodology, numerous extensions to the standard methods were examined. Each method was chosen to allow the full robustness of results to be methodologically verified. For all of the sensitivity analyses, we restricted the analysis to outcomes classified as key anthropometric, diet, PA and psychological variables. These are the outcomes for which we used a 95% CI in the main results (see *Statistical significance*). We report the sensitivity analyses for FU1 and FU2, unless stated otherwise.

# Multiple imputation

Imputation was conducted for one outcome at a time. For each outcome, the following items were included in the imputation process: outcome of interest, baseline value of outcome, related outcomes (BMI-z at follow-up, height at follow-up, weight at follow-up, waist z-score at follow-up, sum of four skinfolds at follow-up, PedsQL total score at follow-up and PA expenditure at follow-up), treatment arm, ethnicity of individual (white, South Asian, black African Caribbean and other), deprivation quintile of individual (IMD 2010 quintiles), sex, percentage of school population white, percentage of school population black African Caribbean, percentage of school population for free school meals.

To ensure that our inferences are valid, we allow for clustering in the multiple imputation procedure.<sup>82,83</sup> The multiple imputation procedure involves fitting a conditional model for each variable with missing data in which the variable is linearly regressed on all other variables (those with and without missing data). It then uses a Gibbs sampling approach (100 iterations), updating each set of parameters, in turn, conditional on the others. A mixed-effects linear regression model was used to analyse the imputed data. We report the analyses for three models: unadjusted, partially adjusted and fully adjusted. Rubin's rule<sup>84</sup> is used to pool the effect estimates of 10 sets of imputed data. Transformations used in the imputation process were consistent with the main analysis. In the imputation model for binary outcomes, the variable was linear regression on all other variables. A logistic model was then fitted to the data and an odds ratio was estimated. This was then converted to a RD.

# Different levels of clustering

Our primary analysis was to allow for clustering at the school level, but we explored sensitivity to models in which clustering at both the class and the school level are included. For this, we added an additional nested random-effects structure into our models, allowing class to be nested within school. We report the treatment effect from these models in addition to the ICCs attributable to the correlation at school and class level for each outcome.

### Alternative methods for baseline adjustment

In this repeated cross-sectional cluster trial, we had information on baseline values and follow-up-values. Adjustment for baseline values allows mitigation against any imbalances and also improves the precision of the treatment effect. However, when adjusting for baseline values in our complete-case analysis, we could include only those observations for which both baseline and follow-up-values were available. This resulted in considerable exclusion of data. We therefore explored several methods that have been proposed in the literature<sup>85,86</sup> as alternative ways of adjusting for baseline values that might lead to fewer observations being excluded.

First, instead of adjusting for individual baseline values, adjustment using cluster-level means was undertaken. This resulted in only observations without a follow-up value being excluded. Second, we treated each observation in the data set, both baseline and follow-up, as an outcome and included an indicator to denote which observations were exposed and which were unexposed to the intervention, and another variable to indicate which were baseline and which were follow-up-values. We then fitted a mixed model with a random effect for cluster, a random effect for individual (to allow dependence between the repeated measures on the same person) and an interaction between treatment and period, which is the intervention effect.

#### Treatment by cluster variation in heterogeneity

Our main analyses assumed that the ICC was the same in both arms. An intervention might induce heterogeneity or even homogeneity. To allow for this, we additionally fitted models in which two random effects were included. One random effect was included for schools in the control arm, and a second random effect was included for schools in the intervention arm.

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# Chapter 6 Results

# **Participant flow**

A chart summarising the eligibility, trial arm allocation and subsequent progress of schools (cluster level) and consented pupils (participant level) is provided in *Figure 7*.

# Assessing the risk of bias in the WAVES study

A timeline cluster tool for the WAVES study is provided in *Figure 8* and *Table 11*. Schools were identified and recruited using a weighted random sampling process to guarantee a mix of ethnicities within the study. Following this, letters and accompanying documentation were sent to each school for distribution to the parents of their year 1 pupils. Following the recruitment of schools and pupils, baseline pupil measures were undertaken. During baseline assessment and recruitment, there was no allocation to the intervention, so it was completely blinded. The randomisation process was conducted after baseline assessment. A blocked balancing algorithm was used to randomise schools to the treatment arms. Participating schools were then informed of their allocation.

Owing to the nature of the intervention, it was impossible to blind pupils, parents or teachers to their allocation. Efforts were made to keep research staff responsible for pupil assessment blind to allocation, but complete blinding was not possible. The majority of the assessments were undertaken by sessional staff who were not advised of allocation, but trial arm could have been revealed to them by a comment from a school pupil or member of school staff. A questionnaire was used to try to assess awareness of allocation among these staff, and, from the 17 completed, only one staff member indicated that he/she had ever been aware of arm allocation, suggesting that, in general, blinding of the sessional staff was maintained. In addition, it was not possible to blind core research team staff to allocation, as they were involved in the process evaluation observations of the intervention. The main role of these staff members was to supervise the sessional measurement staff and the fitting of the activity monitors; however, the involvement of core research staff in assessments was sometimes necessary.

# Recruitment

Group 1 schools and pupils were recruited between April and May 2011. G2 schools were recruited between January and April 2012, with pupil recruitment from January to May 2012. In total, 149 eligible schools were approached to obtain the target number of 54 recruited schools. From the 2462 eligible pupils within the participating schools, parental consent for study measurements was obtained for 1467 children (59.6%). The consent was 'opt in' for the full set of measures for 1384 pupils (94% of consents) and 'opt out' for the limited measures for 83 pupils (6% of consents). [For dates defining the measurement periods (baseline and FU1–3), see *Chapter 2*.]

# **Baseline data**

A comparison of baseline demographic characteristics between pupils with and pupils without parental consent to participate in the WAVES study measures is provided in *Table 12*. These data were requested from schools for all of the pupils who were eligible to take part in the WAVES study. However, some schools were prepared to provide the information for consented pupils only. From individuals for whom the data were available, compared with those without consent, pupils with consent were less likely to be

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FIGURE 7 The CONSORT flow diagram for the WAVES study randomised controlled trial. Reproduced from Adab *et al.*,<sup>87</sup> with permission.



**FIGURE 8** A timeline cluster diagram to assess the risk of bias. The rings and stick figures refer to the stages that involve schools (cluster) and pupils (individuals), respectively. A stage involving school-level only is represented by a ring only, whereas a stage involving pupils only is represented by a stick figure only. Stages involving pupils and schools are represented by both rings and stick figure (e.g. baseline observations). The shading of the background of the boxes refers to the level of blinding present. Boxes with dark green shading refer to stages with complete blinding, boxes with light green shading refer to partial blinding, and no shading indicates no blinding. Points that are separated by distinct boxes for intervention and control arms represent stages that differ between the trial arms. Reproduced from Adab *et al.*,<sup>87</sup> with permission.

of South Asian (30.5% vs. 40.8%) or black African Caribbean (7.9% vs. 9.1%) ethnicity, or to be living in an area classified as being one of the 20% most deprived in England (54.9% vs. 64.2%).

Baseline pupil-level demographic characteristics and key anthropometric, diet, PA and psychological data are presented in *Table 13*, both overall and by trial arm, with the data by trial arm showing some imbalance at baseline between the groups. A comparison of intervention with control participants' demographic characteristics shows that they were less likely to be male (49.2% vs. 52.7%), more likely to be of South Asian (32.7% vs. 28.6%) or black African Caribbean (9.2% vs. 6.8%) ethnicity, and more likely to be from more deprived households (mean IMD 2010 score 39.8 vs. 37.6). In terms of the prespecified key anthropometric, diet, PA and psychological variables, intervention arm participants had higher mean BMI

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# TABLE 11 Explanation of the stages shown in Figure 8

Stage number	Stage description
1	<i>Cluster identification</i> All state-maintained schools in the West Midlands that included school years 1–5 and that were within a 35-mile radius of the University of Birmingham were eligible for inclusion. Two hundred schools were then sampled using a weighted random sampling process to ensure a sufficient mix of ethnicities. The 200 schools were ordered using a random number generator and sequentially invited to take part in the study until the required sample size was met. The sampling process and random ordering of the sample were carried out by the trial statistician
2	<i>Cluster recruitment</i> Schools were initially approached by letter, before follow-up telephone communication and face-to-face visits to interested schools. This process was carried out by the trial co-ordinator
3	Patient identification All year 1 pupils (aged 5–6 years) were eligible to take part in the study. Participating schools were advised that the research team would provide a letter and accompanying documentation for each eligible pupil for distribution by the school to their parent/carer
4	Patient recruitment An invitation letter, an information leaflet and a consent form for each eligible pupil were sent to schools for distribution to their parent/carer. Opt-in parental consent was used for the full set of measures in both G1 and G2 schools. In addition, for G2 schools with low recruitment numbers for the opt-in consent, an opt-out consent was used for a limited set of the measures. Pupils for whom consent was withdrawn or dropped owing to them leaving the school were excluded from the time point at which this happened. Pupils who joined the school at a later date (i.e. year 2 onwards) were not included
5	Participant and cluster baseline assessment Baseline measurements were taken when participating pupils were in year 1 (aged 5–6 years). Pupils' date of birth, sex, ethnicity and postcode (used as a proxy for deprivation) were obtained from a parent questionnaire or from school records. Assessment of outcomes was carried out by trained research staff using standardised procedures and validated instruments. Collection of dietary information was undertaken using a validated method, completed by researchers (in school) and a parent/carer (out of school). Psychosocial measures were assessed through validated questionnaires administered to the pupils by trained researchers. PA was measured objectively over 5 days, including at a weekend, using Actiheart monitors. School-level data were collected from local education authorities or from a questionnaire completed by the head teacher or a nominated representative
6	<i>Randomisation</i> A blocked balancing algorithm was used to randomise schools to the control and intervention arms. The algorithm randomly selected one of a number of allocation designs, which minimised the imbalance between a set of prespecified covariate means. The covariates included were percentage of pupils within the school eligible for free school meals, percentage of South Asian pupils within the school, percentage of black African Caribbean pupils within the school, percentage of white pupils within the school and the number of pupils within the school. Participating schools were then informed of their allocation
7a	Intervention delivery No blinding for pupils, parents or teachers. Implementation fidelity was assessed throughout the intervention year using a range of methods, including direct observation, logbooks, parent and school staff questionnaires, research staff experiences and qualitative evaluation
7b	Usual care No blinding for pupils, parents or teachers
8	<i>Outcome assessment: FU1</i> FU1 measurements were taken when participating pupils were in year 3 (aged 7–8 years). Assessment of outcomes was carried out by trained research staff using standardised procedures and validated instruments. Collection of dietary information was undertaken using a validated method, completed by researchers (in school) and a parent/carer (out of school). Psychosocial measures were assessed through validated questionnaires administered to the pupils by trained researchers. PA was measured objectively over 5 days, including at a weekend, using Actiheart monitors
9	<i>Outcome assessment: FU2</i> FU2 measurements were taken when participating pupils were in year 4 (aged 8–9 years). Assessment of outcomes was carried out by trained research staff using standardised procedures and validated instruments. Collection of dietary information was undertaken using a validated method, completed by researchers (in school) and a parent/carer (out of school). Psychosocial measures were assessed through validated questionnaires administered to the pupils by trained researchers. PA was measured objectively over 5 days, including at a weekend, using Actiheart monitors
10	Outcome assessment: FU3 FU3 measurements were taken when participating pupils were in year 5 (aged 9–10 years). Assessment of outcomes was carried out by trained research staff using standardised procedures and validated instruments. Collection of dietary information was undertaken using a validated method, completed by researchers (in school) and a parent/carer (out of school). Psychosocial measures were assessed through validated questionnaires administered to the pupils by trained researchers

TABLE 12 Pupil-level baseline characteristics for pupils with parental consent for participation compared with thosefor pupils without parental consent for participation

	Pupils		
Characteristic: <i>N</i> (number with consent)	With parental consent	Without parental consent	Total
Sex: N = 2218 (1467), n (%)			
Male	749 (51.1)	396 (52.7)	1145 (51.6)
Female	718 (48.9)	355 (47.3)	1073 (48.4)
Not known <sup>a</sup>	O <sup>a</sup>	244ª	244ª
Ethnicity: N = 2165 (1451), n (%)			
White British	658 (45.3)	222 (31.1)	880 (40.6)
South Asian	443 (30.5)	291 (40.8)	734 (33.9)
Black African Caribbean	115 (7.9)	65 (9.1)	180 (8.3)
Other	235 (16.2)	136 (19.0)	371 (17.1)
Not known <sup>a</sup>	16ª	281ª	297ª
IMD quintile: N = 2093 (1439), n (%)			
1 (most deprived)	790 (54.9)	433 (66.2)	1223 (58.4)
2	274 (19.0)	85 (13.0)	359 (17.2)
3	146 (10.1)	58 (8.9)	204 (9.7)
4	119 (8.3)	36 (5.5)	155 (7.4)
5 (least deprived)	110 (7.6)	42 (6.4)	152 (7.3)
Not known <sup>a</sup>	28ª	341ª	369ª
IMD score: N = 2093 (1439), median (IQR)	38.9 (20.1–49.5)	44.6 (26.9–54.4)	40.2 (21.7–51.4)
a Not included in denominator for calculation of percenta	ges.		

# **TABLE 13** Key baseline characteristics of school pupils participating in the WAVES study overall and by trial arm for all schools

	Arm		
Characteristic: N (number in intervention arm)	Intervention	Control	Total
Demographic			
Age (years): $N = 1397$ (662), mean (SD) – not known: intervention = 27, control = 43	6.31 (0.30)	6.27 (0.31)	6.29 (0.31)
Sex: N = 1467 (689), n (%)			
Male	339 (49.2)	410 (52.7)	749 (51.1)
Female	350 (50.8)	368 (47.3)	718 (48.9)
Ethnicity: N = 1451 (676), n (%)			
White British	297 (43.9)	361 (46.6)	658 (45.3)
South Asian	221 (32.7)	222 (28.6)	443 (30.5)
Black African Caribbean	62 (9.2)	53 (6.8)	115 (7.9)
Other	96 (14.2)	139 (17.9)	235 (16.2)
Not known	13ª	3ª	16ª
			continued

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	Arm		
Characteristic: <i>N</i> (number in intervention arm)	Intervention	Control	Total
IMD quintile: <i>N</i> = 1439 (670), <i>n</i> (%)			
1 (most deprived)	392 (58.5)	398 (51.8)	790 (54.9)
2	120 (17.9)	154 (20.0)	274 (19.0)
3	72 (10.7)	74 (9.6)	146 (10.1)
4	65 (9.7)	54 (7.0)	119 (8.3)
5 (least deprived)	21 (3.1)	89 (11.6)	110 (7.6)
Not known	19ª	9ª	28ª
IMD score: $N = 1439$ (670), median (IQR) – not known: intervention = 19, control = 9	39.80 (21.86–52.68)	37.60 (17.89–48.79)	38.93 (20.14–49.49)
Anthropometric			
BMI-z: <i>N</i> = 1392 (660), mean (SD) – not known: intervention = 29, control = 46	0.23 (1.24)	0.15 (1.20)	0.19 (1.22)
Height (cm): <i>N</i> = 1396 (664), mean (SD) – not known: intervention = 25, control = 46	118.63 (5.60)	118.18 (5.38)	118.39 (5.49)
Waist circumference z-score: <i>N</i> = 1259 (589), mean (SD) – not known: intervention = 100, control = 108	0.77 (1.24)	0.66 (1.25)	0.71 (1.25)
Sum of four skinfolds <sup>b</sup> (mm): <i>N</i> = 1137 (540), median (IQR) – not known: intervention = 149, control = 181	28.55 (23.30–35.43)	28.10 (23.00–36.60)	28.35 (23.10–36.05)
Body fat %: <i>N</i> = 1376 (660), mean (SD) – not known: intervention = 29, control = 62	21.30 (5.35)	20.95 (5.22)	21.12 (5.28)
Weight status: $^{c} N = 1392$ (660), $n$ (%)			
Underweight (≤2nd centile)	20 (3.0)	20 (2.7)	40 (2.9)
Healthy weight (> 2nd and < 85th centiles)	495 (75.0)	562 (76.8)	1057 (75.9)
Overweight ( $\geq$ 85th and < 95th centiles)	61 (9.2)	63 (8.6)	124 (8.9)
Obese (≥95th centile)	84 (12.7)	87 (11.9)	171 (12.3)
Not known	29ª	46 <sup>a</sup>	75ª
24-hour dietary intake			
Energy (kJ in 24 hours): N = 1187 (562), median (IQR) – not known: intervention = 127, control = 153	6904 (5865–8054)	6911 (5804–7964)	6907 (5829–8002)
Five or more portions of fruit and vegetables: $N = 1187$ (562), $n$ (%)			
Yes	336 (59.8)	405 (64.8)	741 (62.4)
No	226 (40.2)	220 (35.2)	446 (37.6)
Not known	127ª	153ª	280ª
PA			
PA energy expenditure (kJ/kg/day): $N = 1052$ (492), mean (SD) – not known: intervention = 197, control = 218	96.43 (23.16)	94.08 (24.38)	95.18 (23.83)
$\geq$ 60 minutes' MVPA/24 hours: $N$ = 1048 (491), $n$ (%)			
Yes	228 (46.4)	276 (49.6)	504 (48.1)
No	263 (53.6)	281 (50.4)	544 (51.9)
Not known	198ª	221ª	419ª

**TABLE 13** Key baseline characteristics of school pupils participating in the WAVES study overall and by trial arm for all schools (*continued*)

**TABLE 13** Key baseline characteristics of school pupils participating in the WAVES study overall and by trial arm for all schools (*continued*)

	Arm		
Characteristic: N (number in intervention arm)	Intervention	Control	Total
Psychological			
PedsQL total score: $N = 1384$ (663), median (IQR) – not known: intervention = 26, control = 57	71.74 (60.87–82.61)	73.91 (60.87–82.61)	71.74 (60.87–82.61)
CHU9D utility score: $N = 1350$ (643), mean (SD) – not known: intervention = 46, control = 71	0.84 (0.13)	0.82 (0.14)	0.83 (0.14)

a Not included in denominator for calculation of percentages.

b Subscapular skinfold + suprailiac skinfold + biceps skinfold + triceps skinfold.

c Based on UK 1990 reference centile curves and applying the cut-off points used for population monitoring.

and waist z-scores (0.23 vs. 0.15 and 0.77 vs. 0.66, respectively) and body fat percentage (21.30 vs. 20.95), and are less likely to meet the current government healthy lifestyle recommendations for children (46.4% vs. 49.6% meeting the 60-minute minimum target for being at least moderately physically active and 59.8% vs. 64.8% consuming five or more portions of fruit and vegetables a day) than those in the control arm.

For the additional anthropometric, diet, PA and psychological variables considered, there was a reasonably good balance between the control and intervention arms (*Table 14*). This was also generally true for the school-level characteristics, as shown in *Table 15*.

	Arm		
Characteristic: N (number in intervention arm)	Intervention	Control	Total
Anthropometric			
Subscapular skinfold (mm): <i>N</i> = 1187 (558), median (IQR) – not known: intervention = 131, control = 149	5.98 (5.05–7.30)	5.80 (4.95–7.20)	5.85 (5.00–7.25)
Suprailiac skinfold (mm): $N = 1184$ (565), median (IQR) – not known: intervention = 124, control = 159	6.50 (4.75–9.45)	6.10 (4.55–9.30)	6.30 (4.70–9.33)
Biceps skinfold (mm): $N = 1220$ (580), median (IQR) – not known: intervention = 109, control = 138	6.15 (4.80–7.80)	6.15 (4.70–8.40)	6.15 (4.70–8.10)
Triceps skinfold (mm): $N = 1213$ (574), median (IQR) – not known: intervention = 115, control = 139	9.80 (7.90–12.30)	10.00 (7.95–12.60)	9.90 (7.90–12.45)
Thigh skinfold (mm): $N = 1031$ (494), median (IQR) – not known: intervention = 195, control = 241	13.43 (11.10–16.75)	13.30 (10.90–17.20)	13.35 (10.93–17.00)
Bioimpedance ( $\Omega$ ): $N = 1373$ (657), mean (SD) – not known: intervention = 32, control = 62	656.13 (81.30)	654.00 (82.33)	655.02 (81.82)
PA			
Sedentary hours/24 hours: <i>N</i> = 1048 (491), mean (SD) – not known: intervention = 198, control = 221	14.42 (1.88)	14.57 (1.78)	14.50 (1.83)
MVPA minutes/24 hours: $N = 1048$ (491), median (IQR) – not known: intervention = 198, control = 221	57.91 (42.52–85.90)	59.47 (42.80–81.53)	58.68 (42.59–82.84)
			continued

#### TABLE 14 Additional baseline characteristics of school pupils participating in the WAVES study overall and by trial arm

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**TABLE 14** Additional baseline characteristics of school pupils participating in the WAVES study overall and by trial arm (continued)

	Arm		
Characteristic: <i>N</i> (number in intervention arm)	Intervention	Control	Total
Blood pressure			
Systolic (mmHg): <i>N</i> = 1332 (634), mean (SD) – not known: intervention = 55, control = 80	95.67 (9.04)	98.10 (10.06)	96.94 (9.66)
Diastolic (mmHg): $N = 1332$ (634), mean (SD) – not known: intervention = 55, control = 80	62.18 (7.99)	64.21 (8.59)	63.24 (8.37)
24-hour dietary intake			
Fat (grams in 24 hours): N = 1187 (562), median (IQR) – not known: intervention = 127, control = 153	56.08 (45.39–69.28)	54.74 (44.75–67.58)	55.55 (45.06–68.13)
Free sugar (grams in 24 hours): $N = 1187$ (562), mean (SD) – not known: intervention = 127, control = 153	76.63 (31.01)	76.13 (30.88)	76.37 (30.93)
Fibre (grams in 24 hours): $N = 1187$ (562), median (IQR) - not known: intervention = 127, control = 153	11.00 (8.80–13.68)	11.35 (8.99–13.95)	11.20 (8.91–13.80)
Fruit and vegetables (grams in 24 hours): $N = 1187$ (562), median (IQR) – not known: intervention = 127, control = 153	226.92 (132.00–330.09)	247.58 (157.25–341.40)	233.08 (143.62–334.36)
Psychological			
PedsQL physical functioning score: $N = 1384$ (663), mean (SD) – not known: intervention = 26, control = 57	73.06 (18.07)	74.87 (17.26)	74.00 (17.67)
PedsQL psychosocial functioning score: $N = 1384$ (663), mean (SD) – not known: intervention = 26, control = 57	69.47 (17.95)	69.28 (18.19)	69.37 (18.07)
PedsQL emotional functioning score: $N = 1384$ (663), mean (SD) – not known: intervention = 26, control = 57	73.36 (22.20)	71.68 (23.05)	72.49 (22.65)
PedsQL social functioning score: $N = 1383$ (662), mean (SD) – not known: intervention = 27, control = 57	67.72 (22.34)	68.60 (21.71)	68.18 (22.01)
PedsQL school functioning score: $N = 1382$ (663), mean (SD) – not known: intervention = 26, control = 59	67.35 (21.72)	67.54 (21.56)	67.45 (21.63)
KIDSCREEN-52 bullying: $N = 1374$ (661), mean (SD) – not known: intervention = 28, control = 65	11.74 (3.20)	12.05 (2.97)	11.91 (3.08)
Body image satisfaction score: $N = 1374$ (663), mean (SD) – not known: intervention = 26, control = 67	0.17 (2.07)	0.43 (2.05)	0.31 (2.06)
Ω, ohm.			

#### TABLE 15 Baseline characteristics of schools participating in the WAVES study overall and by trial arm

Characteristic	Intervention arm, median (IQR) ( <i>n</i> = 26)	Control arm, median (IQR) ( <i>n</i> = 28)	Total arm, median (IQR) ( <i>N</i> = 54)
% black African or Caribbean pupils on roll	3.70 (1.40–8.30)	6.06 (0.88–12.70)	5.10 (1.01–11.90)
% South Asian pupils on roll	22.70 (1.39–51.90)	21.80 (2.30–48.30)	21.80 (2.30–48.30)
% of pupils eligible for a free school meal	29.60 (19.31–41.60)	23.59 (14.50–34.80)	27.00 (19.31–37.80)
Total number of pupils on roll	300 (216–394)	327 (202–478)	327 (206–429)

# **Numbers analysed**

All of the analyses undertaken were by intention to treat. At baseline, one or more of the variables needed to calculate the primary outcome was not available for 75 pupils. This was mainly due to consented children being absent from school on measurement days, although six had left the school and a handful did not assent to some measurements: two children did not agree to either height or weight measurement and an additional child did not agree to height measurement only. One intervention arm school (pupils = 20) was excluded from all of the analyses involving follow-up data because of its withdrawal from the study after baseline measurement completion. Fifty-three schools (control arm, n = 28; intervention arm, n = 25) were therefore included in the FU1 and FU2 analyses. In addition to the 20 pupils from the withdrawn school, a further 160 were lost to FU1: 28 owing to the parent withdrawing consent and 132 owing to the pupil changing school. The maximum number of pupils available for analysis at FU1 was therefore 1287, with primary outcome data available for 1249 pupils (the gap being due to pupil absence on measurement days).

Between FU1 and FU2, an additional 118 pupils were excluded: 27 owing to the parent withdrawing consent and 91 owing to the pupil no longer attending the school, resulting in a maximum number of 1169 pupils available for analysis at FU2 (1145 with primary outcome data). Analyses at FU3 were for G1 schools (n = 27: control, n = 14; intervention, n = 13; maximum number of pupils available for analysis n = 509, primary outcome data available n = 488). The number of participants included for each outcome (overall and by trial arm) is provided for all of the models in the first column of each results table. Numbers vary between outcomes because of either lack of assent from a few children for some measures or exclusion of data as previously described (see *Chapter 2*). For the primary analysis of the secondary outcomes, data availability was lowest in relation to the PA and thigh skinfold thickness variables (n = 720 and n = 571, n = 826 and n = 610, at FU1 and FU2, respectively). For the remaining outcomes, valid data were available for between 902 and 1200 children at FU1, 724 and 1096 children at FU2, and 330 and 468 children at FU3 (G1 schools only for prespecified key variables).

# **Outcomes and estimation**

The results for the prespecified key anthropometric, diet, PA and psychological variables are presented for both continuous and binary outcomes at FU1 in *Table 16* (corresponding ICCs are reported in *Table 17*), at FU2 in *Table 18* (corresponding ICCs are reported in *Table 19*) and at FU3 in *Table 20* (corresponding ICCs are reported in *Table 21*). Results are reported below for the partially adjusted primary analysis (which adjusts for the baseline value of the outcome only) and also for the fully adjusted model (which additionally adjusts for the prespecified pupil and school-level baseline characteristics). When values are reported without value model specification, the values are for the partially adjusted analyses. With the exception of height, included for BMI interpretation, the outcomes are reported for each time point in the same order as the variables are presented in the results tables.

#### Primary outcomes

#### Body mass index z-score (at follow-ups 1 and 2)

At FU1, in the partially adjusted primary analysis, the mean BMI-z was lower in the intervention arm than in the control arm, with a MD of –0.075. However, this was not statistically significant (95% CI –0.183 to 0.033; p = 0.175). This estimate was robust to covariate adjustment, as the fully adjusted estimate (MD –0.077, 95% CI –0.191 to 0.037; p = 0.186) does not differ much from that of the partially adjusted model.

At FU2, the difference in mean BMI-z between the trial arms is smaller, but remains lower in the intervention arm than in the control arm, with a MD of –0.027. However, this difference is also not statistically significant (95% CI –0.137 to 0.083). There is a slight increase in the MD (MD –0.042) after covariate adjustment but the outcome remains insignificant.

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Follow-up outcome	Arm			Intervention vs. control						
variable: N = total participants	Intervention		Control							
( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous</b> outcomes BMI-z	Mean (SD) or median (IQR) <sup>c</sup>	MD (95% CI)	p-value	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>			
N = 1249 (n = 574, unadjusted)	0.23 (1.24)	0.34 (1.34)	0.15 (1.20)	0.23 (1.27)	0.101 (–0.073 to 0.275)	0.255	–0.075 (–0.183 to 0.033)	0.175	–0.077 (–0.191 to 0.037)	0.186
N = 1197 (n = 556, partially adjusted)										
N = 837 (n = 393, fully adjusted)										
Height (cm)										
N = 1251 (n = 575, unadjusted)	118.63 (5.60)	127.37 (6.09)	118.18 (5.38)	127.03 (5.75)	0.346 (–0.255 to 0.947)	0.259	–0.073 (–0.652 to 0.505)	0.804	–0.198 (–0.798 to 0.402)	0.517
N = 1200 (n = 558, partially adjusted)										
N = 837 (n = 392, fully adjusted)										
Waist z-score										
N = 1151 (n = 528, unadjusted)	0.77 (1.24)	1.05 (1.36)	0.66 (1.25)	0.87 (1.32)	0.177 (0.005 to 0.348)	0.043	0.026 (–0.168 to 0.220)	0.794	0.019 (–0.122 to 0.161)	0.789
N = 1069 (n = 490, partially adjusted)										
N = 796 (n = 368, fully adjusted)										
Sum of four skinfolds (	mm) <sup>d,e</sup>									
N = 1048 (n = 488, unadjusted)	28.55 (23.30–35.43)	31.48 (24.57–43.65)	28.10 (23.00–36.60)	29.40 (23.63–41.67)	1.317 (–0.231 to 2.864)	0.095	0.366 (–0.157 to 0.890)	0.170	0.417 (–0.193 to 1.027)	0.180
N = 902 (n = 421, partially adjusted)										
N = 683 (n = 323, fully adjusted)										

# TABLE 16 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU1

variable: <i>N</i> = total	Arm									
participants	Intervention		Control							
intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Body fat %										
N = 1236 (n = 574, unadjusted)	21.30 (5.35)	21.79 (6.73)	20.95 (5.22)	20.87 (6.30)	0.841 (–0.040 to 1.722)	0.061	0.040 (–0.707 to 0.786)	0.917	0.048 (–0.749 to 0.845)	0.906
N = 1169 (n = 553, partially adjusted)										
N = 822 (n = 391, fully adjusted)										
Energy intake (kJ in 24	! hours) <sup>f</sup>									
N = 1112 (n = 507, unadjusted)	6904 (5865–8054)	7152 (6107–8376)	6911 (5804–7964)	7074 (5963–8233)	122.611 (–213.680 to 458.902)	0.475	61.531 (–217.772 to 340.834)	0.666	30.988 (–257.865 to 319.840)	0.833
N = 978 (n = 449, partially adjusted)										
N = 803 (n = 369, fully adjusted)										
PA energy expenditure	e (kJ/kg/day)									
N = 868 (n = 395, unadjusted)	96.43 (23.16)	91.70 (23.71)	94.08 (24.38)	91.27 (25.42)	–0.207 (–4.552 to 4.137)	0.926	–0.866 (–5.389 to 3.658)	0.708	–1.762 (–5.753 to 2.228)	0.387
N = 724 ( $n = 335$ , partially adjusted)										
N = 658 (n = 310, fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 1231 (n = 554, unadjusted)	71.74 (60.87–82.61)	76.09 (65.22–84.78)	73.91 (60.87–82.61)	76.09 (65.22–84.78)	–0.662 (–2.805 to 1.481)	0.545	–0.630 (–3.487 to 2.227)	0.665	–0.437 (–3.354 to 2.481)	0.769
N = 1171 (n = 538, partially adjusted)										
N = 817 (n = 375, fully adjusted)										
										continued

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#### Follow-up outcome variable: N =total (n = number in)Fully adjusted<sup>b</sup> Partially adjusted<sup>a</sup> CHU9D utility score N = 1215 (n = 550,0.84 (0.13) 0.87 (0.11) 0.82 (0.14) 0.86 (0.10) 0.012 0.230 0.010 0.300 0.015 0.185 (-0.007 to 0.037) unadjusted) (-0.007 to 0.030) (-0.009 to 0.029) N = 1130 (n = 519,partially adjusted) N = 786 (n = 358,fully adjusted) **Binary outcomes** n (%) n (%) n (%) n (%) RD (95% CI) p-value RD (95% Cl) p-value RD (95% CI) p-value Obese<sup>h</sup> N = 1249 (n = 574)87 (11.89) 100 (14.81) 0.381 -0.036 0.074 -0.007 0.676 84 (12.73) 93 (16.20) 0.014 unadjusted) (-0.018 to 0.053) (-0.066 to 0.004) (-0.038 to 0.031) N = 1197 (n = 556,partially adjusted) N = 837 (n = 393)fully adjusted) Obese/overweight<sup>h</sup> N = 1249 (n = 574,145 (21.97) 165 (28.75) 150 (20.49) 167 (24.74) 0.040 0.093 -0.013 0.655 0.000 0.994 (-0.006 to 0.095) (-0.061 to 0.048) (-0.050 to 0.064) unadjusted) N = 1197 (n = 556,partially adjusted) N = 837 (n = 393)

#### TABLE 16 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU1 (continued)

N = 837 (n = 35)fully adjusted)

Follow-up outcome	Arm				Intervention vs. con	trol				
variable: <i>N</i> = total participants	Intervention		Control							
( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Five or more portions	of fruit and vege	etables <sup>i</sup>								
N = 1112 (n = 507, unadjusted)	336 (59.79)	244 (48.13)	405 (64.80)	297 (49.09)	–0.010 (–0.085 to 0.080)	0.820	-0.014 (-0.090 to 0.077)	0.753	0.004 (–0.057 to 0.074)	0.900
N = 978 (n = 449, partially adjusted)										
N = 803 (n = 369, fully adjusted)										
Achieving $\geq$ 60 minute	es of PA <sup>i</sup>									
N = 866 (n = 396, unadjusted)	228 (46.44)	207 (52.27)	276 (49.55)	234 (49.79)	0.015 (–0.076 to 0.126)	0.762	0.041 (–0.058–0.163)	0.446	0.005 (–0.078 to 0.105)	0.911
N = 720 (n = 334, partially adjusted)										
N = 654 (n = 310, fully adjusted)										
<ul> <li>a Adjusted for basel</li> <li>b Adjusted for basel</li> <li>b baseline school-lee</li> <li>free school meale</li> <li>c Summary statistics</li> <li>d Transformed via in</li> <li>e Sum of four skinfor</li> <li>f Transformed via sin</li> <li>h Adjusted for basel</li> <li>Adjusted for basel</li> </ul>	line outcome. line outcome, b vel covariates [s eligibility]. s presented are nverse. olds comprised s hatural logarithm quaring. line BMI-z.	aseline pupil-lev ize (number of p either mean (SD summation of b n.	el covariates [se pupils on roll), p ) or median (IQ iceps, subscapul	x, ethnicity, dep ercentage of sch R). ar, suprailiac an	rivation (IMD score for lool population South / d triceps measurement:	home postc Asian, percer s.	ode), 24-hour total ener ntage of school populat	gy intake, P ion black Af	'A energy expenditure] frican Caribbean, perce	and ntage with

j Adjusted for minutes of PA per 24 hours.

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#### TABLE 17 Intracluster correlation coefficients: key anthropometric, diet, PA and psychological variables – FU1, point estimate (95% Cl)

Outcome	Unadjusted ICC	ICC adjusted for treatment arm	Partially adjusted ICC <sup>a</sup>	Fully adjusted ICC <sup>b</sup>
Continuous outcomes				
BMI-z	0.0211 (0.0074 to 0.0590)	0.0193 (0.0063 to 0.0577)	0.0858 (0.0501 to 0.1432)	0.0805 (0.0441 to 0.1423)
Height (cm)	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)	0.2913 (0.2096 to 0.3893)	0.3750 (0.2813 to 0.4790)
Waist z-score	0.0136 (0.0027 to 0.0650)	0.0089 (0.0010 to 0.0772)	0.1538 (0.0950 to 0.2394)	0.1094 (0.0619 to 0.1860)
Sum of four skinfolds (mm)	0.0051 (0.0001 to 0.1808)	0.0029 (0.0000 to 0.5966)	0.1466 (0.0906 to 0.2286)	0.1215 (0.0710 to 0.2002)
Body fat %	0.0252 (0.0101 to 0.0616)	0.0208 (0.0074 to 0.0572)	0.1032 (0.0620 to 0.1669)	0.1059 (0.0620 to 0.1752)
Energy intake (kJ in 24 hours)	0.0534 (0.0275 to 0.1012)	0.0525 (0.0269 to 0.1000)	0.0418 (0.0184 to 0.0921)	0.0363 (0.0148 to 0.0865)
PA energy expenditure (kJ/kg/day)	0.0493 (0.0220 to 0.1068)	0.0493 (0.0220 to 0.1068)	0.0819 (0.0410 to 0.1570)	0.0556 (0.0222 to 0.1329)
PedsQL total score	0.0403 (0.0189 to 0.0839)	0.0395 (0.0184 to 0.0829)	0.0394 (0.0181 to 0.0839)	0.0176 (0.0037 to 0.0799)
CHU9D utility score	0.0577 (0.0297 to 0.1094)	0.0559 (0.0286 to 0.1066)	0.0587 (0.0296 to 0.1134)	0.0604 (0.0293 to 0.1203)
Binary outcomes				
Obese <sup>c</sup>	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)
Obese/overweight <sup>c</sup>	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)	0.0192 (0.0052 to 0.0684)	0.0040 (0.0000 to 0.6448)
Five or more portions of fruit and vegetables <sup>d</sup>	0.0390 (0.0171 to 0.0864)	0.0390 (0.0171 to 0.0865)	0.0313 (0.0118 to 0.0806)	0.0000 (0.0000 to 0.0000)
Achieving $\geq$ 60 minutes of PA <sup>e</sup>	0.0641 (0.0326 to 0.1222)	0.0642 (0.0327 to 0.1225)	0.0770 (0.0382 to 0.1488)	0.0568 (0.0241 to 0.1282)

FU1, follow-up 1.

a Adjusted for treatment arm and baseline value of the outcome.

b Adjusted for treatment arm, baseline value of the outcome, baseline pupil level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake, PA energy expenditure] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of those with free school meal eligibility].

c Adjusted for baseline BMI-z.

d Adjusted for total grams of fruit and vegetables consumed per day.

e Adjusted for minutes of PA per 24 hours.

 TABLE 18 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU2

Follow-up outcome	Arm				Intervention vs. contr	ol				
variable: <i>N</i> = total participants	Intervention		Control							
( <i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or median (IQR) <sup>®</sup>	Mean (SD) or median (IQR) <sup>c</sup>	Mean (SD) or median (IQR) <sup>c</sup>	Mean (SD) or median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)ª	p- <i>value</i> <sup>c</sup>
N = 1145 (n = 524, unadjusted) N = 1094 (n = 505, partially adjusted) N = 772 (n = 359, fully adjusted)	0.23 (1.24)	0.42 (1.34)	0.15 (1.20)	0.31 (1.32)	0.103 (–0.053 to 0.258)	0.197	-0.027 (-0.137 to 0.083)	0.627	-0.042 (-0.163 to 0.080)	0.500
Height (cm)										
N = 1146 (n = 524, unadjusted) N = 1096 (n = 506, partially adjusted) N = 773 (n = 359, fully adjusted)	118.63 (5.60)	134.73 (6.68)	118.18 (5.38)	134.86 (6.43)	–0.135 (–0.945 to 0.675)	0.744	-0.483 (-1.120 to 0.154)	0.137	–0.639 (–1.235 to –0.044)	0.035
Waist z-score										
N = 990 (n = 446, unadjusted) $N = 923 (n = 414, partially adjusted)$ $N = 703 (n = 320, fully adjusted)$	0.77 (1.24)	1.15 (1.25)	0.66 (1.25)	0.90 (1.35)	0.240 (0.041 to 0.440)	0.018	0.103 (-0.042 to 0.248)	0.163	0.068 (-0.085 to 0.221)	0.383
										continued

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Follow-up outcome	Arm				Intervention vs. control					
participants	Intervention		Control							
( <i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Sum of four skinfolds (i	mm) <sup>d,e</sup>									
N = 845 (n = 381, unadjusted)	28.55 (23.30–35.43)	34.70 (25.50–49.95)	28.10 (23.00–36.60)	31.93 (24.00–48.90)	1.927 (–0.402 to 4.256)	0.105	0.644 (0.103 to 1.186)	0.020	0.532 (–0.077 to 1.141)	0.087
N = 724 ( $n = 334$ , partially adjusted)										
N = 560 (n = 262, fully adjusted)										
Body fat %										
N = 1115 (n = 516, unadjusted)	21.30 (5.35)	22.52 (7.48)	20.95 (5.22)	21.58 (7.26)	0.921 (–0.020 to 1.863)	0.055	0.344 (–0.396 to 1.085)	0.362	0.166 (–0.715 to 1.047)	0.712
N = 1051 (n = 495, partially adjusted)										
N = 747 (n = 354, fully adjusted)										
Energy intake (kJ in 24	hours) <sup>f</sup>									
N = 1015 (n = 453, unadjusted)	6904 (5865–8054)	7656 (6436–9118)	6911 (5804–7964)	7817 (6748–9212)	–214.643 (–561.717 to 132.430)	0.225	–139.552 (–467.690 to 188.585)	0.405	–273.658 (–616.542 to 69.225)	0.118
N = 895 (n = 401, partially adjusted)										
N = 729 (n = 331, fully adjusted)										
PA energy expenditure	(kJ/kg/day)									
N = 690 (n = 305, unadjusted)	96.43 (23.16)	79.66 (22.26)	94.08 (24.38)	78.60 (22.43)	1.184 (–3.254 to 5.623)	0.601	0.001 (–4.371 to 4.373)	0.999	-0.224 (-4.120 to 3.672)	0.910
N = 571 (n = 253, partially adjusted)										
N = 520 (n = 237, fully adjusted)										

# TABLE 18 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU2 (continued)

variable: $N = \text{total}$ participants ( $n = \text{number in}$ intervention arm) PedsQL total score <sup>g</sup> N = 1116 (n = 495, unadjusted) N = 1055 (n = 477, partially adjusted) N = 755 (n = 346, fully adjusted) CHU9D utility score	Intervention Baseline 71.74 (60.87–82.61) 0.84 (0.13)	FU2 82.61 (71.74–89.13)	Control Baseline 73.91 (60.87–82.61)	FU2 80.43 (71.74–89.13)	Unadjusted 0.997 (-1.301 to 3.295)	0.395	Partially adjusted <sup>a</sup> 1.248 (-1.453 to 3.948)	0.365	Fully adjusted <sup>b</sup> 1.246 (-1.083 to 3.575)	0.294
(n = number in intervention arm) PedsQL total score <sup>9</sup> N = 1116 (n = 495, unadjusted) N = 1055 (n = 477, partially adjusted) N = 755 (n = 346, fully adjusted) CHU9D utility score	Baseline 71.74 (60.87–82.61) 0.84 (0.13)	FU2 82.61 (71.74–89.13)	Baseline 73.91 (60.87–82.61)	FU2 80.43 (71.74–89.13)	Unadjusted 0.997 (-1.301 to 3.295)	0.395	Partially adjusted <sup>a</sup> 1.248 (-1.453 to 3.948)	0.365	Fully adjusted <sup>b</sup> 1.246 (-1.083 to 3.575)	0.294
PedsQL total score <sup>9</sup> N = 1116 (n = 495, unadjusted) N = 1055 (n = 477, partially adjusted) N = 755 (n = 346, fully adjusted) CHU9D utility score	71.74 (60.87–82.61) 0.84 (0.13)	82.61 (71.74–89.13)	73.91 (60.87–82.61)	80.43 (71.74–89.13)	0.997 (–1.301 to 3.295)	0.395	1.248 (–1.453 to 3.948)	0.365	1.246 (–1.083 to 3.575)	0.294
N = 1116 (n = 495, unadjusted) $N = 1055 (n = 477, partially adjusted)$ $N = 755 (n = 346, fully adjusted)$ $CHU9D utility score$	71.74 (60.87–82.61) 0.84 (0.13)	82.61 (71.74–89.13)	73.91 (60.87–82.61)	80.43 (71.74–89.13)	0.997 (–1.301 to 3.295)	0.395	1.248 (–1.453 to 3.948)	0.365	1.246 (–1.083 to 3.575)	0.294
N = 1055 (n = 477, partially adjusted) N = 755 (n = 346, fully adjusted) <i>CHU9D utility score</i>	0.84 (0.13)									
N = 755 (n = 346, fully adjusted) CHU9D utility score	0.84 (0.13)									
CHU9D utility score	0.84 (0.13)									
	0.84 (0.13)									
N = 1131 ( <i>n</i> = 517, unadjusted)		0.89 (0.09)	0.82 (0.14)	0.90 (0.09)	–0.004 (–0.018 to 0.011)	0.617	-0.006 (-0.021 to 0.010)	0.481	–0.007 (–0.023 to 0.009)	0.405
N = 1049 (n = 486, partially adjusted)										
N = 741 (n = 344, fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n <i>(%)</i>		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 1145 (n = 524, unadjusted)	84 (12.73)	108 (20.61)	87 (11.89)	112 (18.04)	0.026 (–0.014 to 0.076)	0.227	-0.004 (-0.040 to 0.041)	0.837	0.020 (–0.019 to 0.069)	0.336
N = 1094 (n = 505, partially adjusted)										
N = 772 (n = 359, fully adjusted)										
Obese/overweight <sup>h</sup>										
N = 1145 (n = 524, unadjusted)	145 (21.97)	176 (33.59)	150 (20.49)	187 (30.11)	0.035 (–0.017 to 0.096)	0.201	0.002 (–0.053 to 0.069)	0.948	0.004 (–0.047 to 0.065)	0.892
N = 1094 (n = 505, partially adjusted)										
N = 772 (n = 359, fully adjusted)										

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# TABLE 18 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU2 (continued)

Follow-up outcome variable: <i>N</i> = total	Arm				Intervention vs. control					
variable: N = total participants	Intervention		Control							
( <i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>®</sup>		Fully adjusted <sup>b</sup>	
Five or more portions of	of fruit and vege	tables <sup>i</sup>								
N = 1015 (n = 453, unadjusted)	336 (59.79)	253 (55.85)	405 (64.80)	317 (56.41)	–0.006 (–0.079 to 0.079)	0.891	0.012 (–0.068 to 0.103)	0.789	0.002 (–0.074 to 0.091)	0.954
N = 895 ( $n = 401$ , partially adjusted)										
N = 729 (n = 331, fully adjusted)										
Achieving $\geq 60$ minutes of PA <sup>i</sup>										
$N = 700 \ (n = 307, unadjusted)$	228 (46.44)	70 (22.80)	276 (49.55)	120 (30.53)	–0.077 (–0.149 to 0.026)	0.127	–0.068 (–0.147 to 0.048)	0.215	–0.067 (–0.146 to 0.049)	0.219
N = 575 (n = 254, partially adjusted)										
N = 524 (n = 239, fully adjusted)										
<ul> <li>a Adjusted for baseline outcome.</li> <li>a Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake, PA energy expenditure] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage with free school meal eligibility].</li> <li>c Summary statistics presented are either mean (SD) or median (IQR).</li> <li>d Transformed via inverse.</li> <li>e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.</li> </ul>										

f Transformed via natural logarithm.
g Transformed via squaring.
h Adjusted for baseline BMI-z.
i Adjusted for total grams of fruit and vegetables consumed per day.
j Adjusted for minutes of PA per 24 hours.

TABLE 19 Intracluster correlation coefficients: key anthropometric, diet, PA and psychological variables – FU2, point estimate (95% CI)

Outcome	Unadjusted ICC	ICC adjusted for treatment arm	Partially adjusted ICC <sup>a</sup>	Fully adjusted ICC <sup>b</sup>
Continuous outcomes				
BMI-z	0.0051 (0.0001 to 0.1774)	0.0025 (0.0000 to 0.7649)	0.0331 (0.0126 to 0.0838)	0.0219 (0.0048 to 0.0933)
Height (cm)	0.0066 (0.0004 to 0.0971)	0.0066 (0.0004 to 0.0972)	0.1591 (0.1020 to 0.2396)	0.1260 (0.0752 to 0.2034)
Waist z-score	0.0360 (0.0144 to 0.0871)	0.0258 (0.0081 to 0.0793)	0.0648 (0.0322 to 0.1262)	0.0557 (0.0248 to 0.1205)
Sum of four skinfolds (mm)	0.0393 (0.0148 to 0.0998)	0.0369 (0.0135 to 0.0970)	0.0436 (0.0151 to 0.1193)	0.0469 (0.0155 to 0.1334)
Body fat %	0.0131 (0.0024 to 0.0678)	0.0086 (0.0008 to 0.0864)	0.0468 (0.0207 to 0.1020)	0.0476 (0.0192 to 0.1133)
Energy intake (kJ in 24 hours)	0.0499 (0.0238 to 0.1019)	0.0480 (0.0225 to 0.0995)	0.0521 (0.0243 to 0.1081)	0.0380 (0.0145 to 0.0959)
PA energy expenditure (kJ/kg/day)	0.0570 (0.0225 to 0.1369)	0.0565 (0.0222 to 0.1364)	0.0753 (0.0329 to 0.1634)	0.0527 (0.0173 to 0.1495)
PedsQL total score	0.0717 (0.0387 to 0.1292)	0.0712 (0.0384 to 0.1281)	0.0674 (0.0355 to 0.1240)	0.0458 (0.0186 to 0.1084)
CHU9D utility score	0.0459 (0.0215 to 0.0954)	0.0450 (0.0208 to 0.0947)	0.0540 (0.0259 to 0.1092)	0.0526 (0.0226 to 0.1174)
Binary outcomes				
Obese <sup>c</sup>	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)	0.0033 (0.0000 to 0.6713)	0.0000 (0.0000 to 0.0000)
Obese/overweight <sup>c</sup>	0.0007 (0.0000 to 1.0000)	0.0000 (0.0000 to 0.0000)	0.0321 (0.0121 to 0.0822)	0.0143 (0.0020 to 0.0967)
Five or more portions of fruit and vegetables <sup>d</sup>	0.0442 (0.0180 to 0.1043)	0.0443 (0.0181 to 0.1044)	0.0491 (0.0201 to 0.1150)	0.0173 (0.0027 to 0.1039)
Achieving $\geq$ 60 minutes of PA <sup>e</sup>	0.0870 (0.0427 to 0.1692)	0.0793 (0.0372 to 0.1611)	0.0872 (0.0406 to 0.1776)	0.0797 (0.0343 to 0.1742)

a Adjusted for treatment arm and baseline value of the outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake, PA energy expenditure] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage with free school meal eligibility].

c Adjusted for baseline BMI-z.

d Adjusted for total grams of fruit and vegetables consumed per day.

e Adjusted for minutes of PA per 24 hours.

# TABLE 20 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU3

Follow-up outcome	Arm				Intervention vs. control					
variable: N = total participants	Intervention		Control							
( <i>n</i> = number of in intervention arm)	Baseline	FU3	Baseline	FU3	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous</b> outcomes BMI-z	Mean (SD) or median (IQR) <sup>c</sup>	Mean (SD) or median (IQR) <sup>c</sup>	Mean (SD) or median (IQR) <sup>c</sup>	Mean (SD) or median (IQR) <sup>c</sup>	MD (95% CI)	p-value	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 488 (n = 242, unadjusted)	0.29 (1.24)	0.49 (1.37)	0.28 (1.12)	0.63 (1.22)	-0.143 (-0.352 to 0.067)	0.182	-0.204 (-0.396 to -0.013)	0.037	–0.177 (–0.336 to –0.017)	0.030
N = 467 (n = 232, partially adjusted)										
N = 345 (n = 173, fully adjusted)										
Height (cm)										
N = 489 (n = 242, unadjusted)	118.95 (5.74)	138.70 (6.84)	118.75 (5.60)	138.89 (6.69)	–0.188 (–1.368 to 0.993)	0.755	–0.035 (–0.781 to 0.711)	0.927	-0.003 (-0.735 to 0.729)	0.993
N = 468 (n = 232, partially adjusted)										
N = 346 (n = 173, fully adjusted)										
Waist z-score										
N = 471 (n = 234, unadjusted)	0.86 (1.17)	1.07 (1.30)	0.92 (1.14)	1.17 (1.28)	–0.134 (–0.459 to 0.190)	0.418	-0.114 (-0.423 to 0.194)	0.467	–0.089 (–0.365 to 0.188)	0.529
N = 439 (n = 211, partially adjusted)										
N = 331 (n = 160, fully adjusted)										

Follow-up outcome	Arm				Intervention vs. control						
variable: <i>N</i> = total participants	Intervention		Control								
( <i>n</i> = number of in intervention arm)	Baseline	FU3	Baseline	FU3	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
Sum of four skinfolds (i	mm) <sup>d,e</sup>										
N = 404 (n = 199, unadjusted)	29.02 (24.48–35.65)	37.70 (26.60–52.20)	30.55 (24.45 – 40.10)	36.10 (26.40–55.75)	-0.479 (-4.205 to 3.247)	0.801	0.398 (–0.771 to 1.567)	0.504	0.657 (–1.066 to 2.381)	0.455	
N = 330 (n = 166, partially adjusted)											
N = 250 (n = 123, fully adjusted)											
Body fat %											
N = 487 (n = 241, unadjusted)	21.33 (5.19)	22.51 (8.15)	21.18 (5.21)	22.60 (8.03)	–0.106 (–1.752 to 1.540)	0.900	-0.765 (-2.004 to 0.474)	0.226	–0.876 (–2.146 to 0.393)	0.176	
N = 463 (n = 230, partially adjusted)											
N = 344 (n = 172, fully adjusted)											
Energy intake (kJ in 24	hours) <sup>f</sup>										
N = 466 (n = 224, unadjusted)	6907 (5858–7964)	8100 (6902–9626)	7071 (5948–8038)	7993 (6887–9260)	89.663 (–444.253 to 623.578)	0.742	135.524 (–326.225 to 597.273)	0.565	16.932 (–415.049 to 448.914)	0.939	
N = 395 (n = 197, partially adjusted)											
N = 330 (n = 161, fully adjusted)											
PedsQL total score <sup>g</sup>											
N = 486 (n = 240, unadjusted)	72.83 (63.04–84.78)	82.61 (73.91–91.30)	73.91 (63.04–82.61)	82.61 (73.91–91.30)	0.180 (–2.930 to 3.291)	0.910	–0.073 (–3.628 to 3.481)	0.968	0.123 (–3.272 to 3.519)	0.943	
N = 463 (n = 230, partially adjusted)											
N = 344 (n = 172, fully adjusted)											

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#### Follow-up outcome Intervention vs. control . (*n* = number of in Fully adjusted<sup>b</sup> intervention arm) Partially adjusted<sup>a</sup> CHU9D utility score N = 486 (n = 241,0.84 (0.13) 0.91 (0.09) 0.82 (0.14) 0.90 (0.09) 0.012 0.151 0.008 0.389 0.013 0.207 (-0.004 to 0.029) (-0.010 to 0.026) (-0.007 to 0.034) unadjusted) N = 453 (n = 223)partially adjusted) N = 333 (n = 164,fully adjusted) **Binary outcomes** n (%) n (%) RD (95% CI) p-value RD (95% CI) p-value RD (95% CI) p-value Obese<sup>h</sup> N = 488 (n = 242,39 (13.36) 55 (22.73) 43 (13.15) 54 (21.95) 0.008 0.788 -0.031 0.306 -0.024 0.449 (-0.075 to 0.044) unadjusted) (-0.043 to 0.073) (-0.079 to 0.033) N = 467 (n = 232,partially adjusted) N = 345 (n = 173,fully adjusted) Obese/overweight<sup>h</sup> N = 488 (n = 242,67 (22.95) 87 (35.95) 67 (20.49) 89 (36.18) -0.002 0.958 -0.026 0.543 -0.028 0.460 unadjusted) (-0.078 to 0.093) (-0.097 to 0.065) (-0.091 to 0.051) N = 467 (n = 232)partially adjusted) N = 345 (n = 173,fully adjusted)

#### TABLE 20 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU3 (continued)

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Follow-up outcome	Arm				Intervention vs. control						
variable: <i>N</i> = total participants	Intervention		Control								
(n = number of in intervention arm)	Baseline	FU3	Baseline	FU3	Unadjusted	Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>			
Five or more portions o	f fruit and veget	tables <sup>i</sup>									
N = 466 (n = 224, unadjusted)	160 (60.61)	135 (60.27)	207 (72.13)	138 (57.02)	0.032 (–0.084 to 0.177)	0.614	0.013 (–0.107 to 0.164)	0.845	–0.007 (–0.103 to 0.110)	0.901	
N = 395 (n = 197, partially adjusted)											
N = 330 (n = 161, fully adjusted)											
a Adjusted for baselir b Adjusted for baselir baseline school-leve	ne outcome. ne outcome, ba el covariates [siz	aseline pupil-leve ze (number of p	el covariates [sex, upils on roll), perc	ethnicity, depriv	ation (IMD score for ho of population South Asia	me postcoc an, percenta	le), 24-hour total energy age of school population	/ intake, PA n black Afr	A energy expenditure] a ican Caribbean, percen	nd tage with	

free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

### TABLE 21 Intracluster correlation coefficients: key anthropometric, diet, PA and psychological variables – FU3, point estimate (95% CI)

Outcome	Unadjusted ICC	ICC adjusted for treatment arm	Partially adjusted ICC <sup>a</sup>	Fully adjusted ICC <sup>b</sup>
Continuous outcomes				
BMI-z	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)	0.0423 (0.0112 to 0.1475)	0.0025 (0.0000 to 0.9999)
Height (cm)	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)	0.0839 (0.0376 to 0.1770)	0.0701 (0.0253 to 0.1797)
Waist z-score	0.0363 (0.0088 to 0.1371)	0.0355 (0.0087 to 0.1338)	0.1314 (0.0637 to 0.2516)	0.0943 (0.0375 to 0.2178)
Sum of four skinfolds (mm)	0.0200 (0.0023 to 0.1520)	0.0201 (0.0023 to 0.1533)	0.0945 (0.0326 to 0.2442)	0.1097 (0.0386 to 0.2745)
Body fat %	0.0143 (0.0013 to 0.1422)	0.0143 (0.0013 to 0.1422)	0.0502 (0.0161 to 0.1457)	0.0477 (0.0127 to 0.1633)
Energy intake (kJ in 24 hours)	0.0541 (0.0186 to 0.1471)	0.0542 (0.0188 to 0.1465)	0.0483 (0.0142 to 0.1517)	0.0156 (0.0009 to 0.2139)
PedsQL total score	0.0408 (0.0107 to 0.1434)	0.0411 (0.0108 to 0.1437)	0.0314 (0.0058 to 0.1519)	0.0179 (0.0011 to 0.2281)
CHU9D utility score	0.0048 (0.0000 to 0.7046)	0.0020 (0.0000 to 0.9995)	0.0102 (0.0003 to 0.2426)	0.0043 (0.0000 to 0.9778)
Binary outcomes				
Obese <sup>c</sup>	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)	0.0123 (0.0005 to 0.2214)	0.0000 (0.0000 to 0.0000)
Obese/overweight <sup>c</sup>	0.0000 (0.0000 to 0.0000)	0.0000 (0.0000 to 0.0000)	0.0204 (0.0023 to 0.1575)	0.0102 (0.0002 to 0.3697)
Five or more portions of fruit and vegetables <sup>d</sup>	0.0593 (0.0193 to 0.1678)	0.0581 (0.0189 to 0.1649)	0.0541 (0.0160 to 0.1669)	0.0000 (0.0000 to 0.0000)

a Adjusted for treatment arm and baseline value of the outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake, PA energy expenditure] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage with free school meal eligibility].

c Adjusted for baseline BMI z-score.

d Adjusted for total grams of fruit and vegetables consumed per day.
### Secondary outcomes

#### Body mass index z-score (at follow-up 3)

At FU3, both the partially and the fully adjusted models show a statistically significant (and similar) difference in mean BMI-z between arms. The same direction of effect as at previous follow-ups was observed, with a lower mean BMI-z in the intervention arm than in the control arm, and a MD of -0.204 (95% CI -0.396 to -0.013; p = 0.037) and -0.177 (95% CI -0.336 to -0.017; p = 0.030) in the partially and fully adjusted models, respectively.

#### Waist z-score

At FU1 and FU2, the mean waist z-score was slightly higher in the intervention arm than in the control arm (MD of 0.103 and 0.026, respectively), whereas at FU3 it was slightly lower (MD –0.114). However, observed differences were not significant in either of the adjusted models at any time point.

#### Sum of four skinfolds

At FU1, FU2 and FU3, the sum of skinfolds was slightly higher in the intervention arm than in the control arm (MD 0.366, 0.644 and 0.398, respectively). These differences were not statistically significant in any model at any time point.

#### Body fat percentage

At FU1 and FU2, body fat percentage was very slightly higher in the intervention arm participants than in the control arm participants (MD 0.040 and 0.344, respectively), but lower at FU3 (MD –0.765). None of these differences was statistically significant.

#### Energy intake

The median number of kilojoules of energy consumed over the 24-hour period assessed, in participants in the intervention arm compared with those in the control arm, was a little higher at FU1 and FU3 (MD of 61.5 kJ and 135.5 kJ, respectively), but slightly lower at FU2 (MD –139.6 kJ). The differences observed, however, were not statistically significant in either the partially (values reported here) or the fully adjusted models.

#### Physical activity energy expenditure

This was measured in only the first two follow-up periods and the differences observed were extremely small [MD (intervention vs. control) –0.866 kJ/kg/day and 0.001 kJ/kg/day at FU1 and FU2, respectively] and not significant.

# Quality of life (Paediatric Quality of Life Inventory total score and Child Health Utility 9D utility score)

In both the partially (values presented) and the fully adjusted models, only very minor and non-significant differences in overall quality of life were observed between intervention and control arm participants at all time points. Using the PedsQL total score, MDs of –0.630, 1.248 and –0.073 were observed at FU1, FU2 and FU3, respectively, with the equivalent values of 0.010, –0.006 and 0.008 for the CHU9D utility score.

#### Proportion obese

At FU1, 16.2% of those in the intervention arm and 14.8% of those in the control arm were classified as obese. The partially adjusted RD of -0.036 (95% CI -0.066 to 0.004; p = 0.074) indicates that the risk of being obese at FU1 after adjusting for baseline BMI-z is 3.6% lower in the intervention arm than in the control arm. Although the difference in risk approaches significance in the partially adjusted model, after the additional covariate adjustment the association becomes weaker (RD -0.007, 95% CI -0.050 to 0.064; p = 0.676).

At FU2, the proportion of those classified as obese increases in both arms but remains higher in the intervention arm (20.61%) than in the control arm (18.04%). After adjustment for baseline BMI-z, there is a very small negative difference in risk between the intervention and control arms (RD –0.004), but this is

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not significant (p = 0.837), and in the fully adjusted model the effect is reversed (RD 0.020) and is, again, not significant (p = 0.336).

Further increases in the proportion who were obses are observed at FU3 but the difference between the arms is lower than at the previous follow-ups (intervention, 22.73% obses; control, 21.95% obses). The RD in both the partially (RD –0.031) and the fully adjusted (RD –0.024) models show a reduced risk of obesity in the intervention arm compared with the control arm, but the observed differences in risk are not statistically significant (p = 0.306 and p = 0.449, respectively).

#### Proportion obese/overweight

A similar pattern was seen for the percentage of participants who were classified as being overweight (including obese). This proportion increased over time in both the intervention and control groups [baseline to FU3: intervention arm, 21.97%, 28.75%, 33.59% and 35.95%; and control arm, 20.49%, 24.74%, 30.11% and 36.18%)]. The proportions overweight/obese were higher in the intervention arm than in the control arm at baseline, and FU1 and FU2, and although the proportions were more similar between arms at FU3, in contrast with the previous time points, the proportion was slightly higher in the control arm. After adjusting for baseline BMI-z, at FU1 and FU3 the risk of being overweight was lower in the intervention arm than in the control arm (RD -0.013 and -0.026, respectively). The estimate was robust to covariate adjustment at third follow-up (RD -0.028), but not at first follow-up (RD 0.000). At second follow-up there was very little difference in the risk of being at least overweight between the arms (RD 0.002). None of these observed differences was statistically significant.

#### Proportion meeting government recommendation for fruit and vegetable consumption

The proportion of children eating at least five portions of fruit and vegetables at FU1 was 48.13% in the intervention arm and 49.09% in the control arm. After adjustment for baseline grams of fruit and vegetable consumption, the RD of the intervention arm compared with the control arm showed that participants in the intervention arm were 1.4% less likely than those in the control arm to meet the government fruit and vegetable consumption recommendation. However, the difference between arms was not significant (p = 0.753). The fully adjusted model showed a small difference in the opposite direction (RD 0.004), but again this was not statistically significant (p = 0.900).

At FU2, compared with at FU1, a greater proportion of children met the government fruit and vegetable consumption recommendation in both arms, with the proportion remaining slightly lower in the intervention arm (55.85%) than in the control arm (56.41%). There were small positive RDs between intervention and control arms in both the partially (RD 0.01) and the fully (RD 0.002) adjusted models, but neither difference was statistically significant (p = 0.789 and p = 0.954, respectively).

The proportion of children eating at least five portions of fruit and vegetables increased again between FU2 and FU3, but the increase was greater in the intervention arm such that, in contrast with the previous time points, the proportion was greater in the intervention arm (60.27%) than in the control (57.02%) arm. The RD in the partially adjusted model showed that participants in the intervention arm were 1.3% more likely than those in the control arm to meet the government recommendation, but the difference was not statistically significant (p = 0.845). The RD was small but reversed after covariate adjustment (–0.007) and was also not significant (p = 0.901).

#### Proportion meeting government recommendation for physical activity in children

The proportion of children doing at least 60 minutes of at least moderate PA per day increased between baseline and FU1 in the intervention arm by 5.8%, whereas there was no real change in the control arm (difference = 0.24%). There was, however, a big reduction in both arms between FU1 and FU2, with the change being greater in the intervention arm than in the control arm (intervention, 52.27% to 22.8%; control, 49.79% to 30.53%). After adjustment for baseline minutes of at least moderate PA, the RD at FU1 (RD 0.041) shows that, compared with those in the control arm, participants in the intervention arm were 4.1% more likely to achieve the minimum 60-minute PA government target. The RD at second

follow-up (RD –0.068) suggests that this is reversed at that time point, with participants in the intervention arm being 6.8% less likely than those in the control arm to meet the recommendation. None of the observed differences was statistically significant. PA data were not collected at third follow-up.

## Additional anthropometric, diet, physical activity and psychological outcomes

The results for the prespecified additional anthropometric, diet, PA and psychological variables are presented for both continuous and binary outcomes at first follow-up in *Table 22* (corresponding ICCs are reported in *Table 23*) and at second follow-up in *Table 24* (corresponding ICCs are reported in *Table 23*). Although a few significant differences between the intervention and control arms were observed for the additional outcomes, there was no consistent message and, apart from one outcome (subscapular skinfold at FU2), the differences observed were not significant in either the partially or the fully adjusted model. Significant differences, however, are reported below.

In the primary analysis (adjusted only for baseline outcome), there were no significant differences observed at FU1. However, there was a statistically significant difference at FU1 in the fully adjusted model in relation to free sugar intake (MD –5.636 g, 95% CI –12.285 to 1.014 g; p = 0.029) and body image satisfaction (MD 0.251, 95% CI –0.026 to 0.528; p = 0.020). With regard to the former, there was also a difference approaching significance at FU2 in the partially adjusted model (MD –7.886 g, 95% CI –18.488 to 2.716 g; p = 0.055) that was strengthened and became significant after the additional covariate adjustment in the fully adjusted model (MD –9.22 g, 95% CI –19.032 to 0.592 g; p = 0.015). The direction of effect was consistent across both follow-up time points, with greater mean free sugar consumption in the 24-hour period assessed in the control arm than in the intervention arm.

At FU2, the primary analysis showed a significant difference between the intervention and control arms for subscapular skinfold (MD 0.198, 95% CI –0.028 to 0.423; p = 0.024), with the estimate being robust to covariate adjustment (MD 0.199, 95% CI –0.016 to 0.414; p = 0.017). Although the MD shows that the mean subscapular skinfold thickness was higher in the intervention arm than in the control arm, the difference is in fact very small (< 0.2 mm). For the same time point, a difference [again very small (MD 0.241)] in the same direction approaching statistical significance (p = 0.059) is also observed for suprailiac skinfold in the partially adjusted analysis, but the difference reduces and is no longer significant after covariate adjustment.

### **Ancillary analyses**

#### Prespecified subgroup analyses

For tables presenting the results of the prespecified subgroup analyses at FU1 and FU2, see *Appendix 60*. For each characteristic considered in the subgroup analysis (ethnicity, fidelity, sex, deprivation and weight status), the results are presented in a separate table (first for FU1 and then for FU2), followed by a further table presenting the outcomes of the interaction tests undertaken to determine whether or not there is a statistically significant difference in treatment effect between the subgroups considered for each characteristic.

Although the CIs and *p*-values for a few outcomes in some of the subgroups were suggestive of a statistically significant intervention effect, there were no consistent patterns in general, and the difference in intervention effect between the subgroups was not accompanied by a significant interaction term.

The subgroup analysis including only participants of black African Caribbean ethnicity was the only one with some consistent patterns that were worth considering. At FU1, the MD in the intervention arm compared with the control arm favoured the intervention for all measures of adiposity. The differences were statistically significant in the fully adjusted models for BMI-z (MD –0.372, 95% CI –0.652 to –0.091; p = 0.009), waist z-score (MD –0.689, 95% CI –1.044 to –0.333; p < 0.001) and body fat percentage (MD –2.198, 95% CI –4.278 to –0.118; p = 0.038). The negative values for the MDs show that the value of the mean for these outcomes is higher in the control arm than in the intervention arm after adjustment for baseline outcome and the prespecified covariates.

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# TABLE 22 Adjusted differences for additional anthropometric, diet, PA and psychological variables between control and intervention groups at FU1

Follow-up outcome	Arm	Arm				Intervention vs. control						
variable: <i>N</i> = total participants	Intervention		Control									
( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>			
<b>Continuous</b> outcomes Subscapular skinfold (r	<b>Mean (SD) or m</b> mm) <sup>d</sup>	nedian (IQR) <sup>c</sup>	Mean (SD) or n	nedian (IQR) <sup>c</sup>	MD (99% CI)	p- <i>value</i>	MD (99% CI)	p- <i>value</i>	MD (99% CI)	p- <i>value</i>		
N = 1097 (n = 509, unadjusted)	5.98 (5.05–7.30)	6.55 (5.20–9.00)	5.80 (4.95–7.20)	6.20 (5.15–8.40)	0.188 (–0.243 to 0.619)	0.260	0.005 (–0.167 to 0.177)	0.940	0.006 (–0.184 to 0.196)	0.935		
N = 973 (n = 453, partially adjusted)												
N = 733 (n = 346, fully adjusted)												
Suprailiac (mm) <sup>d</sup>												
N = 1100 (n = 511, unadjusted)	6.50 (4.75–9.45)	6.75 (4.80–11.80)	6.10 (4.55–9.30)	6.10 (4.50–10.40)	0.413 (–0.215 to 1.042)	0.090	0.178 (–0.136 to 0.493)	0.144	0.226 (–0.189 to 0.642)	0.161		
N = 977 (n = 460, partially adjusted)												
N = 745 (n = 356, fully adjusted)												
Biceps (mm) <sup>e</sup>												
N = 1118 (n = 520, unadjusted)	6.15 (4.80–7.80)	6.88 (5.30–9.85)	6.15 (4.70–8.40)	6.60 (5.00–9.25)	0.340 (–0.313 to 0.992)	0.180	0.181 (–0.093 to 0.456)	0.089	0.153 (–0.175 to 0.480)	0.230		
N = 1018 (n = 480, partially adjusted)												
N = 772 (n = 369, fully adjusted)												

Follow-up outcome	Arm				Intervention vs. con	trol				
variable: <i>N</i> = total participants	Intervention		Control							
( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Triceps skinfold (mm) <sup>e</sup>										
N = 1122 (n = 517, unadjusted)	9.80 (7.90–12.30)	11.30 (8.35–15.05)	10.00 (7.95–12.60)	10.60 (8.50–14.70)	0.320 (–0.420 to 1.060)	0.265	0.073 (–0.211 to 0.357)	0.508	0.061 (–0.252 to 0.374)	0.617
N = 1018 (n = 474, partially adjusted)										
N = 772 (n = 365, fully adjusted)										
Thigh skinfold (mm) <sup>f</sup>										
N = 1045 (n = 486, unadjusted)	13.43 (11.10–16.75)	15.90 (12.00–20.70)	13.30 (10.90–17.20)	15.05 (11.80–20.40)	0.357 (–0.768 to 1.482)	0.414	–0.038 (–0.468 to 0.391)	0.819	–0.124 (–0.630 to 0.382)	0.527
N = 826 (n = 391, partially adjusted)										
N = 640 (n = 304, fully adjusted)										
Bioimpedance (Ω)										
N = 1229 (n = 569, unadjusted)	656.13 (81.30)	660.28 (87.46)	654.00 (82.33)	655.07 (86.82)	5.030 (–15.061 to 25.120)	0.519	6.884 (–5.419 to 19.187)	0.150	6.679 (–4.804 to 18.163)	0.134
N = 1160 (n = 546, partially adjusted)										
N = 815 (n = 385, fully adjusted)										
Sedentary time (hours)	'24 hours)									
N = 866 (n = 396, unadjusted)	14.42 (1.88)	14.01 (2.12)	14.57 (1.78)	14.08 (2.20)	0.016 (–0.511 to 0.543)	0.938	–0.045 (–0.610 to 0.521)	0.839	0.156 (–0.384 to 0.697)	0.456
N = 720 (n = 334, partially adjusted)										
N = 654 (n = 310, fully adjusted)										
										continued

Follow-up outcome	Arm				Intervention vs. cont	rol				
participants	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>6</sup>	
MVPA time (minutes/2-	4 hours) <sup>f</sup>									
N = 866 (n = 396, unadjusted)	57.91 (42.52–85.90)	62.07 (38.80–102.97)	59.47 (42.80–81.53)	59.80 (40.91–96.95)	–2.092 (–13.957 to 9.774)	0.650	–1.310 (–11.843 to 9.224)	0.749	–3.939 (–16.561 to 8.682)	0.421
N = 720 (n = 334, partially adjusted)										
N = 654 (n = 310, fully adjusted)										
Systolic blood pressure	(mmHg)									
N = 1197 (n = 552, unadjusted)	95.67 (9.04)	95.35 (8.78)	98.10 (10.06)	95.29 (8.22)	0.003 (–1.980 to 1.986)	0.997	0.624 (–1.725 to 2.973)	0.494	0.931 (–1.307 to 3.169)	0.284
N = 1100 (n = 513, partially adjusted)										
N = 778 (n = 369, fully adjusted)										
Diastolic blood pressur	e (mmHg)									
N = 1197 (n = 552, unadjusted)	62.18 (7.99)	62.08 (7.81)	64.21 (8.59)	62.19 (7.43)	–0.158 (–1.905 to 1.589)	0.816	0.335 (–1.721 to 2.392)	0.675	0.945 (–1.247 to 3.137)	0.267
N = 1100 (n = 513, partially adjusted)										
N = 778 (n = 369, fully adjusted)										
Fat intake (grams in 24	t hours) <sup>d</sup>									
N = 1112 (n = 507, unadjusted)	56.08 (45.39–69.28)	60.95 (47.32–71.98)	54.74 (44.75–67.58)	57.36 (46.87–70.15)	2.157 (–2.233 to 6.546)	0.206	1.426 (–2.291 to 5.143)	0.323	1.260 (–2.336 to 4.857)	0.367
N = 978 (n = 449, partially adjusted)										
N = 803 (n = 369, fully adjusted)										

TABLE 22 Adjusted differences for additional anthropometric, diet, PA and psychological variables between control and intervention groups at FU1 (continued)

RESULTS

Follow-up outcome	Arm				Intervention vs. con	trol				
variable: <i>N</i> = total participants	Intervention		Control							
( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Free sugars in 24 hours	s intake (grams in .	24 hours)								
N = 1112 (n = 507, unadjusted)	76.63 (31.01)	72.05 (33.03)	76.13 (30.88)	75.31 (32.88)	–3.242 (–13.239 to 6.755)	0.404	–4.329 (–12.781 to 4.124)	0.187	–5.636 (–12.285 to 1.014)	0.029
N = 978 (n = 449, partially adjusted)										
N = 803 (n = 369, fully adjusted)										
Fibre intake (grams in 2	24 hours) <sup>f</sup>									
N = 1112 (n = 507, unadjusted)	11.00 (8.80–13.68)	11.76 (9.41–14.62)	11.35 (8.99–13.95)	11.77 (9.18–14.46)	–0.010 (–0.954 to 0.934)	0.977	0.013 (–0.767 to 0.793)	0.965	0.008 (–0.914 to 0.930)	0.982
N = 978 (n = 449, partially adjusted)										
N = 803 (n = 369, fully adjusted)										
Fruit and vegetables in	take (grams in 24	hours) <sup>g</sup>								
N = 1112 (n = 507, unadjusted)	226.92 (132.00–330.09)	200.23 (91.79–315.28)	247.58 (157.25–341.40)	201.84 (116.16–316.56)	–5.387 (–44.140 to 33.367)	0.720	–2.875 (–33.148 to 27.399)	0.807	–5.652 (–41.150 to 29.847)	0.682
N = 978 (n = 449, partially adjusted)										
N = 803 (n = 369, fully adjusted)										
PedsQL physical function	oning score									
N = 1231 (n = 554, unadjusted)	73.06 (18.07)	77.79 (16.28)	74.87 (17.26)	78.86 (15.14)	–1.020 (–4.367 to 2.327)	0.433	-0.649 (-4.006 to 2.708)	0.618	–0.191 (–3.498 to 3.116)	0.882
N = 1171 (n = 538, partially adjusted)										
N = 817 (n = 375, fully adjusted)										

Follow-up outcome	me Arm			Intervention vs. control						
participants	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
PedsQL psychosocial fu	inctioning score									
N = 1230 (n = 554, unadjusted)	69.47 (17.95)	71.27 (16.58)	69.28 (18.19)	72.10 (15.81)	–0.797 (–4.033 to 2.440)	0.526	–0.661 (–3.798 to 2.475)	0.587	–0.679 (–3.352 to 1.993)	0.513
N = 1170 (n = 538, partially adjusted)										
N = 817 (n = 375, fully adjusted)										
PedsQL emotional fund	ctioning score									
N = 1231 (n = 554, unadjusted)	73.36 (22.20)	75.88 (21.02)	71.68 (23.05)	75.75 (20.67)	–0.068 (–4.223 to 4.087)	0.966	–0.045 (–4.236 to 4.147)	0.978	0.115 (–3.954 to 4.184)	0.942
N = 1171 (n = 538, partially adjusted)										
N = 817 (n = 375, fully adjusted)										
PedsQL social function	ing score									
N = 1230 (n = 554, unadjusted)	67.72 (22.34)	70.89 (20.52)	68.60 (21.71)	72.39 (19.39)	–1.397 (–4.903 to 2.109)	0.305	–1.134 (–4.634 to 2.366)	0.404	–1.137 (–4.193 to 1.918)	0.338
N = 1169 (n = 537, partially adjusted)										
N = 816 (n = 374, fully adjusted)										
PedsQL school function	ning score									
N = 1229 (n = 554, unadjusted)	67.35 (21.72)	67.04 (20.03)	67.54 (21.56)	68.07 (18.72)	–0.847 (–4.730 to 3.036)	0.574	–0.810 (–4.533 to 2.912)	0.575	–0.876 (–4.331 to 2.579)	0.514
N = 1167 (n = 538, partially adjusted)										
N = 814 (n = 375, fully adjusted)										

# TABLE 22 Adjusted differences for additional anthropometric, diet, PA and psychological variables between control and intervention groups at FU1 (continued)

RESULTS

Follow-up outcome	Arm				Intervention vs. control						
variable: N = total participants	Intervention		Control								
( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
KIDSCREEN-52 bullying	g score										
N = 1227 (n = 552, unadjusted)	11.74 (3.20)	13.21 (6.95)	12.05 (2.97)	14.22 (10.14)	–1.006 (–2.431 to 0.420)	0.069	–1.101 (–2.655 to 0.453)	0.068	–0.544 (–1.930 to 0.842)	0.312	
N = 1156 (n = 533, partially adjusted)											
N = 806 (n = 370, fully adjusted)											
Body image satisfactio	n score										
N = 1218 (n = 550, unadjusted)	1.54 (1.39)	1.37 (1.17)	1.56 (1.40)	1.27 (1.11)	0.080 (–0.136 to 0.296)	0.341	0.041 (–0.168 to 0.251)	0.611	0.015 (–0.168 to 0.216)	0.847	
N = 1149 (n = 533, partially adjusted)											
N = 805 (n = 372, fully adjusted)											

 $\Omega$ , ohm.

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake, PA energy expenditure] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage with free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Transformed via 1/square root.

f Transformed via natural logarithm.

g Transformed via square root.

Outcome	Unadjusted ICC	ICC adjusted for treatment arm	Partially adjusted ICC <sup>a</sup>	Fully adjusted ICC <sup>b</sup>
Suprascapular skinfold (mm)	0.0051 (0.0001 to 0.1860)	0.0041 (0.0000 to 0.2871)	0.0716 (0.0389 to 0.1282)	0.0747 (0.0400 to 0.1351)
Suprailiac skinfold (mm)	0.0258 (0.0094 to 0.0692)	0.0246 (0.0087 to 0.0676)	0.2433 (0.1655 to 0.3427)	0.2260 (0.1500 to 0.3257)
Biceps skinfold (mm)	0.0444 (0.0209 to 0.0920)	0.0427 (0.0198 to 0.0898)	0.1416 (0.0861 to 0.2242)	0.1313 (0.0777 to 0.2133)
Triceps skinfold (mm)	0.0166 (0.0042 to 0.0636)	0.0150 (0.0034 to 0.0637)	0.1720 (0.1113 to 0.2562)	0.1441 (0.0897 to 0.2234)
Thigh skinfold (mm)	0.0131 (0.0025 to 0.0651)	0.0126 (0.0023 to 0.0654)	0.1047 (0.0590 to 0.1789)	0.0985 (0.0535 to 0.1745)
Bioimpedance (Ω)	0.0623 (0.0342 to 0.1108)	0.0616 (0.0337 to 0.1099)	0.0510 (0.0253 to 0.1002)	0.0241 (0.0070 to 0.0795)
Sedentary time (hours/24 hours)	0.0551 (0.0259 to 0.1134)	0.0552 (0.0259 to 0.1135)	0.0634 (0.0292 to 0.1321)	0.0554 (0.0229 to 0.1281)
MVPA time (minutes/24 hours)	0.0799 (0.0422 to 0.1463)	0.0800 (0.0422 to 0.1464)	0.0954 (0.0501 to 0.1742)	0.0688 (0.0308 to 0.1466)
Systolic blood pressure (mmHg)	0.0608 (0.0315 to 0.1141)	0.0608 (0.0315 to 0.1142)	0.1130 (0.0671 to 0.1839)	0.0979 (0.0546 to 0.1695)
Diastolic blood pressure (mmHg)	0.0570 (0.0290 to 0.1091)	0.0570 (0.0289 to 0.1090)	0.1064 (0.0627 to 0.1750)	0.1049 (0.0595 to 0.1784)
Fat intake (grams in 24 hours)	0.0436 (0.0206 to 0.0900)	0.0422 (0.0198 to 0.0878)	0.0317 (0.0120 to 0.0812)	0.0269 (0.0092 to 0.0764)
Free sugars in 24 hours intake (grams in 24 hours)	0.1421 (0.0903 to 0.2167)	0.1400 (0.0886 to 0.2141)	0.0954 (0.0539 to 0.1634)	0.0556 (0.0259 to 0.1154)
Fibre intake (grams in 24 hours)	0.0530 (0.0268 to 0.1021)	0.0530 (0.0268 to 0.1021)	0.0452 (0.0202 to 0.0977)	0.0338 (0.0130 to 0.0852)
Fruit and vegetables intake (grams in 24 hours)	0.0395 (0.0172 to 0.0879)	0.0392 (0.0170 to 0.0876)	0.0420 (0.0179 to 0.0956)	0.0136 (0.0020 to 0.0870)
PedsQL physical functioning score	0.0450 (0.0217 to 0.0910)	0.0438 (0.0209 to 0.0896)	0.0459 (0.0217 to 0.0945)	0.0356 (0.0135 to 0.0908)

TABLE 23 Intracluster correlation coefficients: additional anthropometric, diet, PA and psychological variables – FU1, point estimate (99% CI)

0.0327 (0.0140 to 0.0744)

0.0295 (0.0116 to 0.0732)

0.0158 (0.0041 to 0.0589)

0.0368 (0.0165 to 0.0801)

0.0143 (0.0031 to 0.0646)

0.0256 (0.0090 to 0.0702)

 $\Omega$ , ohm.

a Adjusted for treatment arm and baseline value of the outcome.

PedsQL psychosocial functioning score

PedsQL emotional functioning score

PedsQL social functioning score

PedsQL school functioning score

Body image satisfaction score

KIDSCREEN-52 bullying

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake, PA energy expenditure] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population Black African Caribbean, percentage with free school meal eligibility].

0.0321 (0.0137 to 0.0738)

0.0296 (0.0116 to 0.0732)

0.0142 (0.0033 to 0.0592)

0.0361 (0.0160 to 0.0794)

0.0111 (0.0017 to 0.0680)

0.0232 (0.0075 to 0.0696)

0.0292 (0.0117 to 0.0709)

0.0317 (0.0127 to 0.0770)

0.0144 (0.0032 to 0.0614)

0.0293 (0.0117 to 0.0715)

0.0107 (0.0015 to 0.0738)

0.0176 (0.0043 to 0.0689)

0.0018 (0.0000 to 0.9956)

0.0062 (0.0001 to 0.2537)

0.0000 (0.0000 to 0.0000)

0.0077 (0.0005 to 0.1145)

0.0000 (0.0000 to 0.0000)

0.0000 (0.0000 to 0.0000)

# TABLE 24 Adjusted differences for additional anthropometric, diet, PA and psychological variables between control and intervention groups at FU2

Follow-up outcome	Arm				Intervention vs. co	ntrol				
variable: <i>N</i> = total participants	Intervention		Control							
( <i>n</i> =number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous</b> outcomes Subscapular skinfold (r	<b>Mean (SD) or me</b>	edian (IQR) <sup>c</sup>	Mean (SD) or m	edian (IQR)'	MD (99% CI)	p- <i>value</i>	MD (99% CI)	p- <i>valu</i> e	MD (99% CI)	p- <i>value</i>
N = 913 (n = 405, unadjusted)	5.97 (5.05–7.30)	6.90 (5.40–11.10)	5.80 (4.95–7.20)	6.38 (5.05–9.72)	0.502 (–0.184 to 1.188)	0.059	0.198 (–0.028 to 0.423)	0.024	0.199 (–0.016 to 0.414)	0.017
N = 811 (n = 362, partially adjusted)										
N = 620 (n = 285, fully adjusted)										
Suprailiac (mm) <sup>d</sup>										
N = 931 (n = 413, unadjusted)	6.50 (4.75–9.45)	7.90 (5.05–13.55)	6.10 (4.55–9.30)	7.13 (4.60–13.35)	0.441 (–0.306 to 1.189)	0.128	0.241 (-0.088 to 0.571)	0.059	0.161 (–0.200 to 0.523)	0.251
N = 824 (n = 373, partially adjusted)										
N = 639 (n = 293, fully adjusted)										
Biceps (mm) <sup>e</sup>										
N = 980 (n = 435, unadjusted)	6.15 (4.80–7.80)	7.50 (5.40–11.05)	6.15 (4.70-8.40)	7.30 (5.15–10.90)	0.278 (–0.713 to 1.268)	0.470	0.198 (–0.178 to 0.575)	0.175	0.166 (–0.189 to 0.521)	0.229
N = 887 (n = 400, partially adjusted)										
N = 681 (n = 312, fully adjusted)										
										continued

Follow-up outcome	Arm				Intervention vs. cor	ntrol				
variable: N = total participants	Intervention		Control							
( <i>n</i> =number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Triceps skinfold (mm) <sup>e</sup>										
N = 980 (n = 436, unadjusted)	9.80 (7.90–12.30)	12.80 (9.10–16.90)	10.00 (7.95–12.60)	11.90 (9.00–16.95)	0.318 (–0.787 to 1.423)	0.459	0.087 (–0.231 to 0.405)	0.483	0.088 (–0.237 to 0.414)	0.484
N = 881 (n = 394, partially adjusted)										
N = 672 (n = 306, fully adjusted)										
Thigh skinfold (mm) <sup>f</sup>										
N = 789 (n = 354, unadjusted)	13.43 (11.10 to 16.75)	17.60 (12.85–22.65)	13.30 (10.90–17.20)	16.75 (12.40–22.95)	0.263 (–1.132 to 1.658)	0.628	0.111 (–0.398 to 0.620)	0.574	0.016 (–0.495 to 0.528)	0.935
N = 610 (n = 280, partially adjusted)										
N = 480 (n = 222, fully adjusted)										
Bioimpedance (Ω)										
N = 1118 (n = 513, unadjusted)	656.13 (81.30)	659.80 (85.22)	654.00 (82.33)	655.40 (83.73)	6.302 (–13.573 to 26.178)	0.414	9.099 (–4.237 to 22.435)	0.079	12.160 (0.523 to 23.797)	0.007
N = 1051 (n = 490, partially adjusted)										
N = 744 (n = 348, fully adjusted)										
Sedentary time (hours/	'24 hours)									
N = 700 (n = 307, unadjusted)	14.42 (1.88)	15.86 (1.86)	14.57 (1.78)	15.73 (1.94)	0.112 (–0.496 to 0.720)	0.635	0.186 (–0.443 to 0.814)	0.447	0.287 (–0.368 to 0.941)	0.260
N = 575 (n = 254, partially adjusted)										
N = 524 (n = 239, fully adjusted)										

# TABLE 24 Adjusted differences for additional anthropometric, diet, PA and psychological variables between control and intervention groups at FU2 (continued)

RESULTS

Follow-up outcome	Arm				Intervention vs. co	ntrol				
variable: <i>N</i> = total participants	Intervention		Control							
( <i>n</i> =number in intervention arm)	Baseline	FU2	Baseline	FU2	- Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
MVPA time (minutes/2	24 hours) <sup>f</sup>									
N = 866 (n = 396, unadjusted)	57.91 (42.52–85.90)	40.79 (31.47–57.19)	59.47 (42.80–81.53)	44.36 (32.85–67.94)	-4.162 (-12.856 to 4.532)	0.218	-3.332 (-10.706 to 4.042)	0.245	–4.314 (–12.697 to 4.070)	0.185
N = 720 (n = 334, partially adjusted)										
N = 651 (n = 308, fully adjusted)										
Systolic blood pressure	e (mmHg)									
N = 1083 (n = 483, unadjusted)	95.67 (9.04)	96.98 (8.30)	98.10 (10.06)	97.75 (8.21)	–0.728 (–2.429 to 0.974)	0.271	0.310 (–1.528 to 2.148)	0.664	0.577 (–1.431 to 2.584)	0.459
N = 996 (n = 447, partially adjusted)										
N = 711 (n = 325, fully adjusted)										
Diastolic blood pressur	re (mmHg)									
N = 1083 (n = 483, unadjusted)	62.18 (7.99)	63.29 (7.46)	64.21 (8.59)	63.50 (7.34)	-0.020 (-1.892 to 1.851)	0.978	0.482 (–1.570 to 2.533)	0.545	0.517 (–1.605 to 2.639)	0.530
N = 996 (n = 447, partially adjusted)										
N = 711 (n = 325, fully adjusted)										
Fat intake (grams in 24	4 hours) <sup>f</sup>									
N = 1015 (n = 453, unadjusted)	56.08 (45.39–69.28)	65.66 (51.81 to 79.88)	54.74 (44.75–67.58)	67.41 (54.59–81.08)	–2.605 (–7.519 to 2.310)	0.172	–1.943 (–6.629 to 2.742)	0.285	–2.740 (–7.652 to 2.171)	0.151
N = 895 (n = 401, partially adjusted)										
N = 729 (n = 331, fully adjusted)										
										continued

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Follow-up outcome	e Arm				Intervention vs. control					
participants	Intervention		Control							
(n =number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Free sugars in 24 hour.	s intake (grams in 2-	4 hours)								
N = 1015 (n = 453, unadjusted)	76.63 (31.01)	74.50 (32.18)	76.13 (30.88)	81.21 (35.16)	–7.778 (–18.815 to 3.259)	0.069	–7.886 (–18.488 to 2.716)	0.055	–9.220 (–19.032 to 0.592)	0.015
N = 895 (n = 401, partially adjusted)										
N = 729 (n = 331, fully adjusted)										
Fibre intake (grams in .	24 hours) <sup>f</sup>									
N = 1015 (n = 453, unadjusted)	11.00 (8.80–13.68)	12.44 (10.01–15.47)	11.35 (8.99–13.95)	12.77 (10.44–15.66)	–0.391 (–1.419 to 0.636)	0.327	–0.163 (–1.162 to 0.837)	0.675	–0.461 (–1.499 to 0.577)	0.253
N = 895 (n = 401, partially adjusted)										
N = 729 (n = 331, fully adjusted)										
Fruit and vegetables in	take (grams in 24 h	ours) <sup>9</sup>								
N = 1015 (n = 453, unadjusted)	226.92 (132.00–330.09)	218.06 (115.60–348.41)	247.58 (157.25–341.40)	219.28 (116.54–341.33)	8.155 (–39.775 to 56.085)	0.661	14.195 (–29.969 to 58.360)	0.408	14.598 (–34.821 to 64.018)	0.447
N = 895 (n = 401, partially adjusted)										
N = 729 (n = 331, fully adjusted)										
PedsQL physical function	oning score									
N = 1115 (n = 493, unadjusted)	73.06 (18.07)	83.71 (13.86)	74.87 (17.26)	84.18 (12.85)	–0.089 (–3.684 to 3.507)	0.949	0.118 (–3.411 to 3.646)	0.932	0.704 (–2.557 to 3.965)	0.578
N = 1054 (n = 475, partially adjusted)										
N = 752 (n = 344, fully adjusted)										

# TABLE 24 Adjusted differences for additional anthropometric, diet, PA and psychological variables between control and intervention groups at FU2 (continued)

RESULTS

Follow-up outcome	Arm				Intervention vs. co	ontrol				
variable: <i>N</i> = total participants	Intervention		Control							
( <i>n</i> =number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
PedsQL psychosocial fu	nctioning score									
N = 1113 (n = 492, unadjusted)	69.47 (17.95)	77.52 (14.40)	69.28 (18.19)	76.27 (14.96)	1.607 (–1.667 to 4.881)	0.206	1.593 (–1.598 to 4.784)	0.198	1.468 (-1.480 to 4.415)	0.200
N = 1052 (n = 474, partially adjusted)										
N = 751 (n = 343, fully adjusted)										
PedsQL emotional func	tioning score									
N = 1114 (n = 493, unadjusted)	73.36 (22.20)	83.42 (18.11)	71.68 (23.05)	81.57 (18.86)	2.151 (–1.499 to 5.802)	0.129	1.972 (–1.766 to 5.710)	0.174	2.021 (–1.745 to 5.787)	0.167
N = 1053 (n = 475, partially adjusted)										
N = 752 (n = 344, fully adjusted)										
PedsQL social functioni	ing score									
N = 1113 (n = 492, unadjusted)	67.72 (22.34)	76.72 (18.31)	68.60 (21.71)	75.81 (18.91)	1.061 (–2.523 to 4.646)	0.446	0.993 (–2.517 to 4.503)	0.466	1.089 (–2.305 to 4.483)	0.409
N = 1051 (n = 473, partially adjusted)										
N = 751 (n = 343, fully adjusted)										
PedsQL school function	ning score									
N = 1113 (n = 492, unadjusted)	67.35 (21.72)	72.40 (17.50)	67.54 (21.56)	71.42 (18.21)	1.344 (–2.631 to 5.318)	0.384	1.698 (–2.181 to 5.577)	0.260	1.447 (-2.077 to 4.971)	0.290
N = 1050 (n = 474, partially adjusted)										
N = 749 (n = 343, fully adjusted)										

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#### TABLE 24 Adjusted differences for additional anthropometric, diet, PA and psychological variables between control and intervention groups at FU2 (continued)

Follow-up outcome	Arm			Intervention vs. control						
participants	Intervention		Control							
( <i>n</i> =number in intervention arm)	Baseline	FU2	Baseline	FU2	– Unadjusted		Partially adjusted <sup>a</sup>		d <sup>a</sup> Fully adjusted <sup>b</sup>	
KIDSCREEN-52 bullying	2									
N = 1116 (n = 496, unadjusted)	11.74 (3.20)	14.30 (7.92)	12.05 (2.97)	14.05 (6.28)	0.249 (–0.907 to 1.406)	0.579	0.594 (–0.482 to 1.671)	0.155	0.359 (–0.799 to 1.516)	0.425
N = 1046 (n = 475, partially adjusted)										
N = 746 (n = 342, fully adjusted)										
Body image satisfaction	n score									
N = 1110 (n = 494, unadjusted)	1.54 (1.39)	1.19 (1.04)	1.56 (1.40)	1.11 (0.96)	0.081 (–0.091 to 0.253)	0.226	0.049 (–0.132 to 0.229)	0.487	–0.024 (–0.185 to 0.137)	0.700
N = 1044 (n = 476, partially adjusted)										
N = 748 (n = 344, fully adjusted)										
Ω, ohm.										

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake, PA energy expenditure] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage with free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Transformed via 1/square root.

f Transformed via natural logarithm.

g Transformed via square root.

ABLE 25 Intracluster correlation	coefficients: additional	anthropometric, diet,	, PA and psychological	variables - FU2, point est	imate (99% CI)
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Outcome	Unadjusted ICC	ICC adjusted for treatment arm	Partially adjusted ICC <sup>a</sup>	Fully adjusted ICC <sup>b</sup>
Suprascapular skinfold (mm)	0.0668 (0.0330 to 0.1305)	0.0627 (0.0301 to 0.1262)	0.0766 (0.0398 to 0.1423)	0.0463 (0.0192 to 0.1074)
Suprailiac skinfold (mm)	0.0205 (0.0049 to 0.0821)	0.0200 (0.0047 to 0.0820)	0.1432 (0.0827 to 0.2364)	0.1361 (0.0754 to 0.2333)
Biceps skinfold (mm)	0.0893 (0.0487 to 0.1580)	0.0886 (0.0482 to 0.1574)	0.1461 (0.0878 to 0.2331)	0.1276 (0.0728 to 0.2142)
Triceps skinfold (mm)	0.0413 (0.0176 to 0.0940)	0.0400 (0.0167 to 0.0930)	0.1061 (0.0596 to 0.1819)	0.1074 (0.0590 to 0.1877)
Thigh skinfold (mm)	0.0128 (0.0011 to 0.1301)	0.0122 (0.0009 to 0.1393)	0.0356 (0.0083 to 0.1400)	0.0140 (0.0004 to 0.3311)
Bioimpedance (Ω)	0.0620 (0.0322 to 0.1159)	0.0614 (0.0320 to 0.1149)	0.0805 (0.0443 to 0.1419)	0.0394 (0.0149 to 0.1002)
Sedentary time (hours/24 hours)	0.1238 (0.0710 to 0.2070)	0.1229 (0.0703 to 0.2060)	0.1236 (0.0679 to 0.2146)	0.1261 (0.0676 to 0.2232)
MVPA time (minutes/24 hours)	0.1406 (0.0815 to 0.2318)	0.1354 (0.0775 to 0.2259)	0.1491 (0.0847 to 0.2493)	0.1591 (0.0904 to 0.2647)
Systolic blood pressure (mmHg)	0.0329 (0.0126 to 0.0834)	0.0304 (0.0110 to 0.0813)	0.0550 (0.0263 to 0.1111)	0.0561 (0.0253 to 0.1198)
Diastolic blood pressure (mmHg)	0.0740 (0.0407 to 0.1310)	0.0740 (0.0406 to 0.1311)	0.1027 (0.0604 to 0.1691)	0.1020 (0.0574 to 0.1748)
Fat intake (grams in 24 hours)	0.0542 (0.0267 to 0.1071)	0.0517 (0.0250 to 0.1040)	0.0558 (0.0269 to 0.1122)	0.0485 (0.0213 to 0.1066)
Free sugars in 24 hours intake (grams in 24 hours)	0.1356 (0.0797 to 0.2214)	0.1242 (0.0714 to 0.2073)	0.1000 (0.0516 to 0.1848)	0.0818 (0.0386 to 0.1651)
Fibre intake (grams in 24 hours)	0.0572 (0.0283 to 0.1121)	0.0560 (0.0275 to 0.1108)	0.0579 (0.0278 to 0.1166)	0.0234 (0.0062 to 0.0843)
Fruit and vegetables intake (grams in 24 hours)	0.0625 (0.0311 to 0.1217)	0.0624 (0.0310 to 0.1214)	0.0668 (0.0332 to 0.1301)	0.0438 (0.0179 to 0.1035)
PedsQL physical functioning score	0.0877 (0.0503 to 0.1485)	0.0876 (0.0502 to 0.1485)	0.0844 (0.0472 to 0.1465)	0.0749 (0.0378 to 0.1427)
PedsQL psychosocial functioning score	0.0518 (0.0249 to 0.1044)	0.0503 (0.0241 to 0.1019)	0.0485 (0.0228 to 0.0999)	0.0203 (0.0042 to 0.0913)
PedsQL emotional functioning score	0.0304 (0.0114 to 0.0786)	0.0287 (0.0106 to 0.0758)	0.0308 (0.0116 to 0.0791)	0.0008 (0.0000 to 1.0000)
PedsQL social functioning score	0.0235 (0.0071 to 0.0753)	0.0233 (0.0070 to 0.0749)	0.0208 (0.0056 to 0.0739)	0.0046 (0.0000 to 0.5299)
PedsQL school functioning score	0.0512 (0.0252 to 0.1011)	0.0505 (0.0249 to 0.0999)	0.0457 (0.0213 to 0.0950)	0.0213 (0.0049 to 0.0877)
KIDSCREEN-52 bullying	0.0042 (0.0001 to 0.2254)	0.0040 (0.0001 to 0.2460)	0.0008 (0.0000 to 1.0000)	0.0077 (0.0003 to 0.1939)
Body image satisfaction score	0.0109 (0.0013 to 0.0835)	0.0087 (0.0007 to 0.1026)	0.0122 (0.0016 to 0.0884)	0.0000 (0.0000 to 0.0000)

 $\Omega$ , ohm.

a Adjusted for treatment arm and baseline value of the outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake, PA energy expenditure] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage with free school meal eligibility].

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In addition, there was a significant positive RD between the arms in terms of achieving 60 minutes of at least moderate PA (RD 0.446, 95% CI 0.010 to 1.255; p = 0.043). This means that in the black African Caribbean subgroup, after baseline and covariate adjustment, the participants in the intervention arm were 44.6% more likely than those in the control arm to meet the government guideline for PA in children and young adults. The interaction terms were not significant for any of these observed differences.

At FU2, a similar pattern was seen in terms of adiposity. In the fully adjusted analyses BMI-z (MD –0.613, 95% CI –1.053 to –0.173; p = 0.006), waist z-score (MD –1.029, 95% CI –1.417 to –0.641; p = < 0.001), sum of four skinfolds (MD –3.485, 95% CI –5.497 to –1.473; p = 0.001) and body fat percentage (MD –3.437, 95% CI –6.289 to –0.585; p = 0.018) were all significantly lower among children in the intervention arm than among those in the control arm. The proportion of children with excess weight was also lower in the intervention arm than in the control arm (partially adjusted model RD –0.193, 95% CI –0.282 to –0.038; p = 0.021; fully adjusted model RD –0.349, 95% CI –0.391 to –0.123; p = 0.017), indicating a lower prevalence of 19.3% and 34.9% in the partially and fully adjusted models, respectively. The proportion who were obese (RD –0.131, 95% CI –0.201 to –0.002; p = 0.047) was also lower, but only in the partially adjusted model, indicating that after baseline value adjustment the intervention arm participants are 13.1% less likely to be obese than participants in the control arm.

In terms of behavioural outcomes, however, PA energy expenditure (partially adjusted model MD –14.565, 95% CI –27.44 to –1.689; p = 0.027; fully adjusted model MD –15.80, 95% CI –29.817 to –1.782; p = 0.027), likelihood of achieving 60 minutes of at least moderate PA (RD –0.282, 95% CI –0.293 to –0.130; p = 0.016) and consumption of at least five portions of fruit and vegetables (partially adjusted model RD –0.283, –0.429 to –0.030; p = 0.033; fully adjusted model RD –0.502, 95% CI –0.593 to –0.204; p = 0.009) were all significantly lower among intervention children than among control children.

At FU2, the interaction tests showed significant intervention effect for sum of four skinfolds (partial and fully adjusted models, interaction terms of 0.036 and 0.005, respectively), physical activity energy expenditure (partial and fully adjusted models, interaction terms of 0.006 and < 0.001, respectively) and proportion at least overweight (partial and fully adjusted models, interaction terms of 0.003 and 0.028, respectively).

#### Exploratory subgroup analyses (by school group)

This analysis was prompted by the observed difference in magnitude of effect size for BMI-z between arms at FU2 compared with at FU3 (see *Appendix 60*). We found a statistically and clinically significant difference between trial arms in the G1 school participants at 27 months in favour of the intervention. However, at both FU1 and FU2 (where we had combined data for participants in G1 and G2 schools), the difference between arms was small and not statistically significant. To interpret this finding we needed to know whether or not this could be a late intervention effect, or whether or not there were differences between G1 and G2 schools. As part of this exploration, we considered differences in baseline characteristics, contextual differences (within schools or at a wider policy level, given that intervention delivery between groups was 1 year apart) or differences in the way in which the intervention was delivered. As we were not aware of any major contextual differences, and the process evaluation provided no evidence of differences in terms of intervention delivery, we undertook this exploratory analysis.

Baseline characteristics in G1 (*Table 26*) and G2 (*Table 27*) schools are presented separately below. In G1 schools the mean BMI-z in intervention and control arms was similar (0.29 and 0.28, respectively). However, in G2 schools, there was an imbalance, with higher mean BMI-z in the intervention arm (0.19) than in the control arm (0.04). Overall, BMI-z was also higher in G1 schools than in G2 schools. Owing to these baseline differences, an exploratory analysis of primary and secondary outcomes between trial arms at FU1 and FU2 was undertaken. The findings are described below, and tables presenting these results are shown in *Appendix 61*.

#### Continuous outcome: body mass index z-score

At FU1, the mean BMI-z in G1 was 0.35 (SD 1.32) in the intervention arm and 0.53 (SD 1.16) in the control arm. This corresponds to an unadjusted MD in BMI-z between intervention and control arms in G1 of -0.176 (95% CI -0.375 to 0.024; p = 0.084). This indicates that the average BMI-z was smaller in the

# **TABLE 26** Key baseline characteristics of school pupils participating in the WAVES study overall and by trial arm for G1 schools only

	Arm		
Characteristic <i>N</i> (number in intervention arm)	Intervention	Control	Total
Demographic			
Age (years): N = 621 (293), mean (SD) – not known: intervention = 9, control = 20	6.34 (0.30)	6.32 (0.30)	6.33 (0.30)
Sex			
N=650 (302), n (%)			
Male	137 (45.4)	180 (51.7)	317 (48.8)
Female	165 (54.6)	168 (48.3)	333 (51.2)
Ethnicity			
N = 645 (298), n (%)			
White British	154 (51.7)	181 (52.2)	335 (51.9)
South Asian	82 (27.5)	83 (23.9)	165 (25.6)
Black African Caribbean	25 (8.4)	23 (6.6)	48 (7.4)
Other	37 (12.4)	60 (17.3)	97 (15.0)
Not known	4ª	1ª	5ª
IMD quintile			
N=636 (291), n (%)			
1 (most deprived)	128 (44.0)	179 (51.9)	307 (48.3)
2	67 (23.0)	73 (21.2)	140 (22.0)
3	48 (16.5)	35 (10.1)	83 (13.1)
4	44 (15.1)	25 (7.2)	69 (10.8)
5 (least deprived)	4 (1.4)	33 (9.6)	37 (5.8)
Not known	1ª	3ª	14ª
IMD score			
N = 636 (291), median (IQR) – not known: intervention = 11, control = 3	30.25 (17.14–44.36)	37.55 (19.84–46.29)	32.87 (17.59–46.09)
Anthropometric BMI-z			
N = 619 (292), mean (SD) – not known: intervention = 10, control = 21	0.29 (1.24)	0.28 (1.12)	0.29 (1.18)
Height (cm)			
N = 619 (292), mean (SD) – not known: intervention = 10, control = 21	118.95 (5.74)	118.75 (5.60)	118.84 (5.66)
Waist circumference z-score			
N = 600 (273), mean (SD) – not known: intervention = 29, control = 21	0.86 (1.17)	0.92 (1.14)	0.89 (1.16)
Sum of four skinfolds <sup>b</sup> (mm)			
N = 512 (240), median (IQR) – not known: intervention = 62, control = 76	29.03 (24.48–35.65)	30.55 (24.45–40.10)	29.68 (24.48–37.93)
			continued

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	Arm		
Characteristic <i>N</i> (number in intervention arm)	Intervention	Control	Total
Body fat %			
N = 616 (291), mean (SD) – not known: intervention = 11, control = 23	21.33 (5.19)	21.18 (5.21)	21.25 (5.20)
Weight status <sup>c</sup>			
N = 619 (292), n (%)			
Underweight (≤2nd centile)	8 (2.7)	2 (0.6)	10 (1.6)
Healthy weight (> 2nd and < 85th centiles)	217 (74.3)	258 (78.9)	475 (76.7)
Overweight ( $\geq$ 85th and < 95th centiles)	28 (9.6)	24 (7.3)	52 (8.4)
Obese (≥95th centile)	39 (13.4)	43 (13.1)	82 (13.2)
Not known	10≈	21≈	31≈
<b>24-hour dietary intake</b> Energy (kJ in 24 hours)			
N = 551 (264), median (IQR) – not known: intervention = 38, control = 61	6907 (5858–7964)	7071 (5960–8030)	7015 (5900–8009)
Five or more portions of fruit and vegetables			
N = 551 (264), n (%)			
Yes	160 (60.6)	207 (72.1)	367 (66.6)
No	104 (39.4)	80 (27.9)	184 (33.4)
Not known	38ª	61ª	99ª
PA			
PA energy expenditure (kJ/kg/day)			
N = 528 (244), mean (SD) – not known: intervention = 58, control = 64	93.07 (21.69)	91.82 (22.42)	92.39 (22.07)
$\geq$ 60 minutes' MVPA/24 hours			
N = 525 (242), n (%)			
Yes	88 (36.4)	133 (47.0)	221 (42.1)
No	154 (63.6)	150 (53.0)	304 (57.9)
Not known	60ª	65ª	125ª
<b>Psychological</b> PedsQL total score			
N = 617 (292), median (IQR) – not known: intervention = 10, control = 23	72.83 (63.04–84.78)	73.91 (63.04–82.61)	73.91 (63.04–82.61)
CHU9D utility score			
N = 594 (277), mean (SD) – not known: intervention = 25, control = 31	0.84 (0.13)	0.82 (0.14)	0.83 (0.14)

a Not included in denominator for calculation of percentages.

b Subscapular skinfold + suprailiac skinfold + biceps skinfold + triceps skinfold.

c Based on UK 1990 reference centile curves and applying the cut-off point used for population monitoring.

**TABLE 27** Key baseline characteristics of school pupils participating in the WAVES study overall and by trial arm for G2 schools only

	Arm		
Characteristic N (number in intervention arm)	Intervention	Control	Total
<b>Demographic</b> Age (years)			
N = 776 (369), mean (SD) – not known: intervention = 18, control = 23	6.28 (0.30)	6.22 (0.31)	6.25 (0.31)
Sex			
N=817 (387), n (%)			
Male	202 (52.2)	230 (53.5)	432 (52.9)
Female	185 (47.8)	200 (46.5)	385 (47.1)
Ethnicity			
N = 806 (378), n (%)			
White British	143 (37.8)	180 (42.1)	323 (40.1)
South Asian	139 (36.8)	139 (32.5)	278 (34.5)
Black African Caribbean	37 (9.8)	30 (7.0)	67 (8.3)
Other	59 (15.6)	79 (18.5)	138 (17.1)
Not known	9 <sup>a</sup>	2 <sup>a</sup>	11ª
IMD quintile			
N = 803 (379), n (%)			
1 (most deprived)	264 (69.7)	219 (51.7)	483 (60.1)
2	53 (14.0)	81 (19.1)	134 (16.7)
3	24 (6.3)	39 (9.2)	63 (7.8)
4	21 (5.5)	29 (6.8)	50 (6.2)
5 (least deprived)	17 (4.5)	56 (13.2)	73 (9.1)
Not known	8ª	6ª	14 <sup>a</sup>
IMD score			
N = 803 (379), median (IQR) – not known: intervention = 8, control = 6	42.75 (30.92–55.24)	37.88 (16.42–50.46)	41.63 (22.69–51.65)
Anthropometric BMI-z			
N = 773 (368), mean (SD) – not known: intervention = 19, control = 25	0.19 (1.24)	0.04 (1.26)	0.11 (1.25)
Height (cm)			
N = 777 (372), mean (SD) – not known: intervention = 15, control = 25	118.37 (5.48)	117.73 (5.15)	118.04 (5.32)
Waist circumference z-score			
N = 659 (316), mean (SD) – not known: intervention = 71, control = 87	0.69 (1.30)	0.41 (1.29)	0.54 (1.30)
Sum of four skinfolds <sup>b</sup>			
(mm) $N = 625$ (300), median (IQR) – not known: intervention = 87, control = 105	27.55 (22.13– 35.30)	26.75 (22.15– 34.05)	27.20 (22.15–34.85)
			continued

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	Arm		
Characteristic N (number in intervention arm)	Intervention	Control	Total
Body fat %			
N = 760 (369), mean (SD) – not known: intervention = 18, control = 39	21.27 (5.49)	20.76 (5.22)	21.01 (5.35)
Weight status <sup>c</sup>			
N = 773 (368), n (%)			
Underweight (≤2nd centile)	12 (3.3)	18 (4.4)	30 (3.9)
Healthy weight (> 2nd and < 85th centiles)	278 (75.5)	304 (75.1)	582 (75.3)
Overweight ( $\geq$ 85th and < 95th centiles)	33 (9.0)	39 (9.6)	72 (9.3)
Obese (≥95th centile)	45 (12.2)	44 (10.9)	89 (11.5)
Not known	19ª	25ª	44 <sup>a</sup>
<b>24-hour dietary intake</b> Energy (kJ in 24 hours)			
N = 636 (298), median (IQR) – not known: intervention = 89, control = 92	6894 (5871–8098)	6739 (5700–7830)	6833 (5779–7988)
Five or more portions of fruit and vegetables			
N = 636 (298), n (%)			
Yes	176 (59.1)	198 (58.6)	374 (58.8)
No	122 (40.9)	140 (41.4)	262 (41.2)
Not known	89ª	92ª	181ª
<b>PA</b> PA energy expenditure (kJ/kg/day)			
N = 524 (248), mean (SD) – not known: intervention = 139, control = 154	99.73 (24.11)	91.81 (22.42)	97.98 (25.20)
$\geq$ 60 minutes' MVPA/24 hours			
N = 523 (249), n (%)			
Yes	140 (56.2)	143 (52.2)	283 (54.1)
No	109 (43.8)	131 (47.8)	240 (45.9)
Not known	138ª	156°	294ª
<b>Psychological</b> PedsQL total score			
N = 767 (371), median (IQR) – not known: intervention = 16, control = 34	69.57 (56.52–80.43)	71.74 (60.87–82.61)	71.74 (58.70–80.43)
CHU9D utility score			
N = 756 (366), mean (SD) – not known: intervention = 21, control = 40	0.83 (0.14)	0.81 (0.15)	0.82 (0.14)

a Not included in denominator for calculation of percentages.

b Subscapular skinfold + suprailiac skinfold + biceps skinfold + triceps skinfold.

c Based on UK 1990 reference centile curves and applying the cut-off points used for population monitoring.

intervention arm than in the control arm in G1. After adjusting for baseline BMI-z, the MD in BMI-z in G1 was -0.233 (95% CI -0.345 to -0.122; p < 0.001). This estimate is robust to covariate adjustment, as the fully adjusted estimate does not differ much (MD -0.258, 95% CI -0.355 to -0.160; p < 0.001).

For G2, at FU1, the mean BMI-z was 0.33 (SD 1.35) in the intervention arm and -0.00 (SD 1.31) in the control arm. This corresponds to an unadjusted MD in BMI-z between intervention and control arms in G2 of 0.331 (95% CI 0.128 to 0.534; p = 0.001). This indicates that the average BMI-z was greater in the intervention arm than in the control arm in G2. After adjusting for baseline BMI-z, the MD in BMI-z in G2 was 0.079 (95% CI -0.088 to 0.246; p = 0.353). The fully adjusted estimate of the MD in BMI-z was 0.136 (95% CI -0.025 to 0.297; p = 0.097).

At FU1, the mean BMI-z was greater in G1 than in G2. This corresponds to the group effect of 0.529 (95% CI 0.302 to 0.756; p = < 0.001) in the unadjusted analyses. This represents the average difference in BMI-z between G1 and G2, and indicates that the average BMI-z was 0.529 higher in G1 than in G2. After adjusting for all covariates, the group effect was 0.294 (95% CI 0.148 to 0.440; p < 0.001). In all of the three models, there was a statistically significant difference at the 5% level between the mean BMI-z of G1 and G2.

At first follow-up there is evidence to suggest that the intervention behaved differently across randomised G1 and G2 on BMI-z. In the unadjusted model, the *p*-value for the interaction between group and arm (< 0.001) indicates that there is a statistically significant difference at the 5% level between the intervention effect on BMI-z. This difference is statically significant in the partially adjusted model (p = 0.001) and in the fully adjusted model (p < 0.001).

### Other continuous outcomes for group 1 schools

For waist z-score and body fat percentage, there was a similar pattern of effects to that observed for BMI-z, with effects favouring the intervention in G1 schools at FU1, although the differences were of borderline statistical significance. The MD in sum of skinfolds at both follow-up points, and for waist z-score at FU2, were higher in the intervention arm than in the control arm, although the differences were not statistically significant.

The CHU9D utility score was higher in the intervention arm than in the control arm in G1 schools at FU1 (partially adjusted model 0.026, 95% CI –0.001 to 0.053; p = 0.056; fully adjusted model 0.031, 95% CI 0.000 to 0.062; p = 0.050). At FU2, the difference between groups was much smaller and not statistically significant (partially adjusted model 0.006, 95% CI –0.010 to 0.022; p = 0.44; fully adjusted model 0.013, 95% CI –0.004 to 0.029; p = 0.127).

### Binary outcome: obesity

In G1 at FU1, 16.85% of those in the intervention arm and 17.75% of those in the control arm were classified as obese. The unadjusted RD of -0.009 (95% CI -0.045 to 0.037; p = 0.674) indicates that the risk of being obese is 0.9% lower in the intervention arm than in the control arm. After adjusting for baseline BMI-z, the RD of being obese is -0.056 (95% CI -0.092 to -0.005; p = 0.035). When adjusting for all of the covariates, the association becomes slightly weaker (RD -0.037, 95% CI -0.069 to 0.004; p = 0.076).

At FU1, 15.64% of those in the intervention arm in G2 were classified as obese, compared with 12.57% of those in the control arm. The risk of being obese is 3.1% higher in the intervention arm than in the control arm. This corresponds to the unadjusted RD of 0.031 (95% CI –0.014 to 0.093; p = 0.202). The RD of being obese in G2 after adjusting for baseline BMI-z is –0.022 (95% CI –0.063 to 0.042; p = 0.428). After adjusting for all of the covariates, the RD of being obese in G2 is 0.016 (95% CI –0.039 to 0.104).

At first follow-up, there is not a statistically significant difference between the intervention effect on the risk of being obese between G1 and G2 (p = 0.196). This indicates that there is insufficient evidence to suggest that the intervention behaved differently in G1 compared with G2 with respect to lowering the risk of obesity. There is not a statistically significant difference in the risk of obesity between G1 and G2 (p = 0.200) or in the fully adjusted model (p = 0.658).

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# Sensitivity analyses

For tables presenting the results of the sensitivity analyses at FU1 and FU2, see *Appendix 62*. Results are presented for the key anthropometric, diet, PA and psychological variables in the same order as described in *Chapter 5* (see *Sensitivity analyses*): multiple imputation (FU1 then FU2), different levels of clustering (FU1 then FU2), alternative methods for baseline adjustment (FU1 then FU2) and treatment by cluster variation in heterogeneity (FU1 then FU2). There were no important changes in any conclusions as a result of undertaking any of these sensitivity analyses.

#### Harm

Potential harm from the intervention was objectively assessed by the wider psychosocial outcomes. Quality of life (assessed using the PedsQL), as total score or subdomains, did not differ significantly between arms at either FU1 or FU2. Similarly, there were no significant differences between the arms at any follow-up point in terms of social acceptance (KIDSCREEN-52) or body image dissatisfaction. Therefore, we found no evidence of harm from the intervention.

# **Chapter 7** Cost-effectiveness of an obesity-prevention intervention programme in primary school-aged children

#### Summary

In this chapter, the economic evaluation conducted alongside the WAVES trial is reported. Obesity costs the NHS millions of pounds every year, increasing to billions of pounds if wider societal costs are also included. Obese children are at an increased risk of health problems and also more likely to become obese adults, so it is vital that robust evidence is produced on the cost-effectiveness of interventions to prevent obesity in children. The overall aim in this chapter is to estimate the cost-effectiveness of the WAVES obesity prevention intervention programme in primary school-aged children. To achieve this, an analysis comparing the cost-effectiveness of the intervention with that of no intervention was undertaken. The primary analysis was based on the outcome measure QALYs. A secondary analysis based the evaluation on cost per obesity case prevented. Given the school-based multifaceted nature of the intervention, the analysis was from the public sector perspective and therefore included costs falling on the schools. All of the costs are expressed in the year 2014. Missing data were addressed using multiple imputation methods, and the uncertainty surrounding the cost-effectiveness estimates was examined through the use of the net benefit regression (NBR) framework and presented using cost-effectiveness acceptability curves (CEACs). The analysis of cost-effectiveness was carried out in accordance with current best-practice methods for conducting economic evaluation alongside cluster randomised controlled trials.<sup>88</sup>

# Aim

The aim was to estimate the cost-effectiveness of an obesity prevention intervention programme in primary school-aged children.

### **Methods**

#### Data collection

In order to conduct the economic evaluation, information on both the costs and the QALYs was required.<sup>89</sup> As with standard practice, the base-case analysis assumed that the intervention was 'up and running', that is, it excluded sunk costs. These costs were included, however, within the sensitivity analyses. To calculate the costs of the intervention, resource use was collected throughout the intervention period to which unit costs were applied. To calculate QALYs, health-utility data were collected using the CHU9D) instrument<sup>46</sup> at baseline (start of the intervention), at FU1, which was 3 months post intervention (15 months since baseline), and at FU2, which was 18 months post intervention (30 months since baseline). Outcomes were collected at the individual level and costs were collected at the cluster level (e.g. a teacher preparing for a nutrition lesson); these cluster-level costs were then averaged across the children within the cluster to derive individual-level costs for the intervention.

#### Costs

Cluster-level resource use was combined with unit costs to calculate the total cluster-level cost. The costs associated with the intervention were split into three phases:

- 1. development/set-up costs
- 2. implementation costs
- 3. delivery/running costs.

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*Table 28* outlines the cost items that were associated with each phase of the intervention. The first phase comprised costs associated with the development and set-up of the intervention. These costs included staff time for the development of materials for the intervention and its delivery. Implementation costs were costs associated with the printing of intervention materials and staff training. Phase 3 costs were focused on the delivery of the intervention. These were the costs associated with the intervention once it was 'up and running' and included all of the aspects that were associated with delivering the intervention on an ongoing basis. The base-case analysis assumed that the intervention was in a steady state and thus included only phase 3 costs. Set-up and implementation costs were considered, however, within the sensitivity analyses.

There were four main components to the intervention, each of which contained subcomponents:

- 1. cooking workshops (including short healthy eating class lessons)
- 2. signposting of PA opportunities
- 3. increased levels of PA
- 4. the use of role models (Villa Vitality component).

Study-specific resource use collection instruments were developed for these four components of the intervention.

#### The cooking component

The resource use associated with the cooking component of the intervention was measured using school staff-completed logbooks. School staff recorded how much time was spent on both the preparation and the delivery of the workshops and classroom sessions. On most occasions it was the teacher who was involved, and sometimes TAs were used. When 'other staff' members were listed but their roles were not described, a TA-level role was assumed. The materials used in the workshops were purchased and delivered by the research team in person. Parents were also invited, and their time and travel costs were acquired from a resource use questionnaire. Receipts for the materials used in the cooking workshops were logged and costed to estimate the average material cost per class. The costs associated with delivering the materials to the schools were calculated from the mileage and time it took for the research assistant to travel to each school.

#### The physical activity component

Each school within the intervention arm was asked to pick two of the offered PA packages. The costs associated with these packages were recorded as implementation costs and are detailed in *Table 29*. The PA component was delivered either during class time or at lunchtime. All resource use associated with the preparation and delivery of the packages was recorded using school staff-completed logbooks.

Phase 1: interven	tion development and	Ph	ase 2: intervention	Ph	ase 3: intervention
trial set-up costs		im	plementation costs	de	livery/running costs
<ul> <li>Development of intervention</li> <li>Cost of school (research staff</li> <li>Development of Researcher pre</li> <li>Staff time sper for year 2 child</li> </ul>	of teacher handbook explaining visit to explain intervention and teacher time plus travel costs) of cooking workshop paration time for staff training it adapting Villa Vitality package Iren	•	Initial printing of teacher handbooks Staff training costs Development of signposting leaflets	•	School staff time Intervention materials and equipment for delivery 'Package' costs (e.g. Villa Vitality) Relevant printing costs Venue hire Transport costs Updating signposting

#### TABLE 28 Cost items by intervention phase

## TABLE 29 Unit costs

Туре	Resource use item	Unit cost, £ (two dp)	Assumptions	Source
School costs	Hour of teacher time	20.09/hour	Based on standard contracted 1265 hour/year	Department of Health and Department for Education (2013–14) salary scales – M3
	Hour of TA time	9.04/hour		ONS 2014 New Earnings Survey <sup>90</sup>
	Lunchtime assistant lady	7.75/hour		ONS 2014 New Earnings survey <sup>90</sup>
	Supply cover	200/day, 100/half-day		Specified by attendee at training workshop
University staff time	Hour of administrative support time	11.67	Adjusted per hour on the assumption of 7.5 hours per day, 104 days' weekend, 15 closed days' and 25 days' annual leave	Official university pay scales (2013–14); spine point 35
	Hour of research assistant/associate time	16.48	As above	Official university pay scales (2013–14); grade 6 Spine point 26
	Hour of research fellow time	18.54	As above	Official university pay scales (2013–14); grade 7 spine point 30
	Hour of senior research fellow time	32.44	As above	Official university pay scales (2013–14); grade 9 spine point 49
	Hour of professorial time	44.37	As above	Official university pay scales (2013–14); professorial band 2, spine point 11
One-off intervention costs	Villa Vitality package	1979.66/class	One-off payment, which included the day and printing. Unit cost adjusted to 2014 prices and divided across classes	Trial team finance records
	Cooking workshop mate	rials: breakfast		
	Raisins	0.36	Resource use was captured from the shopping lists for	Tesco (Tesco PLC, Welwyn Garden City, UK)
	Tinned fruit	0.34	GZ schools in the trial. An implicit assumption is that	Asda (Asda, Leeds, UK)
	Cereals	2.33	the resource use was the same for G1 schools in the	Asda
	Weetabix (Weetabix Food Company, Kettering, UK)	1.80	trial	Asda
	Bran flakes (Kellogg Company, Manchester, UK)	0.68		Asda
	Chopping boards	0.7		IKEA (IKEA, Leiden, the Netherlands)
	Knives	0.02		Asda
	Spoons	0.02		Asda
	Bowls	0.10		Asda
	Kitchen towels	0.34		Asda
				continued

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Type Resource use item	Unit cost, £ (two dp)	Assumptions	Source
Archive boxes	1.29		Asda
Perishables	6.34		Trial estimate
Cooking workshop mat	erials: lunch		
Tuna	0.70	Items were bought in bulk;	Asda
Sweetcorn	0.49	the unit cost represents the per-unit cost	
LF salad cream	0.95		
Bowls	0.10		
Spoons	0.02		
Kitchen rolls	0.34		
Cooking workshop mat	erials: dinner		
Couscous	0.68	8 Prices adjusted to 2014	Asda
Tinned beans	0.29	prices	
Sweetcorn	0.49		
Vegetable stock	0.98		
Kitchen rolls	0.34		
Spoons	0.02		
Bowls	0.10		
PA materials			
Wake Up Shake Up	26.11	Prices adjusted to 2014	Unit costs identified from
Activate	277.59	prices	collected by the trial team
Positive Play	87.08		
Take 10	51.81		
Travel costs Mileage	0.45 per mile		HMRC/gov.uk guidance <sup>91</sup>

#### TABLE 29 Unit costs (continued)

Villa Vitality programme

This part of the intervention was split into the following subcomponents:

- two Villa Vitality days
- one Villa Vitality school-based session (run by football club staff)
- classroom challenges and class project.

The Villa Vitality days were purchased at a fixed cost, which was then averaged across all of the classes to derive a cost per class. When school staff had supervised the children during the Villa Vitality days, the costs that were associated with their time were included. Parents were also welcome to attend the Villa Vitality days and, when this happened, their time and resource use were recorded in travel cost questionnaires and included within the sensitivity analysis, for which a wider perspective was adopted.

Teaching staff completed logbooks to record the resource use that was associated with the delivery of the classroom sessions.

#### Signposting

The resource use associated with the signposting included printing and the delivery of materials to the schools. All of the purchase orders and receipts for printing were recorded and the cost of delivery was estimated based on the number of sheets posted. This item of expenditure was treated as an ongoing cost, as it required either updating (generic signposting sheet) or complete revision (school-specific signposting sheet) at the start of each intervention year and was therefore included as part of the intervention cost within the base-case analysis.

#### Unit costs and assumptions

This section outlines the justification of, and source for, the unit costs applied to each component of the intervention, as outlined in *Table 29*.

#### School unit costs

Unit costs for an hour of a teacher's time were calculated using the mid-scale point on the standardised Department for Education salary scales.<sup>92</sup> Resource use was measured on a per-hour basis. The annual salary scales were based on a contracted 1265 hours per year. Thus, to estimate the cost per hour, the annual salary was divided by 1265 hours. Annual salary scales were not available for TAs, LTAs or dinner ladies, and so to calculate the hourly unit costs for these roles the estimates were based on unit costs published by the Office for National Statistics in its 2014 New Earnings Survey.<sup>90</sup>

#### University unit costs

Included within the sensitivity analyses were the costs associated with the set-up and implementation of the intervention. Many of these costs were incurred by the research institute at the University of Birmingham. These costs included administration and research staff time. To calculate the unit costs for each of these roles, the 2014 University of Birmingham academic/support staff salary scales were used. Appropriate mid-points of the salary scale were selected for each staff position. These salaries were then converted to an hourly rate assuming that staff worked 7.5 hours per day excluding weekends, university 'closed days' and public holidays.

#### Other unit costs

For the cooking workshops, the unit costs for the cooking materials used were based on the purchase price of each item. For the PA elements of the intervention, the fixed costs associated with the activity packages chosen were recorded by the trial team and the receipts were retained.

All of the costs were adjusted to 2014 prices. Finally, for various aspects of the intervention, there were associated travel costs. When travel by car was recorded, the Her Majesty's Revenue & Customs guidance was used and a £0.45-per-mile cost was applied in line with standard practice.

#### **Outcomes**

#### Measuring quality-adjusted life-years

After initial pilot research on the acceptability, reliability and validity of competing preference-based measures for children,<sup>93</sup> the CHU9D instrument was used to collect quality-of-life information for the children. The CHU9D<sup>46</sup> features nine dimensions of child HRQL: worried, sad, pain, tired, annoyed, schoolwork/homework, sleep, daily routine and ability to join in activities. Each dimension contains five severity levels, resulting in 1,953,125 unique health states that are associated with the measure. Responses from the CHU9D questionnaires were transformed into quality-of-life (utility) weights derived from a UK general population sample using an algorithm developed by Stevens *et al.*<sup>46</sup> This gives a possible utility value set of between 0.33 (worst health state) and 1 (best health state). The QALYs were then calculated for each individual child using the area under the curve method,<sup>94</sup> which uses the trapezium rule.

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#### Assessing quality-adjusted life-year differences

To control for differences in baseline utility between the intervention and control arms,<sup>94</sup> prespecified covariates were adjusted for based on a statistical analysis plan. These were cluster-level variables, which were used in the randomisation (size of school, proportion of pupils eligible for free school meals, ethnic mix of pupils), and pupil-level factors (sex, baseline CHU9D score, ethnicity, deprivation, baseline total energy consumption and baseline PA energy expenditure).<sup>95</sup>

Thus, three models are reported within the analysis:

- 1. a linear regression model
- 2. a multilevel regression model controlling for baseline utility
- 3. a multilevel regression model controlling for baseline utility and prespecified covariates.

The first model is an unadjusted model, that is, a linear regression of costs (or QALYs) on the independent intervention dummy variable. The data, however, were clustered, and, to account for this, the second model adopts a hierarchical approach to account for clustering while also controlling for baseline utility to address baseline differences. The third and final model, and the one used for the primary analysis, adds the prespecified covariates to model 2. This model, therefore, adjusts for clustering and baseline utility, as well as the covariates specified within the analysis plan. All of the multilevel models were implemented using Stata's 'mi estimate: mixed' command, using maximum likelihood estimation to fit a multilevel mixed-effect linear regression including a random effect for the level 2 school variable using multiply imputed data.

#### Multiple imputation

Resource use data were collected at the cluster-level, whereas health outcome data were collected at the individual level; consequently, any reason for missing data (the missingness mechanism) varied for these two different types of data. The cost and QALY data were therefore imputed separately to include the relevant covariates within the imputation model and then combined to form a complete data set. During the imputation process, to account for the hierarchical nature of the data, all of the individual-level data were imputed using multilevel multiple imputation. This was implemented through REALCOM-IMPUTE software in conjunction with Stata 13. Thirty imputations were conducted, resulting in 30 complete data sets. Rubin's rule,<sup>84</sup> which incorporates uncertainty around the predicted values, was used to calculate pooled estimates of the mean costs and QALYs, as well as Cls. Given the number of missing data, the base-case analysis uses the imputed data.

#### Analyses

Our primary analysis was a CUA examining the cost per QALY gained for all of the children. In this trial context, the control group was no intervention, and, therefore, no costs were associated with this arm. To calculate the ICER between the intervention and control arms, the differences in costs and QALYs were analysed jointly, and to account for both the correlation between costs and outcomes<sup>96</sup> and the clustered nature of the trial, the NBR framework<sup>97,98</sup> was applied. This facilitates the calculation of the ICER and the analysis of uncertainty via a CEAC while controlling for any baseline differences and clustering effects.<sup>97</sup> As the economic evaluation was carried out alongside the trial, only costs and outcome data collected from the trial were included. All costs and outcomes were discounted at 3.5%.

#### Sensitivity analysis methods

A series of sensitivity analyses were conducted.

#### Sensitivity analysis 1: different multiple imputation methods

To test the sensitivity of the results to the multiple imputation model used for the base-case analysis (random-effects imputation model), a fixed-effects imputation model was applied.

#### Sensitivity analysis 2: including set-up and implementation costs

The base-case analysis assumed that the intervention was in a 'running state' and thus included only costs that were associated with the ongoing delivery of the intervention. Within the trial, however, there were a number of set-up and implementation costs that were also captured, and, to test how sensitive the results were to these costs, the costs were included in the second sensitivity analysis.

#### Sensitivity analysis 3: including wider costs

For two components of the intervention (Villa Vitality and the cooking workshops), some parents attended. As requested, schools invited all of the parents of the children in the intervention year (year 2) to attend the cooking workshops, with levels of actual parental attendance varying between schools. Some schools also invited parents to attend the Villa Vitality days as helpers. The third sensitivity analysis tested the sensitivity of the results to the inclusion of these costs. Parents' time and travel costs were collected using time and travel cost questionnaires, but, unfortunately, there was a low response rate. To estimate the opportunity cost of time, occupation details were used to assume income levels using the New Earnings Survey 2014.<sup>90</sup> When no occupation was listed, the national minimum wage was assumed as a valid cost of leisure time. As data were collected for only a small number of schools, these costs were averaged and applied to other schools for which data were missing.

#### Sensitivity analysis 4: best-case scenario

Within the trial, not all of the children in each class were included in the study. This was due to parents not consenting their children to be part of the measurement element of the study. As a result, there were children in the class who received the intervention but were not part of the study. On average, there were 17 children with parental consent to undertake measurements in each class. To examine the best-case scenario, sensitivity analysis 4 assumed that all of the children received the intervention and that all classes comprised 30 children. The average cost was, therefore, reduced per child.

#### Secondary analysis

#### Cost per 'case of obesity prevented'

A secondary analysis was conducted to assess the cost-effectiveness of the intervention in terms of cost per 'case of obesity prevented'. Cases of interest were defined as children who were not obese at baseline but became obese by FU2. That is, if the intervention was effective, fewer children should be transitioning from a non-obese state to an obese state in the intervention arm than in the control arm. To examine this, a transition dummy variable was created to represent whether or not the child had transitioned from a non-obese state to an obese state throughout the duration of the trial. A multilevel logit model including a dummy variable for the intervention was used to assess the impact of the intervention on the likelihood of transitioning to an obese state while controlling for clustering and other relevant covariates. This was implemented within Stata 13 using the 'melogit' command, with the school variable being the level 2 identifier.

### Results

### Impact of intervention on health-related quality of life

Table 30 outlines the response rate for the CHU9D instrument.

*Table 31* describes the mean utility values at each time point for the whole sample, the control arm and the intervention arm. The mean utility at baseline for all of the children was 0.826. At baseline, the mean utility for the control arm was 0.816 compared with 0.836 for the intervention arm; this difference was adjusted for within the main CUAs.<sup>94</sup>

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		Missing (%)	
Time point	CHU9D completed, <i>n</i> (%)	Control arm	Intervention arm
Baseline	1350 (92)	7	9
FU1	1215 (83)	20	15
FU2	1131 (77)	25	21

#### TABLE 30 Number of consented children with a completed CHU9D at each time point

#### TABLE 31 Health-related quality of life measured using CHU9D at each time point

Measurement time point	All participants: mean (95% Cl)	Control arm: mean (95% Cl)	Intervention arm: mean (95% Cl)
Baseline ( $n = 1350$ )	0.826 (0.818 to 0.833)	0.816 (0.805 to 0.827)	0.836 (0.826 to 0.846)
FU1 ( <i>n</i> = 1215)	0.863 (0.857 to 0.869)	0.858 (0.850 to 0.866)	0.868 (0.858 to 0.877)
FU2 ( <i>n</i> = 1128)	0.896 (0.890 to 0.901)	0.898 (0.891 to 0.905)	0.893 (0.884 to 0.901)

*Figure 9* shows the CHU9D utility scores only for complete cases (n = 991), for which there was measurement at all three points. The mean utility value for the control arm was statistically significantly (p < 0.05) lower (indicating a poorer quality of life) at baseline than for the intervention arm. By FU2, however, the mean utility value associated with the control arm had increased and slightly superseded the intervention arm.

#### Examining the impact on quality-adjusted life-years

Table 32 describes the unadjusted mean QALYs for each arm of the trial. At FU2, the intervention group accrued 2.17 QALYs, compared with 2.14 QALYs for the control group. This difference was not significant at the 0.05 significance level, given the way that QALYs are calculated using the 'area under the curve' method, and as highlighted in *Figure 9*, the extra QALYs within the intervention arm are probably due to the large imbalance at baseline.





#### TABLE 32 Unadjusted QALYs accrued (pre-imputation)

Measurement time point	All participants, mean (95% Cl)	Control arm, mean (95% Cl)	Intervention arm, mean (95% Cl)
FU1 ( <i>n</i> = 1130)	1.053 (1.046 to 1.060)	1.045 (1.036 to 1.055)	1.063 (1.052 to 1.073)
FU2 ( <i>n</i> = 995)	2.154 (2.142 to 2.167)	2.141 (2.124 to 2.157)	2.171 (2.152 to 2.189)

After conducting multiple imputation, the unadjusted QALY estimates remain similar to those pre imputation (*Table 33*).

#### Incremental analysis: effectiveness

*Table 34* describes the incremental difference in mean QALYs between the intervention and control group for the data with no adjustment, with adjustment for clustering and baseline differences, and with adjustments for clustering, baseline differences and the prespecified covariates using multilevel multivariate regression.

When controlling for baseline utility, clustering and the covariates, the mean QALY difference for FU1 and FU2 was negligible and insignificant.

Of interest, we explored the differences in mean QALYs between the intervention and control groups by trial intervention year. *Table 35* outlines the results. The coefficient for incremental QALYs in G1 schools at all follow-up points is positive, indicating that more QALYs were attained in the intervention group than in the control group. In contrast, however, the corresponding coefficient for G2 schools is negative, indicating the opposite effect, namely that fewer QALYs were attained in the intervention group than in the control group.

#### TABLE 33 Unadjusted QALYS accrued (post imputation)

Measurement time point	All participants, mean (95% Cl)	Control arm, mean (95% Cl)	Intervention arm, mean (95% CI)
FU1	1.055 (1.048 to 1.062)	1.046 (1.038 to 1.055)	1.064 (1.055 to 1.074)
FU2	2.153 (2.141 to 2.164)	2.144 (2.130 to 2.159)	2.163 (2.145 to 2.180)

#### TABLE 34 Incremental difference in QALYs

No adjustment		Adjusted for clustering and baseline utility		Adjusted for clustering, baseline utility and covariates		
time point	MD (95% CI)	<i>p</i> -value	MD (95% CI)	<i>p</i> -value	Mean (95% Cl)	<i>p</i> -value
FU1	0.018 (0.005 to 0.031)	0.006	0.005 (–0.008 to 0.017)	0.461	0.005 (–0.008 to 0.018)	0.429
FU2	0.019 (–0.003 to 0.041)	0.097	0.005 (–0.025 to 0.034)	0.791	0.006 (–0.024 to 0.036)	0.701

#### TABLE 35 Mean QALY difference by school group

Incremental QALYs for the intervention group by group (adjusted for clustering, baseline utility and covariates)					
	G1		G2		
Measurement time point	MD (95% CI)	<i>p</i> -value	MD (95% CI)	<i>p</i> -value	
FU1	0.016 (0.000 to 0.034)	0.65	-0.006 (-0.022 to 0.010)	0.463	
FU2	0.039 (-0.002 to 0.079)	0.06	-0.026 (-0.063 to 0.010)	0.164	

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#### Resource use and costs

Details of all resource use and costs for the intervention group are displayed in *Tables 36–38*. Compared with the running costs, the set-up and development costs of the intervention were relatively low. In terms of the set-up costs, the largest component of cost was the time attributed to research staff developing materials for the intervention, in particular the development of the cooking workshop and classroom materials. The largest cost driver for implementing the intervention related to the time of the teaching staff and the cost of staff cover for attending the training sessions. Other significant costs related to the creation of the signposting materials and the purchasing of the PA packages. The ongoing running/delivery costs had the biggest impact on the overall costs of the intervention. Of the main components of the intervention, in terms of delivery, the cheapest by far was the signposting. The most expensive component of the trial was the Villa Vitality sessions, which accounted for over half of the running costs.

#### Set-up/development costs

Component	Resource type	Resource use per class (SD)ª	Mean cost per class, £ (SE)		
Intervention handbook development	Staff time (hours)				
	Professor	0.025	1.11		
	Senior research fellow	0.025	0.81		
	Research fellow	0.15	2.78		
	Printing handbooks				
	Number of handbooks	2.5	11.47		
Intervention set-up meeting (researcher	Staff time (hours)				
visit to school)	Research fellow travel/meeting time	1.014 (0.647)	18.79 (1.896)		
	Teacher meeting time	0.324 (0.133)	6.53 (0.423)		
	Travel costs (miles)				
	Mileage	18.6 (19.39)	8.37 (1.38)		
Development of cooking workshop/	Staff time				
classroom materials	Research associate	6.5	107.12		
	Research fellow	1.75	32.45		
Preparing trainers for central training	Staff time (hours)				
session	Research associate	0.325	5.36		
	Research fellow	0.2	3.71		
Adapting Villa Vitality for children aged	Staff time (hours)				
6–7 years	Senior research fellow	0.125	4.06		
	Research fellow	0.25	4.64		
	Research associate	0.25	4.12		
Preparing Villa Vitality teacher packs and	Staff time (hours)				
liaising with schools	Research associate	1.5	24.72		
Total mean set-up/development cost per school (f)			363.14		
Total mean set-up/development cost per class (£)			236.04		
Total mean set-up/development cost per consented child (£)			13.70		
Total mean set-up/development cost per intervention child, assuming a class size of 30 pupils (£) 7.8			7.87		
a Total resource use/number of classes ( $n = 40$ ).					

#### TABLE 36 Resource use: intervention set-up and development

#### Implementation costs

#### TABLE 37 Resource use: intervention implementation

Component	Resource type	Resource use per class (SD)ª	Mean cost per class, £ (SE)		
Cooking workshop central training costs (teacher training to deliver cooking workshops)	University costs				
	Staff time (hours)				
	Research associate	1.2	19.78		
	Research fellow	0.6	11.12		
	Materials				
	Two sessions, each estimated as the cost of one breakfast, lunch and dinner workshop (£40.95); thus, £81.90 for both, then divided back through the number of classes attended to get cost per class	n/a	2.04		
	School/participant costs				
	Staff time (hours)				
	Teacher attendance time	3.8 (3.3)	76.36 (12.13)		
	TA attendance time	3.2 (3.14)	28.93 (5.19)		
	Travel costs				
	Travel costs (£)		12.49 (2.47)		
	TA travel time (hours)	1.15 (1.45)	10.42 (2.39)		
	Teacher travel time (hours)	1.26 (1.31)	25.37 (4.79)		
	Teacher cover costs				
	Cost of cover	n/a	116 (18.79)		
	Special dependant arrangements (£)	n/a	1.44 (1.27)		
PA packages	PA packages				
	Activate	0.51 (19 packs total)	142.55		
	Take 10	0.46 (17 packs total)	23.80		
	Wake Up Shake Up	0.32 (12 packs total)	8.47		
	Positive Play	0.43 (16 packs total)	37.66		
Total mean implementation cost per school (£)					
Total mean implementation cost per class (£)			516.42		
Total mean implementation per consented child (£)			29.98		
Total mean implementation cost per ch	ild assuming a class of 30 pupils (£)		17.21		
n/a, not applicable.					

a Total resource use/number of classes (n = 40).

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# Ongoing/intervention delivery costs

# TABLE 38 Resource use: running costs

Component	Resource type	Annual resource use per class (SD)ª	Mean cost per class, £ (SE)		
Development/updating of	Staff time (hours)				
generic signposting for schools	Research associate	1.525	25.13		
Development/updating of school	Staff time (hours)				
specific signposting	Study administrator	0.938	10.94		
	Research associate	4.8	70.86		
Signposting (delivery)	Generic printing				
	Printing	38.75	8.88		
	School-specific printing				
	Printing	38.81 (17.71)	14.38 (1.39)		
	Delivery				
	Cost of delivery	n/a	2.94		
Villa Vitality	Package				
	Villa Vitality package	1	1979.66		
	Villa Vitality day 1				
	Teacher time	8.88 (4.33)	178.48 (17.75)		
	TA time	11.65 (5.06)	105.28 (9.34)		
	Villa Vitality school visit				
	Teacher time	6.77 (2.12)	135.94 (9.1)		
	TA time	5.61 (4.72)	50.75 (9.10)		
	Villa Vitality day 2				
	Teacher time	7.79 (3.12)	156.57 (12.80)		
	TA time	11.58 (5.14)	104.71 (9.48)		
	Villa Vitality class project and challenges				
	Teacher time	8.17 (6.61)	164.11 (132.81)		
Cooking workshop	Cooking workshop classes: breakfast				
	Teacher time	1.53 (1.05)	30.72 (4.71)		
	TA time	0.40 (0.22)	3.61 (1.98)		
	Cooking workshop classes: lunch				
	Teacher time	1.43 (0.83)	28.76 (4.05)		
	TA time	0.25 (0.58)	2.26 (1.28)		
	Cooking workshop classes: dinner				
	Teacher time	1.22 (1.31)	24.44 (6.81)		
	TA time	0.2 (0.527)	2.26 (1.51)		
	Cooking workshop: breakfast				
	Teacher time	2.13 (0.94)	42.79 (4.21)		
	TA time	0.31 (1.00)	2.83 (2.03)		
	Staff helpers	2.84 (1.91)	25.69 (3.86)		
#### TABLE 38 Resource use: running costs (continued)

Component	Resource type	Annual resource use per class (SD)ª	Mean cost per class, £ (SE)
	Cooking workshop: lunch		
	Teacher time	2.08 (1.07)	41.86 (5.22)
	TA time	0.18 (0.50)	1.60 (1.09)
	Staff helpers	2.06 (1.02)	18.66 (2.24)
	Cooking workshop: dinner		
	Teacher time	1.73 (1.13)	34.66 (7.20)
	TA time	0.25 (0.53)	2.26 (1.51)
	Staff helpers	1.43 (1.65)	12.96 (4.71)
	Cooking workshop packing/purchasing		
	Research fellow	0.3	5.56
	Research associate	0.9	14.83
	Study administration	0.1	1.17
	Cooking workshop printing materials		
	Printing	n/a	100.09
	Cooking workshop delivering materials		
	Research associate time breakfast	0.79 (0.61)	12.95 (2.26)
	Breakfast travel costs	n/a	10.29 (2.36)
	Research associate time lunch	0.80 (0.67)	13.16 (2.68)
	Lunch travel costs	n/a	10.39 (2.65)
	Research associate time dinner	0.95 (0.72)	15.71 (3.76)
	Dinner travel costs	n/a	12.98 (4.19)
	Cooking workshop materials: breakfast		
	Raisins	7.25	2.58
	Tinned pineapple	4	1.37
	Weetabix	1	2.33
	Bran flakes	1	1.80
	Chopping boards	7.25	4.96
	Knives	28.5	0.46
	Spoons	35	0.57
	Bowls	35	3.42
	Kitchen towels	1	0.34
	Archive box	1	1.29
	Perishables	1	6.35
			continued

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#### TABLE 38 Resource use: running costs (continued)

Component	Resource type	Annual resource use per class (SD)ª	Mean cost per class, £ (SE)		
	Cooking workshop materials: lunch				
	Tuna	5	3.52		
	Sweetcorn	3	1.46		
	LF salad cream	0.6	0.57		
	Bowls	20	1.95		
	Spoons	20	0.33		
	Kitchen rolls	2	0.67		
	Cooking workshop materials: dinner				
	Couscous	1	0.68		
	Tinned beans	2	0.59		
	Sweetcorn	2	0.98		
	Vegetable stock	1	0.98		
	Kitchen rolls	1	0.34		
	Spoons	30	0.49		
	Bowls	30	2.93		
PA	PA term 1				
	Teacher time	11.12 (6.70)	223.44 (31.72)		
	TA time	1.35 (3.40)	12.25 (7.26)		
	LTS time	2.16 (4.15)	16.74 (7.59)		
	PA term 2				
	Teacher time	17.35 (10.99)	348.60 (47.09)		
	TA time	0.48 (0.98)	4.38 (1.89)		
	LTS time	4.21 (7.57)	27.14 (11.85)		
	PA term 3				
	Teacher time	18.90 (12.63)	379.88 (73.27)		
	TA time	0.32 (0.64)	2.93 (1.66)		
	LTS time	6.50 (12.40)	50.38 (27.74)		
Total mean running cost per school (£)			7058.19		
Total mean running cost per class (£)		4587.82			
Total mean running cost per consent		266.35			
Total mean running cost per child as		152.93			
LF, low fat; LTS, lunchtime supervisor a Total resource use/number of class	LF, low fat; LTS, lunchtime supervisor; n/a, not applicable. a Total resource use/number of classes ( $n = 40$ ).				

#### Missing cost data

For all of the components of the intervention for which the resource use data were collected by the research team, there were no missing data. For much of the intervention, however, the cost data were collected from logbooks and there were extensive missing data. Some teachers failed to complete the logbooks, citing time constraints; other logbooks were returned, but without completion of the requested cost data; some logbooks were completed but lost by the school; and other logbooks were reported to have been returned

but were never received. Given the multifaceted nature of the intervention, there were large numbers of missing data (*Table 39*).

The high levels of missing data for both costs and QALYs provide a strong case for using multiple imputation.

#### Incremental analysis of cost

Multiple imputations (30 imputations) were run for each subcomponent of cost, and these were then combined to calculate the total costs of the intervention. Therefore, the analysis of cost was conducted on 30 data sets.

*Table 40* outlines the incremental costs of the intervention arm compared with the control arm after adjusting for clustering, baseline utility and the covariates. Unsurprisingly, given the assumed 'no costs' associated with the control arm, the intervention arm was statistically significantly more expensive than the control arm.

Intervention cost subcomponent	Missing data (%)
Intervention handbook development and set-up	0 (collected by trial team)
Development and preparation for cooking workshop central training	0 (collected by trial team)
Adapting Villa Vitality materials and developing Villa Vitality packs	0 (collected by trial team)
Cooking workshop central training	26
Development of signposting materials	0 (collected by trial team)
Signposting printing and postage	0 (collected by trial team)
PA and Villa Vitality package costs	0 (collected by trial team)
PA term 1	55
PA term 2	45
PA term 3	70
Cooking workshop and classes: breakfast	52.5
Cooking workshop and classes: lunch	57.5
Cooking workshop and classes: dinner	75
Villa Vitality day 1	40
Villa Vitality class project and challenges	47.5
Villa Vitality: school visit	45
Villa Vitality day 2	40

#### TABLE 39 Missing data by cost component

#### TABLE 40 Incremental cost analysis

No adjustment	Adjusted for clusterin D adjustment Adjusted for clustering baseline utility and c		Adjusted for clustering, baseline utility and covaria	ates	
MD (95% CI)	<i>p</i> -value	MD (95% CI)	<i>p</i> -value	MD (95% CI)	<i>p</i> -value
262.57 (254.98 to 270.16)	0.000**	267.24 (240.22 to 294.25)	0.000**	267.39 (240.64 to 294.14)	0.000**
**p<0.05.					

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#### Cost-utility analysis

The CUA combines the incremental costs with the incremental QALYs to produce an ICER. The ICER associated with the base case is £46,083 per QALY and, thus, the intervention is not cost-effective. Through the net benefit framework it is possible to assess the uncertainty around the ICER, while also considering clustering and the correlation between costs and outcomes. Given the very small effect size, and the uncertainty around the effect size, it is unsurprising to find extremely large levels of uncertainty around the ICER. At the NICE-recommended willingness-to-pay (WTP) threshold of £20,000–30,000 per QALY, the control arm is more likely to be cost-effective than the intervention arm. At the lower threshold of £20,000 per QALY, there is just a 30% chance that the intervention is more cost-effective than usual practice. Even at a WTP threshold of £100,000 per QALY, the intervention arm has only a 59% chance of being the more cost-effective option. The reason underlying this uncertainty can be attributed to the lack of effect of the intervention. As the effect size approaches zero, the CIs around the net benefit widen.

*Figure 10* shows the net benefits associated with the intervention at different levels of WTP. As the WTP threshold increases, the CIs widen, showing the increasing levels of uncertainty.

This is reflected in the CEAC (*Figure 11*), which shows the probability of the intervention being cost-effective at different levels of WTP for a QALY. Owing to the negligible treatment effect, even at high levels of WTP per QALY there is only a slightly better than 50 : 50 chance that the intervention is the more cost-effective option.



FIGURE 10 Net benefit of intervention at differing WTP levels.



FIGURE 11 Cost-effectiveness acceptability curve.

#### Sensitivity analysis

#### Sensitivity analysis 1: different multiple imputation method

When an alternative imputation strategy that utilised a fixed effect for clusters was applied, there was little impact on the results (*Table 41*). The overall ICER reduced to just under £42,000 per QALY; however, the estimates remained extremely uncertain, given the small and inconsistent effect size. This is reflected in the CEAC shown in *Figure 12*.

#### Sensitivity analysis 2: including set-up and implementation costs

As expected, the inclusion of set-up and implementation costs led to an increase in the ICER associated with the intervention and an even less favourable CEAC. The addition of the set-up and implementation costs increased the mean costs by £43.66, increasing costs to £311.07 per child. This increase in cost had a notable impact on the ICER, increasing the ICER to £53,610 per QALY.

The CEAC (*Figure 13*) shows the impact of the higher levels of cost moving the CEAC downwards, especially at the lower levels of WTP than with the base-case analysis. Again, because of the lack of effect of the intervention, there is a great deal of uncertainty surrounding the results.

#### Sensitivity analysis 3: including wider costs

As with sensitivity analysis 2, the inclusion of wider costs results in the ICER rising to just under £52,000 per QALY. As shown by the CEAC in *Figure 14*, there was little chance that the intervention is cost-effective. At a WTP of £20,000 per QALY, there is just a 26% chance that the intervention is more cost-effective than usual care. When wider costs are considered, the intervention remains not cost-effective.

#### Sensitivity analysis 4: best-case scenario

In this scenario it is assumed that there are 30 children in every class; therefore, the cost has reduced to £155.53 per child. This produced a more favourable cost-effectiveness result, with the ICER falling to approximately £26,804 per QALY. Although this would be borderline cost-effective, it is again important to note the uncertainty around this best-case estimate, as demonstrated in the CEAC in *Figure 15*.



### TABLE 41 Incremental QALYs, adjusted for clustering, baseline utility, covariates, with alternative imputation strategy

FIGURE 12 Cost-effectiveness acceptability curve with alternative fixed-effect imputation strategy.

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FIGURE 14 Cost-effectiveness acceptability curve: including wider costs.



FIGURE 15 Cost-effectiveness acceptability curve: best-case scenario.

Again, because of the lack of treatment effect within the trial, there is a great deal of uncertainty surrounding all cost-effectiveness results. Even at a WTP of £100,000 per QALY, there would be only a 62% probability that the intervention is more cost-effective than usual care.

#### Cost per obesity case prevented

The purpose of the intervention is to prevent obesity and it is therefore important to consider the intervention in terms of its success at preventing children transitioning to an obese state. In the control arm, 7% of the children transitioned to an obese health state at FU2, having been in a non-obese state at baseline. In contrast, 10% of those in the intervention arm transitioned into an obese state in the intervention arm. That is, more children in the intervention arm transitioned into an obese state than those in the control arm. This is reflected by the results of the multilevel logit model. To demonstrate the lack of effect of the intervention, the odds ratio associated with children in the intervention arm transitioning into an obese state is 1.17 (95% CI 0.66 to 2.09) when controlling for covariates. This indicates that those in the intervention arm are more likely to transition into an obese state than those in the intervention arm are more likely to transition into an obese state than those in the intervention arm are more likely to transition into an obese state than those in the control arm. It should be noted, however, that this is not a significant difference. This negative finding, however, makes it impossible to assess the cost per obesity case prevented as a result of there being zero cases of obesity prevented by the intervention. These results reflect the primary trial analysis of the health outcomes data, which indicates that there was no notable impact of the intervention on clinical outcomes.

#### Conclusion

The economic evaluation has summarised the methods and results for capturing both the incremental costs that were associated with the intervention and the incremental effectiveness. The economic evaluation analysed both costs and benefits jointly using the NBR framework. In terms of costs, the intervention costs were largely driven by the Villa Vitality package and school staff time for delivering the intervention. With respect to the analysis of effectiveness and cost-effectiveness, the main result is the lack of intervention effect in terms of QALY gain or in terms of obesity prevention. The economic evaluation suggests that the intervention, despite its relatively low cost on a per-child basis, has negligible benefits, and thus fails to demonstrate cost-effectiveness. When considering the uncertainty surrounding the ICERs, the lack of treatment effect becomes apparent and a great deal of uncertainty underlies the apparent cost-effectiveness. Consequently, even when considering a particularly high WTP threshold for QALYs, and a reduced intervention cost as in sensitivity analysis 4, there is still a vast amount of uncertainty about whether or not the intervention would be deemed cost-effective.

A number of challenges were encountered within the economic evaluation, which included dealing with clustering, and also missing data. Clustering was largely accounted for within the analysis by implementing multilevel imputation and analysis models. The second of these challenges, that is, the missing data, proved to be a significant limitation. In terms of effectiveness data, follow-up rates were good and the level of attrition throughout the follow-up periods was typical for a trial. For the cost data, however, missing data were a much more significant challenge. This largely relates to the methods of resource use collection. Resource use as recommended by best practice was collected alongside the trial. Collection of many of the resource use data was through teacher logbooks, which varied by component. Given the multifaceted nature of the intervention, and the consequently large number of cost components, it is perhaps unsurprising that missing cost data were pervasive throughout. Consequently, a complete-case analysis would have removed nearly every single child from the analysis. Multiple imputation, as recommended in the literature, was therefore necessary to address this and to make best use of the data.

This was a trial-based economic evaluation and, thus, health-care costs were not considered, as any potential health-care usage from being obese would occur well into the future. Had the intervention been effective in preventing obesity, it would have been possible to model future cost savings and health improvements using a decision-analytic modelling approach. A direct result of the lack of effectiveness of the intervention was that this modelling stage was, unfortunately, not required.

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## Chapter 8 Discussion

#### **Summary of findings**

The WAVES study is one of the largest cluster randomised controlled trials of childhood obesity prevention to date, with a sufficient sample size to ascertain the effectiveness of the intervention on BMI-z and incorporating a cost-effectiveness analysis.

In terms of our primary outcomes, we found no evidence of a significant intervention effect on BMI-z at 3 and 18 months after the end of the intervention period (although the direction of effect favoured the intervention). There were also no consistent intervention effects on any of the secondary anthropometric, behavioural, clinical or psychological outcomes. However, in the subgroup of participants who underwent a third follow-up at 27 months (G1 schools), there was a statistically significant and clinically important difference in BMI-z in favour of the intervention (MD -0.204, 95% CI -0.396 to -0.013 in the partially adjusted model and MD -0.177, 95% CI -0.336 to -0.017 in the fully adjusted model). There was no statistically significant intervention effect for the other anthropometric measures, although the direction of effect for some favoured the intervention. There was no significant difference between the trial arms in terms of quality of life, self-perception or body image dissatisfaction, suggesting that there was no evidence of harm from the intervention.

Alongside the trial, an economic evaluation provided evidence on the cost-effectiveness of the intervention compared with no intervention. A trial-based CUA, based on outcome of cost per QALY, was conducted. Using the CHU9D, at 18 months post intervention the incremental cost-effectiveness of the intervention compared with no intervention was £46,083 per QALY (or £26,804 per QALY for the best-case scenario, taking into account all of those who received the intervention, rather than just those who consented to measurements). The intervention is therefore not cost-effective using NICE-recommended WTP threshold of £20,000–30,000 per QALY. This is mainly a result of the lack of intervention effect in terms of QALY gains, which led to a high level of uncertainty around the ICERs.

#### Subgroup effects

In terms of sociodemographic and clinical subgroups, we found no consistent pattern suggesting heterogeneity of treatment effects by sex, household level of deprivation or baseline weight status. There was a statistically significant effect in favour of the intervention for most anthropometric measures in children from the black African Caribbean ethnic subgroup in the fully adjusted models at FU1 and FU2. There was an inconsistent pattern in relation to behavioural outcomes in this subgroup, but the intervention group had lower levels of PA and consumed fewer portions of fruit and vegetables at FU2 than the control group. Such an effect was not seen in any other ethnic subgroup. We considered the credibility of this finding representing a true subgroup effect, based on recommended criteria (*Table 42*).<sup>99</sup> Although this was a prespecified subgroup analysis that fulfilled the design criteria, there was no significant interaction effect, and the contextual evidence to support such a finding is mixed. The relatively small size of this subgroup also makes interpretation more complex. Therefore, on balance, it is possible, but uncertain, that the intervention was effective only in this subgroup.

Overall, there was no evidence of the intervention resulting in inequity and it was unlikely that there was a differential effect of the intervention in the black African Caribbean subgroup.

In view of the BMI-z results at FU3, a post hoc exploratory analysis was undertaken to compare intervention effects between G1 and G2 schools. This showed a statistically significant effect in the fully adjusted models for BMI-z in favour of intervention at FU1 (-0.23, 95% CI -0.34 to -0.12) and FU2 (-0.17, 95% CI -0.34 to 0.00) in the G1 schools, which was maintained at FU3 (-0.20, 95% CI -0.40 to -0.01). In G2 schools,

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TABLE 42 Assessment of the credibility of intervention effect in the black African Caribbean ethnic subgroup

Credibility criteria considered	Assessment outcome
Design	
Was the subgroup variable a baseline characteristic?	Yes
Was the subgroup variable a stratification factor at randomisation?	Yes
Was the subgroup hypothesis specified a priori?	Yes
Was the subgroup analysis one of a small number of subgroup hypotheses tested ( $\leq$ 5)?	Subgroups: sex, household deprivation (IMD), baseline weight status and ethnicity
Analysis	
Was the test of interaction significant (interaction $p < 0.05$ )?	No
Was the significant interaction effect independent, if there were multiple significant interactions?	No
Context	
Was the direction of subgroup effect correctly prespecified?	Yes
Was the subgroup effect consistent with evidence from previous related studies?	Somewhat
Was the subgroup effect consistent across related outcomes?	Yes
Was there any indirect evidence to support the apparent subgroup effect, for example biological rationale, laboratory tests, animal studies?	Theoretical evidence of potential heterogeneity by ethnicity. No supportive evidence from process evaluation

there were non-significant differences between arms, with the direction of effect favouring the control (0.08, 95% CI –0.09 to 0.25 at FU1; and 0.09, –0.04 to 0.22 at FU2). This was not a prespecified analysis and should, therefore, be interpreted with caution. Credibility of a genuine subgroup effect is suggested by the following:

- significant interaction between group and the treatment arm
- consistency in terms of direction of effect for most anthropometric measures
- consistency of direction and size of effect at all follow-up periods
- significant difference in mean BMI-z at baseline between G1 and G2 schools.

Although mean BMI-z was very similar at baseline between the trial arms in G1 schools, there was a large baseline imbalance in G2 schools, with greater BMI-z in the intervention arm than in the control arm. This may be an explanation for the observed difference in effect between the two groups of schools.

However, other factors suggest that this observation may not be a genuine subgroup effect:

- The analysis was not specified a priori.
- Taken together with the prespecified subgroup analyses, there were five categories of subgroup hypotheses that have been tested (with a total of 11 variables).
- There was no consistency of effect in terms of behavioural outcomes.

On balance, there is a possibility of a genuine subgroup effect.

#### Strengths and limitations

The WAVES study addresses many of the limitations that have been identified in previous childhood obesity prevention trials.

#### Design

We used a cluster randomised control design to take account of clustering at school level, with a sufficiently large sample to provide sufficient power for assessment of the primary outcomes. The participating schools and children were sampled to represent a wide range of ethnicities and socioeconomic backgrounds. This allowed consideration of subgroup effects in the analysis. Full allocation concealment was achieved by undertaking all of the baseline measurements prior to randomisation.

#### Intervention

The intervention was developed in a phased and rigorous way, using the MRC framework for complex interventions as a guide,<sup>56,57</sup> and following a successful feasibility trial.<sup>52</sup> The final multicomponent intervention package included many of the elements identified as promising in systematic reviews,<sup>18,19</sup> and incorporated a range of behaviour change techniques, including four that were most associated with positive outcomes in previous childhood obesity prevention trials (prompt generalisation of behaviour, practice, model behaviour and goal-setting).<sup>100</sup>

#### Outcome assessment

The outcomes were assessed with mainly objective measurements, using validated instruments and standardised protocols. In addition to BMI-z, we undertook a range of anthropometric measurements to account for reported limitations of using BMI in children. Dietary and PA levels were objectively assessed using validated instruments, which is a strength compared with subjective measurements in many previous trials. Loss to follow-up was relatively small, with 79% of pupils retained to the second follow-up, and the loss of one school.

#### Data analysis

We had a prespecified analysis plan, we took account of clustering in the analysis, and the findings were robust to a range of sensitivity analyses.

#### Long-term follow-up

This was one of few trials that undertook longer-term follow-up to assess whether or not any intervention effects would be sustained. This longer-term follow-up was important in helping to interpret the findings, as we have shown a consistent magnitude of effect in terms of difference in BMI-z between intervention and control arms in G1 schools.

#### **Process evaluation**

A detailed process evaluation was undertaken alongside the trial, and this has helped to contextualise the findings and interpret the results.

#### **Economic analysis**

The WAVES study was the first trial of childhood obesity prevention that incorporated an economic analysis alongside the study. Nevertheless, there were also a number of limitations.

The block balancing algorithm to allocate schools to intervention or control arm was based on data at school (cluster) level. However, within clusters, only children from one year group were eligible for the trial, and, among those eligible, just over half consented to study measurements. There was baseline imbalance between the arms in relation to the outcome of interest and, although the primary analysis adjusted for baseline measures, this may have not fully accounted for the imbalance. Such baseline imbalance is a known limitation of cluster trials and can best be overcome with recruitment of larger numbers of clusters.<sup>101–103</sup>

The fact that consent for study measurements was obtained for only 60% of eligible pupils means that there is the potential for selection bias. However, the comparison of demographic characteristics between consented and non-consented pupils showed only small differences in relation to ethnicity and deprivation.

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Intervention delivery was variable, with two schools failing to deliver any, and some only partially delivering, components. However, a subgroup analysis by implementation fidelity did not show any evidence of subgroup effect. Although follow-up to 18 months was in all groups, longer-term follow-up (to 27 months) was limited to a subset of participating schools, which limits interpretation. At each follow-up time point there was loss to follow-up, with the potential introduction of follow-up bias. The proportion of participants without primary outcome data at follow-up for those included in the measurement time point and with baseline primary outcome data available was 14%, 21% and 25% at FU1, FU2 and FU3, respectively. It is worth noting, however, that the majority of this loss to follow-up was a result of either school dropout (one G2 school, 20 participants with baseline primary outcome data) or participants having changed school between baseline measurements and follow-up. The proportions lost to follow-up for either consent withdrawal or not being available at school on the day of measurement were relatively small (4%, 5% and 7% for FU1, FU2 and FU3, respectively). A comparison has been undertaken of pupil-level demographic and weight status characteristics for those with baseline primary outcome data who also had follow-up data with those who were lost to follow-up at each time point. Although, with the exception of sex, there are some differences between those with and those without follow-up data, in general the differences are relatively small, with inconsistency in characteristics between the three follow-up time points.

In terms of weight status (non-overweight vs. overweight/obese) there was very little difference in proportions at FU1 or FU2 (proportion at least overweight, follow-up data available vs. lost to follow-up: 21% vs. 22.1% and 22.0% vs. 22.2%, at FU1 and FU2, respectively). However, at FU3, those lost to follow-up were less likely than those successfully followed up to be overweight or obese (19% vs. 22.5%).

With regard to ethnicity at both FU1 and FU2, those lost to follow-up were less likely than those retained to be white (FU1 40.6% vs. 45.9, FU2 42.6% vs. 45.9%) or South Asian (FU1 26.2% vs. 30.9%, FU2 24.6% vs. 31.8%) and more likely to be black (FU1 11.2% vs. 7.5%, FU2 12.5% vs. 6.9%) or in the other ethnic group category (FU1 21.9% vs. 15.6%, FU2 20.4% vs. 15.4%). A similar pattern was observed at FU3 for the South Asian (19.7% vs. 27.2%), black (11.6% vs. 6.4%) and other (17% vs. 14.8%) ethnic groups, but there was no difference in the proportion who were white between those with and those without follow-up data.

The final characteristic considered was deprivation. There were no consistent patterns in terms of deprivation among those who were successfully followed up compared with those lost to follow-up at the different time points. The analysis did consider subgroup effects, but the sample size for subgroup analysis was insufficient to detect anything other than larger effects. Furthermore, the prespecified ethnic subgroups were heterogeneous themselves. Smaller subgroup effects, therefore, cannot be dismissed.

#### Assessment of behavioural outcomes

Dietary intake was assessed objectively and data were collected prospectively using average portion sizes that were specific to the child's age and sex. This reduced the potential for recall bias and the need for weighing food. The CADET provided a guick, easy to administer tool, requiring minimal training and having a relatively low respondent burden. However, as the dietary intake estimate is based on only one weekday record of consumption, it may not be reflective of habitual intake. As with any dietary assessment tool there also a risk of misreporting<sup>104</sup> and there may have been seasonal variation<sup>105</sup> between the baseline and follow-up data collection periods. Furthermore, adaptations to the CADET to align it to  $MW7^{30}$  and smooth anomalous portion sizes may have undermined the validation of this tool. In addition, there were two important considerations. First, the CADET was a written tool and, therefore, if English literacy was an issue, completing the record correctly may have been problematic. However, in an attempt to reduce the impact of this, participants were provided with an instructional DVD on how to complete the CADET booklet. This information was also available online. Second, the CADET was developed to capture foods that were typically consumed in the UK. Although there was an attempt to represent some foods that may be consumed in other cultures, this was limited and, therefore, it may have been difficult to accurately complete the record if the participant consumed a non-Western diet. Despite these limitations, we achieved useable data from  $\approx$  89% of children at both follow-up points. This is much higher than the

completion rate for dietary assessment in our feasibility study<sup>52</sup> and similar to that reported in other studies in children.<sup>106,107</sup>

Physical activity assessment was also objective, and we aimed to obtain data over 5 days including a weekend. However, not all of the children were compliant, and usable data were available for 69.4% at FU1 and 61.1% at FU2. This is higher than or similar to the rates achieved in other similar studies.<sup>106,108</sup>

#### **Comparison with other studies**

Our findings build on the findings of previous reviews by addressing a number of important weaknesses in previous randomised controlled trials of childhood obesity prevention. Two major systematic reviews suggested that there was moderate<sup>19</sup> to strong<sup>18</sup> evidence of effectiveness of school-based interventions in preventing childhood obesity. Nevertheless, both reviews acknowledged study heterogeneity, the variable quality of included studies and the lack of longer-term follow-up as limiting factors in the interpretation. A meta-analysis included in the Cochrane review<sup>18</sup> showed that the summary magnitude of effect in terms of BMI-z from pre to post intervention relative to the change in the control group was –0.15 units. This was smaller than the effect size that was used for estimating sample size for our trial. Nevertheless, the WAVES study was larger than most of the 31 previous obesity prevention trials in primary school children that were included in the meta-analysis (sample size of individuals in included studies = 30–1807) and substantially larger than the 21 studies considered to have a low risk of bias (n = 9-574). Furthermore, many of these previous trials had not taken account of the clustered nature of the data during analysis.

Despite the methodological limitations of many of the previous trials, the summary effect size of 0.15-unit difference in BMI-z between intervention and control groups is relatively small. Previous studies have shown that a reduction in BMI-z of 0.25 units is associated with improved cardiometabolic risk in obese adolescents.<sup>53</sup> Nevertheless, even smaller reductions of 0.15 units, <sup>109</sup> or even of 0.1 units (equivalent to 0.5 kg in body weight for an average 10-year-old boy), <sup>110</sup> have also been shown to be associated with important measurable health benefits. Given the trend of increasing obesity with increasing age and over time, such small reductions in BMI-z at a population level are, therefore, clinically important.

Since the publication of the reviews, findings have become available from another well-conducted, large, school-based cluster randomised controlled trial in the UK.<sup>106</sup> The Active for Life Year 5 intervention was adapted from a promising programme that had been developed and evaluated in the USA, which included training of teachers, provision of lessons to children in school year 5 (aged 9–10 years) and interactive homework that involved parents. The primary aim was to increase PA levels, reduce sedentary time and improve fruit and vegetable intake in the target group. This large trial, which included > 2000 children from 60 schools, found no evidence of an intervention effect immediately after the end of the 1-year intervention period. There was also no effect on weight-related secondary outcome measures.

Findings from a more ambitious European community- family- and school-based intervention programme aimed at childhood obesity prevention were also recently reported.<sup>111</sup> The 2-year intervention was developed using intervention mapping and included community involvement, media campaigns, school classroom, curricular and homework activities, active playgrounds and other environmental changes at school level, as well as parental education materials. The effects of the intervention were evaluated in a sample of over 16,000 children aged 2–10 years from eight European countries. At the end of the intervention period, there was no evidence of intervention effect on measures of adiposity.

The lack of evidence of any significant effect on adiposity at the end of the intervention period in these two larger trials is similar to the overall findings in our trial and adds to the larger body of evidence showing mixed or weak results from dietary and PA interventions.

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#### Interpretation of study findings

Several factors may have contributed to the absence of evidence of effects on primary outcomes in the WAVES study and other trials.

#### Target behaviours addressed by intervention

In the WAVES study, as in other similar childhood obesity prevention studies, the multicomponent intervention package addressed dietary and PA behaviours. These target behaviours are generally associated with adiposity levels in observational studies, but there are conflicting views on whether or not all associations are causal.<sup>112</sup> Unless there is a strong causal link between the target behaviour and the desired outcome, interventions will not be effective.<sup>113</sup> Furthermore, within the complex web of causal factors, modifying one behaviour may lead to compensatory action that offsets any positive effects. For example, engaging in additional PA may be accompanied by the consumption of more energy-dense foods as a reward.

#### Strategies for behaviour change

Although the common behaviour change strategies that have been associated with successful childhood obesity prevention interventions have been summarised,<sup>100,114</sup> it is not known which are the most effective.

#### Intervention delivery

The intervention was delivered by non-researchers, similar to other school-based and community studies. The degree to which the intervention was delivered as intended was variable, and, although the fidelity of implementation was high overall, a few schools failed to implement the intervention fully or at all. Although this reflects more closely the probable effects of the intervention if it is implemented outside a trial setting, the efficacy of the true intervention cannot be fully assessed. Intercomponent differences in fidelity were mainly driven by required teacher workload, enthusiasm and support from senior staff. Although teachers were encouraged to tailor the PA component of the intervention to their particular circumstances, this component was the most challenging for them. The need to deliver this component on a daily basis was burdensome, and, even among schools that had developed a routine, the full 'dose' of 30 minutes per day was not achieved.

#### Duration of intervention and timing of follow-up

Most childhood obesity prevention interventions are of short duration (up to 12 months). It is unlikely that an intervention will have long-term effects unless it is ongoing or unless changes in the environment continue to support behaviour change. Although the aim of the intervention was to facilitate sustainable changes, few teachers intended to continue delivering the intervention after the end of the study. Even if sustained behaviour change is achieved, intervention effects on weight status may take a longer time to manifest.<sup>112</sup>

#### Wider context

There is increasing emphasis on obesity prevention, and a number of local and national initiatives have started over recent years. Although the findings from the feasibility study suggested that the intervention was promising, intervention delivery for the trial and subsequent follow-up measurements took place some years later, during which time wider environmental changes may have diluted any effects. Furthermore, although school is an important setting for influencing children's health behaviour, wider impacts from the family and community, including socioeconomic circumstances, must also be considered. Food marketing and easy access to less healthy foods, as well as environments that discourage walking and PA, may also affect behaviour.<sup>11</sup> The qualitative data from teachers<sup>115</sup> and parents,<sup>116</sup> collected as part of our process evaluation, support the possibility that these wider influences have a greater effect than any school-based intervention.

#### Interpretation from the WAVES process evaluation

The extensive process evaluation suggests that intervention delivery was variable, although the majority of intervention schools delivered most of the components, and teachers reported that the implementation of the programme was relatively easy and manageable.<sup>115</sup> Furthermore, teachers commented on the ease of use of the intervention, their appreciation of the flexibility to adapt resources to their individual circumstances and the inclusive nature of activities, meaning that all children could get involved regardless of academic or motor skill level. The teachers also discussed how the key messages of the intervention supported existing practice and the ethos of school responsibility for the whole child.<sup>115</sup> When exploring the views of parents, all were supportive and appreciative of the programme, but there was some differentiation in terms of the perceived impact. Families from higher socioeconomic areas considered that they gained little additional knowledge and already practised healthy behaviours, whereas positive lifestyle changes were more likely to be reported by families from more disadvantaged communities.<sup>116</sup> However, our subgroup analysis did not support this finding.

The signposting information was resource intensive to produce and not recalled by participants. Therefore, this component is unlikely to have had any impact.

Although in most schools the PA component was not delivered at the intended intensity, overall, the average daily increase in MVPA exposure achieved was around 12 minutes. This is close to the 15 minutes per day of additional activity that is promoted by 'The Daily Mile' initiative, which has been reported to be simple and feasible to deliver and has been associated anecdotally with positive changes. Schools that did implement this component often reported positive effects in terms of concentration and mood among children, although a minority of schools reported negative effects. Schools were more likely to deliver the intervention if they planned and timetabled PA into their daily routine.

Most of the cooking workshops were delivered and covered the key content and activities. However, parental attendance at the workshops was just over 40%. Schools that had pre-existing parent engagement relationships were more likely to involve parents. Parents and children reported improved knowledge, skills and diet as a result of these workshops.<sup>116</sup> Teachers also observed increased knowledge and some behavioural changes among the children as a result of this element of the intervention.<sup>115</sup>

The Villa Vitality component of the intervention was particularly well received by teachers, as it was seen to draw together the key messages and provide the opportunity for children to practise healthy lifestyle behaviours in an inspirational setting outside the classroom.<sup>115</sup> Children recalled this component vividly and parents commented on the impact of this visit in terms of the role models and the weekly challenges.<sup>116</sup>

The process evaluation also highlighted challenges in delivery of the intervention. Competing demands on teachers' time and pressure for academic achievement meant that intervention delivery could be compromised. In addition, support from parents, the wider school and government was seen as important for facilitating intervention delivery. The sustainability of any intervention effect was also questioned, as parents and teachers considered that a 1-year programme may be insufficient for long-term behaviour change.

#### Implications of findings

Our overall conclusion is that the WAVES study intervention did not have a significant effect on our prespecified primary outcomes. The post hoc exploratory analysis demonstrated heterogeneity of effects between G1 and G2 schools, which may be explained by differences in the baseline characteristics and more marked adiposity imbalance between the arms in G2. We found no evidence of harm or inequity.

Schools offer an important setting for delivering obesity prevention interventions, as they reach the majority of children, have long-term and in-depth contact with children, and offer a space in which

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children can observe and practise health behaviours that contribute to obesity prevention. A meta-synthesis of qualitative studies exploring the role of primary schools in preventing childhood obesity highlighted the need for schools, parents and government to work together to promote healthy lifestyles in children and support activities in the school setting.<sup>117</sup> School staff view the provision of healthy lifestyles education as a key school responsibility in relation to children's holistic development, but they need national and local policies to be in place to support the delivery of a health-promoting environment and curriculum.<sup>118</sup> From September 2014, primary schools in the UK were expected to teach children about food, cooking and nutrition under the national curriculum. Schools are also encouraged to offer 5 hours of PA opportunities per week,<sup>119</sup> although this rarely happens in practice.

Although our findings do not support the wider implementation of the WAVES study intervention, the PA and cooking workshop components could be considered by schools to fulfil their mandated responsibilities. These components are relatively low cost, have been shown to be acceptable and feasible to deliver, are appreciated by teachers, children and parents, and are not associated with any harm. Furthermore, the possibility of potential benefit cannot be completely dismissed. The Daily Mile initiative is gaining popularity,<sup>120</sup> and, although the WAVES study PA component was not identical, the overall aim was similar. Future interventions could focus on optimising delivery of this component by (1) further training teachers to help them feel more confident with delivery, (2) encouraging teachers' understanding of the importance of increased PA on wider outcomes, including positive academic achievement and (3) facilitating timetabling of the activity by encouraging teachers to consider competing demands and plan delivery to suit their class needs. The cooking workshops could fulfil the new national curriculum requirements. Future programmes should focus on how to better engage parents in the delivery of such workshops.

In summary, this theory-informed, multicomponent intervention, which was feasible to deliver and was well received by children and parents, was not cost-effective, did not result in a significant reduction in obesity prevalence overall and did not alter diet or PA levels in children. Schools are important settings for accessing children and their families, but are one of several levels of environments that influence behaviour. Delivery of knowledge and skills to support healthy lifestyles is one of the mandatory functions of schools. School staff recognise the importance of encouraging healthy behaviours within the context of children's wider well-being. Future school-based interventions need to be integrated within a wider societal framework and supported by upstream interventions. This includes having supportive policies to promote social and environmental change. Interventions at multiple levels are needed to tackle the complex set of interacting factors that contribute to childhood obesity.<sup>121</sup> A realist review and synthesis of the literature on childhood obesity prevention studies could further inform future interventions. By considering the variety of contexts in which interventions were delivered, and the different strategies used in relation to the patterns of outcomes, such an approach can be used to build a theory to explain how, why and for which groups intervention components may be effective.

In terms of methodology, future cluster randomised controlled trials need to take appropriate steps to ensure a balanced allocation of intervention and control across key characteristics in order to reduce the risk of chance bias. This could be achieved by increasing the number of clusters.

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#### **Contributions of authors**

**Professor Peymane Adab** (Professor of Chronic Disease Epidemiology and Public Health, Institute of Applied Health Research) led the trial as principal investigator, prepared the summary, introduction and discussion chapters and assisted with preparation of the results chapter.

**Professor Timothy Barrett** (Leonard Parsons Professor of Paediatrics, Institute of Cancer and Genomic Sciences) was a co-investigator and advised on the anthropometric measurement tools used and arranged for initial training of research staff to undertake measurements. He also contributed to the trial design, measurement procedures and interpretation of findings.

**Professor Raj Bhopal** (Bruce and John Usher Chair in Public Health) was a co-investigator and has contributed to the trial design, measurement procedures and interpretation of findings.

**Professor Janet E Cade** (Professor of Nutritional Epidemiology and Public Health, School of Food Science and Nutrition) was a co-investigator, developed the dietary intake assessment tool used in the study and supervised all of the processing of the dietary intake data collected using the tool. In collaboration with other colleagues at the University of Leeds, she revised the dietary intake part of the outcomes section of the methods chapter.

**Dr Alastair Canaway** (Research Fellow, Clinical Trials Unit) undertook the cost-effectiveness analysis under the direction of the trial health economist. He also prepared the cost-effectiveness chapter.

**Professor Kar Keung Cheng** (Professor of Public Health and Primary Care, Institute of Applied Health Research) was a co-investigator and advisor to the trial management team. He has contributed to the trial design, measurement procedures and interpretation of findings.

**Dr Joanne Clarke** (Research Fellow, Institute of Applied Health Research) assisted in both measurement and process evaluation data collection and was one of the two main researchers responsible for consolidating and analysing the process evaluation data. She assisted in the preparation of the interventions chapter.

**Dr Amanda Daley** (Reader in Behavioural Medicine, Institute of Applied Health Research) was a co-investigator and has contributed to the trial design and aspects of intervention design, and interpretation of findings.

**Professor Jonathan Deeks** (Professor of Biostatistics, Institute of Applied Health Research) was a co-investigator and advised on statistical aspects of the trial and in the interpretation of findings.

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**Professor Joan Duda** (Professor of Sport and Exercise Psychology, School of Sport, Exercise and Rehabilitation Sciences) was a co-investigator and contributed to the trial design, psychological measurement instruments and interpretation of findings.

**Professor Ulf Ekelund** (Professor of Physical Activity and Health, Department of Sport Medicine, Norwegian School of Sport Sciences/ Cambridge MRC Epidemiology Unit) was co-investigator and advised on PA assessment, and oversaw the training of researchers in collecting Actiheart data and the processing of the PA data. He prepared the PA part of the outcomes section of the methods chapter in collaboration with other colleagues at the MRC Epidemiology Unit.

**Dr Emma Frew** (Reader in Health Economics, Institute of Applied Health Research) was a co-investigator and the trial health economist. She advised on all aspects of the cost-effectiveness component of the study. She assisted in both the preparation and the revision of the cost-effectiveness chapter.

**Dr Paramjit Gill** (Reader in Primary Care Research, Institute of Applied Health Research) was a co-investigator and contributed to the trial design, measurement procedures and interpretation of findings.

**Dr Tania Griffin** (Research Fellow, Institute of Applied Health Research) was part of the main study team and was responsible for all of the aspects of the process evaluation component of the study. She assisted in the preparation and revision of the process evaluation of intervention implementation chapter.

**Dr Karla Hemming** (Senior Lecturer in Biostatistics, Institute of Applied Health Research) was the trial statistician and a member of the Trial Steering Committee and undertook the sampling and random allocation procedures. She advised on all of the aspects of the main study analyses and revised the statistical analysis methods chapter and part of the statistical elements of the methods chapter. She also assisted in the preparation of the results chapter.

**Mrs Kiya Hurley** (Research Assistant, Institute of Applied Health Research) supervised the measurement teams throughout the study, prepared the dietary intake part of the outcomes section of the methods chapter and revised all of the outcomes section of the methods chapter.

**Dr Emma R Lancashire** (Senior Research Fellow, Institute of Applied Health Research) was the trial co-ordinator for the study and led the trial management team. She prepared the methods, interventions, process evaluation of intervention implementation and results chapters. She undertook the analysis for, and produced, the CONSORT flow diagram and the pupil- and school-level baseline characteristics tables.

**Mr James Martin** (Research Assistant, Institute of Applied Health Research) undertook the main study analyses, including sensitivity and ancillary analyses, under the direction of the trial statistician. He produced all of the key and additional variable results tables and prepared the statistical analysis methods chapter. He also assisted in the preparation of the results chapter.

**Ms Eleanor McGee** (Public Health Nutrition Lead Birmingham Community Healthcare NHS Trust) was a co-investigator and contributed to the trial design, measurement procedures and interpretation of findings.

**Dr Miranda J Pallan** (Senior Lecturer in Public Health, Institute of Applied Health Research) was a co-investigator and part of the trial management team, working alongside the principal investigator and trial co-ordinator at all stages. She assisted in the preparation and revision of the process evaluation of intervention implementation chapter.

**Professor Jayne Parry** (Professor of Policy and Public Health, Institute of Applied Health Research) was a co-investigator and advised on process evaluation and contributed to trial design, measurement procedures and interpretation of qualitative data.

**Dr Sandra Passmore** (Education Advisor, Birmingham Services for Education) was a co-investigator and contributed to liaison with schools, intervention design and interpretation of findings.

All authors have read and approved the final version.

#### **Trial Steering Committee**

We would like to thank and acknowledge members of the external trial steering committee for overseeing the trial:

Dr Kelvin Jordan, Keele University: chairperson/statistician.

Professor Peter Whincup, St George's, University of London: subject expert.

Dr Louise Longworth, Brunel University: health economist.

Mr John Bennett, PHSE advisor: public representative.

## Medical Research Council Epidemiology Unit, University of Cambridge

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#### **Data sharing statement**

All available data are available from the corresponding author on request.

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## **Appendix 1** Height measurement standardised operating procedure

- 1. Ask the child to remove their shoes, socks and any hair ornaments, jewellery, buns, or braids from the top of the head.
- 2. Ask the child to stand upright with their heels touching the back of the platform. Ensure they are positioned facing forwards with their heels and buttocks in contact with the vertical board.
- 3. Move indicator so that it is touching top of head, but not pressing down.
- 4. If the child has a hair style which stands well above the top of their head, (or is wearing a joora or turban) record this on the back of the recording sheet to the nearest mm. If the respondent is wearing a joora, or other religious headwear, explain to them what you want to do first and be guided by the child. **Never touch religious headwear without obtaining consent from the child first.**



5. Make sure the child's head is facing forward (not tilted up or down) with eyes looking straight ahead. As a rule of thumb, the eyes should be roughly level with the top of the ears.

- 6. Explain to the child what you are going to do in Step 7.
- Cup the child's head in your hands, placing the heels of your palms either side of the chin, with your thumbs just in front of the ears, and your fingers going round towards the back of the neck.



- 8. Ask child to breathe in.
- 9. Firmly but gently, lift the child's head upwards towards the head plate, ensuring their heels are kept on the floor and taking care not to alter the level of the head (i.e. Step 5).
- 10. Release the pressure and allow the child to stand relaxed. If the measurement has been done correctly, the child should be able to step off the measure without ducking their head.
- 11. Record the reading to the nearest mm.

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- 12. Take a repeat measurement (the child must step off the measure between readings), go from step 5.
- 13. If the two measurements disagree by more than 4mm, take a third measurement.

#### Notes:

- a) Record on the back of the recording sheet, anything that may affect or interfere with the measurement (for example, refusal to remove shoes, hairstyles and accessories, or posture problems, e.g. bow legs, arthritis)
- b) If you were unable to obtain the height for whatever reason, write the reason in the comments section on the back of the recording sheet.

#### ENSURE THAT YOU USE THE ANTIBACTERIAL HAND GEL PROVIDED IN BETWEEN EACH CHILD MEASURED AND THAT THE PLATFORM OF THE MEASURE IS CLEANED USING ANTIBACTERIAL SPRAY

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# **Appendix 2** Weight measurement standardised operating procedure

- 1. The Tanita scales should be set up on a flat surface ensuring that the spirit level indicator is level.
- 2. Ask the child to remove shoes, socks and any heavy items of clothing e.g. jumper or cardigan. Also, ask them to remove any heavy items of jewellery and check that their pockets are empty. (NB. If the child does not want to remove socks/tights, note this on the back of the recording sheet).
- 3. Record if the child has been to the toilet prior to coming into the measurement room. (Children should have been asked to go to the toilet before entering the measurement room).
- 4. **Children are not to step on scales until instructed.** Enter 0.0 for clothes weight. Press enter.



5. Ask child to step on scales. The child's weight should be evenly distributed on both feet. Ask the child to stand upright, hands by their sides and head level with eyes looking straight ahead. Check that the child's heels and feet cover both metal pads. If feet are unable to cover electrodes, change to weight only mode.

- 6. Press male or female.
- 7. Press standard.
- 8. Enter the age in years.
- 9. Enter height in whole centimetres, rounding up or down, as appropriate. If rounding would result in 2 different whole centimetre values (e.g. if one measurement was 66.4 and the other was 66.5), use the higher of the two values.
- 10. Ask the child to stand perfectly still "Be a statue."
- 11. Once the green light stops flashing, the Tanita will print the results. From this printout, record the weight, to the nearest gram, on the recording sheet.
- 12. Check the Impedance if it is less than  $350.0 \Omega$ , take the weight again.
- 13. On the top of the printout, write the child's ID number and date of birth. Staple the printout to the recording sheet.



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14. If an error message occurs, check the table overleaf and adjust if required. If error messages occur repeatedly press "weight only" button, to obtain weight.

Note the following in the comments sections of the measurement recording sheet:

- If you successfully obtained the weight but the child had a cast, amputation or medical prostheses.
- If you successfully obtained the weight but the child retained heavy clothing or items on his/her person for cultural reasons.
- If the child refuses to remove their shoes in order to step on the scale.
- If you were unable to obtain the weight for whatever reason state why.

Error	Meaning	Action
E- 01	Abnormal impedance	Improve conductivity by
	compared to height and	cleaning feet or placing
	weight. E.g. problem with	water on electrodes
	electrode contact, feet	
	dirty, calluses, poor	
	contact	
	If the above does not	Unable to proceed
	solve the problem, it	
	means the body fat ratio	
	exceeds the measuring	
	capacity	
E-11	Measurement impossible	Use in another place
	because of excessive	
	vibration or electrical	
	noise	
E-12, 13, or 14	Machine requires	
	adjustment	
E-16	Impedance measurement	Improve conductivity by
	unstable	cleaning feet or placing
		water on electrodes

Error Messages:

No printout	No. of print outs selected	Ensure the machine has	
	is <0, an incorrect brand	been instructed to	
	of paper has been used,	printout and the correct	
	the paper roll is in an	paper is being used.	
	incorrect position or there	Open the paper hold and	
	is a paper jam	check the position of the	
		paper and clear any	
		jams	
P-End	Paper has ran out or is	Ensure there is paper on	
	jammed	the roll and that the	
		Paper Release Lever is	
		not in "Up" position	
Uuuu	Power has been turned off	Do not place anything or	
	during measurement	stand on scales before	
		starting measurement	
	Maximum weight capacity	Record this on the	
	has been exceeded	recording sheet	
Feed key	No of print outs selected	Use Body Fat	
not functioning	is 0 Weight scale mode is	Measurement Mode and	
	selected	select >0 for number of	
		printout	

## USE AN ANTIBACTERIAL SPRAY TO CLEAN THE SCALES IN BETWEEN EACH CHILD

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## **Appendix 3** Pupil measurement data sheet

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#### Stick Pupil I.D. Label here.

#### WAVES Pupil Measurement Sheet 2015

Staple Tanita Printout here.

Tanita Scale No:		BP Tru Machine No:		Calliper No:		
	Date:	Time of measurements:	Room temperature:	Gender:	Non dominant side:	
Name of person taking measure	//	:	°c	Male	Right	
				Female	Left	
	Height: (to nearest 0.1 cm)	1. cm	2. cm	3. (if 1st 2 differ by more than 0.4cm)		
	Weight:	Has been to the toilet?	1.			
	(to nearest 0.1 kg)	Yes / No	kg			
	Blood Pressure:	1. Right - Systolic / Diastolic	2. Right - Systolic / Diastolic	3. (If error message/ out-of-range) Right arm	Cuff size:	
		/	/	/		
	Pulse Rate:	1.Right	2. Right	<ol> <li>(If error message/ out-of-range) Right ann</li> </ol>		
	State of the Child: (Please tick)	Relaxed     Nervous	Still     Restless	Silent Not Silent	If the state of the child changes after the first reading please record in the comments section overleaf	
	Within the last 30 minutes has the child: (Please tick)	Exercised 🗆 Yes 🗆 No	Eaten food 🗖 Yes 🗆 No	Had a drink 🛛 Yes 🗔 No		
	Skinfold Biceps: (to nearest 0.1 mm)	۰ mm	2. mm	3. (If 1st 2 differ by more than 0.4 mm)	4.(If none of 1st 3 within 0.4 mm)	
	Skinfold Triceps: (to nearest 0.1 mm)	۰ mm	². mm	3. (If 1st 2 differ by more than 0.4 mm)	4.(If none of 1st 3 within 0.4 mm)	
	Skinfold Subscapular: (to nearest 0.1 mm)	۔ mm	² mm	3. (If 1st 2 differ by more than 0.4 mm)	4.(If none of 1st 3 within 0.4 mm)	
	Skinfold Suprailiac: (to nearest 0.1 mm)	۰ mm	2. mm	3. (If 1st 2 differ by more than 0.4 mm)	4.(If none of 1st 3 within 0.4 mm)	
	Skinfold Thigh: (to nearest 0.1 mm)	۰ mm	². mm	3. (If 1st 2 differ by more than 0.4 mm)	4.(If none of 1st 3 within 0.4 mm)	
	Thigh Circumference: (to meanewt 0.1 cm)	۰. cm	2. . cm	3. (If 1st 2 differ by more than 0.2 mm) . CM		
	Arm Circumference: (to nearest 0.1 cm)	1 . cm	2. cm	3. (If 1st 2 differ by more than 0.2 cm)		
	Waist Circumference: (to nearest 0.1 cm)	cm	2 cm	3. (If 1st 2 differ by more than 0.4 cm)		
	Actiheart Monitor:	N°:		Date Fitted:	//	

Dept of Public Health, Epidemiology, and Bio-Statistics, University of Birmingham
#### Comments:

Non dominant side:			
Height:			
Weight:			
Blood Pressure:			
State of the Child:			
Activity/Food/Drink:			
Skinfold Biceps:			
Skinfold Triceps:			
Skinfold Subscapular:			
Skinfold Suprailiac:			
Skinfold Thigh:			
Thigh Circumference:			
Arm Circumference			
Waist Circumference:			
Actiheart monitor:			

# **Appendix 4** Waist circumference standardised operating procedure

- 1. Ask the child to stand feet shoulder width apart with their arms crossed over the chest. It may help to tell the children to think of giving themselves a hug.
- 2. Explain to the child what you are going to do, and that you are going to have to lift their t-shirt.
- Feel the upper right hip bone of the child until you locate the border of the iliac crest. Draw a short horizontal line just above this border. Draw a short vertical line to cross this mark, level with the centre of the body.



4. Repeat on the left side.



5. Extend the tape around the waist, ensuring that the bottom edge of the tape is on the horizontal line of the crosses. Check that the tape sits parallel to the floor, rests firmly but does not compress the skin, is not twisted and no clothes are caught under the tape. Always position the zero end of the tape below the section containing the

measurement value and check that the child is not breathing in.

- 6. Record the measurement to the nearest mm.
- 7. Remove the tape measure and repeat from Step 5.
- 8. If the first two measurements disagree by more than 4mm, take a third measurement.

## ENSURE THAT YOU USE THE ANTIBACTERIAL HAND GEL PROVIDED IN BETWEEN EACH CHILD MEASURED

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# **Appendix 5** Skinfold measurement standardised operating procedure

## Waves quick reference for skinfold measures

- Ensure all measurements are made on child's NON DOMINANT SIDE.
- Check the needle on the calliper has returned to 0 after each measurement.
- Test the callipers on the child's finger to reassure them that the pinch shouldn't be painful.
- Support the callipers at all times so they do not hurt the child.
- One measurement should be taken at each of the sites and then the cycle should be repeated.
- If difference between the 2 measures is more than 4mm take another measurement.
- Use antibacterial gel between each child measured.

### Triceps skinfold (back of arm)

Ask child to stand with their non-dominant arm bent at 90 degrees at their elbow.

If not already marked, measure and mark the midpoint.

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Identify the skinfold **2 cm above the cross** (if struggling start close to elbow and work upwards).

Maintain the pinch with one hand and use the other to take the calliper reading at the mark.





### **Biceps skinfold (front of arm)**

Ask child to stand facing you with non-dominant arm hanging loosely by side palms facing forwards.

If not already marked, measure and mark the midpoint.

Continue with the bicep skinfold as for the triceps measurement.





### Subscapular skinfold (on the back)

Ask child to stand facing away from you with their hands hanging by their side.

Feel for the inferior angle of the shoulder blade and mark with a cross (if struggling ask child to put arm behind back to help identify point).

Identify the skinfold at  $45^{\circ}$  angle to the spine (see pictures) **2 cm away from the mark** (towards the spine).

Maintain the pinch with one hand and use the other to take the calliper reading at the mark.





Suprailiac Skinfold (side of stomach, near the hip)

Ask child to stand with their side to you with their hands hanging by their side.

If not already marked, feel for the top of the iliac crest on the child's non dominant side. Mark a **horizontal line** (parallel to the floor) **just above the top of the crest**. Make a **cross at the same level as this line on the midaxillary line** (which extends from the centre of the armpit down the side of the torso).

Identify the skinfold at 45° angle (sloping down) between the cross and the horizontal line.

Take the skin fold at the horizontal line (marked just above the iliac crest).





### Thigh skinfold

Ask the child to sit on a chair, measure down the front of the non-dominant thigh and mark the midpoint.

Ask the child to face you resting their body weight on dominant leg, bending knee slightly of their non dominant leg.

Identify the skinfold **2 cm above the marked point** and take skinfold measurement **on the marked point.** 

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# **Appendix 6** Actiheart fitting standardised operation procedure

- Explain the monitor is going to be attached to the skin underneath the child's tshirt, and will be stuck on with sticky pads. Explain that they should keep the monitor on for 5 days, and that they do not need to take it off, not even for swimming, showering, bathing or sleeping.
- 2) Record the Actiheart number (located on the back of the Actiheart) and date on the recording sheet.
- 3) Give the child a paper towel and ask them to rub their skin across their whole chest at level of sternum. This is important to remove any moisture or residue on the skin to ensure the pads stick to the skin well.



- 4) Clip the monitor on to the electrodes.
- 5) Remove the backing from the electrodes.
- 6) Ask the child to use their right arm to hold their t-shirt up and leave their left arm by their side. Place the smaller end of the Actiheart on the participant first (this end is placed closest to the child's left arm, but not so that it can be caught by the arm).



7) Place one finger under the wire, so the wire is not fully taught, and place the main piece of the Actiheart below the sternum (or as far towards the child's right arm as necessary). It is important that there is not enough slack in the wire to allow the circular part of the Actiheart (the main piece) to spin around more than 90

degrees as this will create false readings.

- Ask the child to press down on the electrodes to ensure they have created a firm hold.
- 9) Remind the child they should keep the Actiheart on for 5 days. Explain that if it becomes loose or falls off, they have been provided with spare sticky pads so an adult can replace the Actiheart using the instructions provided.



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# **Appendix 7** Child questionnaire administration standardised operating procedure

- 1. Never lead or guide the response.
- 2. Questions can be re-worded if the child does not understand the question, however be careful not to give additional explanations:

E.g. Original Question: Do you have trouble sleeping?

**Re-worded:** Do you find it hard to sleep? **Expanded too far:** Do you find it hard to get to sleep in bed at night? Do you find it hard to stay asleep at night?

- 3. If a child asks for more information, e.g. 'what kind of big things?' Ask them to tell you what they think it could be, rather than telling them.
- 4. Use the picture cards to assist with long questionnaires.
- 5. If a parent is present whilst the questionnaires are being administered, please note this on the questionnaire along with whether the parent was having an obvious influence on the child's responses or whether the child altered any of their replies in response to a parent's reaction.
- 6. All questions and responses need to be kept as confidential as possible, therefore if another child is distracting the child you are talking to, ask them to go back to the colouring station.
- 7. In the event that a child discloses sensitive information, or if you are concerned about the child or others around them, the researcher has a duty of care to take steps to protect the child/other. Explain to the child that you are concerned and that you will have to talk to someone about it. Inform a member of University Staff and complete the Child Protection Disclosure Form.
- 8. If for any reason you are unable to complete one or more of the questionnaires for a child i.e. problem with the child, time constraints etc., please submit a blank answer form with the child's id sticker on and an explanation as to why that questionnaire was not completed.

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# **Appendix 8** Blood pressure measurement standardised operating procedure

- 1. Show them the device and tell them that the cuff will be placed around their upper arm. When you press a button it will inflate and they should expect a squeeze around their arm (assure them that it isn't painful, suggested wording 'it won't hurt but it will feel tight around your arm, the most important thing is to keep your arm really still and floppy). The cuff will then deflate slowly.
- 2. Explain to the child that you are going to take their blood pressure and to do this you need them to sit as still and quietly as possible for a few minutes. Ask them to roll their sleeve up to their shoulder (tight or restrictive clothing should be removed).
- 3. Child should be seated with their arm on the table, palm facing up. Remind the child to keep their arm floppy and not to fidget or talk.
- 4. Record room temperature, state of child (relaxed / nervous; still / restless; silent / not silent), tick whether or not they have exercised or had any food or drink in the previous 30 minutes and enter what cuff size was used.
- 5. All measures are done on the right arm. Place the cuff on the upper arm with the indicator mark over the brachial artery.





(manual mode).

6. The bladder (the part of the cuff that inflates) cuff is positioned between the elbow and the shoulder with the cuff tubing pointing towards the fingers. Ensure the indicator arrow on the cuff falls within the range. Four cuff sizes are available: child; small adult; adult; large adult.

7. The display should show SP. If SP is not displayed press the 'Cycle' button to change it to SP

- 8. After the child has been sitting in a relaxed stated for at least 3 minutes, take the first reading.
- 9. Record the reading (systolic, diastolic and pulse) in the space provided on the measurement recording sheet.



- 10. If error messages occur, check list overleaf and adjust if necessary before continuing.
- 11. Leave a minimum of 3 minutes before taking the second reading. Repeat steps 3 to 10.
- 12. Check that the 2 readings fall within the normal range (see table overleaf). If any readings are outside this range, or missing due to error take another reading and record on the sheet.
- 13. If errors persist or BP is outside the normal range, only continue for a maximum of 3 readings per child and record all error messages/BP readings.

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14. If you are unable to take any of the readings, record the reason why for each reading in the comments section on the back of the recording sheet.

## ENSURE THAT YOU USE THE ANTIBACTERIAL HAND GEL PROVIDED IN BETWEEN EACH CHILD MEASURED

## Other:

Press Stop to pause measurements

Press Review to look at past readings

To stop inflation or cause rapid deflation pull cuff tubing out of machine

Press Clear to wipe the memory of readings

## Normal BP ranges for different age children

Age	Systolic	Diastolic
7	92-125	55-86
8	94-127	55-88
9	95-130	57-90

Error Codes:

- -- User cancelled
- E0 weak pulse
- **E1** Motion artefact
- E3 6 Inflation/deflation errors Action: check for kinks or leaks
- **E20 21** Indeterminate BP reduce motion.
- **E23 26** Out of range error recording sheet.

Action: none. Action: tighten cuff/check for leaks Action: reduce motion of child Action: check for kinks or leaks

- Action: tighten cuff/check for leaks,
  - Action: mark this on the measurement

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## **Appendix 9** Baseline school questionnaire



## UNIVERSITY<sup>OF</sup> BIRMINGHAM

## SCHOOLS QUESTIONNAIRE

- This questionnaire is designed to explore the facilities, initiatives and general environment relating to food, physical activity and health in the schools participating in the WAVES study. It is really important that this questionnaire is completed by all schools who have agreed to take part in the study, and we would greatly appreciate it if you could take the time to complete this questionnaire for us.
- Most questions require ticking a box  $\checkmark$ , but some ask for further comments or information. We would be grateful if you could answer *all* of the questions. You may need to consult with other members of staff in order to answer some of the questions.
- Your answers will remain confidential and you will not be identifiable as an individual in any reports arising from this questionnaire.
- If you have any *school policies* relating to diet, physical activity or health in general, we would be most grateful if you could attach a copy of the relevant policies to your completed questionnaire. For each policy you attach, it would be helpful if you could indicate when it was originally written and, if it has been reviewed and updated, when this took place.
- Please return the completed questionnaire ASAP to: XXXX
- If you have any questions please contact XXXX

## Section 1: Healthy eating in school

1. School name\_\_\_\_\_

Your name\_\_\_\_\_

Your role within the school\_\_\_\_\_

**2.** Which of the following does your school's policy relating to food cover? (please tick all that apply)

School does not have a policy relating to food
Curricular content
Extra-curricular initiatives
Participation in national initiatives (e.g. School Fruit & Vegetable scheme, Healthy Schools initiative)
Provision of food in school
Consumption of food in school
School events (e.g. fetes)
School educational visits
Rewards to children
Children's birthdays
Pastoral care and welfare (e.g. Free school lunches)
Other (please specify)

If your school has a policy relating to food, how effective do you believe the policy has been in promoting healthy eating?

Very effective Moderately effective Has had no effect

Please attach a copy of any school policies relating to food to this questionnaire, indicating on the front when it was originally written and the dates of any revisions

**3.** Please rate the following statement by ticking one of the boxes below "Healthy eating is high on our list of priorities in this school"

<b>4.</b> How is healthy eating actively promoted in your school? (please tick all that ap	ply)
Not actively promoted	S
Lunchtime/after school activities	g parents
School educational visits	
Outside visitors (e.g. school dietician)	dı
Tuck shops Breakfast clubs	
Health weeks Posters/media	

If you have ticked any of the above, please give some details on what your school offers in relation to each of the items that have been ticked

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If healthy eating is not actively promoted please indicate the main reason for this

	Strongly supported	Supported	Weakly supported	Not supported
School governors				
Senior Leadership Team				
Teachers				
Teaching support staff				
Catering & lunchtime supervision staff				
Other school staff				
School Council				
Pupils				
Parents				

## 5. In your opinion, to what extent do you think that healthy eating is supported by:

6. What break time food provision does your school offer? (please tick all that apply)

	Tuck shop
	Vending machine
	Provision of free fruit and vegetables for children age 7+
	No provision other than fruit for 4-6 year olds
	Other (please specify)
If you have ticked 'tuck available from these	shop' or 'vending machine' above, please give examples of the sorts of foods
<b>7.</b> Does your scho	ol provide water throughout the day to pupils? $\Box$ Yes $\Box$ No
<b>lf "Yes"</b> please describe	how water is provided to pupils
8. How is lunch p	rovided in schools? (please tick all that apply)
Hot school meals	
Cold food provided	in school (e.g. sandwiches)
Pupils can bring lun	ch from home (approximately what proportion do so?%)
Pupils can go home	for lunch (approximately what proportion do so?%)
Other (please speci	fy)

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<b>9.</b> For school provi provisions for dietar	ded meals do pupils have a ch y requirements?)   Yes [	oice of what they car	n eat (other than
<b>If Yes,</b> please give detail	s of this (eg. Choice of 2 main o	courses, and 2 puddir	ngs)
<b>10.</b> Do you have a c	ontract with a school meals pr	ovider? 🛛 Yes 🗌	J <sub>No</sub>
If "Yes":			
Please state the name o	f the provider:		
<b>If "No",</b> what is / are the	e reason(s)? (please tick all tha	t apply)	
	Control over what food is	provided 🗖 Practic	cal issues
	Economic constraints	D Poor p	revious experience
	Other (Please specify)		
<b>11.</b> How are school	meals provided?		
	Brought in ready prepared	Prepared/Cooked	on site
	Other (please specify)		
• <b>12.</b> Does the scho	ol have any income from s	chool food provisi	on? 🛛 Yes 🗆 No
<i>If "Yes",</i> how imp	ortant is this as a source of	f funds for the scho	ool?
	□ Very important	□ Important	

□ Limited importance

 $\Box$  Not at all important

<b>13.</b> Does the school receive sponsorship from any industry relat	ted to food or drink?	
	Yes	ΠNο
If "Yes" please describe		
<b>14.</b> Does your school have a breakfast club?	Yes	ΠNο
If "Yes":		
Is this available for all pupils?	Yes	ΠNο
If "No" please give details of the breakfast club availability		
Is there a fee to attend the breakfast club?	s 🗖 No	
If "Yes" please give details		
What proportion of children in the school attend the breakfast	club on an average da	v?
0-20% 21-40% 41-60%	U U	
□ 61-80% □ 81-100%		
<b>15.</b> Does your school have an after-school club providing childc	are for working paren	its?
		No
If "Yes", what proportion of children in the school attend this of	n an average day?	
0-20% 21-40% 41	1-60%	
61-80% 81-100%		
What food is offered at the after-school club?		
□ None		
Cold snacks (please give examples)	)	
Warm food (please give examples)		
Drinks (please give examples)		
Other (please give examples)		

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## Section 2: Physical activity in school

**16.** Which of the following does your school's policy relating to physical activity cover? (please tick all that apply)

School does not have a policy relating to physical activity
Having a designated physical activity co-ordinator
Raising the profile of physical activity
Playtime activity
Training of staff with regard to physical activity
Curricular physical activity
Out of school hours activities
School sports partnerships and community links
Physical activities for staff
Other (please specify)
If your school does not have a policy relating to physical activity, please indicate the main reason for this

If your school has a policy relating to physical activity, how effective has the policy been in increasing participation in physical activity in the school?

Very effective Moderately effective Has had no effect

Please attach a copy of any school policies relating to physical activity to this questionnaire indicating on the front when it was originally written and the dates of any revisions

**17.** Please rate the following statement by ticking one of the boxes below "*Physical activity is high on our list of priorities in this school*"

Strongly agree Agree Neutral	Disagree Strongly disagree
<b>18.</b> How is physical activity promoted in yo	our school? (Please tick all that apply)
Not actively promoted	Curricular sessions
Posters/media	Lunchtime activities
After school activities	Activities involving parents
School educational visits	School garden
Health weeks	Walk to school campaigns/initiatives
Other (please specify)	
If you have ticked any of the above, please give to each of the items that have been ticked	e some details on what your school offers in relation

If physical activity is not promoted in your school please indicate the main reason for this

**19.** In your opinion, to what extent do you think promotion of physical activity is supported by:

	Strongly supported	Supported	Weakly supported	Not supported
School governors				
Senior Leadership Team				
Teachers				
Teaching support staff				
Lunchtime supervision staff				
Other school staff				
School Council				
Pupils				
Parents				

**20.** What is the total curriculum time (in minutes) allocated to physical education for pupils in each year group per week, and how much time do pupils actually spend being physically active during this allocated time (excluding changing time, time to arrive at venue etc.)?

Year group	Allocated curricular time per week for PE (minutes)	Actual time spent being physically active during PE sessions per week (minutes)
Reception		
Year 1		
Year 2		
Year 3		
Year 4		
Year 5		
Year 6		

**21.** In practice, how difficult is it to deliver the allocated amount of curricular physical education per week?

	Very difficult	Difficul	t Mostly okay	Never a problem
Reception				
Year 1				
Year 2				
Year 3				
Year 4				
Year 5				
Year 6				

If you have answered *difficult or very difficult* for any of the year groups above, please give reasons for your answer:

22. Who teaches physical education in the school? (Please tick all that apply)

Specialist PE teacher

Teacher who is not a specialist in PE

Adult specialist from outside of the school

Other (please specify) \_

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Team sports (e.g. football, netball)	Aerobics/keep fit
Dance	Gymnastics
Racquet sports (e.g. tennis, badminton)	Swimming
Athletics (e.g. running, jumping, field games)	
Other (please specify)	

**24.** Please give the duration of break times and lunchtime in school:

Foundation:	Morning breakminutes	
	Lunchtimeminutes	
	Afternoon breakminutes	
Key Stage 1:	Morning breakminutes	
	Lunchtimeminutes	
	Afternoon breakminutes	
Key Stage 2:	Morning breakminutes	
	Lunchtimeminutes	
	Afternoon break minutes	

**25.** During which of the following does the school offer any structured physical activity sessions? (please tick all that apply)

Before school starts

Morning break

Lunchtime

Afternoon break

At the start of morning lessons

At the start of afternoon lessons

Uther (excluding timetabled PE)

During none of the above

Please give some details of the activities offered in relation to each of the boxes you have ticked above. Please indicate which year groups participate in each of the activities

If structured physical activity sessions in addition to timetabled PE are not offered in your school, please give the main reason for this

**26.** What facilities/equipment are available for physical activities during breaks and lunchtimes, and how often are they used? (please tick all that apply)

	Not	Available and used:					
	available	Always	Usually	Occasionally	Never		
Playground							
Playing field							
Hard court area (e.g. for tennis or basketball)							
Playground games							
Permanent playground equipment							
Portable play equipment							
Other							
		1					

**27.** For how many sports/physical activities does the school provide or have links to clubs?\_\_\_\_\_

How many of these clubs are provided by the school?\_\_\_\_

Please list the type of club provided by the school, the year group(s) it is on offer to, and whether it takes place at lunchtime or after school

Type of club	Year group(s) it is on offer to	Lunchtime or after school

**28.** Are there any transport services for pupils provided by the school?  $\Box$  Yes  $\Box$  No

If "Yes" what services are provided? (Please tick all that apply)



Supervised walking/walking bus

Supervised cycling

Uther (please specify)\_\_\_\_\_

If "No", has your school tried any of the above, or considered them in the past?

|--|

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Section 3: O	ther healthy l	ifestyle initiativ	ves
29. Is your scho	ol part of the National	Healthy Schools Program	me? 🖵 Yes 🖵 No
<i>lf "Yes",</i> ho	w long has your school	been part of this program	me?
VAD	rs <b>If "No"</b> , is there a i	reason why the school has	s not become part of
his programme?	,, sector		
his programme? <b>30.</b> Does the sc activities) to: (please	hool offer any healthy l	ifestyle activities (e.g. hea	lthy eating, physical
to: (please	hool offer any healthy l tick all that apply)	ifestyle activities (e.g. hea	Ithy eating, physical
to: (please f you have ticked a	hool offer any healthy l tick all that apply) Parents ny of the above, please	ifestyle activities (e.g. hea Members of give details of activities o	Ithy eating, physical the local communit ffered:
this programme? <b>30.</b> Does the sc activities) to: (please	hool offer any healthy l tick all that apply) Parents ny of the above, please	ifestyle activities (e.g. hea Members of give details of activities o	Ithy eating, physical the local communit ffered:
<b>30.</b> Does the sc activities) to: (please	hool offer any healthy l tick all that apply) Parents ny of the above, please	ifestyle activities (e.g. hea Members of give details of activities o	t might contribute to

**32.** Is the school planning to start any *new* such initiatives in the next 12 months?

	Yes No
<i>If "Yes",</i> please give details	
<b>33.</b> Is your school currently taking part in any other research studies	s related to health? □Yes □No
<i>If "Yes",</i> please give details	

**34.** In your opinion, to what extent is there room for improvement in relation to promoting *healthy eating* within each of the following areas in your school?

	None	Little	Some	Substantial
School curriculum				
Extracurricular activities				
School as medium for family education				
School as medium for community education				
School meal provision				

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	None	Little	Some	Substantial
School curriculum				
Extracurricular activities				
School as medium for family education				
School as medium for community education				
School sports/physical activity facilities				

**36.** Does the school support staff development with regard to encouraging healthy lifestyles for

children? Yes No

If "Yes", please give details of the available opportunities for staff development:

## Thank you very much for taking part in the WAVES study and for taking the time to complete this questionnaire

## Appendix 10 Generic signposting sheet

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Included images are used under license from shutterstock.com: Young boys playing football and Brother and sister outdoors on bicycles/Monkey Business Images

Boy on monkey bars/Karin Jaehne Little girls rake autumn leaves in garden/Ints Tomsons Girl jumping on trampoline with cloudy sky in the background/Martinan

# **Appendix 11** Anonymised school-specific signposting sheet

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## \* ☆ ☆ \*

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### Shot-Put

Make a ball out of aluminium foil or use a tennis ball. Hold the ball in the palm of one hand. Place that hand next to your ear. Push the ball into the air extending your arms. Do not move your feet. The longest distance wins.

#### Hammer Throw

Stuff a bag with newspaper and tie it up with a long string. Hold the end of the string and spin around 🛧 3 times. Let go. The longest distance wins.

#### 100 Inch Dash

Mark a start and finish line. Move your feet as fast as you can - but only one inch at a time. The winner is the person who crosses the finish line first.

\*\*\*\*\*

Source: www.atozkidsstuff.com/olygamerules.html

## <u>Remember:</u>

Children should have a minimum of 60 minutes of activity

### every day!

WAVES (West Midlands ActiVe lifestyle and healthy Eating in School children) study, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT. Tel: 0121 414 3921. Email: wavesstudy@contacts.bham.ac.uk

Dear Parents / Guardians,

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Your child's school has been selected to take part in the West Midlands ActiVe lifestyle and healthy Eating in School children study (WAVES study). During the coming year, your child will take part in a programme of activities designed to encourage children to make healthy lifestyle choices.





Children should aim to have a minimum of 60 minutes of activity per day. This can be in one block or lots of short bursts of activity throughout the day.

This information is about physical activity opportunities in your area and other ideas for activities.

Many thanks,

The WAVES Study Research Team University of Birmingham

UNIVERSITY<sup>OF</sup> BIRMINGHAM




Buffery Park, Selborne Rd, DV2 8LA (1 η//e). Multi-use games area, children's play area, tennis courts, football pitches.

Haden Hill Park, Halesowen Rd, Cradley Heath, B64 7JU (2.1 miles). Children's playgrounds, walks, nature reserve.

Grange Park, Walters Row, Dudley, DY1 2BH (2.2 miles). Multi-use games area, football pitches. Haden Hill Leisure Centre, Barrs Rd, Cradley Heath B64 7HA (2.2 m/les), Tel. 0845 659 4815—select Option O. Swimming pools, swimming lessons, 'Fun, Float and Flume' sessions.

Tipton Swimming Centre, Queens Rd., Tipton. DY4 8ND (3.9 miles), Tel. 0845 6594815—select Option 9. Swimming lessons for children. playground, indoor play barn, free play sessions for children.

Tipton Sports Academy, Fit 4 Kidz (A high energy 90minute session of organised games and play), Gospel Oak Rd., Tipton, DY4 OBS (5.4 η<sub>l</sub>/les), Tel. 0845 6594815, Email: leisure@sandwell.gov.uk

### 🏀 Things to do near you: 💱

#### Dance groups:

Acorn Dance Studio, Blowers Green Pumphouse, Peartree Lane, Dudley DY2 0XP (1.2 miles), Tel. 07702 376169 or 01384 483 636. www.acornperformingarts.co.uk

Time Step Dance Studio, 18 Wolverhampton Street, DY1 1DB (*L> ηjiles*), Tel. 07936 718478 www.timestepdancestudio.co.uk

Step Up School of Dance, Dingle Community Centre, Madeley Road, Dudley, DY2 8NT. (1.6 miles) Tel. 07950 985 392.

### Football Clubs:

Brierley Hill Bullets Junior Football Club, 6 Burmese Way, Rowley Regis, B65 8QA (1.9 miles), 01384 212809 keithsharman@hotmail.com

Football, Wellington Road, Dudley, DY1 1UH. (1.7 miles). Tel: 01384 812800. Kids football for children aged 5 - 8 at the Dudley Leisure Centre. Prices range from £1.75 to £3.50.

Netherton Colts Football Club, Netherton, Dudley (0.2 miles). Tel. 07730 766124.

a site interstering a straight and a straight and a straight and a straight a

### Indoor Play:

Jitterbugs Party World, Cardale St, Blackheath (2.5 miles), Tel. 0121 561 3866. Soft-play and climbing wall. www.jitterbugspartyworld.co.uk

Scallywags Indoor Play Centre, Level Street, Next to Fitness First, Brierley Hill, Dy5 1UA. (1.8 miles). Tel. 01384 77004, www.scallywagsindoorplay.com

Visit: www.dayoutwiththekids.co.uk/things-to-do/dudley Contains information on fun routes to walk with the family and great days out in and around Dudley.

\*Included

Images are used under license from shutterstock.com: Brother and sister outdoors on bicycles/Monkey Business Images Boy on monkey bars/Karin Jaehne

### Appendix 12 Take 10 suitable activities chart

ACTIVITIES AND CHALLENGES FOR SMALL SPACES			
		Sufficiently	
	Activity name	active?	
1	Pass the beanbag	Yes	
2	Beside the sea	Yes	
3	Row your boat	Yes	
4	Fairytale Fun	Yes	
5	Direction	Yes	
6	Circles	Yes	
7	Noah's ark	Yes	
8	Tigger Pooh	Yes	
9	Animal Dice	Yes	
10	Cycling	Yes	
11	Circuit	Yes	
12	Fruit squash	Yes	
13	Pass the beanbag	Yes	
14	Let's go	Yes	
15	Pirates are	Yes	
16	Fairytale Fun	Yes	
17	directions	Yes	
18	Squares	Yes	
19	Skipping	Yes	
20	Cartoon fun	Yes	
21	Dancing Dice	Yes	
22	Cycling	Yes	
23	Circuit	Yes	

Take 10 – lis	st of activities indic	ating whether they ar	e sufficiently active	enough for the WAV	ES study physica	l activity target
TURC TO II.	st of activities mate	ating whether they ar	c sufficiently active	chough for the wave	Lo study physica	i accivity target

RUNNING AND CHASING GAMES			
		Sufficiently	
	Activity name	active?	
25	Bean bag chase	Yes	
26	Bean bag frenzy	Yes	
27	Circle chase	Yes	
28	Circle chase 2	Yes	
29	Follow my leader	Yes	
30	Freeze	Yes	
31	Horses and Jockeys	Yes	
32	Ladders	Yes	
33	Stuck in the Mud	Yes	
34	Tails	Yes	
35	Traffic lights	Yes	

COORDINATION AND MANIPULATION					
CHALLENGES					
		Sufficiently			
	Activity name	active?			
36	Action mimes	Yes		59	F
37	Bubble fun	No		60	
38	Double Doodle 1	No		61	D
39	Follow the leader	Yes		62	
40	Magic hands	No		63	Т
41	Number up 1	No		64	Т
42	Old Macdonald	Yes		65	\
43	Rollstop!	No		66	W
44	Rolling journey	No		67	
45	Sculpturing	No		68	Т
46	Imaginary Rope	Yes		69	
47	Figure of 8s	No		70	
48	Bean Bag Catch	No		71	
49	Circle Pass	No		72	
50	Double Doodle 2	No		73	
51	Dropcatch	No		74	D
52	<b>Emotional Actions</b>	No		75	
53	Friendly Backs	No		76	١
54	Move and Bee	Yes		77	ł
55	Number up 2	No		78	
56	Pair imaginary	Yes		79	
57	Seated rowing 1	Yes		80	
58	Simon says	No		81	Li
					_

ACTION RHYMES		
		Sufficiently
	Activity name	active?
59	Five little Monkeys	No
60	Clap your hands	No
61	Down in the Jungle	No
62	Teddy bear	No
63	The bear came over	No
64	There was a little	No
65	Wheels on the bus	No
66	Wind the bobbin up	No
67	Boa Constrictor	No
68	The grand old duke	No
69	If your happy	No
70	Oliver Twist	No
71	Row your boat	No
72	One finger one	No
73	Dingle Dangle	No
74	Do your ears hang	No
75	Going for a ride	No
76	What shall we do?	No
77	Head, shoulders	No
78	Hockey Cokey	No
79	Johnny Taps	No
80	Junk food	No
81	Little Rabbit Foo Foo	No

No



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My Bonnie

My father ... Push the damper in

Peter Rabbit

Hands on myself

Swimming Swimming

Ten in the bed

This old man

When I was one

When you go ...

$\overline{\mathbf{\infty}}$	$\infty$
$\infty$	$\infty$
	<b>.</b>

## **Appendix 13** Cooking workshop teacher training: presentation slides

A vailable on request from either Professor Peymane Adab (p.adab@bham.ac.uk) or Dr Emma Lancashire (e.r.lancashire@bham.ac.uk).

## **Appendix 14** Cooking workshop: parent invitation letters

Dear Parent/Carer,

Since the beginning of this term, our school has been enjoying several different activities as part of the University of Birmingham's WAVES study. The study is aiming to test a programme of activities designed to support children in keeping their weight at a healthy level by promoting healthy eating and physical activity. We have already started the physical activity programmes during the school day, which the children (and teachers!) are enjoying.

To encourage the children to eat healthily we will be running three cooking workshops over the year to encourage children to choose, prepare, cook and enjoy healthy meals. These interactive, fun sessions will involve games and activities, as well as teaching the children food preparation and cooking skills.

The topic of the first workshop is a healthy breakfast. To support the children's learning and to enable the whole family to benefit from this exciting session, we would like to invite a family member to attend the session which will take place on:

#### DATE AND TIME

We appreciate that this is during the school day and therefore it may be difficult for some parents/carers to attend, but we think that your child will really enjoy cooking and learning with you. They might even start to help out with meals at home! Grandparents, aunts, uncles or any other family member are very welcome to attend in your place.

Please return the reply slip below by **DATE** to indicate whether you will be attending.

Thank you.

Yours sincerely,

Child's name

Class:

I .....(NAME) will/will not be attending the cooking workshop on

#### DATE AND TIME

The following person will attend in my place: .....

Signed:.....

Dear Parent/Carer,

As part of the University of Birmingham's WAVES study which our school is taking part in, there are three cooking workshops throughout the year. Last term we looked at healthy breakfast, and this term we are looking at healthy snacks and packed lunches. The cooking workshops are interactive, fun sessions, involving games and activities, as well as teaching the children food preparation and cooking skills in a safe environment. All the ingredients and equipment will be provided at school. To support the children's learning and to enable the whole family to benefit from this exciting session, we would like to invite a family member to attend the cooking workshop on healthy packed lunches and snacks. If you cannot make it, grandparents, aunts or uncles or any other family members are very welcome to attend in your place.

The next workshop will take place on:

#### DATE AND TIME

A family member is very welcome to come along, even if it was not possible to attend the previous session on breakfast. We appreciate that this is during the school day and therefore it may be difficult for some parents/carers to attend, but we think that your child will really enjoy cooking and learning with you. They might even start to help out with meals at home! Please return the reply slip below by **DATE AND TIME** 

Thank you.

Yours sincerely,

Child's name	Class:
I(NAME) will/will not be attending	the cooking workshop on
DATE AND TIME	
The following person will attend in my place:	
Signed:	

Dear Parent/Carer,

As part of the University of Birmingham's WAVES study which our school is taking part in, there are three cooking workshops throughout the year. Last term we looked at healthy lunches and snacks, and this term we are looking at having a healthy evening meal. The cooking workshops are interactive, fun sessions, involving games and activities, as well as teaching the children food preparation and cooking skills in a safe environment. All the ingredients and equipment will be provided at school. To support the children's learning and to enable the whole family to benefit from this exciting session, we would like to invite a family member to attend the cooking workshop on having a healthy evening meal. If you cannot make it, grandparents, aunts or uncles or any other family members are very welcome to attend in your place.

The next workshop will take place on:

### DATE AND TIME

A family member is very welcome to come along, even if it was not possible to attend the previous sessions on breakfast / lunch and snacks. We appreciate that this is during the school day and therefore it may be difficult for some parents/carers to attend, but we think that your child will really enjoy cooking and learning with you. They might even start to help out with meals at home! Please return the reply slip below by **DATE AND TIME** 

Thank you.

Yours sincerely,

Child's name

Class:

I .....(NAME) will/will not be attending the cooking workshop on

### DATE AND TIME

The following person will attend in my place: .....

Signed:.....

### **Appendix 15** Breakfast cooking workshop: poster



# **Appendix 16** Lunch and snacks cooking workshop: poster

UNIVERSITY BIRMINGHA	DF M	WAVES
WAVES	5 study ínt	tervention
Со	oking work	eshop
U		B
As part of the Univer will be running 3 <b>wo</b> i prepa	sity of Birmingham's W r <b>kshop</b> sessions to teac re, cook and enjoy heal	AVES study, this year we ch children how to choose, thy meals.
To support the chil m	dren's learning, we wou ember to attend the se	Ild like to invite a family ssions.
The next works	hop will focus on <b>s</b>	nacks and lunch:
CLASS		
DATE		
TIME		

# **Appendix 17** Evening meals cooking workshop: poster



## **Appendix 18** Breakfast cooking workshop lesson 1: teacher presentation slides



- 1) Concentration at school, 2) Good marks, 3) PE, and 4) Playing with classmates
- You should eat breakfast everyday, otherwise you can't learn your lessons and you can't catch up with your friends in the playground and PE lessons.





 Cereals are healthy breakfast option, but children should learn what kind of cereals are more healthy. High fibre cereals are healthier because they help children to feel fuller for longer and blood sugar levels rise steadily.



- 1) Healthy cereal helps kids not to get constipation.
- You can explain that healthy cereal can prevent some diseases like heart disease and diabetes when they get older (If you think they can't understand, just tell them that it is good for their health and help to go to toilet easily).















Some images included in this appendix are from iStock.com:

Supermarket foods flat icons set/Macrovector Two plastic yoghurt pots/Magone

WAVES

WAVES

**Appendix 19** Breakfast cooking workshop lesson 2: teacher presentation slides



- . ..
- Can you think of breads from different countries?

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What kind of toast and breads are healthy?

- Breads that are brown or contain seeds are healthier.
- They contain fibre which:
  - Keeps us full for longer.
  - Helps us to go to the toilet.

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Split the class into 6 groups, deal out the cards in equal proportions. Each player puts down one card each, if two of the same card are put down, the first player to put their hand on the pile and shout 'BREAD!' gets to keep all the cards in the pile. The game then starts again. The player left with the most cards at the end wins.

## **Appendix 20** Breakfast cooking workshop lesson 3: teacher presentation slides



- Start with asking couple of questions like "What type of milk is the healthiest"?, "What cereals are healthy"? and "Name couple of healthy breads".
- 2) Then ask children to think of other foods they normally eat with breads/toasts.



- Spreads and toppings can be tasty-but some spreads and toppings are not very healthy.
- Explain why some spreads like chocolate spread and some toppings like sausages are not good for their health.
- You can also remind them to brush their teeth after having breakfast to stop tooth decay.



Ask the children which group they would put each of the foods into: Every day or treat.



- Ask children to think of healthy breakfast and make their own menu. They can ask for adult's help at home.
- Then they can draw their breakfast and bring it back to school to enter a competition which will be held before Christmas.

## **Appendix 21** Breakfast cooking workshop lesson 4: teacher presentation slides



- 1) Concentration at school, 2) Good marks, 3) PE, and 4) Playing with classmates
- You should eat breakfast everyday, otherwise you can't learn your lessons and you can't catch up with your friends in the playground and PE lessons.



- 1) It is good for children to know that semi-skimmed milk is better for their health. But the main aim is to drink milk for breakfast everyday.
- 2) You can ask who prefers to have his/her milk cold/hot.
- You can suggest to add honey to hot milk if some of children don't like to have plain milk.

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You can print the slide for each child or they can do the game as a group. They
can take the paper to home as "take-home message".

# **Appendix 22** Lunch and snacks cooking workshop lesson 1: teacher presentation slides







WAVES

NIHR Journals Library www.journalslibrary.nihr.ac.uk

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Quiz - Guess the fruit

## **Appendix 23** Lunch and snacks cooking workshop lesson 2: teacher presentation slides





### Other types of snacks

In lesson 1, we looked at the types of fruit and vegetables which would be good to have as snacks at school.

Sometimes, we need a slightly bigger snack to keep us going until our next meal, for example after school.

### Can you think of some healthy snacks for after school?

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Word search - Fruit and Vegetables

# **Appendix 24** Lunch and snacks cooking workshop lesson 3: teacher presentation slides







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Worksheets are provided (Design your own picnic box).

# **Appendix 25** Evening meals cooking workshop lesson 1: teacher presentation slides



•There are lots of different ingredients that can make up a healthy dinner – just as before the important points to stress are that a healthy dinner: •Contain vegetables or fruit

•Is low in salt

•Is low in sugar

Is lower in fat





Slide where the children say whether the meals are breakfast, lunch, dinner or snack and whether it is an everyday meal or a treat.





Baked crisps?









Some images included in this appendix are from iStock.com:

Chicken curry and rice/Rafal Stachura Breakfast with fried eggs and vegetables/Olha\_Afanasieva Mexican food – beef fajitas and bell peppers/Rez-art Baked beans on toast/Robyn Mackenzie Pile of potato chips/Spaxiax **Appendix 26** Evening meals cooking workshop lesson 2: teacher presentation slides







WAVES



Milk Fruit juice (1 a day) Diluted squash

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The best drink to have is water

Insert Change 4 Life image of me sized meals:

www.nhs.uk/Change4Life/supporterresources/downloads/302468\_C4L\_MeSizedMealsPosterfamilyacc.pdf

### Have 'Me Sized Meals'

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WAVES



Do 60 minutes of physical activity every day



Images included in this appendix are from iStock.com:

Granola with milk/Ansonsaw

Fruit and vegetables, Healthy fresh fruits and vegetables backgrounds/SerAlexVi Clear plastic water bottles with blue caps/Ferlistockphoto Young parents with children riding bikes in park/Monkeybusinessimages

# **Appendix 27** Evening meals cooking workshop lesson 3: teacher presentation slides



- What would you do if you felt like you wanted to sneeze while you were cooking?
- 2. What would you do if you needed to go to the toilet while you were cooking?

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 Put down any food or equipment. Move away from the cooking area to sneeze. Blow your nose and wash your hands properly with soap and warm water and then dry them.

2: Take off your apron and leave it in the kitchen. Go to the toilet. Wash your hands properly with soap and warm water and then dry them. Go back to the kitchen and put on your apron.



e.g. Boiled, grilled, roasted, mixed, poured, measured out



All children should have used the skills of peeling fruit and chopping in the breakfast and lunch workshops

Images included in this appendix are from iStock.com:

Jogging icons flat/Macrovector Modern flat fitness and wellness icons/Vectoriart

# **Appendix 28** Breakfast cooking workshop: session plan

#### Session Plan for: Cooking Skills Workshop 1: Breakfast Developed By: WAVES study research team



**APPENDIX 28** 

Session title: Cooking Skills Workshop 1: Breakfast

Specific support needs:	Resources to be used/Equipment needed:	
1-2 volunteers to help with group activities (optional)	<ul> <li>Powerpoint slides</li> <li>Activity resources</li> <li>Parent Handout Information</li> <li>Evaluation forms</li> <li>Time and travel cost form</li> <li>Teacher's log book</li> </ul>	<u>To be bought</u> Any fruit which is in season and easy to chop/peel (e.g. strawberries, bananas, Satsuma's) Semi-Skimmed milk Low-fat natural yogurt <u>Provided by University</u> Plastic disposable bowls Plastic disposable knives and spoons Chopping boards Tinned (in juice) Pears or Peach halves Raisins Cereals – Wheat Bisks, Bran Flakes, Mini Shredded Wheat

Overall aims for this session: The aim of this cooking workshop is to improve children's and their families' dietary behaviours through improved nutrition knowledge, food preparation skills and confidence in preparing healthy breakfast.

#### Objectives for the lesson:

- Raise awareness of what to look for when planning a healthy breakfast.
- Support parents to choose high fibre, low sugar, and low fat breakfasts.
- To give the children the opportunity to prepare and taste a high fibre cereal topped with fruit.

#### Assessment methods:

Evaluation forms, Time and travel cost questionnaires and Log book

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## **Session Plan for:** Cooking Skills Workshop 1: Breakfast **Developed By:** WAVES study research team

Timing	Teaching activities	Learning activities	Key Learning Points/Learning outcomes	Resources
10 mins	Introduction	Why is it important to eat breakfast every day?	n/a – assessing what the group already know.	Slides 1- 11
	Introduce Bert.	What is a healthy breakfast?		
		What does a healthy breakfast do?		
10 mins	Fibre – high fibre foods keep us full and help us to go to the toilet.	WHOLE GROUP ACTIVTY 1: Which breakfast food keeps them fuller for longer?	High fibre foods are best to have as an everyday breakfast.	Slides 12-16
	High fibre foods include wholemeal and granary breads, course brown cereals like wholewheat cereal biscuits and bran flakes fruit vegetables and beans			

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#### Session Plan for: Cooking Skills Workshop 1: Breakfast Developed By: WAVES study research team



15 mins	Sugar – high sugar foods are not great for breakfast as they do not keep us full for very long. Too much sugar is bad for our	<b>GROUP ACTIVTY 2:</b> How many teaspoons of sugar are in the breakfast food and drinks?	It is really easy to have too much sugar. High sugar foods and drinks should be a treat	Slide 17- 20 Laminated cards
	teeth and can cause us to put on too much weight.	Split the session into smaller groups and get them to match the food/drink to the number of teaspoons of sugar contained in them.	instead of every day.	
	<ul> <li>Children should have no more than 8 heaped teaspoons of sugar a day. The aim should be to have less than this.</li> </ul>			
	<ul> <li>High sugar cereals like chocolate flavour toasted rice and sugar frosted flakes of corn are better to have as a treat rather than every day.</li> </ul>			
	<ul> <li>High sugar toppings like chocolate spread are also good for treats but are not good for every day.</li> </ul>			

Timin	g Teaching activities	Learning activities	Key Learning Points/Learning outcomes	Resources
	<ul> <li>Fruit drinks do not count as fruit portion.</li> <li>Fruit juices contain a lot of natural sugar and so it is better to only have one glass a day. Whole fruit is better to have than fruit juice.</li> </ul>			

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WAVES

## **Session Plan for:** Cooking Skills Workshop 1: Breakfast **Developed By:** WAVES study research team

10 mins	<ul> <li>Fat - We all need a little bit of fat but it is important not to have too much in the diet as it can make us put on too much weight.</li> <li>□ Some fats can be reduced in the diet by making simple changes to the way food is cooked. Encourage the children to think of cooking/preparation methods (e.g. boiling or poaching eggs instead of frying, cutting excess fat off meat).</li> </ul>	GROUP ACTIVTY 3: Which foods are everyday and which ones are treat? Lay out the cards on the table picture side up. Ask the children (in groups with the help of their parents if applicable) to pick the foods they think are everyday foods and which foods are best to only have as a treat. Cards are colour coded on the back so children can flip them over to find out if they got it right.	Some foods are high in fat and so should be a treat (e.g. sausages, chocolate spread and fried eggs).	Slides 21-22
5 mins	Reinforcing the key messages		There are lots of different breakfasts that can be healthy. There is something for everyone.	Slide 23
30 mins	<ul> <li>Breakfast Skills:</li> <li>Lay out the 3 different breakfast cereals in large serving bowls and have the milk and yogurt available.</li> <li>Ask the parents to take the children to wash their hands ready for preparing the fruit.</li> </ul>	<ul> <li>Ask the children to pick a breakfast cereal that they would like to try.</li> <li>Ask them to chop/peel each of the fruit ready for eating e.g. chop the green stalks off the strawberries, chop the peach/pear halves/banana into chunks.</li> </ul>	The skills of preparation and chopping. Tasting new foods and getting new breakfast ideas. Clearing up.	Food, chopping boards, bowls, cutlery.
Timing	Teaching activities	Learning activities	Key Learning Points/Learning outcomes	Resources
	Wash the fruits and put them into separate bowls (unprepared).	<ul> <li>Each of the children can then create and try their own healthy breakfast.</li> <li>You could set up a reward system (e.g. sticker) if a child tries something new.</li> <li>Children must help to clear up as part of the activity.</li> </ul>		

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#### Session Plan for: Cooking Skills Workshop 1: Breakfast Developed By: WAVES study research team



,

ſ	10 mins	Conclusion: Thank everyone for coming;		Evaluation form
		ask each parent/guardian to complete an		
		evaluation form and time and travel cost		Parent take-home
		form. Hand out the parent take-home		information.
		information sheet.		

Don't forget to fill in the log book and return it with the

#### 'Parent evaluation forms' and 'Time and travel cost forms

# **Appendix 29** Lunch and snacks cooking workshop: session plan

#### Session Plan for: Cooking Skills Workshop 2: Lunch and Snacks Developed By: WAVES Study Research Team Date: January 2012



Session title: Cooking Skills Workshop 2: Packed lunches, Breaks and Snacks

Specific support needs:	Resources to be used/Equipment needed:	
Volunteers to help with group activities (optional)	<ul> <li>≈ PowerPoint slides</li> <li>≈ Activity cards ('make a healthy packed lunch')</li> <li>≈ Parent 'Take home' information</li> <li>≈ Pens</li> <li>≈ Parent evaluation forms</li> <li>≈ Time and travel cost questionnaire</li> <li>≈ Logbook</li> </ul>	To be bought Wholemeal wraps (plain wraps if wholemeal no available) Grated cheese (low fat variety if possible) Salad (Lettuce, Cucumber, carrot batons) Low fat soft cheese Provided by University Tinned tuna Tinned tuna Tinned sweetcorn Kitchen towels and other utensils

**Overall aims for this session:** The aim of this training session is to improve children's and families' dietary behaviours through nutrition knowledge, food preparation skills and confidence in preparing healthy meals.

#### Objectives for the lesson:

- · Raise awareness healthy snacks and packed lunches for school or a day out.
- · Support parents to choose snacks and lunchtime foods which are high in fibre, low sugar, low fat.
- · To allow the children to prepare and taste a 'healthy wrap' with their choice of fillings.

#### Assessment methods:

Parent/Guardian evaluation forms, time and travel costs questionnaire and teacher Log book

## **Session Plan for:** Cooking Skills Workshop 2: Lunch and Snacks **Developed By:** WAVES Study Research Team **Date:** January 2012



5 mins       Introduction and session aims       n/a         15 mins       Snacks – what is the optimum number of snacks per day? 3 meals + 2 snacks (This is only a rough guide and will vary depending on the activity levels of the children each day).       WHOLE C Naming hereits and will vary depending on the activity levels of the children each day).         The children are re-introduced to Bert in his quest for healthy eating.       A mid-morning snack is the ideal time to introduce a portion of fruit or	The group know the expected outcome of the session       Slides 1- 2         OUP ACTIVITY 1:       • Fruit and vegetables contain lots of the vitamins and minerals we need – mid-morning break is an ideal time to introduce a portion of fruit or vegetables.       Slide 3 -11         • There are other foods which can be good to have as snacks but they should be low in sugar and for an or spirit or vegetable vitaming and       • There are other minerals
15 mins       Snacks – what is the optimum number of snacks per day? 3 meals + 2 snacks (This is only a rough guide and will vary depending on the activity levels of the children each day).       WHOLE C         The children are re-introduced to Bert in his quest for healthy eating.       A mid-morning snack is the ideal time to introduce a portion of fruit or       WHOLE C	<ul> <li>OUP ACTIVITY 1: Fruit and vegetables contain lots of the vitamins and minerals we need – mid-morning break is an ideal time to introduce a portion of fruit or vegetables.</li> <li>There are other foods which can be good to have as snacks but they should be low in sugar and for any other provide vitaming and provide vitaming vitaming and provide vitaming vitaming and provide vitaming vitaming vitaming and provide vitaming v</li></ul>
vegetables as many of the children will have been used to receiving free F+V at break time through the school until Yr 1. (Some schools may still	<ul> <li>High fibre carbohydrate foods like bread and cereal keep us full ond below us go to the toilot</li> </ul>
provide this to Yr2+). Activity 1 aims to highlight and extend the children's current knowledge about what a healthy snack is.	<ul> <li>Dairy is important for children's bones and teeth – milk, yoghurt and cheese are great foods for snacks, but low-fat versions are the best</li> </ul>
20 minsBert's School trip: this section is mainly aimed at those children who have a packed lunch for school; The aim of this session is not to encourage children to switch to packed lunches but to raise the nutritional standard for those who do.SMALL GR On each Lunchbox n design Bert school trip a school trip a mainly aimed at those children to school; The children to switch to packed lunches but to raise the nutritional standard for those who do.SMALL GR On each Lunchbox n design Bert school trip a school trip a uto a packed lunches school trip a the school trip a 	UP ACTIVITY 2:       What is a healthy lunch?       Slides 12 – 22         ible place an A3       Be able to design a lunch for Bert as healthy lunch for his a small group and feed back to the teacher.       Slides 12 – 22         and cards provided en to write or draw il foods they would Bert's Lunch.       and cards provided to the teacher.       Slides 12 – 22

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## **Session Plan for:** Cooking Skills Workshop 2: Lunch and Snacks **Developed By:** WAVES Study Research Team **Date:** January 2012

Teaching activities Timing Key Learning Points/Learning Learning activities Resources outcomes could take in his school lunch. Explain that a healthy lunch (this is Ask each group to feed back to the same for school dinners) should the teacher what they gave Bert have certain things in it, such as: for Lunch. fruit: at least one portion. vegetables: one portion. o meat, fish or other sources of non-dairy protein: such as lentils, kidney beans, chickpeas, hummus and falafel) a starchy food: such as any type of bread, pasta, rice, couscous, noodles, potatoes or other type of cereals. dairy food or drinks: such as low-fat milk, cheese, yoghurt, and fromage frais. a drink: such as water, fruit juice, milk and smoothies. Remind them that if Bert has fruit juice in his lunch it should be the only one he has that day. Making a healthy lunch food -INDIVIDUAL ACTIVITY 3: Children will have the opportunity to Slides 23 - 25 20 mins Making a healthy lunchtime wrap. prepare and taste a healthy wrap. Recap the lessons learnt today. They will gain skills in spreading, Food, kitchen roll, chopping and wrapping. strong plastic The aim of this activity is to give the knives. children the opportunity to have a go It is important that the children are at making and trying their own healthy given the opportunity to try this for lunch food. themselves.

#### Session Plan for: Cooking Skills Workshop 2: Lunch and Snacks Developed By: WAVES Study Research Team Date: January 2012



Timina	Teaching activities	Learning activities	Key Learning Points/Learning	Desources
ming	reaching activities	Learning activities	outcomes	Resources
	A wholemeal wrap filled with salad and soft-cheese/cheese/tuna is a good option for a healthy lunch and will allow the children to try food that they may not have tasted previously. Ask the parents to take the children to wash their hands ready for preparing the food. Please be mindful of allergies in your classes and adjust accordingly.		Clearing up.	
10 mins	Conclusion: Thank everyone for coming; ask them to complete an evaluation form and hand out the information to take away. Return the completed questionnaires and your completed logbook to the WAVES Office.			Evaluation form Information to take away. Log book.

WAVES (West Midlands ActiVe lifestyle and healthy Eating in School children) Study, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT.

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# **Appendix 30** Evening meals cooking workshop: session plan

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### Session Plan for: Cooking Skills Workshop 3: Evening Meal Developed By: WAVES Study Research Team Date: April 2012

Session title: Cooking Skills Workshop 3: Evening Meal

Specific support needs:	Resources to be used/Equipment needed:	
Volunteers to help with group activities (optional)	<ul> <li>≈ PowerPoint slides</li> <li>≈ Food group bingo cards</li> <li>≈ Parent 'Take home' information</li> <li>≈ Pens</li> <li>≈ Parent evaluation forms</li> <li>≈ Time and travel cost questionnaires</li> <li>≈ Logbook</li> </ul>	To be bought Spring onions Cherry tomatoes Peppers And any other easy to chop vegetables of your choice. Provided by University Low-Salt stock cubes Couscous Tinned beans Tinned sweetcorn

**Overall aims for this session:** The aim of this training session is to improve children's and families' dietary behaviours through nutrition knowledge, food preparation skills and confidence in preparing healthy meals.

#### Objectives for the lesson:

- · Raise awareness of healthy portion sizes and reinforce the concept of balance and variety.
- · Support parents to choose meals which are high in fibre, low sugar, low fat.
- · To allow the children to prepare and taste a couscous salad.

#### Assessment methods:

Parent/Carer evaluation forms, time and travel cost questionnaires and teacher Log book

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### Session Plan for: Cooking Skills Workshop 3: Evening Meal Developed By: WAVES Study Research Team Date: April 2012



Timing	Teaching activities	Learning activities	Key Learning Points/Learning outcomes	Resources
5 mins	Introduction and session aims	n/a	The group know the expected outcomes of the session	Slides 1- 2
20 mins	Eating patterns: Discuss how many meals and snacks children should aim to have in a day. This is a rough guide – it may vary depending on how active the child is.	Discussion	<ul> <li>Reinforce the idea that you should try to limit snacking. Three healthy meals and two healthy snacks are best every day.</li> </ul>	Slides 3-6
	<ul> <li>Portion Sizes: Discuss 'Me Sized Meals'. The concept behind this is that children need smaller portions than adults. A 5-year-old needs less than a 10-year-old, and a 10-year-old needs less than a grown-up. Serving more food will not make them grow any faster, but will lead to extra fat storing up in their bodies. (Reference: Change4Life, 2012).</li> <li>Healthy Eating Habits: Discuss some of the good things we should do before sitting down to dinner.</li> <li>Washing hands – hygiene</li> <li>Turning off the TV during meals – reduces distractions and encourages children to concentrate their hunger cues.</li> <li>Sitting at the table together – eating is an ideal time in the day to interact socially, helping children to develop social skills as well as learning table manners.</li> </ul>		<ul> <li>Children have smaller tummies than adults and so need less food on their plates. Feeding more food does not help you to grow faster, but leads to extra fat being stored.</li> <li>There are some things that we should do when we eat: <ul> <li>Wash our hands</li> <li>Turn off the TV</li> <li>Sit at the table</li> </ul> </li> </ul>	

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## Session Plan for: Cooking Skills Workshop 3: Evening Meal Developed By: WAVES Study Research Team Date: April 2012

Timing	Teaching activities	Learning activities	Key Learning Boints/Learning	Pesources
mmng	reaching activities	Learning activities	outcomes	Resources
10 mins	Recap food groups. What food groups do we usually eat at dinner time?	WHOLE GROUP ACTIVITY 1: Food group bingo. Note: Card 1 is the winning card so if you do not use all of the cards, please ensure one group has card 1.	Be able to remember what the five food groups are and be able to name some foods from them.	Slide 7-18 Food group binge cards.
5 mins	Re-introduce Bert. Recap 5 a day using Bert.	n/a	We should all be trying to eat 5 portions of fruit and vegetables each day. A portion is roughly what will fit into the palm of your hand.	Slides 19-22
5 mins	Bert wants to try a healthy evening meal: Discuss what people call their evening meal across the country e.g. dinner, tea, supper. Discuss what is meant by a healthy dinner. E.g. low in fat, low in sugar and high in fibre. Can anyone think of an example of a healthy dinner?	Discussion	The evening meal is often called by different names. Children should know that a healthy dinner contains vegetables/fruit, protein and carbohydrates.	Slides 23-26
5 mins	Let's help Bert prepare a healthy dinner: What do we need to do first? - This a re-cap of one of the pre-workshop lessons. Children should be able to remember that we should: • Clean our work area • Tie long hair back • Wash our hands • Remove jewellery	n/a	Children should be able to remember that before we cook we should: • Clean our work area • Tie long hair back • Wash our hands • Remove jewellery You may get a few extra ones e.g. put on our apron	Slides 27-28

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#### Session Plan for: Cooking Skills Workshop 3: Evening Meal Developed By: WAVES Study Research Team Date: April 2012



#### WAVES (West Midlands ActiVe lifestyle and healthy Eating in Schoo children) Study, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT. Fax

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# **Appendix 31** Breakfast cooking workshop: teacher presentation slides



1) The aim of children's lesson is the same as cooking workshop for children and parents, but lessons for children were simplified for kids. We convey the same message of increasing fruit and fibre and decreasing sugar and fat through drinks, cereals, toast and bread, and spreads and toppings lessons. Please make sure that parents are aware of the key messages.



 It is an ice breaking question which helps parents and children to think about what they usually have for breakfast.



1) You may ask participants to think why we need to have breakfast everyday.



1) Bert was created to help kids follow the presentation and messages.







1) You may reinforce the message that everybody should eat breakfast everyday and remind the importance of having healthy breakfast.



1) If Bert can eat a variety of food from the four food groups, then he...



1) You may ask children if they remember the lesson on cereals and toast.



What does this slide say:

To feel fuller for longer and to prevent later snacking, Bert should try some starchy foods like a high fibre cereal or wholemeal toast, and a portion of fruit with his breakfast.

Important note:

Please make sure they know eating whole fruit is much better for children's health and is highly recommended.

Fruit Juice contains less fibre and so children should try to eat whole fruits instead. Fruit juice should be limited to one glass per day. Fruit juice drinks, contain very little fruit and therefore not counted as fruit portion.







What does this slide say:

Whole grain cereals are better for us because they are high in fibre. These are good for **EVERY DAY**.

Foods like white bread and sugary cereals won't keep us full for very long and so are better as a **TREAT**.

What is dietary fibre?

Dietary fibre refers to plant cell wall components that are not digestible by human digestive system. Fruits and dried fruits, vegetables and whole grain food such as brown breads and wholegrain cereals are good sources of fibre.



1) Children can have up to 8 heaped teaspoon sugar everyday. But they should aim to have less than 8 heaped spoon of sugar per day. There is some information about sugar content of different drinks and snacks in parent's take-home information sheets.



1) You may use small blocks to record sugar spoon.







# **Appendix 32** Lunch and snacks cooking workshop: teacher presentation slides



- The aim of children's lessons was to prepare the children for the cooking workshop. Since parents/guardians are in charge of making packed lunches, children were just taught on breaks/snacks. But they will try to plan healthy packed lunch with parents' help in the cooking workshop.
- 2) The messages conveyed throughout the lessons and cooking workshop are consistent. These are to increase fruit and fibre intake and to decrease sugar, salt and fat intake. Please make sure that parents are aware of the key messages.



Snacks can be at anytime in the day, however children tend to need a snack at break time to help keep their blood sugar levels constant – this helps delay hunger until lunchtime and boosts concentration.

In general, children also tend to become hungry after school. Some parents choose to serve dinner early to combat this and so a healthy snack later on may help to curb hunger later into the evening. However, if dinner is not served until later in the evening, after school is an ideal time to have a snack.



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- Please reinforce the message of variation and balance. We don't ban consuming any food/drink, but we suggest some food/drink as everyday and some as treat.
- You may tell children that Bert doesn't know what a healthy snack is and they can help Bert to have healthy breaks. They were already taught about the healthy options.
- A healthy snack is low in sugar, fat, and salt and provides some vitamins and minerals. Fresh and dried fruit, vegetables, natural low-fat yogurt, and nuts are examples of healthy snacks.
- 4) Children can have cakes, chocolates, crisps, candies, and juice as treat. But parents should think of the portion sizes as well. If they want to treat their children with chocolate, it's better to give a small piece of chocolate (such as Celebration selections).



- 1) Use this slide to introduce healthy snacks.
- Healthy break is low in fat, sugar, and salt and provides some vitamins and minerals.
- 3) On a day out, children may need to have a big snack which provides them with enough energy to do activities. Small home made sandwiches are a good option. You may ask participants to name healthy sandwich fillings. Mention that you'll talk about healthy sandwiches later (packed lunch).





A healthy snack is high in vitamins and/or minerals, Keeps you fuller for longer, Lower in sugar and Lower in fat

Examples include: fruit, vegetables, low-fat dairy – e.g. yoghurt, starchy foods – toast, sandwiches with a low fat, low sugar filling, breadsticks, cracker.







Why do we need to eat fruit and vegetables: fruit (at least one portion; vegetables (one portion)



What do protein foods do?

Some protein like meat, fish or beans (eg lentils, kidney beans, chickpeas, hummus, peanut butter and falafel).



What do starchy foods do?

A starchy food such as any type of bread, pasta, rice, couscous, noodles, potatoes or other type of cereals.



What do dairy foods do? Why do we need them. Low fat milk, cheese yoghurt, fromage frais or custard are examples of dairy food or drinks.



Why do we need a drink at lunch?

Ask if the children remember what the rule is about fruit juice... Only one glass/carton per day.

A drink: such as water, fruit juice, milk and smoothies.



A3 Lunchbox – Group put together pictures of the things Bert could have for lunch. As a group, decide which foods are everyday or treat



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- 1) Split the class into groups.
- 2) Please consider any allergies in your school and adjust accordingly.
- 3) Making a healthy wrap:
  - 1) Ingredients: Wrap (provide brown wrap if possible), cucumber/lettuce/tomatoes, Cheese
  - 2) Make sure that children learn how to make the wrap see next slide.



Some images included in this appendix are from iStock.com:

Little Caucasian girl/Energy Family time/LittleBee80 **Appendix 33** Evening meals cooking workshop: teacher presentation slides



 The aim of children's lessons was to prepare the children for the cooking workshop. Since parents/guardians are in charge of making dinner, children were taught about foods and drinks for dinner, healthy habits, and health and safety.



Snacks can be at anytime in the day, however children tend to need a snack at break time to help keep their blood sugar levels constant – this helps delay hunger until lunchtime/dinner time and boosts concentration.

In general, children also tend to become hungry after school. Some parents choose to serve dinner early to combat this and so a healthy snack later on may help to curb hunger later into the evening. However, if dinner is not served until later in the evening, after school is an ideal time to have a snack.



Kids really only need portions that match their age. A 5-year-old needs less than a 10-year-old, and a 10-year-old needs less than a grown-up.

Serving more food will not make them grow any faster, but will lead to extra fat storing up in their bodies.





Card 1 is the winning card therefore if you do not use all the cards for your class, please ensure one group has Card 1.














This is Bert. He is 6 years old.

Question:	
	How many portions of fruit and vegetables should Bert be trying to eat every day?
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Bert should be aiming for 5 child-sized portions of fruit and vegetables everyday

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Insert 5-a-day logo:

day logo.jpg

http://www.eatbalanced.com/wp-

content/uploads/2014/01/5-a-

## Do you get 5-a-day? Try having fruit or vegetables as your snack. Always try to have at least one portion of fruit or vegetables with your breakfast, lunch and dinner.







Make sure the cooking area is tidy and clean Tie back long hair Remove any jewellery Wash hands with soap and water





pepper, chopped
 spring onions, sliced
 large tomato, chopped
 Plus another other vegetables of your choice.

Tip the couscous into a heatproof bowl. Pour over the hot stock, cover with a plate to keep the heat in, and soak for 5 minutes.

Mix in with the chopped tomato, spring onions, and pepper. Season to your taste you probably won't need to add any salt, just some pepper. Divide between two plates and serve.

Some images included in this appendix are from iStock.com:

Chicken curry and rice/Rafal Stachura Breakfast with fried eggs and vegetables/Olha\_Afanasieva Mexican food – beef fajitas and bell peppers/Rez-art Baked beans on toast/Robyn Mackenzie Healthy fresh fruits and vegetables backgrounds/SerAlexVi Vegetable collage/VadimZakirov Ingredients pasta tomatoes basil/OlgaMitsova

## **Appendix 34** Breakfast cooking workshop: parent information sheet





#### The West Midlands ActiVe lifestyle and healthy Eating in School children study

HEALTHY BREAKFAST PARENT INFORMATION

#### What is a healthy breakfast?

Children should eat breakfast everyday to remain healthy and energetic. A healthy balanced breakfast helps children to concentrate at school, to keep up with school work, be physically active and play with their friends. A healthy breakfast includes plenty of fruit, fibre and limited amount of sugar and fat.

This handbook provides information about what is meant by a healthy breakfast and includes helpful advice on how to

start the day in a healthy way.



#### What are benefits of consuming plenty of fibre?

WHAT IS DIETARY FIBRE? Fibre is essential for maintaining a healthy digestive system and is obtained from foods of plant origin. Fruit, dried fruits, vegetables, wholegrain products such as wholemeal breads and wholegrain cereals are good sources of fibre.

Fibre helps children and adults to feel fuller for longer as it slows food passing through the digestive system and slows the release of energy. This in turn can help to prevent too much weight gain as you are less likely to need to snack later.

Many high fibre foods are beneficial in other ways. For example, fruits are rich in vitamins and minerals which are essential for healthy development. They also contain antioxidants which help to clear our bodies of harmful toxins.

#### How much fruit a day should children have?

Breakfast is a great time to introduce fruit to the diet. Children should aim to have 5 portions of fruit and vegetables a day. Two or three of these could be fruit. Examples of one adult's



#### What kind of fruit juice counts as fruit portion?

Fruit juice is a drink which is produced by squeezing the juice from a fruit. When fruits are blended or squeezed to form juice, the fibrous structure of the fruits is broken down and all the natural sugars that our body would usually have to work to get to are released. This means that fruit juices are a risk to dental health and due to their low fibre content do not fill children up. For this reason, it is suggested that children and adults should only have one glass of fruit juice per day. It is better to eat the whole fruit to receive the maximum amount of fibre and nutritional benefits.

Fruit juice flavoured drinks (not pure fruit juice), mainly contain sugar, flavour, and water and <u>do not</u> count as a fruit portion. Examples of fruit juice drinks that do not count as a fruit portion include Fruit Shoot and Ribena.

#### Sugar:

Too much sugar can lead to weight gain and tooth decay. Foods that are high in sugar, such as sweets, jams and some cereals, are high in calories, but often offer nothing else to the child's diet and are therefore low in nutritional value.

#### Maximum amount of sugar

The maximum amount of sugar that children should have is 8 heaped teaspoon of sugar per day. A heaped teaspoon is approximately 6g. However, remember that many foods contain added sugars that we don't know about, therefore it is important to read the label. As a general rule, a food is considered high in sugar if it has more than 15g per 100g and low is less than 5g per 100g.

#### How to decrease sugar intake at breakfast?

You can:

- Offer low sugar cereals.
- Pay attention to the sugar content of cereal bars and spreads, try to provide low-sugar versions wherever possible.
- If your child drinks fruit juice at breakfast, try replacing it with whole fruits, and offer water or milk rather than juices.

#### Fat:

Fat provides energy, gives flavour and texture to foods, helps with absorption of some vitamins, and provides support for some organs. Although we need some fat in the diet,

consuming too much fat is bad for our health. High amounts of fat in the diet can increase the risk of obesity as well as the risk of getting several diseases later in life including diabetes, heart disease, arthritis, osteoporosis, and gum disease.

#### What is good and bad fat?

Unsaturated fat is sometimes called good fat. These fats contain Omega 3 and 6, which are essential for a variety of processes in the body including maintaining a healthy blood pressure and supporting the immune system. Unsaturated fats are found in fish, nuts and seeds, and some vegetable oils such as sunflower oil and flaxseed oil.

This is one of the reasons why oily fish, such as mackerel, salmon and sardines are an essential part of a healthy diet.

Saturated fat is sometimes called bad fat and is known to increase the risk of heart disease. Saturated fats mainly come from animal sources and are found in foods such as butter, ghee, and lard, fatty meats and processed meat products like sausages. Certain vegetable products such as coconut oil, cottonseed oil, palm oil, and kernel oil also contain high levels of saturated fat.

Like added sugars, hidden fat is found in many products such as confectionaries, ready-toeat meals, and snacks. Check labels to find out fat content of foods. As a general rule, a food is considered high in fat if it has more than 20g per 100g and low in fat if it has less than 3g of fat per 100g.

#### How to decrease fat intake at breakfast?

You can:

- Replace full-fat milk with semi-skimmed milk.
- Provide low-fat dairy products like low-fat **natural** yoghurt and low-fat cheese.
- Avoid consuming croissants and pastries.
- Decrease use of butter, margarine, and chocolate spread.
- Limit sausages and fatty meat products to special occasions.

#### Ideas to make breakfast healthier:

Encourage children to try wholegrain, low sugar cereals at breakfast like porridge or Weetabix. However, if this proves difficult, start by trying to reduce the sugar content of their current cereal. You could try mixing two cereals, one high sugar and one low sugar to reduce the sugar content, for example – Coco Pops and Rice Krispies.

Serve cereals with semi-skimmed, 1% or skimmed milk to lower the fat content of the meal. There is no need for children who are growing normally to have whole milk after 2 years old.

If your child has toast or bread in the morning, try to encourage wholemeal or granary bread or bread products. There are breads on the market now, which offer a stepping stone between white bread and brown bread, for example "Best of Both", these can help to increase the fibre content of breakfast without making a huge change. Try to use only a small amount of reduced-fat spread (e.g. margarine) or jam.

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Fresh, frozen, tinned and dried fruit all count towards your child's 5 a day. Try adding or fresh fruit like banana or berries or dried fruit like raisins on top of cereal breakfast. You could try chopping your child's favourite fruit to a low-fat natural yogurt to make healthy breakfast option.

For more ideas on how to make breakfasts healthier, visit www.nhs.uk/Change4Life/Pages/breakfast-for-life

#### **Breakfast ideas:**

You can introduce a variety of breakfast dishes to keep children excited about their breakfast options. You can also ask children to think of healthy options and help you to make breakfast at the weekend:

English Muffin with Tomato and Cheese:

- 1 English Muffin (preferably wholemeal)
- 1 teaspoon tomato puree
- A sprinkle of grated cheese.
- 1. Cut the muffin in half and pop into the toaster.
- 2. Once toasted, spread with the tomato puree and sprinkle with the cheese.
- 3. Place until the grill until the cheese melts.
- 4. Serve.

<u>Omelette</u>: This recipe is for a basic omelette however, you can add whatever ingredients that you want to an omelette, e.g. mushrooms, tomatoes, peppers, tuna, torn ham etc. Experiment!

- 2 eggs
- 1 teaspoon olive oil
- A pinch of pepper (optional)

1. Add olive oil to the pan and heat. Spread the olive oil around the pan, ensuring it is well covered. Turn the heat down to a medium heat.

2. Break the eggs into a bowl and mix together using a fork. Add a pinch of black pepper if desired.

- 3. Add the egg mixture to the frying pan and spread all over.
- 4. Move one of the sides and tilt the frying pan so that the uncooked egg fills the gap.
- 5. Repeat on the other side.
- 6. Cook for 2 minutes until the egg is cooked and fold in half.

#### The Egg and Spinach Sunflower:

- 1 egg
- 2 tablespoon of cooked and chopped spinach



- 1 tablespoon olive oil
- Celery stalk/bread stick (optional)

1. Wash and chop spinach and cook for 10 to 15 minutes. You can prepare spinach in advance so you won't run out of time in the morning.

2. Heat the olive oil in the saucepan and add spinach and wait for 3 minutes. Add salt if necessary and stir well. Then make a hole in the middle of saucepan.

3. Wash and break the egg into the hole and put the lid of saucepan. Give 2 minutes to the sunflower to be cooked.

4. Put the sunflower on a plate and you can use celery stalk or bread stick to make perfect sunflower.

5. You could offer a piece of wholemeal bread alongside this meal.

#### Cooked lentils

Lentils are good sources of carbohydrate which helps children to feel fuller for longer. Lentils can be cooked in advance and re-heated in the morning. Some people like to have potatoes with lentils. You can chop a small new potato and add to lentils to cook for 15 minutes.

- ½ cup cooked brown lentils
- 1 tablespoon olive oil
- 1 tablespoon of lime or lemon juice
- 1 small new potato (optional)

1. Cook the lentils in water for an hour. It may take longer depends on the type of lentils you use. Keep refrigerated and use in couple of days.

- 2. Re-heat cooked lentils in the morning for 2 minutes.
- 3. Pour olive oil and lemon juice to a bowl and add and mix lentils.
- 4. You could offer some wholemeal toast alongside this meal.

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Two plastic yoghurt pots/Magone

# **Appendix 35** Lunch and snacks cooking workshop: parent information

#### UNIVERSITY<sup>OF</sup> BIRMINGHAM



### The West Midlands ActiVe lifestyle and healthy Eating in School children study

#### HEALTHY SNACKS AND PACKED LUNCHES PARENT INFORMATION

Welcome to the second edition of the WAVES cooking workshop information. This information focuses on healthy snacks and packed lunches.

#### What is a healthy snack?

Children often get hungry between meals, and a healthy snack can be a good way of keeping their energy levels up. A healthy snack should be low in sugar, salt and fat, high in fibre and provide your child with some vitamins and minerals. Healthy snacks will also help children to feel fuller for longer and keep hunger at bay until meal time. Fruit and vegetables make ideal snacks, however low-fat dairy and starchy foods are also great options. It can sometimes be difficult to find healthy snacks for children, but we hope this information will help you to select some good options.

- Easy-to-eat fruit or vegetables can be good snacks, such as bananas, apples, grapes, easy peel
  oranges, or carrot and cucumber sticks. Preparing snacks at home to take out in small plastic tubs or
  wrapped in cling film can be a cost effective option.
- Dried fruits can also be a good alternative.
- If children are in need of a larger snack, there are lots of other options, such as healthy sandwiches, a bowl of low sugar cereal, fruit bread or malt loaf.
- Water is the best drink for children to have in between meals, and it is important for children to stay hydrated throughout the day.
- Commercially available fruit flavoured drinks (such as Ribena, Fruit Shoot and Rubicon Juice Drinks) are often high in sugar and contain little fruit so it can be important to check the sugar content on the label. Lower sugar options could be diluted squash or diluted pure fruit juices.

#### **Packed lunches**

If your child takes a packed lunch to school, or for day trips, it can sometimes be challenging to put together a selection of healthy foods that you feel confident your child will want to eat. The following section may help to give you some ideas as to what a healthy packed lunch is and a variety of options to keep your child's packed lunch interesting and appealing. Planning for the week in advance can help to make preparing a lunch box each day less time consuming overall.

What is a healthy packed lunch? A healthy packed lunch will help children to feel full and give them sufficient energy for their afternoon activities. It is also a source of important nutrients for their overall health and wellbeing.



What to put in a lunch box? The National Health Service (NHS) has developed recommendations for healthy packed lunches (http://www.nhs.uk/Livewell/childhealth6-15/Pages/Lighterlunchboxes.aspx). A summary of their recommendations are outlined below. They suggest that a healthy lunchbox should contain the following:



#### A starchy food (i.e. bread, pasta or rice)

These are a good source of energy as well as fibre. Wholemeal bread is a good option for sandwiches, and for some variation you could also try alternatives such as pitta pockets or wraps. If your child is reluctant to eat wholemeal bread you could try using varieties which are a combination of both white and wholemeal flour (for example, Hovis Best of Both or Kingsmill 50/50). An alternative to bread could be pasta, rice or couscous salads which if prepared the night before could save an early morning rush. Using leftovers from dinner can also be a time and cost effective option.

#### A protein food (such as meat, fish, eggs or beans)

Protein is important for children's healthy growth and development. Adding a protein filling to a sandwich or mixed in with pasta, rice or couscous will also help children to feel fuller for longer and stay alert for their afternoon activities. Options could include chicken, ham, boiled eggs, canned tuna, lentils or beans.





#### A dairy item (such as milk, cheese or yoghurt)

Dairy food is a good source of calcium and other vitamins and minerals which aid development of children's bones and teeth. Ideal options for the lunch box include yoghurts, small portions of cheese or a carton of semi-skimmed milk.

#### A vegetable or salad item and a portion of fruit

Fruit and vegetables are a good source of fibre as well as essential nutrients for healthy growth and wellbeing. Raw vegetables such as cucumber or carrot sticks can be great for the lunchbox and easy for children to eat with their fingers. The addition of a dip, such as low-fat hummus, cream cheese or salsa can help make the vegetables more exciting. Preparing fruits in advance can also help to make them more appealing for children, such as ready chopped apples or a tub of fruit salad with some seasonal fruits. Tinned fruits put into smaller pots could be taken to school if your child's preferred fruit is not in season, but remember to buy fruits tinned in juice rather than syrup. Dried fruit is also a good option to replace chocolate bar or cakes in the lunchbox. Larger packets of dried fruit are often cheaper than individual portion boxes so it can be more cost effective to divide them up into small sandwich bags.







#### Drinks

Water is a good choice for children's lunchboxes. If your child prefers a flavoured drink, options such as diluted pure fruit juice or diluted squash drinks can be a compromise. Over time you could increase the water content of the diluted juices.

#### Cutting down on foods high in saturated fats and sugars

Some popular lunchtime foods can be high in saturated fats and/or sugars, such as crisps, chocolate bars, processed foods (e.g. sausage rolls) and sweets. These types of foods can encourage children to consume more energy than they require which can lead to weight gain. In addition, foods high in sugar are bad for the teeth, and children will feel energetic for a short time after eating them, but after a little time feel tired, hungry and unable to concentrate.

If you think it will be difficult to remove unhealthy items from your child's lunchbox completely, you could use them as treat foods perhaps once a week. You could also try using snack sized chocolate treats or healthier crisps options, such as baked varieties.





**Keeping lunchbox cool:** During the warmer months, it can be a challenge to ensure your child's lunchbox is kept cool throughout the day. Coolbox lunchboxes and using ice packs can be a good idea. Rather than buying ice packs, you could freeze your child's drink the night before which will ensure their lunch and drink are both cool by lunchtime. Alternatively, make your child's sandwiches using frozen bread, which will have defrosted over the morning and be ready to eat by lunchtime.

#### If you would like more information these websites have lots of useful information on healthy eating in general and have sections on packed lunches:

http://www.nhs.uk/Change4Life http://www.nhs.uk/LiveWell (under the healthy eating menu option on the left hand side)

#### A few packed lunch and recipe ideas



#### **Fruity Cereal bars**

#### 200g raw oats

200g mixed dried fruit/chopped apricots/prunes/raisins 100g no added sugar muesli (or crushed bran flakes, cornflakes or rice krispies) 2 egg whites 4 tablespoons of clear honey 200mls of Pure Apple Juice

- Preheat the oven to gas mark 4 (180°C)
- 2. Mix the oats, muesli and dried fruit together in a bowl
- Warm up the honey over a low heat until it is runny, then add it to the bowl along with the egg whites and apple juice and mix well
- 4. Press the mixture into a greased baking tin
- 5. Bake for 20-25 minutes until golden brown

#### Koukou (Iranian Omelette):

This recipe is an example. You can use a variety of vegetables such as green beans, aubergine, courgette, and onion to make your own omelette. Lentils are also good options. Depending on the vegetables you use, you should steam, grill, or cook vegetables in boiling water in advance.

1 medium potato, peeled and boiled or your own choice of cooked vegetables 2 eggs

2 teaspoon olive oil

A pinch of pepper/spice (optional)

- 1. Break the eggs into a bowl and whisk together using a fork
- 2. Add vegetables and potato to the egg mixture and combine
- Add 2 teaspoons of olive oil to a frying pan and heat. Spread the olive oil around the pan, ensuring it is well covered. Turn the heat down to a medium heat
- 4. Add the mixture to the pan and spread all over
- 5. Cook on one side for 15 minutes
- 6. Cut the mixture to small pieces and flip over them over to cook the other side
- 7. Cook for 15 minutes or until the mixture is well cooked



#### Pasta in vegetable and tomato sauce

Tomato sauce:

- 1 raw onion finely chopped
  - 1 can of chopped tomatoes
  - 2 teaspoons of tomato puree
  - 4 tablespoons of frozen peas (or any other vegetables, e.g. peppers, sweetcorn etc)

Dried or fresh herbs (optional)



**Note:** This sauce recipe will make enough sauce for 4 child sized portions of pasta. Try freezing the remainder for use another time. As a useful general rule, a pasta serving is 1 handful of dried pasta per child, and two handfuls per adult

- 1. Add a tablespoon of water and the onion to a saucepan and cook over a heat
- 2. Cook the onion, stirring regularly, until soft
- Add the tinned tomatoes and tomato puree to the pan, stir together, leaving to simmer over a low heat for 10 minutes
- 4. Add the frozen peas straight into the pan and continue to simmer for a further 5 minutes
- 5. Finish off the sauce with a sprinkling of herbs
- In another saucepan cover the pasta with the boiling water for up to 15 minutes (or follow the cooking instructions on the packet)
- 7. Drain the water from the pasta, mix into the sauce, and allow to cool

#### WAVES Study, Public Health Building,

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## **Appendix 36** Evening meals cooking workshop: parent information

#### UNIVERSITY<sup>OF</sup> BIRMINGHAM



#### The West Midlands ActiVe lifestyle and healthy Eating in School

children study EVENING MEAL PARENT INFORMATION

#### What is a healthy dinner?

- A good balance of important nutrients
- A good source of vitamins and minerals
- Served in the early evening

As with a healthy breakfast and lunch, a healthy dinner is a good source of nutrients, vitamins and minerals. Making a few simple changes can help ensure the whole family is eating a nourishing, well balanced meal.

Basing a meal on a healthy carbohydrate or starchy food is a good place to start. Foods such as potatoes, bread, rice and pasta are good options to help children feel full from their evening meal so that they do not need snacks before bed time. Boiled, jacket or mashed potatoes are the healthier options rather than chips.



Ensuring each meal contains protein is important both to help children feel full, and to help them grow. Good sources of protein include lean meats, fish, beans and lentils. Red meats tend to be higher in saturated fat than white meats so selecting leaner varieties is a good idea, and trying to cut down on red meat can be beneficial. Meat substitutes, such as Quorn, can sometimes be a good alternative to meat as they can help to reduce the fat in a meal and are also convenient as they can be cooked from frozen, for example in a Spaghetti Bolognese.

The evening meal is a good time for children to eat vegetables counting towards their recommended 5-a-day. If your child can be reluctant to eat vegetables, try mixing them in with pasta sauces or sprinkling them on top of a homemade healthy pizza. Serving fruit for dessert is another good way of helping children get their 5-a-day.



It is important for children to drink water throughout the day, and it is a good accompaniment to the evening meal. Pure fruit juices or milk are also good drinks, but remember to only serve one glass of fruit juice per day. Always read the label of fruit-juice drinks as they can often be full of sugar and flavourings. Caffeinated drinks are not a good option to be consumed with or after dinner as they can affect children's sleep.

#### Meals from scratch

Making meals from scratch can be the healthier option as you know exactly what are in them, rather than lots of additives which can be found in ready prepared foods. If you plan for the week ahead it can help to ensure the meals are both time and cost effective. It can also be handy to keep some stock items in the cupboard for those days when you need something quick and simple. For example, a tin of tomatoes and some frozen vegetables can make an easy pasta sauce, or a jacket potato with beans or tuna.

However, there are times when everyone is short of time and preparing meals from scratch may not always be possible. Here are some handy tips:

- Check the label of ready-made foods in the supermarket. Some can be much healthier than others. The luxury and more expensive brands aren't always the healthiest; sometimes the economy ranges offer both better value for money and contain less additives!
- Add a selection of vegetables onto the side of ready prepared meals.
   Frozen vegetables can be ready in less than ten minutes and can help add some good vitamins and minerals to the meal.
- When preparing meals from scratch you could intentionally make extra
  portions and freeze them. Then when you are short of time you will
  have your own home made ready meal!



#### Portion sizes

Portion size is important in ensuring children are eating the right amount for their size and age. Portion sizes have increased in recent years and it is often difficult to tell what a correct portion size is. Using child sized plates and bowls at meal times can be helpful as child sized portions look very small on adult sized plates. There is some useful information on the Change 4 life website about 'me size meals'.

#### http://www.nhs.uk/Change4Life/Pages/kids-portion-sizes.aspx

#### Some new recipe ideas

Sometimes it can be difficult to think of new recipe ideas which are healthy and tasty as well as appealing to children. We have put together a small selection of simple recipes below which you may like to try. There are ideas from all around the world, helping children think about new tastes and what children from other cultures eat and drink. You can also find new recipes on the internet, from cookery books or from other parents, neighbours and friends.

#### Healthy Kebabs (Turkey)

Serves 4

- 900g (2 lbs) of chicken or turkey breast
- 1 tablespoon olive oil
- 1 onion cut into chunks
- · 1 green or red pepper, cut into chunks
- 1 pinch freshly ground black pepper
- 2 tablespoons fresh lime juice □ Kebab sticks
- Cut chicken into cubes. Toss in a mixing bowl along with oil, onion, peppers, salt, black pepper and lime juice. Mix well, cover, and refrigerate overnight.
- 2. Preheat oven grill, griddle pan or barbecue.
- 3. Thread the ingredients, onion and peppers onto skewers, 6 to 8 pieces per skewer and cook for 5 minutes per side (or until the meat is thoroughly cooked through).



#### Mediterranean slice

Suitable for vegetarians, serves 4

- 4 slices of ciabatta
- 4 tbsp green pesto (contains nuts)
- 140 g frozen sliced roasted peppers
- 140 g Tomatoes, diced
- 125 g ball mozzarella, or 85 g cheddar, grated
- Heat oven to 200C/fan 180C/gas 6. Place ciabatta slices on a baking sheet and heat until lightly toasted (appox 15 minutes).
- 2. Remove from the oven and allow to cool to touch.
- 3. Spread the pesto onto ciabatta slices followed by the tomatoes and peppers.
- Tear the mozzarella ball into small pieces, then scatter it (or use cheddar, if you prefer) over the vegetables. Return to the oven or place under the grill for 5 -7 minutes until the cheese has melted.









#### Couscous salad

You could have this on the side of a meal or make it into a main meal itself by adding some lentils or beans, fish or chicken.

Suitable for vegetarians, serves 4

- 100 g couscous
- 250 mls hot low salt vegetable stock
- 2 spring onions
- 2 peppers
- 3 sticks of celery
- 10 cherry Tomatoes
- Any other vegetables of your choice
  - 1. Wash and chop the vegetables.
  - Tip couscous into a large bowl, and pour the stock over.
  - Leave the cous-cous for 10 minutes, until fluffy and all the stock has been absorbed.
  - Add the vegetables to the cous-cous and mix well.

#### Make your own chicken nuggets

- 500g chicken breast
- 1 cup plain flour
- 1 teaspoon mixed herbs
- 1 egg (beaten)
- 250mls low-fat milk
- 3 cups of cornflakes, crushed
- 1. Preheat oven to 180°C.
- 2. Cut the chicken into bite-sized pieces.
- 3. Set out a crumbing station by putting the flour and mixed herbs in the first bowl, the egg beaten with the milk in the second bowl and the crushed cornflakes in the third bowl.
- 4. A few pieces at a time, roll the chicken in the flour, dip into the milk and egg and then roll in the crushed cornflakes.
- 5. Lay these on a wire rack with a tray underneath.
- 6. Bake for 25 minutes (or until cooked through, time will depend on the size of your chicken pieces).

#### Yoghurt Fruit Sundaes



- Fruit of your choice (e.g. frozen berries, defrosted)
- Natural low fat yoghurt (300mls)
- Oats (for decoration)
- 1. Layer the fruit and yoghurt into a glass of bowl.
- 2. Lightly swirl the ingredients together to they become lightly mixed.
- 3. Sprinkle the oats on top of the sundae and serve.

#### <u>Healthy Indian Lassi</u>

Lassi, or yogurt drink, is a healthy drink which is tasty and easy to make.

- Low fat natural Yogurt (250mls)
- Skimmed or Semi Skimmed milk (250mls)
- Fruit of your choice (e.g. cherries, mango, frozen berries, or banana)
- Ice cubes (optional)
- 1. Pour all the ingredients into a blender.
- 2. Blend until smooth.
- 3. Serve!





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## **Appendix 37** Breakfast cooking workshop lesson 2 activity: bread snap cards



Bread roll



Naan



**English Muffin** 



Crumpet



Toast



Baguette



White Bread



Brown Bread



Bagel



















## **Appendix 38** Breakfast cooking workshop interactive game 2: sugar cards





### A can of cola (330mls)

### A bowl of chocolate flavour toa*r*ted rice







2teaspoons of sugar



### A carton of juicy water (200mls)



### A glass of water







### 2 1/2 teaspoons of sugar

# 0 teaspoons of sugar

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### A carton of orange juice (200mls)







3 1/2 teaspoons of sugar



A bowl of whole wheat cereal biscuits

## Only a tiny bit (a pinch of sugar!)


Image of a 200 ml bottle of fruit juice drink

#### A glass of diluted squash

### A bottle of fruit juice drink (200ml/)





of sugar

### 1 teaspoon of sugar

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# **Appendix 39** Breakfast cooking workshop interactive game 2: answers

Sugar game answers.

Item	Sugar teaspoons (1 teaspoon = 6 g of sugar)
A can of cola	6
A carton of orange juice	31/2
A bottle of fruit juice drink	31/2
A carton of juicy water	21/2
A bowl of chocolate-flavour toasted rice	2
A glass of diluted squash	1
A bowl of wholewheat cereal biscuits	A tiny bit
A glass of water	0

**Appendix 40** Breakfast cooking workshop interactive game 3: treat or everyday cards



Jam



Chocolate Spread



Fruit Juice Drink



Bacon



Sausages



White Bread



Croissant



Chocolate flavour toasted



Cola





Boiled Egg



Whole wheat sweetened cereal loops



Low-fat Cream Cheese



A banana



Orange Juice



Wholemeal Bread



Some berries



A glass of milk



Whole wheat malted cereal squares



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## **Appendix 41** Lunch and snacks cooking workshop lesson 1: guess the snack activity



**Appendix 42** Lunch and snacks cooking workshop lesson 2: healthy snacks word search puzzle activity

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		U	U		0			U
	S	Α	Ν	D	W		С	Η
	Ρ	Η	С	Ε	R	Ε	Α	L
	G	R	А	Ρ	Е	S	J	Ζ
	К	V	W	R	Α	Ρ	Q	Т
	G	С	А	R	R	0	Т	S
	С	U	С	U	Μ	В	Ε	R
	L	D	Ζ	Ν	Ρ	Ε	Α	R
Find the snack ideas below in the grid:								
Yoghurt Carrots								
Sandwich					Cucumber			
Cereal					F	Pear		
Grapes					١	Wrap		
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**Appendix 43** Lunch and snacks cooking workshop lesson 3: design a healthy school trip packed lunch – activity





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**Appendix 44** Lunch and snacks cooking workshop interactive game 2: packing a healthy lunch treat or everyday – activity





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**Appendix 45** Evening meals cooking workshop lesson 2: Bert's healthy habits day story – activity

Bert's Healthy Habits Day
Bert wakes up in the morning and has a
• healthy breakfast of
with a glass of He goes for a walk
with his family and they decide to play a game of
At 11am, they stop for a
🗧 snack of They then walk home. 🏅
Before lunch, Bert washes his and sits
down at the table. They have a lunch of
, with a drink of
In the afternoon, Bert
does some colouring and plays a game of
with his sister. His dad
🗧 calls them to have dinner. Bert and his sister wash 🏅
their hands and sit down at the table. They have
Bert's favourite dinner of
After
dinner, Bert and his sister do their reading and have a
snack of Then it is time for bed.
Good night Bert!
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**Appendix 46** Evening meals cooking workshop lesson 3: matching cooking skill words to pictures – activity





# **Appendix 47** Evening meals cooking workshop interactive game 1: food group bingo





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**APPENDIX 4**:

Fr	uit and	Protein	Starchy	Dairy foods	Treat fo
Veg	getables	foods	foods		
(* *****	Carrots	Beans	Bread	Cheese	lce-crean
	Bananas	Chicken	Rice	Semi-skimmed Milk	Chocolati
	<u></u>	Cincken		Setti-skilling	
	Broccoli	Pork	Pasta	Yoghurt	Sweets
2		$\sim$		milk	
C	auliflower	Salmon	Potatoes	Flavoured Milk	Cake
		S		milk	(0.0) × 0
🕴 St	rawberries	Nuts	Crackers	Soya Milk	Biscuits


# **Appendix 48** Villa Vitality teacher's pack







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Acknowledgments

**Contribution of Authors** 

**Trial Steering Committee** 

MRC Epidemiology Unit, University of Cambridge

Nutrition Epidemiology Group, University of Leeds

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ENSURE THAT YOU USE THE ANTIBACTERIAL HAND GEL PROVIDED IN BETWEEN EACH CHILD MEASURED

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## **INTRODUCING VILLA VITALITY**

#### What is the aim of Villa Vitality?

To promote healthy lifestyles in children using the Aston Villa Football Club brand as an iconic role model.

#### Who delivers Villa Vitality?

The main part of Villa Vitality will be delivered by the Villa Vitality team at Aston Villa Football Club. Villa Vitality includes a class project and six weekly challenges to be completed by children which will require supervision by class teachers.

#### What does it involve?

Villa Vitality is a programme run over six weeks, which focuses on developing children's understanding of the importance of eating a healthy balanced diet and undertaking physical activity. The programme aims to motivate children to lead healthy lifestyles by taking the teaching out of a classroom environment and into the engaging setting of a football club. It involves 3 sessions over a 6 week period: two day trips to Aston Villa FC, a visit from Villa Vitality staff to your school, and a class project and challenges for the children to work on over the 6 weeks.

#### Day one (at Aston Villa FC)

The first day at the football club will be divided into three sections; physical activity, healthy eating and the launch of class projects and challenges.

- The physical activity session will involve exercise activities led by Aston Villa's community coaches, teaching children the importance of being physically active and highlighting ways to include physical activity into their daily lives. The sessions are not dependent on sporting ability nor are they football specific.
- The healthy eating session will be delivered by a nutritionist and aims to teach children the importance of eating a healthy balanced diet.
- The class project session will introduce children to the Villa Vitality school project (which they will complete in school time) and also class challenges which are focused on healthy lifestyle behaviours.

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Children will be provided with a booklet of fun activities to take home and complete, which focuses on the key healthy lifestyle messages taught throughout the day.

#### Day two (at school)

Aston Villa coaching staff will visit your school approximately four weeks after the children's first visit to Aston Villa FC for a two hour session. One hour will be spent in a physical activity session run by the coaching staff (e.g. in the school hall or playing fields) during which the key physical activity messages learnt on day one are reiterated. The other hour is used to support the pupils and teachers with their Villa Vitality school project, and class challenges.

#### Day three (at Aston Villa FC)

Day three, conducted at Aston Villa FC is divided into three sections; physical activity, cooking and recording the group project on a CD.

- The physical activity session involves children participating in an hour of physical activity involving dance mats and aerobic routines supervised by qualified instructors.
- The cooking session gives children the opportunity to prepare their own healthy lunch or healthy snacks with an Aston Villa chef, allowing them to develop their cooking skills and learn about food hygiene and safety.
- The recording of the group project gives children the opportunity to record the results of the class projects in the Aston Villa radio studio. A CD of the recording will be sent out to the school (one per child).

#### Where?

The first and final sessions will be held at Aston Villa Football Club. All transport and organisation will be arranged by the Villa Vitality team with your school. In the middle session a member of the Villa Vitality coaching team will attend the school. They will require a space to run the physical activity session for an hour with the children.

#### Staff training / requirements of school

The majority of Villa Vitality will be delivered by staff at Aston Villa FC. Class teachers will be asked to support the class projects and challenges, but this will be fully explained by the Villa Vitality team.



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# **VILLA VITALITY PROGRAMME**



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# SCHOOL PROJECT – THE V FACTOR

#### **Outline:**

Children are required to work in small groups (no more than 5) to produce a song or rap lyrics or a poem or rhyme that incorporates key messages from Day 1 of the Villa Vitality programme.

The groups will need to carry out research to ensure the song or poem contains correct health information and is informative to other pupils.

#### Content:

The lyrics or poem/rhyme should be based around the following key messages:

- The importance of physical activity
- The importance of 5 a day
- The importance of reducing fat and sugar consumption
- The importance of eating a healthy diet · The negative effects of no physical activity

The key messages could be linked to a footballer's diet.

(Note - The lyrics or poem/rhyme may deviate from these themes providing they are still in line with the key objectives of Villa Vitality.)

#### Tasks:

Within each group, tasks should be allocated to all group members to ensure effective team working. Some ideas of tasks that members could be allocated are:

- Song/rhyme/poem writers (Literacy skills)
- Children to type up the work (ICT Skills)
- Children to decide artwork for the project (design and technology)
- All of the group perform together by singing the song or reading the poem to be recorded on day 3 of Villa Vitality (music and drama)

Groups should spend time over the 6 weeks working on writing their chosen song/poem and rehearsing it, as this will help to reinforce the messages learnt on Day 1 of Villa Vitality. Coaches will monitor and assist with progress on the project on Day 2.





# **THE CHALLENGES**

#### **TEACHER INFORMATION**

#### INTRODUCTION TO THE CHALLENGES

This section is to help you and your class work through the 6 class challenges (one for every week of the Villa Vitality programme).

For each challenge there is: -

- A teacher's page: covering the facts behind the challenge, practical tips and launch activity ideas.
- **A parents' page:** outlining the challenge and why it is important with practical tips and ideas to help support their child. These need to be copied and sent out to parents each week.
- A pupil activity sheet: one copy per child will be required for each week.

At the end of each week, pupils who have completed the challenge can stick a sticker onto their football on the 'Class Challenge Poster'.

Pupils who complete all 6 challenges will be awarded with a special certificate on their second visit to Villa Vitality.





#### PARENT INFORMATION

VILLA VITALITY: INTRODUCTION TO THE CHALLENGES

Dear Parent / Carer

Following your child's first visit to Villa Vitality, the class has been asked to complete 6 'class challenges' in the 6 weeks leading up to our return visit.

The class challenges are: -

- 1) 60 minutes of activity each day
- 2) Swap a snack each day
- 3) Drink more water each day
- 4) Eat a healthy breakfast each day
- 5) Eat 5 portions of fruit and vegetables a day
- 6) Plan, cook and eat a healthy balanced meal with your family

Each week, we will be sending home a parent information sheet about the challenge along with a children's activity sheet. We would very much appreciate your support in helping the children to complete these challenges at home.

Thank you,

Year 2 Staff.





#### TEACHER INFORMATION

#### **CHALLENGE 1: 60 MINUTES OF ACTIVITY EACH DAY**

#### Facts behind the challenge

Children need to do at least 60 minutes of activity a day to help them stay happy and healthy. They need to do it to burn off energy and help their muscles and bones grow strong. The more active they are the less likely it is that they will store up excess fat in their bodies which can lead to cancer, type 2 diabetes and heart disease.

#### In practice

The 60 active minutes...

- Don't have to be all in one go
- Don't have to be sport or in the gym
- Can be any kind of activity
- Don't have to be all the same variety is good for different aspects of health
- Should help to increase heart rate
- Don't have to cost anything

### **Possible launch activities**

- Get the class to think of things they do already to be active and how much time this adds up to. Your class should already be doing a minimum of 30 minutes activity at school each day as part of the WAVES Study intervention programme.
- Encourage the class to think of as many varied and fun games and activities as possible that will increase their heart rates.
- Introduce the pupil activity sheet.

#### Review

- Ask the children to keep a note of how much activity they do for the next week using the diary sheets.
- Remind them that they will need to report back this time next week.
- Recap on the reward system for completing their seven-day challenge (stickers on the poster).





#### VILLA VITALITY PARENT INFORMATION

#### CHALLENGE 1: 60 MINUTES OF ACTIVITY EACH DAY

#### Facts behind the challenge

Children need to do at least 60 minutes of activity a day to help them stay happy and healthy. They need to do it to burn off energy and help their muscles and bones grow strong. The more active they are the less likely it is that they will store up excess fat in their bodies which can lead to cancer, type 2 diabetes and heart disease.

#### In practice

The 60 active minutes...

- Don't have to be all in one go
- Don't have to be sport or in the gym
- Can be any kind of activity
- Don't have to be all the same variety is good for different aspects of health
- Should help to increase heart rate
- Don't have to cost anything

#### Tips and ideas

#### 'Half hour max'

You may find it useful to set a limit to how long your children can sit still in front of the TV, computer or video game. Some families have found saying 'Half hour max' of screen time helps them to make sure children jump up and play, or go outside after they've been sitting still for a while.

#### Feet first

Sitting in the car or on the bus uses little energy. If it's a short hop think about using your feet and walking or cycling with the children instead. It's more fun and you can save money too. If the journey is too far, you could always stop a bit earlier, and put your best foot forward for the rest of the journey.

#### After school

Parents tend to over-estimate how much energy children use at school. Remember, they're actually sitting down most of the time. The best way for children to relax after school is to be up and active rather than vegging out.

#### Get up after eating

Don't let them flop after meals. Just being up and about burns off excess energy.

#### Family time

Families that play together have more fun, so find time to do things together after school and make Saturday and Sunday active days.





#### Play

It's what children do best. Running around, having fun with their friends, and burning off energy is a great way of getting some (or all) of their 60 active minutes each day.

Dance

It doesn't have to be at a dance class – you can dance to the radio, or in front of the TV - all that is needed is a great tune and you and your children can have fun dancing anywhere.

Swim

Whether it's lengths of the pool, or having a good splash about, children love having fun in the water.

Bike

Cycling is a great alternative to the car or bus, and can be much more convenient too – no waiting around, no traffic jams or parking problems and no parking charges either. You don't even need to have somewhere to get to; just getting the children out for a bike ride is a great fun activity. Just make sure they are careful and wear a helmet.

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### VILLA VITALITY PUPIL ACTIVITY SHEET

### CHALLENGE 1: 60 MINUTES OF ACTIVITY EACH DAY

MY ACTIVITY DIARY - Write down the activities you do each day.

Name
Monday
Activity:
Tuesday
Activity:
Wednesday
Activity:
Thursday
Activity:
Friday
Activity:
Saturday
Activity:
Sunday
Activity:





#### **TEACHER INFORMATION**

#### **CHALLENGE 2: SWAP A SNACK EACH DAY**

#### Facts behind the challenge

Many snacks can be high in sugar, salt and fat (all the things we shouldn't eat too much of). Swapping snacks for ones lower in fat, salt or sugar can really make a difference to calorie intake and help reduce weight gain. Also, too much sugar is not good for our teeth and too much fat and salt are not good for our hearts.

#### In practice

- Most people eat more snacks than they realise.
- There are no set rules on exactly how many snacks are too many.
- We wouldn't eat sugar straight from the bowl or drink oil straight from the bottle but we don't always think about the sugar and fat hiding in our food and drink.
- Examples of healthier snacks are fruit, low fat yoghurt, malt loaf (with no butter), rice cakes and bread sticks.

#### Possible launch activities

- Guess the sugar using the "Guess the Sugar" quiz sheet ask the children to guess how much sugar they think is in the listed snacks. You may want to show them what a teaspoon is and also measure out and show the teaspoons of sugar for some of the snacks to help them visualise the amounts.
- Count the snacks encourage the class to think about how many snacks they have, when and what.
- Discuss what makes a healthier snack (see above).

#### Review

- Ask the children to keep a note of the snacks they have swapped each day.
- Remind them that they will need to report back this time next week.
- Recap on the reward system for completing their seven-day challenge.



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# **GUESS THE SUGAR**

Try to match the snack foods below to the teaspoons of sugar.

Food & Portion Size	<u>Teaspoons of</u> <u>sugar</u>
<b>Haribo</b> 1 big bag (225g)	8
Mars bar 1 standard bar (62.5g)	5
<b>Kit Kat</b> 4 fingers (48g)	2½
<b>Nutri-grain</b> 1 bar (37g)	2
<b>Cadbury Mini Roll</b> 1 roll (27g)	1½
<b>Chocolate Digestive Biscuits</b> 2 biscuits (35g)	1
<b>Kellogg's Frosties cereal bar</b> 1 bar (25g)	2
Maryland Cookies 2 biscuits	2½
Plain Digestive Biscuits 2 biscuits (28g)	29





### **GUESS THE SUGAR - ANSWERS**

Food / Drink	Portion size	Teaspoons?
Haribo	1 big bag (225g)	29
Mars bar	standard (62.5g)	8
Kit Kat	4 fingers (48g)	5
Nutri-grain	1 bar (37g)	21⁄2
Cadbury Mini Roll	1 roll (27g)	21⁄2
Chocolate Digestive Biscuits	2 biscuits (35g)	2
Kellogg's Frosties cereal bar	1 bar (25g)	2
Maryland Cookies	2 biscuits	1½
Plain Digestive Biscuits	2 biscuits (28g)	1

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#### VILLA VITALITY PARENT INFORMATION

#### **CHALLENGE 2: SWAP A SNACK EACH DAY**

#### Facts behind the challenge

Many snacks can be high in sugar, salt and fat (all the things we shouldn't eat too much of). So try and keep a careful eye on how many of these less healthy snacks the children are having. Swapping snacks for ones lower in fat, salt or sugar can really make a difference to calorie intake and help maintain a healthy weight. Also, too much sugar is not good for our teeth and too much fat and salt are not good for our hearts.

#### In practice

- Most people eat more snacks than they realise.
- There are no set rules on exactly how many snacks are too many.
- We wouldn't eat sugar straight from the bowl or drink oil straight from the bottle but we don't always think about the sugar and fat hiding in our food and drink.
- Examples of healthier snacks are fruit, low fat yoghurt, malt loaf (with no butter), rice cakes and bread sticks.

#### **Tips and Ideas**

These tips might help keep the snack attacks at bay.

#### Keep count

Many families are surprised when they actually count up how many sweets, crisps and biscuits they get through and how much they are spending on snacks. Keep count and you're more likely to cut down – which is good for you and your children and for your purse too.

#### Three regular meals

Children that eat 3 meals a day shouldn't need lots of snacks. If your children seem to be raiding the snack cupboard and biscuit barrel several times a day, think about what meals they're eating and when, and aim for 3 regular meals a day.

#### 'Two Snacks Max'

To fit in with their 3 meals a day, some families find a good way of limiting snacks is to introduce a snacking limit such as 'Two Snacks Max' and to offer just one snack in the morning and one in the afternoon.

#### It's not you, it's the rule

Children, don't blame Mum and Dad! They're just sticking to the rule – 'Two Snacks Max'. Parents, don't feel guilty. If it helps, blame Max!

#### It's kinder to say 'no'

Of course we all love to indulge our children. But in the long run it's kinder to say 'no' to too many snacks. Try to find other ways of rewarding them like giving them stickers, or a trip to the park.





#### One of your five

If you can make one of their snacks a healthier one, all the better. Fruit rather than a biscuit is a great way for children to head towards their 5-a-day.

#### Snack swap

Choose snacks low in fat and without added sugar such as fruit, vegetables, breadsticks, rice cakes or toast, instead of sweets, biscuits, chocolate, cakes and pastries.

#### Food label swap

When shopping compare food labels and switch to the one that's marked lower in sugar or sugar free. Some packaging uses a traffic light system, which makes it even easier to choose food that is lower in sugar. Go for more 'greens' and 'ambers' and fewer 'reds' in your shopping basket.

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## VILLA VITALITY PUPIL ACTIVITY SHEET

CHALLENGE 2: SWAP A SNACK EACH DAY

Name   My SNACK SWAPPING DIARY   Monday   Instead of:   I ate:   Tuesday   Instead of:   I ate:   Wednesday   Instead of:   I ate:   Thursday   Instead of:   I ate:   Thursday   Instead of:   I ate:   Sturday   Instead of:   I ate:   Instead of:   I ate:   Sturday   I ate:   I ate:	
MY SNACK SWAPPING DIARY Monday Instead of: I ate: Tuesday Instead of: I ate: Wednesday Instead of: I ate: Thursday Instead of: I ate: Friday Instead of: I ate: Staturday Instead of: I ate: Staturday Instead of: I ate: I	Name
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Sunday Instead of: I ate:	l ate:
Instead of:	Sunday
l ate:	Instead of:
	l ate:





#### **TEACHER INFORMATION**

#### **CHALLENGE 3: DRINK MORE WATER EACH DAY**

#### Facts behind the challenge

Water makes up about two thirds of our body weight. We need water for lots of different processes to keep our bodies healthy and working properly. Keeping hydrated keeps us healthy and also helps us concentrate. More than half of the added sugar in children's diets comes from sugary drinks so swapping them for water can also cut down the amount of sugar we consume. Water quenches our thirst, is totally free from fat and sugar and has no calories.

#### In practice

- Your class may already have access to and be drinking water throughout the school day. Think about how you promote and encourage this.
- Try to encourage children to drink water at other times of the day / with their meals / at home.
- We need about 6-8 glasses of fluids each day (1.2 litres approx).
- If a child is having a glass of milk or 1 glass of pure fruit juice these should not be encouraged to be swapped for water as they provide valuable calcium and vitamins.

#### Possible launch activities

- What do you drink? Ask the children what they have to drink throughout the day and when they have drinks.
- Discuss how much sugar is in these drinks.
- Ask the class to think how and when they could drink more water.
- Encourage them to consider swapping some of the sugary drinks they have for water.
- The handout may help the children think about what they drink, copies for each day of the challenge could be given to each child to complete.

#### Review

- Ask the children to keep a note of how much water they drink.
- Remind them that they will need to report back this time next week.
- Recap on the reward system for completing their seven-day challenge.



# UNIVERSITY<sup>OF</sup> BIRMINGHAM WAVES

#### VILLA VITALITY PARENT INFORMATION

#### **CHALLENGE 3: DRINK MORE WATER EACH DAY**

#### Facts behind the challenge

Water makes up about two thirds of our body weight. We need water for lots of different processes to keep our bodies healthy and working properly. Keeping hydrated keeps us healthy and also helps us concentrate. More than half of the added sugar in children's diets comes from sugary drinks so swapping them for water can also cut down the amount of sugar we consume. Water quenches our thirst, is totally free from fat and sugar and has no calories.

#### In Practice

- We need about 6-8 glasses of fluids each day (1.2 litres approx).
- Encourage children to drink water at home and with meals.
- If your child is having a glass of milk or 1 glass of pure fruit juice these should not be encouraged to be swapped for water as they provide valuable calcium and vitamins.

#### **Tips and Ideas**

- Provide water to drink at meal times.
- Get a funky water bottle and take it out wherever you go.
- Cut down on sugary drinks gradually, and substitute them with water. Set a limit to the number of sugary drinks consumed, for example no more than one per day.
- Dilute fruit juices with water.
- To add some flavour try adding slices of citrus fruits to water.
- Adding ice cubes can add interest and create a refreshing, ice cold glass of water.





#### VILLA VITALITY PUPIL ACTIVITY SHEET

#### **CHALLENGE 3: DRINK MORE WATER EACH DAY**

Name.....Day.....

Colour a glass for every drink you have in a day. Write the name of the drink under each glass.



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#### **TEACHER INFORMATION**

#### CHALLENGE 4: EAT A HEALTHY BREAKFAST EACH DAY

#### Facts behind the challenge

Breakfast is the most important meal of the day. A healthy, balanced breakfast gets us off to a good start. Breakfast kick-starts the metabolism and gives us that first burst of energy. Breakfast helps us concentrate better throughout the morning because we are not distracted by hunger.

#### In practice

- The foods people eat for breakfast varies greatly.
- A healthy breakfast is based on having some form of starchy carbohydrates such as bread or cereals to give energy.
- It is also a good chance to include a portion of fruit or vegetables.

#### **Possible launch activities**

- Ask the class if they think breakfast is important and why.
- Find out who eats breakfast and what kind of things they eat.
- Discuss what makes up a healthy breakfast.
- Encourage the class to think of different ideas or how they can ensure their breakfast is healthy.

#### Review

- Ask the children to keep a note of what they have for breakfast each day and to complete the pupil activity sheet.
- Remind them that they will need to report back this time next week.
- Recap on the reward system for completing their seven-day challenge.





#### PARENT INFORMATION

#### CHALLENGE 4: EAT A HEALTHY BREAKFAST EACH DAY

#### Facts behind the challenge

Breakfast is the most important meal of the day. A healthy, balanced breakfast gets us off to a good start. Breakfast kick-starts the metabolism and gives us that first burst of energy. Breakfast helps us concentrate better throughout the morning because we are not distracted by hunger.

#### In practice

- The foods people eat for breakfast vary greatly.
- A healthy breakfast is based on having some form of starchy carbohydrates such as bread or cereals to give energy.
- It is also a good chance to include a portion of fruit or vegetables.

#### **Tips and Ideas**

- Base breakfast on starchy foods such as bread or breakfast cereals.
- When choosing cereal, try to go for one that contains wholegrains and is lower in salt and sugar. Also, serve it with semi-skimmed milk, skimmed milk or low-fat yoghurt.
- Try to include some fruit at breakfast time. Put slices of banana on toast, or add chunks of apple, berries or dried fruit to cereal.
- Adding fruit to cereals is also a great way to get children to eat less sugary cereals. Alternatively, try mixing sugary cereals with lower-sugar ones, increasing the amount of lower-sugar cereal over time to get children used to them.
- Make toast with wholemeal or granary bread, and use just a small amount of low-fat spread or jam.
- Porridge oats are cheap and contain lots of vitamins, minerals and fibre. Make porridge with semi-skimmed milk, skimmed milk or water. Try adding a few dried apricots or a sliced banana instead of sugar.
- Try toasted fruit bread as a change from ordinary toast.
- Try to have breakfast together as a family as it encourages children to eat breakfast and get a great start to the day.



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#### VILLA VITALITY PUPIL ACTIVITY SHEET

#### CHALLENGE 4: EAT A HEALTHY BREAKFAST EACH DAY

Name.....Day.....

Draw a picture of what you had to eat and drink for breakfast today. Is it a healthy breakfast?





#### **TEACHER INFORMATION**

#### **CHALLENGE 5: EAT 5-A-DAY**

#### Facts behind the challenge

It is recommended that we all eat at least 5 portions of fruit and vegetables each day. They are important for our health both now and in the future. Fruit and vegetables are packed with essential vitamins, minerals and fibre which may help reduce the risk of diseases like cancer and heart disease. Fruit and vegetables are also low in fat and calories.

#### In practice

- Aim for a variety of different fruits and vegetables and a range of different colours to get a full range of vitamins and minerals.
- A portion of fruit and vegetables is roughly a handful which is relevant whatever your age.
- Fresh, canned, frozen, 100% juice and dried all count towards 5-a-day. Juice should only be counted once per day.
- Canned and frozen fruit and vegetables don't go off as quickly so can be more cost effective.
- Buying fresh fruit and vegetables when they are in season is usually cheaper.
- Just because a product may contain some fruit or vegetables or flavourings they do not necessarily count e.g. Ketchup, fruit yoghurt, squash, juice drinks, jam etc.

#### **Possible launch activities**

- Check the class know how many portions of fruit and vegetables they should be eating.
- Ensure they know how big a portion is.
- Encourage them to eat a variety.
- Encourage the class to count up how many portions they ate yesterday and ways they could eat more this week.

#### Review

- Ask the children to keep a note of how many fruits and vegetables they eat each day.
- Remind them that they will need to report back this time next week.
- Recap on the reward system for completing their seven-day challenge.



# UNIVERSITY<sup>OF</sup> BIRMINGHAM WAVES

#### VILLA VITALITY PARENT INFORMATION

#### **CHALLENGE 5: EAT 5-A-DAY**

#### Facts behind the challenge

It is recommended that we all eat at least 5 portions of fruit and vegetables each day. They are important for our health both now and in the future. Fruit and vegetables are packed with essential vitamins, minerals and fibre which may help reduce the risk of diseases like cancer and heart disease. Fruit and vegetables are also low in fat and calories.

#### In Practice

- Aim for a variety of different fruits and vegetables and a range of different colours to get a full range of vitamins and minerals.
- A portion of fruit and vegetables is roughly a handful which is relevant whatever your age.
- Fresh, canned, frozen, 100% juice and dried all count towards 5-a-day. Juice should only be counted once per day.
- Canned and frozen fruit and vegetables don't go off as quickly so can be more cost effective.
- Buying fresh fruit and vegetables when they are in season is usually cheaper.
- Just because a product may contain some fruit or vegetables or flavourings they do not necessarily count e.g. Ketchup, fruit yoghurt, squash, juice drinks, jam etc.

#### **Tips and Ideas**

It may be easier than you think to give your children five portions of fruit and vegetables a day. Here are lots of different ideas of how to get a portion.

#### Defrost one

Frozen fruit and vegetables count. It only takes a couple of minutes to microwave some frozen peas.

#### Open one

Canned fruit and vegetables count too. Choose canned fruit and vegetables in their own juice/water, which is healthier than eating fruit canned in sugary syrup or vegetables canned in added salt and sugar.

#### Drink one

One glass (150ml) of unsweetened fruit juice or smoothie per day counts as one portion. So they can start on their way to 5-a-day at breakfast.

#### Chop one

Fruit can be fun. Peel it, slice it, make shapes with it. Make it easy to enjoy.





#### Pack one

A portion of fruit and vegetables can help cheer up a lunchbox. Try carrot sticks, baby tomatoes or a banana with a face drawn on the skin.

#### Sprinkle one

It's easy to add fresh, frozen or canned fruit and vegetables to meals. Try sprinkling sweetcorn or pineapple chunks on top of a pizza.

#### Dip one

It's fun to dunk. Cucumber, pepper and carrot sticks all go great with low fat dips.

#### Add one

Try grated or chopped carrots in spaghetti bolognese, or throw tasty vegetables in to a sauce.

#### Snack on one

Fresh and dried fruit counts. Try raisins or dried apricots – they make a great healthy treat. It's also a good idea to pack some healthy snacks for when you're out and about and the children get hungry.

#### Pulse one

Lentils, beans and peas are all pulses that count towards 5-a-day and they can easily be added to stews and salads.



# UNIVERSITY OF BIRMINGHAM

### VILLA VITALITY PUPIL ACTIVITY SHEET CHALLENGE 5: EAT 5 A DAY

See how many portions of fruit and vegetables you eat every day for a week. Draw a picture of each portion of fruit and vegetables you eat each day. Aim for 5 every day!

Name.....

Monday								
Tuesday	Tuesday							
Tuesuay								
Wednesday								
Thursday								
marsaay								
Friday								
Saturday								
Saturday								
Sunday								




#### TEACHER INFORMATION

#### CHALLENGE 6: PLAN, COOK AND EAT A HEALTHY BALANCED MEAL WITH YOUR FAMILY

#### Facts behind the challenge

Planning a meal in advance can help to make sure it is healthy and balanced. Planning a meal can also make shopping trips easier and help with budgeting. Involving the whole family in planning meals ensures everyone gets a say in including things they like or would like to try.

#### In practice

- The Eatwell plate can be helpful to think of the different food groups and sizes of the sections to help achieve a balanced diet.
- Trying to include foods from as many food groups as possible will help to achieve this overall balance.
- All of our meals should be based on carbohydrates (e.g. rice, pasta, potatoes, bread, cereals) to give us energy and wholemeal or brown varieties provide more fibre and fill us up for even longer.
- Meal times are a great time to include some fruit and vegetables too.

#### **Possible launch activities**

- Recap the Eatwell plate and the types of foods we should eat to achieve a healthy, balanced diet. Extra information can be found at <u>www.eatwell.gov.uk</u>
   Discuss how this could be incorporated into different meals.
- Ask the class to think about what they might eat for dinner and consider how healthy this is.
- Discuss ideas for designing a healthy, balanced meal, give out the "Design a Dish" sheet for them to complete at home.

#### Review

- They will have completed all the challenges at the end of this week.
- Remind children to complete "Design a Dish" worksheet to take to Villa.
- Remind them that they will need to report back this time next week and when they return to Villa.





#### VILLA VITALITY PARENT INFORMATION

#### CHALLENGE 6: PLAN, COOK AND EAT A HEALTHY BALANCED MEAL WITH YOUR FAMILY

#### Facts behind the challenge

Planning a meal in advance can help to make sure it is healthy and balanced. Planning a meal can also make shopping trips easier and help with budgeting. Involving the whole family in planning meals ensures everyone gets a say in including things they like or would like to try.

#### In practice

- The Eatwell plate can be helpful to think of the different food groups and sizes of the sections to help achieve a balanced diet.
- Trying to include foods from as many food groups as possible will help to achieve this overall balance.
- All of our meals should be based on carbohydrates (e.g. rice, pasta, potatoes, bread, cereals) to give us energy and wholemeal or brown varieties provide more fibre and fill us up for even longer.
- Meal times are a great time to include some fruit and vegetables too.

#### **Tips and ideas**

- Ask your child to explain what makes up a healthy, balanced diet. They will have been taught the Eatwell plate which is included for your reference.
- They may want to adapt a meal the family already enjoys.
- Alternatively you could use this opportunity to try a new dish and encourage your children to try some new foods too.
- Support your child by helping them to design a healthy meal and plan a time to cook and eat it together.
- This may be a good opportunity to allow your child to help out in the kitchen.





VILLA VITALITY PUPIL ACTIVITY SHEET

CHALLENGE 6: PLAN, COOK AND EAT A HEALTHY BALANCED MEAL WITH YOUR FAMILY

Name..... Draw a picture of your healthy meal.

### Poster 100: The Eatwell Plate

www.foodafactoflife.org.uk/attachments/a1a2c7f4-376e-4c059f857e44.pdf

(last accessed 04/08/2016)

www.foodafactoflife.org.uk/attachments/a1a2c7f4-376e-4c059f857e44.pdf

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## **Appendix 49** Villa Vitality healthy eating session plan

#### **Healthy Eating Session Plan**

Introduce the Eat Well Plate and ask if the group believe it's relevant to a footballer. Explain that the class will be split into groups after and will plan a footballer's diet. All groups will be compared to see who develops the healthiest diet so it is important to pay attention during the session.

#### Q. Do you think a footballer is healthy? Why?

Explain that footballers are very healthy as they train at least 2-3 hours a day and play matches which last 90 minutes. They also eat very healthy balanced diets.

#### Q. Do you know what the Eat Well Plate is?

Ask children to explain what they think the Eatwell plate is and why it looks like it does.

Ask children to explain why they think the plate is split into different sections and why some groups are bigger than others; explain that the bigger groups are the ones we should eat more of emphasizing that it is important to have a balanced diet.

#### Q. Do you think the Eat well Plate is important for you too?

A balanced diet helps to give you a better health.

Introduce the AV footballer

### How does each of the food groups help you and the footballer to become healthier?

#### Fruit and Vegetables

Introduce the section

#### Q. What foods go in this section?

Spinach, peas, okra, Aubergine, cauliflower, apples, pears, bananas, grapes, oranges, etc

#### Q. Why are these foods important for you and a footballer?

They are rich in vitamins, minerals and fibre

**\*\*Clue-** What do they have inside them that is really healthy, they begin with V, M and F. Keep giving them an extra letter of the name until someone answers correctly.

#### Q. Why are vitamins and minerals important?

Help fight coughs and colds, strengthens immune system.

#### Q. What does fibre do for our bodies?

Ask what happens when we eat food? Our body digest it. Explain that inside your tummy we have something called a digestive system and fibre keeps this really healthy

#### Q. How many portions of fruit and vegetable are you supposed to eat a day?

Aim to eat at least 5 portions of fruit and vegetables every day.

#### Q. How big is a portion?

A handful. Give an example of a portion size using the palm of your hand. Explain what counts as a portion and that only one glass of pure fruit juice counts as a portion because it doesn't have all the fibre that fruit has which as we said is really important for a healthy digestive system. Explain that everybody's portion is different depending on the size of your hand the bigger we are the more we need.

#### Q. Where can you find fruit and vegetables in the shops?

Fresh, Frozen, Tinned, Dried, Juice.

\*\*If children struggle with this give an example e.g. You are in the supermarket in a really cold frosty area, where am I? They should come up with Fridge Freezers. So, what has happened to the fruit and vegetables in this section? They are frozen.

### Q. How could the footballer get his 5 portions of fruit and vegetables a day (breakfast, lunch, dinner and snacks)?

Breakfast: Banana on cereal, and Fruit Juice

Snack: Piece of Fruit

Lunch: Raw vegetables sticks/cherry tomatoes/Vegetable soup Dinner: Vegetables or Salad

#### Bread, Rice and starchy foods

Introduce section.

#### Q. What foods go in this section?

Bread, Chapattis, Rotis, Pitta Bread, Breakfast cereals, Rolls, Naan, Pasta, Rice, Potatoes

#### Q. What is another name for this section?

Carbohydrates.

If nobody comes up with the answer, begin to spell the word until someone answers correctly.

#### Q. Why is this food important for you and a footballer?

It provides us with lots of long lasting Energy. Carbohydrate is the main fuel they will use during training and matches. Explain that we are a bit like cars and we need fuel to keep us going just like a car, so CAR-bohydrates are our fuel that keeps us going all day long. Explain and reinforce that they are the best source of energy for our body.

#### Q. Who thinks they need to eat as much as a footballer?

You do not need to eat as much as a footballer. A footballer has to eat a lot of food especially carbohydrates to give him energy so he can keep going and going during a match. He also trains a lot so he has to eat more food than you or me to give him the energy he needs.

#### Q. Who knows how long a football match lasts?

A football match lasts for 90 minutes, so a footballer will have to eat a very healthy balanced meal 1-2 hours before, with lots of carbohydrate to give him energy so he can play at his best. He will have to drink lots of water as well so that he does not become thirsty or dehydrated.

#### Q. What do you think would happen to you if you ate as much as a footballer?

If you eat too much food then this will give your body extra energy that it cannot use. If we eat too much then our body will turn this extra energy into fat and we will put on weight which could lead us to become overweight or obese which is not good for our body.

## Q. Who thinks that they should eat as much as their Mum, Dad, Big Brother, Sister etc?

You should not eat the same amount as adults as they have a bigger tummy than you and if you ate as much as they do then it will make you put on weight.

#### Q. Who has heard of Change4Life?

Explain it's the little brightly coloured people you might have seen on T.V. who want us to live healthy lives.

#### Q. Who has heard of me sized meals? Who can explain what these are?

A me sized meal is a meal that is the right size for you, not too big and not too little, that means you feel full but not too full where your tummy may hurt.

#### Q. What would happen if we ate a meal that was too big for us?

We would put on weight which is not good for our health. It could lead to overweight or obese.

**Energy:** talk through the AV footballer's day and how he will need energy to do day to day things that everyone does but needs even more when he goes football training or plays a game – explain that a football game lasts 1 hr 30 minutes which is a lot of exercise.

Explain that if you eat more energy than you need for the amount of activity you are doing it can lead to overweight.

Show portion size for the pupils of jacket potato (clenched fist) and cereal (mug) using resources

#### Meat, Fish, Eggs and Beans

#### Q.What foods go in this section?

Chicken, meat, fish, eggs, pulses and dals, nuts

If children mention unhealthy forms of meat, fish etc such as battered fish or chicken nuggets explain that the way you cook foods can affect what food group they go into. So if you put fish in batter, like you would get from the fish and chip shop, and place this into the fryer it will absorb lots of fat and then it will go into the purple section.

This will highlight that meat, fish etc can be really healthy but if you cook them wrong then they will become unhealthy as they have a lot of fat in them.

#### Q. Why is this food important for you and a footballer?

Protein helps to build muscle and repair the body.

**Do actions-** Flex arms to display bicep muscle and get the children to do the same. Also explain that protein helps our body to repair cuts we may get when playing in the playground for example.

#### Q. Why would the footballer need muscles?

A footballer needs strong muscle so he can kick the ball far, throw the ball and to run. This will help him to pass, score and win the match!

You also need strong muscles for day to day tasks just like the footballer.

#### **Extra Information if time-**

#### <u>Give example of a muscle and explain that protein helps this muscle to be strong</u> and healthy-

Ask pupils if they know what their heart is made of? Then explain to pupils that their heart is a muscle and you need protein to keep this strong and healthy. Ask the children to clench together one of their fists and explain that this is the size of their heart and it is really important to keep this healthy by exercising and eating a balanced diet.

Show portion size for the pupils of a serving of meat or fish (playing cards) using resources.

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#### Milk and Dairy foods

#### Q. What foods go in this section?

Milk, yogurt and all cheeses

#### Q. What do these foods contain that is really good for us?

Calcium

#### Q. Why is calcium important for you and a footballer?

It gives us healthy bones and teeth

#### Q. Why would the footballer need healthy bones and teeth?

He needs healthy bones and teeth just like you do so that they don't break easily and so that they are nice and strong.

Explain we need approximately 1 pint of milk or equivalent per day

Show portion size for the pupils of a serving of cheese (small matchbox) using resources – this gives the same amount of calcium as  $1/3^{rd}$  pint (175ml) milk or 125g pot of yoghurt

If the following items, ice cream, cream or chocolate are mentioned as an items that go in this section ask the following question-

#### Q. Who thinks that a Dairy Milk chocolate bar/Ice cream/Cream go in this section?

They do not belong in this section as they contain a lot fat and/or sugar and are not good for our health. We should only have these as part of a balanced diet.

#### Sugary and fatty foods

#### Q. What foods go in this section?

Ask the class to name of items they think may belong in this section- Examples are chocolates, fizzy pop, sweets, cake, biscuits, crisps, chips, samosa, Indian sweets, doner kebabs, sausage rolls etc

#### Q. What do these foods give our bodies?

Fat and sugar.

#### Q. What happens if you eat a lot of sugar?

Food and drinks containing lots of added sugar contain calories but often have few other nutrients, so we should try to eat these types of foods only occasionally otherwise they can lead to overweight. Sugary foods and drinks can cause tooth decay, particularly if you have them between meals.

#### Q. Can you think on healthier alternatives?

Replace high sugar/high fat snack with: Fruit, nuts, bread sticks, low fat and sugar yogurt, vegetable sticks

Replace unhealthy high sugar drinks with: water, milk, fruit juice (once a day with a meal)

Highlight the importance of two healthy snacks a day instead of unhealthy snacks-Provide examples e.g. An apple instead of a bag of crisps.

#### Q. What happens if you eat a lot of fat?

Eating lots of fat can make you more likely to put on weight because foods that are high in fat are also high in energy (calories). It can also give you a lot of health problems when you are an adult.

#### Q. Can you think of healthier alternatives?

Fruit, nuts, bread sticks, low fat and sugar yogurt, vegetable sticks

#### Q. Do you know how much sugar is in....

(use pre-prepared test tubes containing the amount of sugar in each item)

Mars Bar Haribo Coca Cola Fruit Shoot Choc digestives

#### Q. Do you know how much fat is in....

(use pre-prepared test tubes containing the amount of fat in each item)

Veg Samosa

Chip shop chips Oven chips Sausage roll

Show portion size for the pupils of a serving crisps (handful) using resources

#### **Review plate**

#### Q. What does Bread, Rice and starchy foods give you?

Energy – Discuss and ask a child to place the word on the footballer **Q. What does Fruit and Vegetables give you?** Vitamins and Minerals – Discuss and ask a child to place the word on the footballer **Q. What does Meat, Fish, Pulses and Dals give you?** Muscles - Discuss and ask a child to place the word on the footballer **Q. What does Milk and Dairy foods\_give you?** 

Calcium for our bones and teeth - Discuss and ask a child to place the word on the footballer **Q. What does Sugary and fatty foods\_give you?** Contain few nutrients so the footballers does not eat these foods often

#### <u>Drinks</u>

#### Q. What kind of drinks would a footballer drink?

Water, smoothies, milk and fruit juices.

#### Q. Why is it important to drink a lot?

All professional footballers, including David Beckham, know how important it is to keep hydrated.

Hydration is a measure of how much water you have in your body. Water is one of the most important nutrients in your diet. You can survive for only a few days without water,

Drinking too little water or losing too much water through sweating will have a negative effect on your performance in training and matches.

#### Q. Is there any other drinks that you can drink that are

healthy? Water, Milk and Fruit Juice (once a day)

Explain that footballers drink healthy drinks most of the time, but when they are very active during training and games they might have drinks that are higher in sugar.

#### Practical session – split class into groups

Explain that each group will be given an eat well plate mat and a footballers 'kit bag' containing the types of foods a footballer might eat. Ask all groups to discuss each food item and place it in the group they think it belongs. Once all groups have finished ask each group to listen to what other groups have for each meal and where they placed each item of food, a different child is nominated each time from each group to answer questions.

**Q.** In the bag what types of food will the footballer eat for breakfast? Cereal, Fruit Juice. Milk

**Q. Can you think on any other healthier alternatives for breakfast?** Toast, Fruit, Porridge, Boiled egg

**Q. What types of foods would the footballer eat for lunch?** Sandwich (sliced bread, bagel, wrap, roll), Tuna, Yogurt, Fruit

**Q. Can you think on any other healthier alternatives for lunch?** Salad, Pasta salad, crackers, Meat

Now that the two meals have been identified, ask each group to work together to develop a healthy meal that they could eat for dinner, remembering all what they have learnt this morning (e.g. 5 a day, portion sizes, healthy alternatives). Complete the Eat Well Plate.

Compare all meals. Discuss the healthy ones and any that are not as healthy ask class can they think on ways to make it a healthier meal e.g. Q. How is the food cooked?

#### <u>Summary</u>

#### Q. How is a footballers' diet different to yours?

We all need the same balanced diet to get the same nutrients A sports person may need to eat more to get enough calories If we are not very active we need to compensate by eating less otherwise the extra calories will cause us to put weight on.

## **Appendix 50** Villa Vitality children's activity booklet

#### **HEALTHY FRUIT SALAD** Serves 4







### **UNIVERSITY** OF **BIRMINGHAM**

WAVES

**APPENDIX 50** 

#### Directions

Pour tinned pineapple and peaches into a large bowl with the juice. Wash, peel and chop all the fruit and to the bowl. Mix well. Place in fridge until ready to eat.







\*\*\*\*\*\*\*\*\*

Dear Parents / Guardians,

#### VILLA VITALITY PROGRAMME

The Villa Vitality programme teaches children about 🖈 living a healthy lifestyle, focusing on being physically 🖈 active and eating a healthy diet. ☆

During the 6 week programme, the children will have the opportunity to visit Aston Villa Football Club twice to learn about leading a healthy life and have one visit from an Aston Villa coach to their school to reinforce the lessons they have learnt. ☆

#### **DAY ONE**

PREPARED

☆

☆ ☆

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☆

The children find out what footballers eat and why healthy eating is \* important. They will take part in a fun physical activity session with 🖈 Aston Villa coaches. The children will also be given a set of challenges 苯 weekly and a project to work on for their next visit to Aston Villa.

#### DAY TWO

An Aston Villa coach will visit your child's school to get the class active and teach them new skills. They will also help the class with their projects and challenges.

#### DAY THREE

★ The children take part in cooking a healthy lunch or food to take away in ★ ★ the Food Academy Community Kitchen. They will also try out the Club's ★  $\frac{1}{2}$ dance mats and record their group project in the Aston Villa Radio ★ Recording Studio. ☆

In this booklet, there are a range of activities for the children to do which supplement the messages they have been given at Villa

Vitality and throughout the WAVES programme. There are also some recipes for you to try at home.

\*\*\*\*\*\*

We hope they enjoy them!

\*

☆

☆ The WAVES study research team and Aston Villa Football Club. ☆

#### VITALITY POTATO WEDGES

#### Serves 4

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#### 8 potatoes

1 tbsp olive oil



Seasonings (e.g. pepper, garlic, chilli –

#### Directions

Preheat the oven to 200°C or Gas Mark 6.

Cut the potatoes into thick wedges.

-Place the wedges into a bowl and mix well with the oil and seasonings.

-Place the wedges on a baking tray and bake in the oven for 20-30 minutes until golden brown and crispy.

#### TUNA AND SALAD WRAP

4 tortilla wraps – plain or wholemeal	¼ cucumber, diced
2 medium sized tomatoes, diced	1 carrot, peeled and grated
¼ iceberg lettuce, shredded	4 tbsp of natural yogurt
1 x 200g tin of tuna in spring	

#### Serves 4

#### Directions

-Mix together all of the ingredients except the tortilla wraps. -Pile the mixture in the middle of each tortilla wrap, fold up the bottom and then fold in each side. The wraps are now ready to eat!

#### **VILLA VITALITY RECIPES**

#### \*\* REMEMBER TO ALWAYS WASH YOUR HANDS AND WORK SURFACES BEFORE YOU START COOKING \*\*

#### VITALITY HEALTHY PIZZA

#### Serves 4

Pizza bread dough (Alternatively, try readymade pizza bases or half a baguette ) 2 cloves garlic, finely chopped 1 small onion, chopped 400g tin chopped tomatoes Oregano dried Low fat cheese grated or fresh mozzarella cheese, ripped or sliced

## 5 basil leaves

Mushrooms, sliced Tomatoes, sliced Optional spicy chicken Optional shredded ham

#### Directions

-Preheat the oven to 200°C or Gas Mark 6.

-Fry the onions and garlic in a little olive oil until soft.

-Add the chopped tomatoes and simmer for five minutes. Allow to cool.

-Stretch dough to form a flat circle and transfer to baking tray or into a pizza tray.

-Pierce the dough with a fork in several places (if using raw dough). -Spread the base with the tomato sauce and arrange the basil leaves on the pizza.

-Add a pinch of pepper.

-Arrange the sliced mushrooms and tomatoes on the pizza.

-Sprinkle with the cheese or arrange with the ripped mozzarella. Add any other toppings you would like to add.

-Finish with the dried oregano.

-Bake for 15 minutes or until the base is cooked and the top is golden.

**TOP TIP:** Experiment with different healthy toppings e.g. tinned pineapple, peppers, sweetcorn.

#### ACTIVITY 1—FRUITS AND VEGETABLES

#### Family Learning Fruit and Vegetable Word Search

See if you can find all the fruit and vegetables listed below. All the words go across from left to right.  $\Rightarrow$ 



**APPENDIX 50** 

You could circle the fruit in one colour and the vegetables in a different colour.



apple	carrot	grape	lettuce	strawberry
banana	cherry	kiwi	orange	swede
broccoli	cucumber	lemon	pea	sweetcorn



#### ACTIVITY 2—KEEPING ACTIVE

#### **ACTIVITY 3—MAKE A FUNNY FACE** Ask an adult to chop up some fruits and vegetables for you to make

a funny face. They could use a peeler to make strips of carrot or grate an apple for hair. Sliced strawberries or kiwis make great eyes and a strip of red pepper will make a smiley mouth. The best bit is getting to eat your funny face when you've finished.

Here are some funny faces made by children with a little help from their parents:











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### **Appendix 51** Observation checklist for Activate

L Section 1					
1.1. Name of school:					
1.2. Name of research	1er:				
1.4 Date:	vcu				
1.5. Time of arrival ar	d departure:				
2 Section 2					
2.1. Were you welcor	ned into the classroom	by the class teacher/ot	her staff?	163	
<ol> <li>Were you welcor</li> <li>Were the childre</li> </ol>	ned into the classroom n pleased to see you?	by the class teacher/ot	her staff?	YES	
<ul><li>2.1. Were you welcor</li><li>2.2. Were the childre</li><li>2.2.1. Comments</li></ul>	ned into the classroom	by the class teacher/ot	her staff?	YES	
<ul> <li>2.1. Were you welcor</li> <li>2.2. Were the childre</li> <li>2.2.1. Comments</li> <li>2.3. If obvious what a Activate? (e.g. registr</li> </ul>	ned into the classroom n pleased to see you? ctivity were the childre ation, maths, art)?	n participating in before	her staff?	YES	
<ul> <li>2.1. Were you welcor</li> <li>2.2. Were the childre</li> <li>2.2.1. Comments</li> <li>2.3. If obvious what a Activate? (e.g. registr</li> <li>2.4. How did the generation of the second secon</li></ul>	ned into the classroom n pleased to see you? ctivity were the childre ation, maths, art)? eral ambience of the cla	en participating in before	e	YES	NO NO  
<ul> <li>2.1. Were you welcor</li> <li>2.2. Were the childre</li> <li>2.2.1. Comments</li> <li>2.3. If obvious what a Activate? (e.g. registr</li> <li>2.4. How did the gene</li> <li>2.5. What proportion</li> <li>activate session?</li> </ul>	ned into the classroom n pleased to see you? ctivity were the childre ation, maths, art)? eral ambience of the cl on of children were 'c	en participating in before assroom appear? on task' (listening or per	e	YES 2 uested task)	NO N
<ul> <li>2.1. Were you welcor</li> <li>2.2. Were the childre</li> <li>2.2.1. Comments</li> <li>2.3. If obvious what a Activate? (e.g. registr</li> <li>2.4. How did the generation of the second secon</li></ul>	n pleased to see you? ctivity were the childre ation, maths, art)? eral ambience of the cl. on of children were 'c	en participating in before assroom appear? on task' (listening or per	e Calm forming the requ	YES 2 uested task)	NO N
<ul> <li>2.1. Were you welcor</li> <li>2.2. Were the childre</li> <li>2.2.1. Comments</li> <li>2.3. If obvious what a Activate? (e.g. registr</li> <li>2.4. How did the generation of the session?</li> <li>2.5. What proportion activate session?</li> <li>none</li> <li>2.5.1. Comments:</li> </ul>	ned into the classroom n pleased to see you? ctivity were the childre ation, maths, art)? eral ambience of the cl on of children were 'c a few	en participating in before assroom appear? on task' (listening or per	e Calm forming the requ	YES 2 uested task)	NO N
<ul> <li>2.1. Were you welcor</li> <li>2.2. Were the childre</li> <li>2.2.1. Comments</li> <li>2.3. If obvious what a Activate? (e.g. registr</li> <li>2.4. How did the gene</li> <li>2.5. What proportionactivate session?</li> <li>none</li> <li>2.5.1. Comments:</li> </ul>	ned into the classroom n pleased to see you? ctivity were the childre ation, maths, art)? eral ambience of the cl on of children were 'co a few	en participating in before assroom appear? on task' (listening or per	e Calm forming the requ	YES yes uested task)	NO N
<ul> <li>2.1. Were you welcor</li> <li>2.2. Were the childre</li> <li>2.2.1. Comments</li> <li>2.3. If obvious what a Activate? (e.g. registr</li> <li>2.4. How did the gene</li> <li>2.5. What proportionactivate session?</li> <li>none</li> <li>2.5.1. Comments:</li> </ul>	ned into the classroom n pleased to see you? ctivity were the childre ation, maths, art)? eral ambience of the cla on of children were 'co a few	en participating in before assroom appear? on task' (listening or per	e	YES yes uested task)	NO N

s section s				
3.1. Description and s	tart time of		3.2. Duration of t	he Activate
(e.g. 0910, after r	egistration)		session (mm.	·/
3.3. How is Activate b	eing delivered?			session? (e.g. 100% or 50%
<ul> <li>Teacher led (teacher</li> <li>DVD led (teacher par</li> </ul>	· leading routines giving instru ticipating but not leading)	ctions with or without E	VD)	
iii. DVD led (teacher NO	T participating)			
v. Other (please describ	g the routines with or without e below):	t DVD support)		
3.3.1. Other / comm	ents:			
3.4. If it is teacher led	, if known report their na	me and role		
(e.g. Mrs Jones, Yr	2 teacher)			
3.5. If teacher or child	led, is s/he supported b	y the: CD	D\	/D Neither
3.6. Number of staff in	n the classroom during th	ne Activate session		
3.7. Number of staff jo	pining in the Activate ses	sion	3.8. For what p did they join ir	roportion of time n? e.g. 50%, 100%
2.9. If not all staff are	narticipating can you tal	why? (e.g. marking	d	
5.5. Il not all stall are	participating can you ten	wity: (e.g. marking	;/ ·····	
3.10. How many child	ren who were	3.11. Do you		
present did <u>not</u> pa sat on the side)?	articipate (i.e.	know why?		
3.12. Did the children	complete the full sessior	n (i.e not interrupte	d)	Yes No
3.12.1. Comments:				
3.13. Does the teache	r tell the class about the	benefits of what th	ev are doing?	Yes No
2.14.16			-,	
(i.e. without the music	:/DVD?) (if you don't kno	w whether it's new	activity tick NK)	
3.15. How enthusiasti	c is the teacher?			
1	2	3	4	5
Not interested				very entriusiastic
3.15.1 Comments:				

Freq	encurently	erform the e	Occasionally	ortably?	Ne <sup>r</sup>	ver
3.17.1 Comments:	chough space to p			ortubiy.		
3.18. For the exercises whi they provided for each	ch involved equipn child?	nent (e.g. sca	rves), were	Yes	No	N/A
3.19. If not, how many child	ren did not have e	equipment?				
3.19.1. Comments:						
3.20. How would you rate t	he overall quality o	of delivery?				
1 Very Poor	2 Poor	3		4 Good	F	5 Strellent
ici yi ool		01	· .			
What proportion of the chi engaged in moderate to vig	ldren are orous activity:	none	a few	some	most	all
3.21. at any point in the ses	sion?					
3.22. for at least half the se	ssion?					
3.23. for most of the sessio	n?					
What proportion of the chi	ldren appeared:	none	a few	some	most	all
3.24. Enthusiastic about the	session?					
3.25. To be enjoying the see	sion?					
3.25.1. Comments:	L		1	1		I
3.26. Were there any childr	en being disruptive	e during the A	Activate?	Yes 🗌	No	
3.27. If yes, how many?	3.28. V	Vas this affec	ting the partic children?	cipation of othe	r Yes	No
3.28.1. Comments: (inc. is t	ne teacher dealing	with it and if	so how?)			
			1			

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4.4	r. comments:						
4.4.	Did you notice a c following Activate	hange in the children's be ?	ehaviour	Yes improved	deterio	Yes prated	No
4.3.:	1. Comments:						
	none	a few	some		most		all
4.3.	What proportion session (once set	n of children were 'on t tled into classroom act	ask' (listeninį ivity).	g or performing	g requested ta	ask) after the	Activate
4.2	.1. Comments:						
	COS CIUN Z IIIIII			5 - 1011			20 milute
4.2.	How long did it ta	ke to resettle the children	n back to class	room activity?	inutor	Morother	10 minut-
	2. sommetter						
4.1.	If obvious, what a after the Activate?	ctivity were the children (e.g. registration, maths)	participating i , art)?	n 			
1 9	Section 4						
	Struggling or unab AND were conseq	le to follow the routines uently NOT ACTIVE					
	Struggling or unab BUT were still ACI	le to follow the routines IVE					
	With a moderate t accuracy	o high degree of					
	the routines?						

# **Appendix 52** Observation checklist for breakfast cooking workshop

	tanaha a tan			
Do not forget to start tin	ing the sessions fr	om the point v	vhen the activi	ty starts.
1 Section 1				
1.1. Name of school:				
1.2. Name of researcher:				
1.3. Class being observed:				
1.4. Date:				
1.5. Time of arrival and departure:				
2 Section 2				
	teacher/other staff?		YES	NO
2.1. Were you welcomed by the class				
<ul> <li>2.1. Were you welcomed by the class</li> <li>2.2. Were the children pleased to see</li> <li>2.2.1. Comments</li> </ul>	you?		YES	NO
<ul> <li>2.1. Were you welcomed by the class</li> <li>2.2. Were the children pleased to see</li> <li>2.2.1. Comments</li> <li>3 Section 3</li> </ul>	you?		YES	NO
<ul> <li>2.1. Were you welcomed by the class</li> <li>2.2. Were the children pleased to see</li> <li>2.2.1. Comments</li> <li>3 Section 3</li> <li>3.1. Description and start time of worshop session (e.g. 0910, after registration)</li> </ul>	you?	3.2. Duration (mins)	YES	NO
<ul> <li>2.1. Were you welcomed by the class</li> <li>2.2. Were the children pleased to see</li> <li>2.2.1. Comments</li> <li>3 Section 3</li> <li>3.1. Description and start time of worshop session (e.g. 0910, after registration)</li> <li>3.2.1. Other / comments:</li> </ul>	you?	3.2. Duratior (mins)	YES	NO
<ul> <li>2.1. Were you welcomed by the class</li> <li>2.2. Were the children pleased to see</li> <li>2.2.1. Comments</li> <li>3 Section 3</li> <li>3.1. Description and start time of worshop session (e.g. 0910, after registration)</li> <li>3.2.1. Other / comments:</li> <li>3.3. If it is teacher led, if known repo (e.g. Mrs Jones, Yr 2 teacher)</li> </ul>	you?	3.2. Duration (mins)	YES	NO
<ul> <li>2.1. Were you welcomed by the class</li> <li>2.2. Were the children pleased to see</li> <li>2.2.1. Comments</li> <li>3 Section 3</li> <li>3.1. Description and start time of worshop session (e.g. 0910, after registration)</li> <li>3.2.1. Other / comments:</li> <li>3.3. If it is teacher led, if known report (e.g. Mrs Jones, Yr 2 teacher)</li> <li>3.4. Is the teacher using powerpoint</li> </ul>	you? t their name and role	3.2. Duration (mins)  Yes	YES	NO
<ul> <li>2.1. Were you welcomed by the class</li> <li>2.2. Were the children pleased to see</li> <li>2.2.1. Comments</li> <li>3 Section 3</li> <li>3.1. Description and start time of worshop session (e.g. 0910, after registration)</li> <li>3.2.1. Other / comments:</li> <li>3.3. If it is teacher led, if known report (e.g. Mrs Jones, Yr 2 teacher)</li> <li>3.4. Is the teacher using powerpoint</li> <li>3.5. Number of staff helping in the worshop is the second seco</li></ul>	t their name and role slides?	3.2. Duration (mins) Yes	YES	NO
<ul> <li>2.1. Were you welcomed by the class</li> <li>2.2. Were the children pleased to see</li> <li>2.2.1. Comments</li> <li>3 Section 3</li> <li>3.1. Description and start time of worshop session (e.g. 0910, after registration)</li> <li>3.2.1. Other / comments:</li> <li>3.3. If it is teacher led, if known report (e.g. Mrs Jones, Yr 2 teacher)</li> <li>3.4. Is the teacher using powerpoint</li> <li>3.5. Number of staff helping in the w</li> <li>3.6. Number of children in workshop</li> </ul>	you? t their name and role slides? prkshop	3.2. Duration (mins) Yes	YES	NO

	elpers (e.g. year 6)					
3.9. Did the children c	omplete the full session	(i.e not interrupted	i)		Yes	No 🗌
3.9.1. Comments:						
Content of the session 3.10. Information: Wh 3.11. Information: Wh 3.12. Activity: Which f 3.13. Information: Ma 3.14. Activity: How mu 3.15. Information: How 3.16. Activity: Breakfa 3.17. Activity: Choppir	n, did the following take y is it important to have at breakfast will keep u ood will keep us fuller fu ximum daily intakes of s uch sugar is there in cert w to reduce fat intake at st foods, treat or every ag and preparing health	e place: e a healthy breakfas s fuller for longer? sugar? tain foods? t breakfast? day? y breakfast?	t?	Yes Yes Yes Yes Yes Yes Yes	No No No No No No No	
3.18. How enthusiastic	c is the main session lea 2	der?		4	5	
Not interested	-				Very enthus	iastic
3.18. Were the childro 3.19. Were the groups	en and parents divided i appropriately sized so	nto groups for the a	activities?	Yes	No	
3.18. Were the childre 3.19. Were the groups 3.20. Was there suffici	en and parents divided i appropriately sized so ient equipment for ever	nto groups for the a everyone could get yone?	activities? involved?	Yes Yes Yes	No No No	
3.18. Were the childre 3.19. Were the groups 3.20. Was there suffic 3.21. Had the school p of the workshop (i	en and parents divided i appropriately sized so ient equipment for ever rovided sufficient fresh .e. fresh fruit, yoghurt e	nto groups for the a everyone could get yone? ingredients for tast tc)?	activities? involved? ing section	Yes Yes Yes	No No No No	
<ul> <li>3.18. Were the childre</li> <li>3.19. Were the groups</li> <li>3.20. Was there suffici</li> <li>3.21. Had the school p of the workshop (i</li> <li>3.21.1. Comments:</li> </ul>	en and parents divided i appropriately sized so ient equipment for ever rovided sufficient fresh .e. fresh fruit, yoghurt e	nto groups for the a everyone could get yone? ingredients for tast vtc)?	activities? involved? ing section	Yes Yes Yes	No No No	
<ul> <li>3.18. Were the childred</li> <li>3.19. Were the groups</li> <li>3.20. Was there sufficing</li> <li>3.21. Had the school provide the workshop (indext)</li> <li>3.21.1. Comments:</li> </ul>	en and parents divided i appropriately sized so ient equipment for ever provided sufficient fresh .e. fresh fruit, yoghurt e	nto groups for the a everyone could get yone? ingredients for tast etc)?	activities? involved? ing section	Yes	No No No	

1 Very Poor	2 Poor	3 OK		4 Good		5 Excellent
3.23. How did the g	eneral ambience of the w	vorkshop app	ear?	Calm 1	2	Chaotic 3
What proportion of t	the parents appeared:	none	a few	some	most	all
3.24. To be enjoying	the session?					
3.25. Interested in th	e session?					
3.26. Got actively inv	olved in the session					
What proportion of t	the children appeared:	none	a few	some	most	all
3.27. To be enjoying	the session?					
3.28. To be intereste	d in the session?					
3.29. Got actively inv	olved in the session					
3.30. Were there any 3.31. If yes, how mar	y children being disruptiv ny? 3.32. v	e during the s Vas this affec	ting the part children?	Yes	No er Yes _	No
3.31.1. Comments: (i	nc. is the teacher dealing	; with it and if	so how?)			
3.33. Do you think ar 3.34. If yes, and poss	ny parents were strugglin ible to tell, approximatel	g due to lang y how many v	uage barrier	? Ye: d?	s I	No
3.34.1. Comments						

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3.35. Were the attending parents given the take home information?	Yes	No 📃
3.35.1. Comments:		
3.36. Were parents given a time and travel questionnaire to fill out?	Yes	No
3.37. Were parents asked to fill out an evaluation form?	Yes	No
3.37.1. Comments:		
3.38. Any other comments:		

## **Appendix 53** Observation checklist for Villa Vitality session 1

#### Observation checklist for Villa Vitality Day One

1.1. Name of school(s	):			
1.2. Name of research	ner:			
1.3. School/Class obs	erved:			
1.4. Date:				
1.5. Time of arrival an	d departure:			
1.6. Teachers' names:				
1.7. Did the session st	art on time? (10am)		YES	NO
1.8. Was the day shor travel time?	tened due to			
Football Academy sess	ion:			
2.1. Person(s) leading	session:			
2.2. No. of children n	ot participating and re	ason(s) why:		
2.3. How enthusiastic	is the coach?			
1 Not interested	2	3	4	5 Verv enthusiastic
2.4. How would you r	ate the overall quality 2	of delivery?	4	5
Very poor	Poor	ок	Good	Excellent
2.5. Does the person	leading actively try to	encourage all children to p	articipate? Yes	, No
2.6. Are the instruction	ons given to the childre	en clear?	Yes	No No
2.7. Are most of the c	hildren able to follow	the instructions given?	Yes	; No

APP	END	IX 53	3
-----	-----	-------	---

2.8. Comments:

What proportion of the children appeared:	none	a few	some	most	all
2.9. Enthusiastic about the session?					
2.10. To be enjoying the session?					
2.11. Comments:					

What proportion of the children are engaged in moderate to vigorous activity:	none	a few	some	most	all
2.12. at any point in the session?					
2.13. for at least half the session?					
2.14. for most of the session?					
2.15. Comments:					

2.16.	Were any children being disruptive?	YES		NO	
2.17.	Are children with special educational needs being included? Yes	5	No	N/A	

2.18.	Are school staff/helpers participating in the session?	Yes	No	
2.19.	Are school staff/helpers supervising the children?	Yes	No	

Nutrition session:						
3.1. Person(s) leading	session:					
3.2. How enthusiastic 1	is the leader?	3		4	Vos	5 enthusiast
3.3. How would you r	te the overall quality of	f deliverv?	I		very	entinusiast
1 Very poor	2 Poor	з ок		4 Good	E	5 Excellent
What proportion of t	he children anneared:	none	a few	some	most	all
3.4. Enthusiastic abou	it the session?			Joine	most	
3.5. To be enjoying th	e session?			_		
3.6. Comments:						
3.7. How are children r	esponding to the session	n? (i.e. are the	ey able to a	nswer questions	as part of sess	ion?)
3.8. How do children re	espond to the group wor	'k sessions? (i.	.e. are they	on task; are they	following inst	ructions, e

3.9. Were any children being disruptive?	YES		NO		
3.10. Are children with special educational needs being YES included?	N	0	N	/A	
3.11. Are school staff/helpers participating in the session?		Yes		No	
3.12. Are school staff/helpers supervising the children?		Yes		No	
3.13. Were children given a short break part way through the session?		Yes		No	
Introduction to the project and challenges					
Antroduction to the project and challenges 4.1. Were the instructions clear? 4.2. Comments:		Yes		No	
ntroduction to the project and challenges 4.1. Were the instructions clear? 4.2. Comments: <u>Four of the stadium</u>		Yes		No	
ntroduction to the project and challenges 4.1. Were the instructions clear? 4.2. Comments: Four of the stadium 5.1. Did the tour go ahead?		Yes		No	
A.1. Were the instructions clear? 4.2. Comments: Tour of the stadium 5.1. Did the tour go ahead? 5.2. Did the majority of children enjoy the tour?		Yes Yes Yes		No	
ntroduction to the project and challenges         4.1. Were the instructions clear?         4.2. Comments:         Four of the stadium         5.1. Did the tour go ahead?         5.2. Did the majority of children enjoy the tour?         5.3. Any other comments:		Yes Yes Yes		No	
Introduction to the project and challenges         4.1. Were the instructions clear?         4.2. Comments:         Four of the stadium         5.1. Did the tour go ahead?         5.2. Did the majority of children enjoy the tour?         5.3. Any other comments:		Yes Yes Yes		No No	
Introduction to the project and challenges         4.1. Were the instructions clear?         4.2. Comments:         Four of the stadium         5.1. Did the tour go ahead?         5.2. Did the majority of children enjoy the tour?         5.3. Any other comments:		Yes Yes Yes		No No	

		 7	
1. Were lunchboxes checked by Villa Vitality staff?	Yes	No	
ner observations		 	
er observations		 	
ier observations 1. Did teachers/staff/helpers seem enthusiastic about Villa Vitality?	Yes	No	
ner observations 1. Did teachers/staff/helpers seem enthusiastic about Villa Vitality?	Yes	No	

7.4. Any other comments:

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Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton
SO16 7NS, UK.
# Appendix 54 Cooking workshop parent evaluation: breakfast

### **UNIVERSITY**OF BIRMINGHAM

(e.g. mother, father, grandmother, carer, etc)

Cooking workshops **Evaluation form 1: Breakfast** 



School:		
Date:		
Your relationship to child:		

1. On a scale of 1 to 5, where 1 means strongly disagree and 5 means strongly agree, please rate your feelings about today's workshop.

	Strongly disagree				Strongly agree
	1	2	3	4	5
The information was useful					
The information was easy to understand					
The workshop was well organised					
The presenters were well informed					
I had a chance to take part in all activities					
I enjoyed the session					

2. Do you think you will make any changes to your child and family's diet following the workshop? YES NO

	Please comment:
3.	Is there anything additional you would have liked to have been in the workshop?
	Please comment:
	Please turn over

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- THANK YOU -

# Appendix 55 Villa Vitality teacher evaluation questionnaire: session 1

### Villa Vitality Day One - school staff evaluation

1. Rate the following statements by how much you agree with them:

		Completely disagree				Completely agree
a)	Children enjoyed Villa Vitality Day One	1	2	3	4	5
b)	Children's nutritional knowledge is likely to improve as a result of the Healthy Eating session	1	2	3	4	5
c)	Children's physical activity skills are likely to improve as a result of the Academy Activity session	1	2	3	4	5
d)	Children responded well to the sessions at Villa Vitality	1	2	3	4	5
e)	Villa Vitality Day One was a worthwhile educational experience for the children	1	2	3	4	5

2. What did you like best about Villa Vitality Day One?

3. Can you think of any ways in which Villa Vitality Day One could be improved? Please describe:

4. Any other comments:

7. Position within school.....

Thank you for your comments. Please hand in to Villa Vitality staff or return to: - Joanne Clarke, WAVES Study, Public Health Building, University of Birmingham, Edgbaston, Birmingham B15 2TT.

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# **Appendix 56** Villa Vitality teacher evaluation questionnaire: whole programme

## Villa Vitality Programme - school staff evaluation

Please rate the following statements on a scale of 1 (completely disagree) to 5 (completely agree):

	completely disagree				Completely agree
Children enjoyed the Villa Vitality programme	1	2	3	4	5
Teaching staff found Villa Vitality worthwhile	1	2	3	4	5
The booking process / admin for Villa Vitality ran smoothly	1	2	3	4	5
Children are more likely to remember messages learnt at Aston Villa than they would in a normal classroom session	1	2	3	4	5
The Villa Vitality staff add a degree of expertise that we would not be able to replicate at school	1	2	3	4	5
The Villa Vitality staff are good role models for the children	1	2	3	4	5
Using footballers as role models for healthy lifestyles is a good idea	1	2	3	4	5
The cooking session improved children's skills in the kitchen	1	2	3	4	5
The dance mats session improved children's physical skills	1	2	3	4	5
The radio recording session was a worthwhile undertaking	1	2	3	4	5
The Villa Vitality teaching pack enabled healthy lifestyles messages to be reinforced back at school	1	2	3	4	5
Children responded well to the 6 weekly challenges	1	2	3	4	5
Parents responded well to the 6 weekly challenges	1	2	3	4	5
The time spent on the weekly challenges was time well spent	1	2	3	4	5
The time spent on the school project 'V Factor' was time well spent	1	2	3	4	5
The Day Two visit to school by the football coach helped to consolidate learning	1	2	3	4	5
Children learnt a lot from Villa Vitality	1	2	3	4	5
Children's understanding of the importance of healthy eating has increased as a result of the Villa Vitality programme	1	2	3	4	5
Children's understanding of the importance of physical activity has increased as a result of the Villa Vitality programme	1	2	3	4	5
Children have made healthy lifestyle behaviour changes as a result of the Villa Vitality programme	1	2	3	4	5
Villa Vitality will have a long-lasting impact on the children	1	2	3	4	5

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Was there any part of Villa Vitality that children did not understand or engage with? Please provide specific comments.

Which element of Villa Vitality do you consider will have most impact? Why?

What proportion of the class **completed** the Weekly Challenges?

When children **did not** complete the Weekly Challenges, what were the reasons for this?

Approximately how much time did you spend in class on the class project?

Approximately how much time did you spend in class on the Weekly Challenges?

Did you initiate any additional projects/activities as a result of Villa Vitality?

[Class teachers only] How many Year 2 children attended Villa Vitality today? ...... out of ......

If any children did not attend, please state reasons why (e.g. illness, no parental consent)

Υοι	r name:School
Pos	ition within school:
Tha	nk you for your comments.
Plea Birn	se hand in to Villa Vitality staff or return to: - Joanne Clarke, WAVES Study, Dept of Public Health, University of ingham, Edgbaston, Birmingham B15 2TT.
Fax:	0121 414 6007; Email: <u>j.l.clarke@bham.ac.uk</u> ; Tel: 0121 415 8060
Any	other comments

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# **Appendix 57** Physical activity logbook: September to December 2012

UNIVERSITY BIRMINGHA	of M	WAVES
WAV	ES study ínter	vention
Physical Ac	tívíty Program	mes Log Book
Septe	mber – Decembe	er 2012
U		B
School		
Class		
No. of children		
Class teacher	******	**************

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### Guide to completing the logbook

This is a log book to record information about the physical activity programmes you are using for the WAVES study intervention throughout the year. There is an example at the beginning to show you how to complete the log book. Please record which member of staff is running each activity by marking the staff initials in the columns denoting the activity programme being used, and then fill in the table below so we know which initials refer to which school staff.

The log book runs from the first week after ½ term up until Christmas. At the end of term, please could you return the log book to the WAVES office (or a member of the WAVES team will pick it up when they visit your school) and we will send you another log book for the following ½ term.

The main thing we ask is that you are completely honest with us. As part of the research we need to understand how the WAVES study intervention programme fits into everyday school life. Ideally each class will fit in an additional 30 minutes of physical activity into the school day. However, if this is not possible on certain days (for example, the children are on a school trip) simply record this in the log book.

#### Staff initials

Staff initials	Name	Role
e.g. MJ	Mary Jones	Year 2 teacher

WAVES study, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT. Tel: 0121 414 3921 or email: t.l.griffin.1@bham.ac.uk

#### W/C - EXAMPLE WEEK

		Packag	ge use	d		Time spent		If activity did not take	Did all the children		If you were not preparing (P) and delivering (D) the
	Activate	Take 10	wusu	P. Play	Time of activity	activity (mins)	Duration of activity (mins)	place or 30 minutes not achieved please note down why below	present in your class today participate?	If not why not?	sessions what would you have been doing instead with your time? (e.g. marking, lesson planning)
Mon		۵,ر			9.10	5 míns	10 míns	-	Yes	-	P - Lesson planning D - Teaching
				A.)	12.30 (lunch)	10 míns	15 mins	-	No	5 children went home for lunch	P - Leisure Time D - Lunchtime supervision
		J.C			3.15	0 míns	5 míns	-	Yes	-	P - N/A D - Teaching
Tues		J.C			9.10	5 míns	15 míns	-	Yes	-	P - Leisure time D - Teaching
				A.J	12.30 (lunch)	0 mins	15 mins	-	Yes	-	P - N/A D - Lunchtime supervision
Wed		J.C			14.30	0 mins	15 míns	-	NO	2 children feeling unwell	P - Lesson planning D - Teaching
				A.J	12.30 (lunch)	0 míns	15 míns	τ.	Yes	-	P - N/A D - Teaching
Thurs		M.J			8.45	0 míns	10 míns	Children on school tríp	Yes	-	P - N/A D - Lesson Planning
Fri					×	X	×	Teacher training day	-	-	-
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W/C - EXAMPLE WEEK

#### Comments box (EXAMPLE)

The children enjoyed the sessions this week. We started a new Take 10 aerobics DVD session, but we are taking it slowly whilst the children learn the moves.

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The positive play sessions have been popular. Some of the children would rather sit quietly in the corner, but to encourage them to get involved we have introduced a reward system so that if they play in the positive play area for at least 15 minutes of their lunch break they get a reward card. 5 reward cards count towards a house point.

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W/C – 8<sup>th</sup> October 2012

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### W/C – 3<sup>rd</sup> December 2012

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# **Appendix 58** Cooking workshop logbook: breakfast

UNIVERSITY BIRMINGH	YOF AM	WAVES
WA	VES studų	y intervention
Cook	ríng works	hops log Book
	(Breakfa	st 2012)
		B
School	***************	***********************************
Class		
No. of children		

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Cooking worksho	ps log book
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Please complete this log book whilst your class participate in the cooking workshop. If you have any questions please do not hesitate to contact us (0121 414 3921 or t.l.griffin.1@bham.ac.uk).

Once you have completed this log book, please return to the WAVES study office (together with parent evaluation sheets and their time and travel cost forms).

WAVES study, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT.

<u>Content</u>	Page
Cooking workshop – Lessons 1 – 4 log sheet	1
Cooking workshop log sheet	2 - 3

	(to be completed by staff member who delivered the cooking workshop lessons)
1. N	ame and role of member of staff who delivered the cooking workshop lessons (and completing this form)
2. W	hat was the topic of the workshop? (Breakfast, Lunch, Dinner)
3. Di	d you deliver all four lessons to the children before the cooking workshop? Yes NO (if no comment below)
4. Aı	nount of time in total you spent <b>preparing</b> for the cooking workshop lessons:
4. 1	Hours Minutes What would you have been doing if you hadn't been preparing for the cooking workshop lessons?
5. /	Amount of <b>total class time</b> you spent <b>delivering</b> the lessons:
	Hours Minutes
6. \	What would you have been doing with your class if you hadn't been spending time delivering the lessons?
7. /	Any issues / comments about the cooking workshop lessons:

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1. Name and role of member of staff who delivered the cooking workshop (and completing this form)  2. What was the topic of the workshop? (Breakfast, Lunch, Dinner)  3. Amount of time in total you spent preparing for the cooking workshop (including advertising to parents, shopp) for food (etc)):  4. What would you have been doing if you hadn't been preparing for the cooking workshop?  5. Amount of class time you spent delivering the workshop:  5. Amount of class time you spent delivering the workshop:  5. Amount of class time you spent delivering the workshop:  5. Amount of class time you spent delivering the workshop:  5. Minutes  6. What would you have been doing with your class if you hadn't been spending time delivering the workshop?  7. Number of children who participated in the workshop  8. Names of children and reasons (if known) for not participating in the workshop:  9. Context of the workshop:  9. Context of the workshop  9. Con	<u>(to</u>	be completed by staff member who delivered the cooking workshop)
2. What was the topic of the workshop? (Breakfast, Lunch, Dinner)  3. Amount of time in total you spent preparing for the cooking workshop (including advertising to parents, shopp) for food (etc)):	1. Name and rol	e of member of staff who delivered the cooking workshop (and completing this form)
3. Amount of time in total you spent preparing for the cooking workshop (including advertising to parents, shoppi for food (etc)):	2. What was the	topic of the workshop? (Breakfast, Lunch, Dinner)
4. What would you have been doing if you hadn't been preparing for the cooking workshop?  5. Amount of class time you spent delivering the workshop: 4. Hours Minutes 6. What would you have been doing with your class if you hadn't been spending time delivering the workshop?  7. Number of children who participated in the workshop  7. Number of children and reasons (if known) for not participating in the workshop:	3. Amount of tir for food (etc)):	ne in total you spent <b>preparing</b> for the cooking workshop (including advertising to parents, shoppin
<ul> <li>5. Amount of class time you spent delivering the workshop:</li> <li> Hours Minutes</li> <li>6. What would you have been doing with your class if you hadn't been spending time delivering the workshop?</li> <li>7. Number of children who participated in the workshop</li> <li></li></ul>	4. What would	you have been doing if you hadn't been preparing for the cooking workshop?
<ul> <li>Hours Minutes</li> <li>What would you have been doing with your class if you hadn't been spending time delivering the workshop?</li> <li>Number of children who participated in the workshop</li> <li>out of</li> <li>Names of children and reasons (if known) for not participating in the workshop:</li> </ul>	5. Amount of c	class time you spent delivering the workshop:
<ul> <li>6. What would you have been doing with your class if you hadn't been spending time delivering the workshop?</li> <li>7. Number of children who participated in the workshop</li> <li> out of</li> <li>8. Names of children and reasons (if known) for not participating in the workshop:</li> </ul>	Hours	Minutes
<ol> <li>Number of children who participated in the workshop</li> <li>out of</li> <li>Names of children and reasons (if known) for not participating in the workshop:</li> </ol>	6. What would	you have been doing with your class if you hadn't been spending time delivering the workshop?
<ol> <li>Number of children who participated in the workshop</li> <li>out of</li> <li>Names of children and reasons (if known) for not participating in the workshop:</li> </ol>		
<ul><li>out of</li><li>8. Names of children and reasons (if known) for not participating in the workshop:</li></ul>	7. Number of d	children who participated in the workshop
8. Names of children and reasons (if known) for not participating in the workshop:	out of	
	8. Names of ch	ildren and reasons (if known) for not participating in the workshop:

9. How many children had at le	ast one parent/carer partic	ipating in the workshop with the	em?
10. Were there any other helper	s? (e.g. Year 6 children, oth	er school staff)	
11. If so how many? Child helper	s Scho	ool staff helpers	
12. Any issues / comments about	t the cooking workshop?		

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# **Appendix 59** Villa Vitality logbook

UNIVERSITY <sup>OF</sup> BIRMINGHAM		WAVES
WA	VES study ínterv	ention
Vílla Ví	tality log Book 20	012/2013
U		B
School		
Class	******	
No. of children	*******************************	
Class teacher	*****	•••••••••

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### Villa Vitality log book

Please complete this log book whilst your class are participating in the 6 week Villa Vitality programme. If you have any questions please do not hesitate to contact us (0121 414 3921 or t.l.griffin.1@bham.ac.uk).

Once you have completed this log book please return to:

WAVES study, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT.

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Villa Vitality Day <b>One</b> log sheet	1
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Villa Vitality challenge 2	4
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Villa Vitality challenge 4	6
Villa Vitality Day <b>Two</b> log sheet	7
Villa Vitality challenge 5	8
Villa Vitality challenge 6	9
Villa Vitality Day <b>Three</b> log sheet	10

	<u>Villa Vi</u>	tality Day One
1. Date of visit:		
<ol> <li>Time spent arranging parental consent (etc):</li> </ol>	Villa Vitality <b>Day One</b>	visit (including liaising with Villa Vitality staff, obtain
Hours Mi	nutes	
3. Number of Year 2 child	lren from your class tha	t attended Villa Vitality <b>Day One</b> :
out of		
4. Names of children not	attending with reasons	why:
5. Please complete the ta	ble below with details f	or each of the school staff that attended with your cla
5. Please complete the ta	ble below with details f	or each of the school staff that attended with your cla What would they have been doing if they hadn attended Villa Vitality Day One?
5. Please complete the ta	ble below with details f	or each of the school staff that attended with your cla What would they have been doing if they hadn attended Villa Vitality Day One?
5. Please complete the ta	ble below with details f	or each of the school staff that attended with your cla What would they have been doing if they hadn attended Villa Vitality Day One?
5. Please complete the ta           Name of staff	ble below with details f	or each of the school staff that attended with your cla What would they have been doing if they hadn attended Villa Vitality Day One?
5. Please complete the ta           Name of staff	ble below with details f	or each of the school staff that attended with your cla What would they have been doing if they hadn attended Villa Vitality Day One?
5. Please complete the ta          Name of staff         Image: staff </td <td>ble below with details f</td> <td>or each of the school staff that attended with your cla What would they have been doing if they hadn attended Villa Vitality Day One?</td>	ble below with details f	or each of the school staff that attended with your cla What would they have been doing if they hadn attended Villa Vitality Day One?
5. Please complete the ta          Name of staff         Image: staff </td <td>ble below with details f</td> <td>for each of the school staff that attended with your cla What would they have been doing if they hadn attended Villa Vitality Day One?</td>	ble below with details f	for each of the school staff that attended with your cla What would they have been doing if they hadn attended Villa Vitality Day One?

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Villa Vitality School Project
The V Factor

1. Amount of time in total you spent preparing for the V factor project:

..... Hours ..... Minutes

2. What would you have been doing if you hadn't been preparing for the V factor project?

3. Amount of class time you spent delivering / working on the V factor project?:

..... Hours ..... Minutes

4. What would you have been doing with your class if you hadn't been spending time **delivering / working on** the V factor project?

5. Any issues / comments about the V factor project?:

Villa Vitality Challenges – Week One	e
60 minutes of activity each day	

1. Amount of time in total you spent preparing for Challenge One:

..... Hours ..... Minutes

2. What would you have been doing if you hadn't been preparing for Challenge One?

3. Amount of class time you spent delivering Challenge One:

..... Hours ..... Minutes

4. What would you have been doing with your class if you hadn't been spending time delivering Challenge One?

5. Number of children that completed Challenge One:

..... out of .....

6. Reasons (if known) for children not completing Challenge One:

7. Any issues / comments about Challenge One:

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	Swap a snack each day
	<u>shup a shack cach day</u>
1. Amount of tin	me in total you spent preparing for Challenge Two:
Hours	Minutes
2. What would y	you have been doing if you hadn't been <b>prenaring</b> for Challenge Two?
	for note been doing if you noon t been preparing for onanenge throu
2 Amount of de	ess time you spont delivering Challenge Two
3. Amount of cla	ass time you spent derivering challenge two:
Hours	Minutes
4. What would y	you have been doing with your class if you hadn't been spending time delivering Challenge Two?
5. Number of ch	nildren that completed Challenge Two:
out of	
	nown) for children not completing Challenge Two:
6. Reasons (if kn	
<ol> <li>Reasons (if kn</li> <li>Any issues / c</li> </ol>	comments about Challenge Two:

	Villa Vitality Challenges – Week Three
	Drink more water each day
1.	Amount of time in total you spent preparing for Challenge Three:
	Hours Minutes
2.	What would you have been doing if you hadn't been preparing for Challenge Three?
3.	Amount of class time you spent delivering Challenge Three:
	Hours Minutes
4.	What would you have been doing with your class if you hadn't been spending time delivering Challenge Three?
5.	Number of children that completed Challenge Three:
	out of
6.	Reasons (if known) for children not completing Challenge Three:
7.	Any issues / comments about Challenge Three:

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	<u>Eat a healthy breakfast each day</u>	
1. Amount of time i	n total you spent preparing for Challenge Four:	
Hours	Minutes	
2. What would you	have been doing if you hadn't been preparing for Challenge Four?	<b>\$</b>
3. Amount of class t	time you spent delivering Challenge Four:	
Hours	Minutes	
4 M/bat would you	have been doing with your class if you hadn't been spending times	delivering Challenge Four?
4. What would you		denvering chanenge rour:
5. Number of childr	en that completed Challenge Four:	
out of		
6 Descens (if know	n) for shildren not completing Challenge Four	
6. Reasons (if knowl	n) for children not completing challenge Four:	
7. Any issues / com	ments about Challenge Four:	

<ol> <li>Date of visit by coach to</li> </ol>	the school :	
2. Time spent arranging Vil	la Vitality <b>Day Two</b> visit (ir	ncluding liaising with Villa Vitality staff, booking hall (etc)):
Hours Min	utes	
3. Number of Year 2 childre	en from your class that pa	rticipated in Villa Vitality Day Two:
out of		
4. Names of children not p	articipating with reasons	why:
<ol> <li>Please complete the tab</li> <li>Name of school staff</li> </ol>	le below with details for e <b>Position</b>	ach of the school staff that participated in Day Two : What would they have been doing if they hadn't
5. Please complete the tab Name of school staff	le below with details for e <b>Position</b>	ach of the school staff that participated in Day Two : What would they have been doing if they hadn't participated in Villa Vitality Day Two?
5. Please complete the tab Name of school staff	le below with details for e <b>Position</b>	ach of the school staff that participated in Day Two : What would they have been doing if they hadn't participated in Villa Vitality Day Two?
5. Please complete the tab Name of school staff	le below with details for e <b>Position</b>	ach of the school staff that participated in Day Two : What would they have been doing if they hadn't participated in Villa Vitality Day Two?
5. Please complete the tab Name of school staff	le below with details for e Position	ach of the school staff that participated in Day Two :           What would they have been doing if they hadn't           participated in Villa Vitality Day Two?
5. Please complete the tab Name of school staff	le below with details for e Position	ach of the school staff that participated in Day Two :           What would they have been doing if they hadn't participated in Villa Vitality Day Two?
5. Please complete the tab Name of school staff	le below with details for e Position	ach of the school staff that participated in Day Two :           What would they have been doing if they hadn't           participated in Villa Vitality Day Two?
5. Please complete the tab Name of school staff	le below with details for e Position	ach of the school staff that participated in Day Two :           What would they have been doing if they hadn't participated in Villa Vitality Day Two?
5. Please complete the tab Name of school staff	le below with details for e Position	ach of the school staff that participated in Day Two :           What would they have been doing if they hadn's           participated in Villa Vitality Day Two?

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	Eat 5 portions of fruit and vegetables a day
1. Amou	int of time in total you spent preparing for Challenge Five:
H	ours Minutes
2. What	would you have been doing if you hadn't been preparing for Challenge Five?
3. Amoı	int of class time you spent delivering Challenge Five:
H	ours Minutes
1. What	would you have been doing with your class if you hadn't been spending time delivering Challenge Five?
5. Num	ber of children that completed Challenge Five:
01	ıt of
5. Reaso	ons (if known) for children not completing Challenge Five:
7. Any i	ssues / comments about Challenge Five:

<u>Villa Vitality Challenges – Week Six</u>
Plan, cook and eat a healthy balanced meal with your family
1. Amount of time in total you spent <b>preparing</b> for Challenge Six::
Hours Minutes
2. What would you have been doing if you hadn't been preparing for Challenge Six?
3. Amount of class time you spent delivering Challenge Six:
Hours Minutes
4. What would you have been doing with your class if you hadn't been spending time <b>delivering</b> Challenge Six?
5. Number of children that completed Challenge Six:
out of
6. Reasons (if known) for children not completing Challenge Six:
<ul> <li>7. Any issues / comments about Challenge Six:</li> </ul>

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	<u>Villa Vita</u>	ality Day Three
1. Date of visit:		
<ol> <li>Time spent arranging (etc):</li> </ol>	Villa Vitality <b>Day Three</b> v	isit (including liaising with Villa Vitality staff, booking ha
Hours M	inutes	
3. Number of Year 2 child	dren from your class that	attended Villa Vitality <b>Day Three</b> :
out of		
4. Names of children not	participating with reaso	ons why:
<ol> <li>Names of children not</li> <li>S. Please complete the table</li> </ol>	able below with details fo	ons why: 
<ol> <li>Names of children not</li> <li>S. Please complete the tail</li> <li>Name of staff</li> </ol>	able below with details fo	ons why: or each of the school staff that attended with your class What would they have been doing if they hadn't attended Villa Vitality Day Three?
<ol> <li>Names of children not</li> <li>Please complete the tail</li> <li>Name of staff</li> </ol>	able below with details for <b>Position</b>	ons why: or each of the school staff that attended with your class What would they have been doing if they hadn't attended Villa Vitality Day Three?
<ol> <li>Names of children not</li> <li>Please complete the tail</li> <li>Name of staff</li> </ol>	able below with details fo	ons why: or each of the school staff that attended with your class What would they have been doing if they hadn't attended Villa Vitality Day Three?
<ul> <li>Names of children not</li> <li>5. Please complete the tail</li> <li>Name of staff</li> <li>I</li> </ul>	able below with details for <b>Position</b>	ons why: or each of the school staff that attended with your class What would they have been doing if they hadn't attended Villa Vitality Day Three?
4. Names of children not 5. Please complete the t Name of staff	able below with details for <b>Position</b>	ons why: or each of the school staff that attended with your class What would they have been doing if they hadn't attended Villa Vitality Day Three?

# **Appendix 60** Prespecified subgroup analyses

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### TABLE 43 Adjusted differences for key variables between control and intervention groups at FU1: ethnicity – white only

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted) <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p-value	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 571 (n = 262,  unadjusted)	0.24 (1.03)	0.34 (1.16)	0.19 (1.07)	0.30 (1.14)	0.007	0.953	-0.103	0.157	-0.104	0.203
N = 548 (n = 257,  partially adjusted)					(-0.230 to 0.244)		(-0.246 to 0.040)		(-0.265 to 0.056)	
N = 402 (n = 188,  fully adjusted)										
Height (cm)										
N = 572 (n = 257, unadjusted)	118.07 (5.34)	126.93 (5.75)	117.50 (5.12)	126.54 (5.71)	0.393	0.418	0.098	0.803	-0.100	0.795
N = 549 (n = 257,  partially adjusted)					(-0.559 to 1.345)		(-0.672 to 0.867)		(-0.853 to 0.653)	
N = 403 (n = 188,  fully adjusted)										
Waist z-score										
N = 522 (n = 237, unadjusted)	0.81 (0.97)	1.00 (1.26)	0.72 (1.09)	0.92 (1.25)	0.076	0.494	0.010	0.945	-0.042	0.666
N = 493 (n = 229,  partially adjusted)					(-0.141 to 0.292)		(-0.269 to 0.288)		(-0.231 to 0.147)	
N = 389 (n = 183,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 475 (n = 216,  unadjusted)	28.45	31.48	27.95	28.45	1.688	0.113	0.555	0.136	0.972	0.081
N = 411 (n = 190,  partially adjusted)	(23.90–34.20)	(24.65–41.35)	(22.75–34.15)	(23.70–38.00)	(-0.397 to 3.772)		(-0.174 to 1.283)		(-0.119 to 2.063)	
N = 331 (n = 153,  fully adjusted)										
Body fat %										
N = 568 (n = 262, unadjusted)	20.61 (4.28)	20.87 (5.73)	20.26 (4.63)	20.06 (5.99)	0.556	0.405	-0.044	0.928	0.054	0.917
N = 544 (n = 256,  partially adjusted)					(-0.751 to 1.863)		(-0.986 to 0.899)		(-U.967 to 1.075)	
N = 398 (n = 187,  fully adjusted)										

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted) <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 508 (n = 229, unadjusted)	6912 (FOCA 7868)	7196	7031	7386	-192.002	0.152	-150.680	0.185	-113.857	0.338
N = 471 ( $n = 217$ , partially adjusted)	(5964–7868)	(0188-8376)	(6144–7964)	(6489–8462)	(-454.492 (0 70.488)		(-373.252 (0 71.892)		(-346.691 (0 118.978)	
N = 392 ( $n = 181$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 404 ( $n = 182$ , unadjusted)	96.48 (20.69)	95.26 (23.68)	97.64 (24.08)	96.23 (25.67)	-0.272	0.934	0.449 ( 5.805 to 7.702)	0.903	-0.054	0.986
N = 338 ( $n = 160$ , partially adjusted)					(-0.074 (0 0.131)		(-6.806 (0 7.703)		(-6.289 (0 6.180)	
N = 320 ( $n = 151$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 574 ( $n = 264$ , unadjusted)	73.91	76.09	73.91	76.09	-0.573	0.706	-0.882	0.678	1.010	0.632
N = 550 (n = 259,  partially adjusted)	(63.04–83.70)	(65.22-86.96)	(60.87-82.61)	(67.39-86.96)	(-3.555 to 2.409)		(-5.040 to 3.276)		(-3.127 to 5.147)	
N = 406 ( $n = 190$ , fully adjusted)										
CHU9D utility score										
N = 565 (n = 260, unadjusted)	0.85 (0.12)	0.88 (0.11)	0.83 (0.14)	0.86 (0.09)	0.020	0.089	0.021	0.081	0.026	0.074
N = 527 (n = 245,  partially adjusted)					(-0.003 to 0.043)		(-0.003 to 0.045)		(-0.003 to 0.055)	
N = 388 (n = 178,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 571 (n = 262, unadjusted)	26 (9.00)	33 (12.60)	33 (9.85)	39 (12.62)	-0.000	0.992	-0.012	0.707	-0.009	0.717
N = 548 ( $n = 257$ , partially adjusted)					(-0.040 to 0.057)		(-0.058 to 0.063)		(-0.046 to 0.046)	
N = 402 ( $n = 188$ , fully adjusted)										
										continued

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#### TABLE 43 Adjusted differences for key variables between control and intervention groups at FU1: ethnicity – white only (continued)

	Arm			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted) <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 571 (n = 262, unadjusted)	49 (16.96)	69 (26.34)	69 (20.60)	74 (23.95)	0.023	0.596	0.012	0.774	0.037	0.441
N = 548 (n = 257,  partially adjusted)					(-0.053 to 0.131)		(-0.061 to 0.115)		(-0.048 to 0.161)	
N = 402 ( $n = 188$ , fully adjusted)										
Five or more portions of fruit and veg	etables <sup>i</sup>									
N = 508 (n = 229, unadjusted)	151 (59.22)	114 (49.78)	193 (64.33)	131 (46.95)	0.028	0.628	0.035	0.553	0.105	0.007
N = 471 ( $n = 217$ , partially adjusted)					(-0.077 to 0.161)		(-0.072 to 0.170)		(0.027 to 0.194)	
N = 392 ( $n = 181$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 402 (n = 181, unadjusted)	87 (39.55)	97 (53.59)	133 (51.35)	120 (54.30)	-0.007	0.918	0.034	0.678	0.006	0.937
N = 333 ( $n = 157$ , partially adjusted)					(-0.126 (0 0.146)		(-0.108 to 0.224)		(-0.119 (0 0.169)	
N = 316 ( $n = 149$ , fully adjusted)										

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

j Adjusted for minutes of PA per 24 hours.

#### TABLE 44 Adjusted differences for key variables between control and intervention groups at FU1: ethnicity – South Asian only

	Arm	Arm				Intervention vs. control						
Follow-up outcome variable:	Intervention		Control									
N = total participants ( $n =$ number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>®</sup>		Fully adjusted <sup>b</sup>			
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR) <sup>c</sup>	Mean (SD) or	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p-value		
N = 389 (n = 190, unadjusted)	-0.00 (1.42)	0.15 (1.52)	-0.03 (1.33)	0.03 (1.46)	0.112	0.498	-0.080	0.367	-0.077	0.422		
N = 369 ( $n = 179$ , partially adjusted)					(-0.213 to 0.437)		(–0.253 to 0.093)		(–0.265 to 0.111)			
N = 259 ( $n = 127$ , fully adjusted)												
Height (cm)												
N = 389 (n = 179, unadjusted)	118.47 (5.79)	126.94 (6.20)	118.17 (5.23)	126.76 (5.58)	0.175	0.719	-0.002	0.995	0.104	0.788		
N = 369 ( $n = 179$ , partially adjusted)					(-0.778 to 1.128)		(-0.734 to 0.730)		(-0.653 to 0.862)			
N = 259 ( $n = 127$ , fully adjusted)												
Waist z-score												
N = 365 ( $n = 180$ , unadjusted)	0.50 (1.43)	1.01 (1.42)	0.49 (1.47)	0.76 (1.49)	0.252	0.091	0.168	0.156	0.194 ( 0.005 to 0.202)	0.056		
N = 329 ( $n = 156$ , partially adjusted)					(-0.040 to 0.544)		(-0.064 to 0.401)		(-0.005 to 0.393)			
N = 237 ( $n = 111$ , fully adjusted)												
Sum of four skinfolds (mm) <sup>d,e</sup>												
N = 333 (n = 167, unadjusted)	29.50	31.55	28.65	31.70	0.712	0.637	0.130	0.768	0.051	0.896		
N = 283 ( $n = 136$ , partially adjusted)	(22.95-37.40)	(26.00-50.00)	(23.20–38.35)	(23.05–47.25)	(-2.240 (0 3.663)		(-0.736 (0 0.997)		(-0.713 to 0.814)			
N = 210 ( $n = 103$ , fully adjusted)												
Body fat %												
N = 385 ( $n = 190$ , unadjusted)	21.41 (5.89)	22.32 (7.60)	21.75 (5.46)	21.84 (6.48)	0.480	0.503	-0.152	0.767	-0.445	0.391		
N = 359 ( $n = 177$ , partially adjusted)					(-0.927 (0 1.888)		(-1.155 (0 0.851)		(-1.462 (0 0.572)			
N = 254 ( $n = 126$ , fully adjusted)												
										continued		

### TABLE 44 Adjusted differences for key variables between control and intervention groups at FU1: ethnicity – South Asian only (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
<i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 351 (n = 171, unadjusted)	6384	7137	6644	6564	501.593	0.093	339.206	0.211	232.957	0.395
N = 293 ( $n = 138$ , partially adjusted)	(5307-8035)	(6151–8418)	(5303-7969)	(5505-7517)	(-84.445 (0 1087.631)		(-192.377 (0 870.788)		(-303.526 (0 769.440)	
N = 246 (n = 116,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 269 (n = 129, unadjusted)	96.30 (23.05)	87.93 (23.53)	95.10 (25.21)	89.57 (26.25)	-1.898	0.607	-2.979	0.430	-3.155	0.427
N = 223 ( $n = 106$ , partially adjusted)					(-9.123 (0 5.327)		(-10.374 to 4.416)		(-10.945 (0 4.635)	
N = 198 (n = 98,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 374 (n = 174, unadjusted)	69.57	76.09	71.74	76.09	-0.702	0.661	-0.728	0.740	0.702	0.719
N = 349 (n = 164,  partially adjusted)	(57.61–80.43)	(05.22-82.01)	(58.70-80.43)	(05.22-84.78)	(-3.839 (0 2.435)		(-5.037 (0 3.581)		(-3.121 (0 4.526)	
N = 242 ( $n = 113$ , fully adjusted)										
CHU9D utility score										
N = 370 (n = 174, unadjusted)	0.83 (0.14)	0.86 (0.11)	0.79 (0.16)	0.86 (0.11)	-0.003	0.856	-0.011	0.478	-0.010	0.560
N = 341 (n = 163,  partially adjusted)					(-0.036 (0 0.030)		(-0.040 (0 0.019)		(-0.045 (0 0.024)	
N = 235 ( $n = 112$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 389 (n = 190, unadjusted)	27 (12.98)	33 (17.37)	23 (10.95)	31 (15.58)	0.018	0.584	-0.050	0.129	0.013	0.728
N = 369 (n = 179,  partially adjusted)					(-0.038 (0 0.101)		(-0.093 (0 0.018)		(-0.049 (0 0.108)	
N = 259 (n = 127,  fully adjusted)										

Arm				Intervention vs. control						
Intervention		Control								
Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
44 (21.15)	54 (28.42)	38 (18.10)	51 (25.63)	0.028	0.495	-0.041	0.281	-0.044	0.339	
				(-0.045 to 0.126)		(-0.100 to 0.039)		(-0.112 to 0.055)		
etables <sup>i</sup>										
94 (54.65)	75 (43.86)	119 (65.75)	94 (52.22)	-0.084	0.184	-0.096	0.167	-0.096	0.189	
				(-0.183 to 0.045)		(-0.204 to 0.046)		(-0.208 to 0.055)		
67 (44.08)	61 (46.56)	76 (46.06)	64 (45.39)	0.007	0.933	-0.003	0.975	0.009	0.916	
				(-0.138 (0 0.220)		(-0.148 (0 0.210)		(-0.130 (0 0.220)		
	Arm Intervention Baseline 44 (21.15) 44 (21.15) 94 (54.65) 94 (54.65) 67 (44.08)	Arm         Intervention         Baseline       FU1         44 (21.15)       54 (28.42)         etables <sup>i</sup> 94 (54.65)         94 (54.65)       75 (43.86)         67 (44.08)       61 (46.56)	Arm       Control         Intervention       Control         Baseline       FU1       Baseline         44 (21.15)       54 (28.42)       38 (18.10)         44 (21.15)       54 (28.42)       38 (18.10)         etables <sup>i</sup> 94 (54.65)       75 (43.86)       119 (65.75)         67 (44.08)       61 (46.56)       76 (46.06)	Arm         Control           Intervention         Control           Baseline         FU1         Baseline         FU1           44 (21.15)         54 (28.42)         38 (18.10)         51 (25.63)           etables <sup>i</sup> 94 (54.65)         75 (43.86)         119 (65.75)         94 (52.22)           67 (44.08)         61 (46.56)         76 (46.06)         64 (45.39)	Arm       Intervention       Control         Baseline       FU1       Baseline       FU1       Unadjusted         44 (21.15)       54 (28.42)       38 (18.10)       51 (25.63) $0.028$ (- $0.045$ to $0.126$ )         etables <sup>i</sup> 94 (54.65)       75 (43.86)       119 (65.75)       94 (52.22) $-0.084$ (- $0.183$ to $0.045$ )         67 (44.08)       61 (46.56)       76 (46.06)       64 (45.39) $0.007$ (- $0.138$ to $0.220$ )	Arm         Control         Intervention vs. control           Baseline         FU1         Baseline         FU1         Unadjusted           44 (21.15)         54 (28.42)         38 (18.10)         51 (25.63)         0.028 (-0.045 to 0.126)         0.495 (-0.045 to 0.126)           etables <sup>i</sup> 94 (54.65)         75 (43.86)         119 (65.75)         94 (52.22)         -0.084 (-0.183 to 0.045)         0.184 (-0.183 to 0.045)           67 (44.08)         61 (46.56)         76 (46.06)         64 (45.39)         0.007 (-0.138 to 0.220)         0.933	Arm         Control         Intervention vs. control         Partially adjusted <sup>3</sup> Baseline         FU1         Baseline         FU1         Duadjusted         Partially adjusted <sup>3</sup> 44 (21.15)         54 (28.42)         38 (18.10)         51 (25.63)         0.028 (-0.045 to 0.126)         0.495         -0.041 (-0.100 to 0.039)           etables'         94 (54.65)         75 (43.86)         119 (65.75)         94 (52.22)         -0.084 (-0.183 to 0.045)         0.184         -0.096 (-0.204 to 0.046)           67 (44.08)         61 (46.56)         76 (46.06)         64 (45.39)         0.007 (-0.138 to 0.220)         0.933         -0.003 (-0.148 to 0.210)	Arm         Intervention         Control           Baseline         FU1         Baseline         FU1         Vadjusted         Partially adjusted <sup>a</sup> 44 (21.15)         54 (28.42)         38 (18.10)         51 (25.63)         0.028 (-0.045 to 0.126)         0.495         -0.041 (-0.100 to 0.039)         0.281           etables'         94 (54.65)         75 (43.86)         119 (65.75)         94 (52.22)         -0.084 (-0.183 to 0.045)         0.184         -0.096 (-0.204 to 0.046)         0.167           67 (44.08)         61 (46.56)         76 (46.06)         64 (45.39)         0.007 (-0.138 to 0.220)         0.933         -0.003 (-0.148 to 0.210)         0.975	Arm         Intervention         Control           Baseline         FU1         Baseline         FU1         Unadjusted         Partially adjusted <sup>a</sup> Fully adjusted <sup>b</sup> 44 (21.15)         54 (28.42)         38 (18.10)         51 (25.63)         0.028 (-0.045 to 0.126)         0.495 (-0.045 to 0.039)         0.281 (-0.100 to 0.039)         -0.044 (-0.112 to 0.055)           etables'         -         -         -         -         -           94 (54.65)         75 (43.86)         119 (65.75)         94 (52.22)         -0.084 (-0.133 to 0.045)         0.184 (-0.138 to 0.220)         -0.096 (-0.204 to 0.046)         0.167 (-0.138 to 0.220)         -0.093 (-0.148 to 0.210)         0.975         0.009 (-0.136 to 0.220)	

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

- d Transformed via inverse.
- e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.
- f Transformed via natural logarithm.
- g Transformed via squaring.
- h Adjusted for baseline BMI-z.
- i Adjusted for total grams of fruit and vegetables consumed per day.
- j Adjusted for minutes of PA per 24 hours.

## TABLE 45 Adjusted differences for key variables between control and intervention groups at FU1: ethnicity – black African Caribbean only

ollow-up outcome variable:	Arm				Intervention vs. control					
N = total participants	Intervention		Control							
( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR)⁰	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e
N = 94 ( $n = 48$ , unadjusted)	0.72 (1.36)	0.79 (1.27)	0.55 (1.05)	0.58 (1.11)	0.209	0.394	-0.044	0.732	-0.372	0.009
N = 90 (n = 46,  partially adjusted)					(-0.272 to 0.690)		(-0.296 to 0.208)		(-0.652 to -0.091)	
N = 50 (n = 22,  fully adjusted)										
Height (cm)										
N = 94 ( $n = 47$ , unadjusted)	121.72 (5.89)	130.64 (6.79)	120.76 (5.51)	129.55 (5.76)	1.092	0.412	0.332	0.623	-0.066	0.911
N = 91 (n = 47,  partially adjusted)					(-1.514 to 3.698)		(-0.991 to 1.656)		(-1.222 to 1.090)	
N = 50 (n = 22,  fully adjusted)										
Waist z-score										
N = 81 (n = 41,  unadjusted)	1.24 (1.52)	1.32 (1.54)	0.85 (1.00)	1.00 (1.03)	0.326	0.248	-0.047	0.808	-0.689	< 0.001
N = 76 (n = 38,  partially adjusted)					(-0.227 to 0.880)		(-0.426 to 0.332)		(-1.044 to -0.333)	
N = 47 (n = 20,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 71 (n = 37, unadjusted)	28.52	32.40	26.30	28.65	0.889	0.791	-0.375	0.558	-0.701	0.270
N = 61 (n = 32,  partially adjusted)	(23.75–40.65)	(21.05–43.65)	(22.50–36.50)	(23.55–42.90)	(-5.676 to 7.454)		(-1.627 to 0.878)		(-1.947 to 0.545)	
N = 37 ( $n = 18$ , fully adjusted)										
Body fat %										
N = 90 (n = 48,  unadjusted)	24.09 (6.53)	24.01 (7.57)	22.66 (4.65)	22.34 (6.57)	1.909	0.301	-0.535	0.642	-2.198	0.038
N = 85 ( $n = 46$ , partially adjusted)					(–1./11 to 5.530)		(–2.789 to 1.719)		(–4.278 to –0.118)	
N = 46 ( $n = 22$ , fully adjusted)										

Follow-up outcome variable:	Arm				Intervention vs. contro	ol				
N = total participants	Intervention		Control							
arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 81 ( $n = 41$ , unadjusted)	7777	6990	7007	7224	-561.581	0.173	-511.770	0.117	-417.325	0.381
N = 66 (n = 30,  partially adjusted)	(6522–8511)	(5/1/-8066)	(51/3–/964)	(6262–8949)	(-1369.895 to 246.733)		(-1151.293 to 127.753)		(-1350.508 to 515.858)	
N = 47 ( $n = 21$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 57 ( $n = 26$ , unadjusted)	87.88 (27.15)	82.69 (21.86)	76.39 (17.45)	80.68 (20.74)	2.011	0.672	0.822	0.896	1.183	0.816
N = 44 ( $n = 20$ , partially adjusted)					(-7.291 to 11.314)		(-11.456 to 13.100)		(-8.801 to 11.167)	
N = 38 ( $n = 15$ , fully adjusted)										
PedsQL total score <sup>9</sup>										
N = 94 ( $n = 48$ , unadjusted)	69.57	73.91	73.91	71.74	0.531	0.892	0.690	0.870	-5.222	0.580
N = 91 (n = 47,  partially adjusted)	(58.70-80.43)	(63.04–85.87)	(60.87–84.78)	(65.22–78.26)	(-7.105 to 8.166)		(-7.572 to 8.952)		(-23./34 to 13.289)	
N = 50 ( $n = 22$ , fully adjusted)										
CHU9D utility score										
N = 94 ( $n = 48$ , unadjusted)	0.81 (0.16)	0.86 (0.12)	0.83 (0.15)	0.85 (0.10)	0.005	0.866	0.007	0.788	-0.035	0.189
N = 89 (n = 45,  partially adjusted)					(-0.050 to 0.059)		(-0.047 to 0.062)		(-0.087 to 0.017)	
N = 48 ( $n = 20$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>valu</i> e
N = 94 ( $n = 48$ , unadjusted)	14 (23.33)	12 (25.00)	13 (25.49)	10 (21.74)	0.033	0.650	-0.090	0.125	-0.028	0.837
N = 90 (n = 46,  partially adjusted)					(–0.081 to 0.240)		(–0.155 to 0.034)		(–0.171 to 0.479)	
N = 50 ( $n = 22$ , fully adjusted)										
										continued

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#### TABLE 45 Adjusted differences for key variables between control and intervention groups at FU1: ethnicity – black African Caribbean only (continued)

Follow-up outcome variable:	Arm				Intervention vs. control						
N = total participants	Intervention		Control								
arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
Obese/overweight <sup>h</sup>											
N = 94 ( $n = 48$ , unadjusted)	23 (38.33)	17 (35.42)	16 (31.37)	15 (32.61)	0.028	0.767	-0.097	0.294	-0.188	0.122	
N = 90 (n = 46,  partially adjusted)					(-0.121 (0 0.285)		(-0.210100.115)		(-0.286 (0 0.081)		
N = 50 (n = 22,  fully adjusted)											
Five or more portions of fruit and veg	etables <sup>i</sup>										
N = 81 ( $n = 41$ , unadjusted)	24 (55.81)	19 (46.34)	28 (65.12)	25 (62.50)	-0.162	0.150	-0.147	0.105	-0.210	0.213	
N = 66 (n = 30,  partially adjusted)					(-0.317 to 0.071)		(-0.282 to 0.036)		(-0.414 to 0.161)		
N = 47 ( $n = 21$ , fully adjusted)											
Achieving $\geq$ 60 minutes of PA <sup>i</sup>											
N = 56 (n = 26, unadjusted)	22 (56.41)	17 (65.38)	15 (45.45)	16 (53.33)	0.121	0.263	0.074	0.612	0.446	0.043	
N = 42 ( $n = 20$ , partially adjusted)					(-0.076 to 0.400)		(-U. 104 TO U.482)		(0.010 to 1.255)		

N = 37 (n = 15, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

j Adjusted for minutes of PA per 24 hours.

**TABLE 46** Adjusted differences for key variables between control and intervention groups at FU1: ethnicity – interaction terms

	<i>p</i> -value of interaction term									
	Unadjust	ed model	Partially adjus	ted model <sup>a</sup>	Fully adjus	ted model <sup>b</sup>				
Variable	South Asian	African Caribbean	South Asian	African Caribbean	South Asian	African Caribbean				
Continuous outcomes										
BMI-z	0.567	0.389	0.961	0.667	0.819	0.678				
Height (cm)	0.734	0.606	0.959	0.621	0.906	0.692				
Waist z-score	0.280	0.340	0.779	0.583	0.344	0.758				
Sum of four skinfolds (mm) <sup>c,d</sup>	0.588	0.931	0.213	0.486	0.188	0.635				
Body fat %	0.797	0.523	0.712	0.773	0.592	0.851				
Energy intake (kJ in 24 hours) <sup>e</sup>	0.044	0.360	0.141	0.380	0.193	0.339				
PA energy expenditure (kJ/kg/day)	0.916	0.816	0.645	0.701	0.433	0.616				
PedsQL total score <sup>f</sup>	0.745	0.642	0.769	0.543	0.949	0.907				
CHU9D utility score	0.120	0.597	0.026	0.659	0.034	0.080				
Binary outcomes										
Obese <sup>g</sup>	0.693	0.698	0.632	0.185	0.847	0.438				
Obese/overweight <sup>9</sup>	0.971	0.970	0.157	0.145	0.186	0.028				
Five or more portions of fruit and vegetables <sup>h</sup>	0.183	0.100	0.185	0.072	0.059	0.076				
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.861	0.269	0.775	0.716	0.543	0.290				

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode),
 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll),
 percentage of school population South Asian, percentage of school population black African Caribbean, percentage of
 free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

i Adjusted for minutes of PA per 24 hours.

## TABLE 47 Adjusted differences for key variables between control and intervention groups at FU1: fidelity score = 3 (higher fidelity)

	Arm									
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or r	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 874 (n = 199, unadjusted)	0.18 (1.15)	0.38 (1.24)	0.15 (1.20)	0.23 (1.27)	0.126	0.193	0.024	0.691	0.007	0.911
N = 832 ( $n = 191$ , partially adjusted)					(-0.064-0.317)		(-0.094-0.142)		(-0.108-0.121)	
N = 587 (n = 143,  fully adjusted)										
Height (cm)										
N = 875 (n = 192, unadjusted)	118.64 (5.87)	127.30 (6.55)	118.18 (5.38)	127.03 (5.75)	0.276	0.438	-0.319	0.282	-0.367	0.242
N = 834 ( $n = 192$ , partially adjusted)					(-0.421-0.972)		(-0.901-0.262)		(-0.982-0.248)	
N = 588 (n = 143,  fully adjusted)										
Waist z-score										
$N = 809 \ (n = 186, \text{ unadjusted})$	0.75 (1.22)	1.05 (1.46)	0.66 (1.25)	0.87 (1.32)	0.173	0.057	-0.031	0.864	-0.030	0.760
N = 752 (n = 173,  partially adjusted)					(-0.005-0.350)		(-0.388-0.326)		(-0.222-0.162)	
N = 564 (n = 136,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 731 (n = 171, unadjusted)	26.35	31.25	28.10	29.40	1.890	0.012	0.912	0.008	0.807	0.030
N = 626 (n = 145,  partially adjusted)	(21.43–32.63)	(26.00–42.15)	(23.00–36.60)	(23.63–41.67)	(0.409 to 3.372)		(0.240 to 1.585)		(0.080 to 1.534)	
N = 476 (n = 116,  fully adjusted)										
Body fat %										
N = 861 (n = 199, unadjusted)	20.92 (5.09)	21.94 (6.43)	20.95 (5.22)	20.87 (6.30)	1.022 (0.104–1.939)	0.029	0.741 (0.011–1.471)	0.047	0.642	0.098
N = 805 (n = 189,  partially adjusted)									(-0.118-1.402)	
N = 572 ( $n = 141$ , fully adjusted)										

	Arm									
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 785 (n = 180, unadjusted)	6936	6931 (5801, 8000)	6911 (5804-7064)	7074	-214.756	0.289	-193.957	0.299	-308.111	0.044
N = 694 ( $n = 165$ , partially adjusted)	(5922-8098)	(0008-1082)	(5804–7964)	(5963-8233)	(-011.405 (0 181.953)		(-559.700 (0 171.786)		(–607.526 to –8.696)	
N = 570 (n = 136,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 598 (n = 125, unadjusted)	96.35 (21.87)	89.90	94.08 (24.38)	91.27 (25.42)	-2.330	0.407	-2.893	0.336	-3.072	0.316
N = 497 ( $n = 108$ , partially adjusted)		(21.07)			(-7.835 (0 3.176)		(-8.788 (0 3.002)		(-9.081-2.937)	
N = 450 ( $n = 102$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
<i>N</i> = 854 ( <i>n</i> = 177, unadjusted)	71.74	76.09	73.91	76.09	-0.137	0.939	0.583 ( .2.886 to 5.052)	0.798	1.179 (	0.520
N = 804 ( $n = 171$ , partially adjusted)	(58.70–80.43)	(65.22-84.78)	(60.87-82.61)	(65.22–84.78)	(-3.646 to 3.372)		(-3.886 to 5.052)		(-2.412 to 4.769)	
N = 566 (n = 124,  fully adjusted)										
CHU9D utility score										
N = 841 (n = 176, unadjusted)	0.83 (0.14)	0.86 (0.11)	0.82 (0.14)	0.86 (0.10)	0.865	< 0.001	0.221	0.036	0.317	< 0.001
N = 775 ( $n = 164$ , partially adjusted)					(0.834 to 0.896)		(0.014 to 0.427)		(0.173 to 0.462)	
N = 545 ( $n = 117$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 874 (n = 199, unadjusted)	26 (11.40)	32 (16.08)	87 (11.89)	100 (14.81)	0.013	0.517	0.001	0.954	0.012	0.664
N = 832 ( $n = 191$ , partially adjusted)					(-0.023-0.058)		(-0.041-0.060)		(-0.036-0.081)	
N = 587 (n = 143,  fully adjusted)										
										continued

#### TABLE 47 Adjusted differences for key variables between control and intervention groups at FU1: fidelity score = 3 (higher fidelity) (continued)

	Arm									
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 874 (n = 199, unadjusted)	46 (20.18)	57 (28.64)	150 (20.49)	167 (24.74)	0.039	0.213	0.033	0.546	0.024	0.569
N = 832 ( $n = 191$ , partially adjusted)					(-0.020-0.113)		(-0.061-0.173)		(-0.051-0.128)	
N = 587 (n = 143,  fully adjusted)										
Five or more portions of fruit and vege	Five or more portions of fruit and vegetables <sup>i</sup>									
N = 785 (n = 180, unadjusted)	129 (62.62)	75 (41.67)	405 (64.80)	297 (49.09)	-0.073	0.303	-0.067	0.392	-0.030	0.576
N = 694 ( $n = 165$ , partially adjusted)					(-0.184 to 0.077)		(-0.188 to 0.102)		(-0.121 to 0.084)	
N = 570 (n = 136,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 596 (n = 126, unadjusted)	87 (48.88)	71 (56.35)	276 (49.55)	234 (49.79)	0.051	0.377	0.075	0.303	0.037	0.556
N = 495 ( $n = 109$ , partially adjusted)					(-0.055 to 0.182)		(-0.059 to 0.252)		(-0.077-0.183)	
N = 447 ( $n = 103$ , fully adjusted)										

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

j Adjusted for minutes of PA per 24 hours.
#### TABLE 48 Adjusted differences for key variables between control and intervention groups at FU1: fidelity score = 2 (medium fidelity)

				5							
	Arm	Arm			Intervention vs. cont	rol					
Follow-up outcome variable:	Intervention		Control								
n =  number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	
N = 827 (n = 152, unadjusted)	0.36 (1.21)	0.39 (1.31)	0.15 (1.20)	0.23 (1.27)	0.135	0.200	-0.170	0.039	-0.178	0.055	
N = 790 (n = 149,  partially adjusted)					(-0.071 to 0.341)		(-0.332 to -0.009)		(-0.359 to 0.004)		
N = 556 (n = 112,  fully adjusted)											
Height (cm)											
N = 828 (n = 149, unadjusted)	118.36 (5.50)	127.60 (6.17)	118.18 (5.38)	127.03 (5.75)	0.573	0.463	0.272	0.671	-0.003	0.997	
N = 791 ( $n = 149$ , partially adjusted)					(-0.957 to 2.103)		(-0.983 to 1.527)		(-1.199 to 1.194)		
N = 557 (n = 112,  fully adjusted)											
Waist z-score											
N = 766 (n = 143, unadjusted)	0.96 (1.17)	1.25 (1.25)	0.66 (1.25)	0.87 (1.32)	0.358	0.027	0.094	0.468	0.098	0.303	
N = 715 ( $n = 136$ , partially adjusted)					(0.040 to 0.676)		(-0.161 to 0.350)		(-0.089 to 0.285)		
N = 532 ( $n = 104$ , fully adjusted)											
Sum of four skinfolds (mm) <sup>d,e</sup>											
N = 693 (n = 133, unadjusted)	31.55	30.80	28.10	29.40	1.835	0.122	-0.012	0.977	0.277	0.523	
N = 606 (n = 125,  partially adjusted)	(25.63–38.55)	(24.70–48.60)	(23.00–36.60)	(23.63–41.67)	(-0.489 to 4.158)		(-0.816 to 0.793)		(-0.574 to 1.127)		
N = 457 (n = 97,  fully adjusted)											
Body fat %											
N = 814 (n = 152, unadjusted)	21.35 (5.15)	21.16 (6.39)	20.95 (5.22)	20.87 (6.30)	0.203	0.700	-0.772	0.207	-0.550	0.426	
N = 765 ( $n = 149$ , partially adjusted)					(-0.830 to 1.236)		(-1.972 to 0.427)		(-1.904 to 0.804)		
N = 543 ( $n = 112$ , fully adjusted)											
										continued	

## TABLE 48 Adjusted differences for key variables between control and intervention groups at FU1: fidelity score = 2 (medium fidelity) (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 742 (n = 137, unadjusted)	6808	7191	6911	7074	141.872	0.472	78.522	0.618	-157.393	0.346
N = 659 (n = 130,  partially adjusted)	(5832–8064)	(6188-8209)	(5804–7964)	(5963-8233)	(-244.429 to 528.173)		(-230.509 to 387.553)		(-484.957 to 170.171)	
N = 537 (n = 103,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 589 (n = 116, unadjusted)	97.78 (23.58)	90.65 (23.30)	94.08 (24.38)	91.27 (25.42)	-1.019	0.711	-2.457	0.476	-3.771	0.283
N = 487 (n = 98,  partially adjusted)					(-0.401 (0 4.303)		(-9.219 (0 4.305)		(-10.656 (0 3.114)	
N = 440 (n = 92,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 830 (n = 153, unadjusted)	71.74	71.74	73.91	76.09	-2.914	0.030	-3.175	0.121	-3.520	0.083
N = 783 ( $n = 150$ , partially adjusted)	(60.87-82.61)	(60.87-82.61)	(60.87-82.61)	(65.22-84.78)	(-5.546 (0 -0.282)		(-7.192 (0 0.842)		(-7.503 (0 0.462)	
N = 555 ( $n = 113$ , fully adjusted)										
CHU9D utility score										
N = 817 (n = 152, unadjusted)	0.83 (0.13)	0.86 (0.12)	0.82 (0.14)	0.86 (0.10)	0.857	< 0.001	0.237	< 0.001	0.254	0.001
N = 755 ( $n = 144$ , partially adjusted)					(0.825 (0 0.889)		(0.118 (0 0.357)		(0.104 (0 0.404)	
N = 535 (n = 107,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p-value	RD (95% CI)	p- <i>value</i>
N = 827 (n = 152, unadjusted)	25 (14.79)	26 (17.11)	87 (11.89)	100 (14.81)	0.023	0.318	-0.053	0.111	0.012	0.631
N = 790 (n = 149,  partially adjusted)					(-0.019 (0 0.079)		(-0.094 (0 0.016)		(-0.031 (0 0.068)	
N = 556 (n = 112,  fully adjusted)										

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline FU1		Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 827 (n = 152, unadjusted)	41 (24.26)	44 (28.95)	150 (20.49)	167 (24.74)	0.042	0.143	-0.046	0.210	0.041	0.265
N = 790 (n = 149,  partially adjusted)					(-0.013 to 0.110)		(-0.101 to 0.030)		(-0.027 to 0.130)	
N = 556 ( $n = 112$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 742 ( $n = 137$ , unadjusted)	96 (61.15)	72 (52.55)	405 (64.80)	297 (49.09)	0.035	0.576	0.038	0.554	0.095	0.060
N = 659 (n = 130,  partially adjusted)					(-0.077 to 0.177)		(-0.077 to 0.183)		(-0.004 to 0.214)	
N = 537 ( $n = 103$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 586 (n = 116, unadjusted)	57 (43.18)	53 (45.69)	276 (49.55)	234 (49.79)	-0.047	0.534	0.019	0.829	-0.059	0.352
N = 483 ( $n = 97$ , partially adjusted)					(-0.168 (0.0.119)		(-0.131 to 0.233)		(-0.160 to 0.075)	

N = 435 (n = 91, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

j Adjusted for minutes of PA per 24 hours.

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or r	nedian (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e
N = 898 (n = 223, unadjusted)	0.19 (1.33)	0.27 (1.44)	0.15 (1.20)	0.23 (1.27)	0.038	0.727	-0.082	0.238	-0.058	0.344
N = 857 (n = 216,  partially adjusted)					(-0.176-0.253)		(-0.218-0.054)		(-0.177-0.062)	
N = 582 ( $n = 138$ , fully adjusted)										
Height (cm)										
N = 900 (n = 217, unadjusted)	118.79 (5.44)	127.28 (5.62)	118.18 (5.38)	127.03 (5.75)	0.255	0.491	-0.165	0.569	-0.294	0.394
N = 859 ( $n = 217$ , partially adjusted)					(-0.471 (0 0.982)		(-0.735 (0 0.404)		(-0.970-0.381)	
N = 583 ( $n = 138$ , fully adjusted)										
Waist z-score										
N = 822 (n = 199, unadjusted)	0.65 (1.30)	0.92 (1.33)	0.66 (1.25)	0.87 (1.32)	0.045	0.662	0.016	0.897	0.001	0.992
N = 760 (n = 181,  partially adjusted)					(-0.155 to 0.245)		(-0.229-0.262)		(-0.169-0.171)	
N = 556 (n = 128,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
$N = 744 \ (n = 184, \text{ unadjusted})$	28.38	31.75	28.10	29.40	0.437	0.658	0.243	0.530	0.337	0.473
N = 632 ( $n = 151$ , partially adjusted)	(23.82–35.38)	(23.27–42.30)	(23.00–36.60)	(23.63–41.67)	(-1.497 to 2.370)		(-0.515 to 1.001)		(-0.585 to 1.259)	
N = 470 (n = 111,  fully adjusted)										
Body fat %										
N = 885 (n = 223, unadjusted)	21.58 (5.69)	22.08 (7.19)	20.95 (5.22)	20.87 (6.30)	1.098	0.066	0.100	0.829	0.081	0.862
N = 831 ( $n = 215$ , partially adjusted)					(-U.U/3 to 2.269)		(-0.805-1.005)		(-0.836-0.999)	
N = 569 (n = 138,  fully adjusted)										

**APPENDIX 60** 

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 795 (n = 190, unadjusted)	6926	7328	6911 (5004-7054)	7074	430.562	0.104	290.758	0.178	393.089	0.082
N = 683 ( $n = 154$ , partially adjusted)	(5805–7971)	(6258–8785)	(5804–7964)	(5963–8233)	(-88.214 to 949.337)		(-132.734 to 714.250)		(-49.579 to 835.758)	
N = 564 ( $n = 130$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 627 (n = 154, unadjusted)	95.52 (24.15)	93.96 (25.90)	94.08 (24.38)	91.27 (25.42)	2.082	0.353	2.224	0.359	0.012	0.996
N = 518 ( $n = 129$ , partially adjusted)					(-2.314 to 6.478)		(-2.529 to 6.977)		(-4.318-4.341)	
N = 464 ( $n = 116$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 901 (n = 224, unadjusted)	71.74	76.09	73.91	76.09	0.642	0.621	0.373	0.828	1.662	0.372
N = 850 (n = 217,  partially adjusted)	(60.87–82.61)	(65.91–86.96)	(60.87-82.61)	(65.22–84.78)	(-1.903 to 3.187)		(-3.001 to 3.747)		(-1.986 to 5.310)	
N = 580 (n = 138,  fully adjusted)										
CHU9D utility score										
<i>N</i> = 887 ( <i>n</i> = 222, unadjusted)	0.84 (0.13)	0.88 (0.10)	0.82 (0.14)	0.86 (0.10)	0.025	0.028	0.021	0.050	0.029	0.004
N = 822 ( $n = 211$ , partially adjusted)					(0.003 (0 0.047)		(0.000 to 0.043)		(0.010 (0.049)	
N = 562 ( $n = 134$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n <i>(%)</i>		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>valu</i> e
N = 898 (n = 223, unadjusted)	33 (12.55)	35 (15.70)	87 (11.89)	100 (14.81)	0.009	0.714	-0.051	0.133	-0.025	0.333
N = 857 ( $n = 216$ , partially adjusted)					(-0.033 to 0.066)		(-0.093 to 0.020)		(-0.063 to 0.030)	
N = 582 ( $n = 138$ , fully adjusted)										
										continued

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#### TABLE 49 Adjusted differences for key variables between control and intervention groups at FU1: fidelity score = 1 (lower fidelity) (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 898 (n = 223, unadjusted)	58 (22.05)	64 (28.70)	150 (20.49)	167 (24.74)	0.040	0.166	-0.031	0.441	-0.030	0.420
N = 857 (n = 216,  partially adjusted)					(-0.015 to 0.107)		(-0.093 to 0.056)		(-0.090 to 0.051)	
N = 582 ( $n = 138$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 795 (n = 190, unadjusted)	111 (55.78)	97 (51.05)	405 (64.80)	297 (49.09)	0.020	0.673	-0.000	0.997	-0.016	0.703
N = 683 ( $n = 154$ , partially adjusted)					(-0.065 to 0.122)		(-0.083 to 0.099)		(-0.091 to 0.073)	
N = 564 ( $n = 130$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 624 (n = 154, unadjusted)	84 (46.41)	83 (53.90)	276 (49.55)	234 (49.79)	0.028	0.664	0.040	0.563	0.027	0.654
N = 514 ( $n = 128$ , partially adjusted)					(-0.086 to 0.174)		(-0.083 to 0.200)		(-0.080 to 0.162)	

N = 460 (n = 116, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

j Adjusted for minutes of PA per 24 hours.

**TABLE 50** Adjusted differences for key variables between control and intervention groups at FU1: fidelity score – interaction terms

	<i>p</i> -value of interaction term									
	Unadjusted	l model	Partially adjuste	ed model <sup>a</sup>	Fully adjust	ted <sup>b</sup>				
Variable	Low fidelity	Medium fidelity	Low fidelity	Medium fidelity	Low fidelity	Medium fidelity				
Continuous outcomes										
BMI-z	0.333	0.911	0.141	0.021	0.274	0.013				
Height (cm)	0.965	0.720	0.638	0.362	0.945	0.415				
Waist z-score	0.235	0.237	0.816	0.539	0.851	0.362				
Sum of four skinfolds (mm) <sup>c,d</sup>	0.093	0.999	0.163	0.055	0.213	0.098				
Body fat %	0.865	0.088	0.154	0.014	0.165	0.026				
Energy intake (kJ in 24 hours) <sup>e</sup>	0.024	0.118	0.047	0.172	0.005	0.241				
PA energy expenditure (kJ/kg/day)	0.061	0.670	0.071	0.901	0.168	0.995				
PedsQL total score <sup>f</sup>	0.674	0.164	0.952	0.169	0.839	0.030				
CHU9D utility score	0.269	0.658	0.447	0.501	0.207	0.440				
Binary outcomes										
Obese <sup>9</sup>	0.878	0.668	0.602	0.192	0.984	0.350				
Obese/overweight <sup>9</sup>	0.986	0.927	0.576	0.192	0.965	0.166				
Five or more portions of fruit and vegetables <sup>h</sup>	0.231	0.214	0.200	0.140	0.367	0.028				
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.754	0.221	0.862	0.684	0.999	0.343				

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

i Adjusted for minutes of PA per 24 hours.

	Arm	Arm				Intervention vs. control				
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or n	nedian (IQR) <sup>c</sup>	Mean (SD) or r	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 640 (n = 280, unadjusted)	0.35 (1.36)	0.50 (1.47)	0.13 (1.25)	0.25 (1.29)	0.253	0.011	-0.076	0.210	-0.098	0.138
N = 618 (n = 272,  partially adjusted)					(0.059 to 0.446)		(-0.194 to 0.043)		(-0.227 to 0.031)	
N = 432 ( $n = 193$ , fully adjusted)										
Height (cm)										
N = 640 (n = 272, unadjusted)	119.32 (5.54)	128.22 (6.08)	118.86 (5.40)	127.72 (5.82)	0.500	0.254	-0.000	0.999	-0.137	0.670
N = 618 (n = 272,  partially adjusted)					(-0.360 to 1.359)		(-0.599 to 0.599)		(-0.769 to 0.494)	
N = 432 ( $n = 193$ , fully adjusted)										
Waist z-score										
N = 601 (n = 266, unadjusted)	0.77 (1.27)	1.15 (1.36)	0.61 (1.23)	0.82 (1.32)	0.329	0.001	0.083	0.288	0.070	0.233
N = 568 (n = 252,  partially adjusted)					(0.135 to 0.523)		(-0.070 to 0.236)		(-0.045 to 0.185)	
N = 418 ( $n = 186$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 542 (n = 245, unadjusted)	25.70	28.70	25.80	25.70	1.674	0.027	0.331	0.226	0.362	0.198
N = 476 (n = 219,  partially adjusted)	(21.30–32.80)	(21.90–40.35)	(21.40–32.10)	(21.70–34.50)	(0.192 to 3.156)		(-0.205 to 0.867)		(–0.189 to 0.914)	
N = 353 ( $n = 167$ , fully adjusted)										
Body fat %										
N = 631 (n = 280, unadjusted)	20.86 (5.19)	21.24 (7.23)	20.21 (4.72)	19.63 (5.89)	1.607	0.001	0.283	0.479	0.210	0.579
N = 598 (n = 270,  partially adjusted)					(U.668 to 2.546)		(-0.500 to 1.067)		(–0.533 to 0.953)	
N = 423 ( $n = 192$ , fully adjusted)										

**APPENDIX 60** 

	Arm				Intervention vs. cont	trol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 572 ( $n = 254$ , unadjusted)	7151	7193	7119	7207	77.484	0.725	36.778	0.848	18.341	0.931
N = 498 ( $n = 219$ , partially adjusted)	(6126-8300)	(6129-8477)	(5998–8223)	(5938–8303)	(-355.031 to 509.999)		(-339.655 to 413.212)		(-395.820 to 432.502)	
N = 411 (n = 183,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 439 (n = 192, unadjusted)	103.42 (23.84)	98.01 (24.10)	100.36	97.25 (25.43)	0.726	0.790	-2.907	0.322	-3.761	0.170
N = 367 (n = 165,  partially adjusted)			(25.02)		(-4.619 to 6.070)		(-8.665 to 2.850)		(-9.128 to 1.605)	
N = 328 ( $n = 150$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 628 (n = 267, unadjusted)	70.65	76.09	73.91	76.09	-1.748	0.149	-1.679	0.295	-1.715	0.317
N = 601 (n = 260,  partially adjusted)	(59.98–82.61)	(63.04–84.78)	(60.87–84.78)	(67.39–84.78)	(-4.124 to 0.627)		(-4.821 to 1.462)		(-5.076 to 1.646)	
N = 420 ( $n = 182$ , fully adjusted)										
CHU9D utility score										
N = 617 (n = 265, unadjusted)	0.83 (0.14)	0.86 (0.11)	0.82 (0.15)	0.86 (0.11)	0.006	0.633	0.005	0.662	0.008	0.506
N = 579 (n = 253,  partially adjusted)					(-0.017 to 0.028)		(-0.018 to 0.028)		(-0.016 to 0.033)	
N = 406 ( $n = 176$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p-value	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 640 (n = 280, unadjusted)	50 (15.20)	59 (21.07)	51 (13.04)	57 (15.83)	0.049	0.015	-0.025	0.233	0.012	0.623
N = 618 (n = 272,  partially adjusted)					(0.009 to 0.100)		(–0.057 to 0.018)		(-0.030 to 0.067)	
N = 432 ( $n = 193$ , fully adjusted)										
										continued

#### TABLE 51 Adjusted differences for key variables between control and intervention groups at FU1: boys only (continued)

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 640 (n = 280, unadjusted)	90 (27.36)	99 (35.36)	78 (19.95)	87 (24.173)	0.112	0.001	0.020	0.558	0.042	0.314
N = 618 (n = 272,  partially adjusted)					(0.043 to 0.197)		(-0.040 to 0.097)		(-0.034 to 0.146)	
N = 432 ( $n = 193$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 572 (n = 254, unadjusted)	157 (57.30)	109 (42.91)	206 (62.05)	135 (42.45)	0.010	0.862	0.011	0.843	0.033	0.497
N = 498 (n = 219,  partially adjusted)					(-0.088 to 0.136)		(-0.086 to 0.136)		(-0.055 to 0.142)	
N = 411 (n = 183,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 435 (n = 189, unadjusted)	138 (56.10)	116 (61.38)	161 (54.76)	141 (57.32)	0.041	0.494	0.051	0.400	-0.011	0.832
N = 362 ( $n = 162$ , partially adjusted)					(-0.069 to 0.174)		(-0.061 to 0.187)		(-0.102 to 0.099)	
N = 323 ( $n = 148$ , fully adjusted)										

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

j Adjusted for minutes of PA per 24 hours.

## TABLE 52 Adjusted differences for key variables between control and intervention groups at FU1: girls only

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
<i>N</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 609 (n = 294, unadjusted)	0.11 (1.10)	0.18 (1.17)	0.16 (1.15)	0.20 (1.25)	-0.038	0.762	-0.041	0.539	-0.054	0.472
N = 579 (n = 284,  partially adjusted)					(-0.281 to 0.206)		(-0.170 to 0.089)		(-0.200 to 0.093)	
N = 405 (n = 200,  fully adjusted)										
Height (cm)										
N = 611 (n = 286, unadjusted)	117.95 (5.59)	126.56 (6.00)	117.40 (5.25)	126.23 (5.57)	0.333	0.438	-0.105	0.736	-0.216	0.499
N = 582 ( $n = 286$ , partially adjusted)					(-0.509 to 1.175)		(-0.716 to 0.506)		(-0.843 to 0.411)	
N = 406 (n = 200,  fully adjusted)										
Waist z-score										
N = 550 (n = 262, unadjusted)	0.76 (1.22)	0.96 (1.36)	0.71 (1.27)	0.94 (1.32)	0.015	0.912	-0.020	0.876	-0.022	0.842
N = 501 (n = 238,  partially adjusted)					(-0.249 to 0.279)		(-0.277 to 0.236)		(-0.241 to 0.197)	
N = 378 (n = 182,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 506 (n = 243, unadjusted)	30.80	33.60	32.00	34.00	0.058	0.966	0.163	0.662	0.144	0.758
N = 426 ( $n = 202$ , partially adjusted)	(25.70–38.35)	(27.75–47.95)	(25.45–40.42)	(27.65–47.55)	(-2.617 to 2.733)		(-0.568 to 0.893)		(-0.770 to 1.057)	
N = 330 (n = 156,  fully adjusted)										
Body fat %										
N = 605 (n = 294, unadjusted)	21.72 (5.49)	22.31 (6.18)	21.79 (5.62)	22.27 (6.47)	-0.102	0.876	-0.215	0.634	-0.074	0.888
N = 571 (n = 283,  partially adjusted)					(-1.381 to 1.178)		(-1.098 to 0.669)		(-1.108 to 0.959)	
N = 399 (n = 199,  fully adjusted)										
										continued

# TABLE 52 Adjusted differences for key variables between control and intervention groups at FU1: girls only (continued)

	<u>Arm</u>				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 540 (n = 253, unadjusted)	6644 (FFOC 7772)	7052	6719	6918	183.372	0.363	59.870	0.723	61.088 ( 220.025 to 201.212)	0.690
N = 480 (n = 230,  partially adjusted)	(5596-7772)	(6100-8207)	(5591-7639)	(5971-8170)	(-211.505 (0 578.248)		(-271.652 (0.391.392)		(-239.035 (0 301.212)	
N = 392 (n = 186,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 429 (n = 203, unadjusted)	89.38 (20.18)	85.73 (21.76)	86.98 (21.57)	84.73 (23.80)	-0.006	0.998	2.126	0.419	0.220	0.928
N = 357 (n = 170,  partially adjusted)					(-5.197 (0 5.164)		(-3.031 (0 7.284)		(-4.500 (0 5.000)	
N = 330 (n = 160,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 603 (n = 287, unadjusted)	71.74	76.09	71.74	73.91	0.699	0.633	1.012	0.635	1.034	0.694
N = 570 (n = 278,  partially adjusted)	(60.87-82.61)	(65.22-84.78)	(58.70-80.43)	(63.13-84.78)	(-2.175 to 3.573)		(-3.169 (0 5.193)		(-4.111 (0 6.178)	
N = 397 (n = 193,  fully adjusted)										
CHU9D utility score										
N = 598 (n = 285, unadjusted)	0.84 (0.12)	0.88 (0.11)	0.81 (0.14)	0.86 (0.10)	0.015	0.112	0.012	0.245	0.013	0.250
N = 551 (n = 266,  partially adjusted)					(-0.004 (0 0.034)		(-0.008 to 0.032)		(-0.009 (0 0.034)	
N = 380 (n = 182,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n <i>(%)</i>		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>
N = 609 (n = 294, unadjusted)	34 (10.27)	34 (11.56)	36 (10.56)	43 (13.65)	-0.023	0.443	-0.039	0.146	-0.041	0.115
N = 579 (n = 284,  partially adjusted)					(-0.066 (0 0.044)		(-0.077 to 0.017)		(-0.077 (0 0.012)	
N = 405 (n = 200,  fully adjusted)										

	Arm				Intervention vs. con	trol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 609 (n = 294, unadjusted)	55 (16.62)	66 (22.45)	72 (21.11)	80 (25.40)	-0.029	0.396	-0.037	0.303	-0.057	0.078
N = 579 (n = 284,  partially adjusted)					(-0.085 to 0.044)		(–0.092 to 0.038)		(-0.105 to 0.007)	
N = 405 ( $n = 200$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 540 (n = 253, unadjusted)	179 (62.15)	109 (42.91)	199 (67.92)	135 (42.45)	-0.031	0.543	-0.046	0.363	-0.017	0.731
N = 480 (n = 230,  partially adjusted)					(-0.119 (0 0.075)		(-0.133 (0 0.058)		(-0.102 (0 0.084)	
N = 392 ( $n = 186$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 431 (n = 207, unadjusted)	90 (36.73)	91 (43.96)	115 (43.73)	93 (41.52)	0.015	0.822	0.044	0.556	0.022	0.749
N = 358 ( $n = 172$ , partially adjusted)					(-0.100 (0 0.172)		(-0.000 10 0.220)		(-0.090 (0 0.164)	

N = 331 (n = 162, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

- d Transformed via inverse.
- e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.
- f Transformed via natural logarithm.
- g Transformed via squaring.
- h Adjusted for baseline BMI-z.
- i Adjusted for total grams of fruit and vegetables consumed per day.
- j Adjusted for minutes of PA per 24 hours.

# TABLE 53 Adjusted differences for key variables between control and intervention groups at FU1: sex – interaction terms

	<i>p</i> -value of interaction term					
Variable	Unadjusted model	Partially adjusted model <sup>a</sup>	Fully adjusted <sup>b</sup>			
Continuous outcomes						
BMI-z	0.027	0.669	0.619			
Height (cm)	0.783	0.408	0.657			
Waist z-score	0.044	0.278	0.879			
Sum of four skinfolds (mm) <sup>c,d</sup>	0.166	0.453	0.559			
Body fat %	0.023	0.163	0.651			
Energy intake (kJ in 24 hours) <sup>e</sup>	0.703	0.962	0.720			
PA energy expenditure (kJ/kg/day)	0.859	0.147	0.252			
PedsQL total score <sup>f</sup>	0.062	0.131	0.193			
CHU9D utility score	0.330	0.392	0.943			
Binary outcomes						
Obese <sup>9</sup>	0.069	0.038	0.084			
Obese/overweight <sup>9</sup>	0.004	0.504	0.700			
Five or more portions of fruit and vegetables $^{\rm h}$	0.660	0.604	0.667			
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.885	0.902	0.713			

a Adjusted for baseline outcome.

 b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

i Adjusted for minutes of PA per 24 hours.

# TABLE 54 Adjusted differences for key variables between control and intervention groups at FU1: IMD score = 1, 2 (more deprived)

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p <i>-value</i>	MD (95% CI)	p-value	MD (95% CI)	p- <i>value</i>
N = 897 (n = 428, unadjusted)	0.21 (1.30)	0.30 (1.39)	0.20 (1.28)	0.28 (1.33)	0.015	0.892	-0.089	0.165	-0.082	0.215
N = 865 (n = 415,  partially adjusted)					(-0.202 to 0.232)		(-0.215 to 0.037)		(-0.212 to 0.048)	
N = 590 (n = 290,  fully adjusted)										
Height (cm)										
N = 898 (n = 416, unadjusted)	118.58 (5.56)	127.42 (6.10)	118.21 (5.44)	127.12 (5.82)	0.300	0.453	-0.128	0.681	-0.206	0.524
N = 867 (n = 416,  partially adjusted)					(-0.483 to 1.082)		(-0.736 to 0.481)		(-0.839 to 0.427)	
N = 591 (n = 290,  fully adjusted)										
Waist z-score										
N = 824 (n = 400, unadjusted)	0.71 (1.29)	1.04 (1.34)	0.72 (1.31)	0.92 (1.39)	0.120	0.269	0.046	0.653	0.010	0.898
N = 770 (n = 373,  partially adjusted)					(-0.093 to 0.333)		(-0.154 to 0.246)		(-0.148 to 0.169)	
N = 556 (n = 269,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 748 (n = 373, unadjusted)	28.45	30.75	29.25	29.70	-0.071	0.936	0.165	0.554	0.177	0.535
N = 654 ( $n = 328$ , partially adjusted)	(22.95–35.30)	(23.80–42.20)	(23.60–37.70)	(23.70–44.40)	(-1.808 to 1.666)		(-0.381 to 0.710)		(-0.382 to 0.735)	
N = 482 ( $n = 246$ , fully adjusted)										
Body fat %										
N = 888 (n = 428, unadjusted)	21.28 (5.37)	21.71 (6.96)	21.42 (5.43)	21.30 (6.65)	0.289	0.594	0.079	0.856	0.109	0.813
N = 843 ( $n = 414$ , partially adjusted)					(-0.772 to 1.349)		(-0.772 to 0.930)		(-0.795 to 1.013)	
N = 580 (n = 290,  fully adjusted)										
										continued

## TABLE 54 Adjusted differences for key variables between control and intervention groups at FU1: IMD score = 1, 2 (more deprived) (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 791 (n = 384, unadjusted)	6978	7116	6895 (5730, 7003)	6959 (FREE 8170)	41.447	0.830	8.003	0.963	-110.936	0.534
N = 683 ( $n = 332$ , partially adjusted)	(5887-8207)	(6074-8333)	(5730-7992)	(5855–8170)	(-330.188 (0 419.081)		(-328.144 (0 344.150)		(-400.253 (0 238.381)	
N = 559 (n = 269,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 601 (n = 288, unadjusted)	97.05 (23.72)	90.79 (23.23)	93.05 (24.16)	88.99 (24.66)	1.519 ( 2.228 to 6.275)	0.540	-0.008	0.997	-0.627	0.781
N = 504 ( $n = 243$ , partially adjusted)					(-3.338 (0 0.373)		(-4.072 (0 4.037)		(-3.032 (0 3.798)	
N = 453 ( $n = 224$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 875 (n = 406, unadjusted)	71.74	76.09	73.91	73.91	-0.311 ( 2.997 to 2.375)	0.820	-0.121	0.949	-0.809	0.708
N = 836 ( $n = 395$ , partially adjusted)	(38.70-82.01)	(03.04-04.76)	(00.87-82.01)	(03.22-04.70)	(-2.997 (0 2.575)		(-3.818 (0 3.370)		(-3.039 (0 3.421)	
N = 567 (n = 271,  fully adjusted)										
CHU9D utility score										
N = 864 (n = 406, unadjusted)	0.83 (0.14)	0.86 (0.11)	0.81 (0.15)	0.86 (0.11)	0.011 ( 0.011 to 0.022)	0.339	0.007	0.518	0.005	0.626
N = 809 (n = 387,  partially adjusted)					(-0.011 (0 0.032)		(-0.014 (0 0.029)		(-0.018 (0 0.027)	
N = 548 (n = 264,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n <i>(%)</i>		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 897 (n = 428, unadjusted)	65 (13.18)	73 (17.06)	73 (13.96)	80 (17.06)	-0.000	0.999	-0.037	0.180	0.005	0.849
N = 865 ( $n = 415$ , partially adjusted)					(-0.038 to 0.049)		(-0.077 to 0.020)		(-0.037 to 0.059)	
N = 590 (n = 290,  fully adjusted)										

	Arm			Intervention vs. con	trol					
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 897 (n = 428, unadjusted)	114 (23.12)	122 (28.50)	116 (22.18)	123 (26.23)	0.023	0.389	-0.014	0.642	-0.000	0.998
N = 865 ( $n = 415$ , partially adjusted)					(-0.026 to 0.082)		(-0.065 to 0.050)		(–0.054 to 0.067)	
N = 590 (n = 290,  fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 791 (n = 384, unadjusted)	260 (61.47)	175 (45.57)	274 (63.57)	185 (45.45)	0.001	0.980	-0.015	0.729	-0.009	0.820
N = 683 ( $n = 332$ , partially adjusted)					(-0.082 to 0.103)		(-0.093 to 0.079)		(-0.080 to 0.075)	
N = 559 (n = 269,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 602 (n = 290, unadjusted)	184 (50.55)	152 (52.41)	189 (48.59)	153 (49.04)	0.034	0.550	0.045	0.445	0.020	0.713
N = 502 ( $n = 242$ , partially adjusted)					(-0.069 to 0.162)		(-0.062 to 0.178)		(–0.076 to 0.138)	

N = 452 (n = 224, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

- d Transformed via inverse.
- e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.
- f Transformed via natural logarithm.
- g Transformed via squaring.
- h Adjusted for baseline BMI-z.
- i Adjusted for total grams of fruit and vegetables consumed per day.
- j Adjusted for minutes of PA per 24 hours.

## TABLE 55 Adjusted differences for key variables between control and intervention groups at FU1: IMD score = 3–5 (less deprived)

	Arm				Intervention vs. contr	rol				
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p-value	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e
N = 337 (n = 138, unadjusted)	0.29 (1.09)	0.43 (1.16)	-0.00 (1.01)	0.11 (1.10)	0.312	0.035	-0.007	0.933	-0.032	0.816
N = 318 (n = 133,  partially adjusted)					(0.023 to 0.601)		(-0.169 to 0.156)		(-0.302 to 0.238)	
N = 247 ( $n = 103$ , fully adjusted)										
Height (cm)										
N = 337 (n = 133, unadjusted)	118.84 (5.71)	127.11 (5.96)	118.09 (5.24)	126.86 (5.65)	0.252	0.535	-0.063	0.878	-0.244	0.543
N = 318 (n = 133,  partially adjusted)					(-0.543 to 1.047)		(-0.863 to 0.737)		(-1.032 to 0.544)	
N = 247 (n = 103,  fully adjusted)										
Waist z-score										
N = 314 (n = 122, unadjusted)	0.95 (1.10)	1.14 (1.15)	0.52 (1.07)	0.79 (1.14)	0.356	0.001	0.002	0.985	0.004	0.970
N = 287 (n = 111,  partially adjusted)					(0.143 (0 0.569)		(-0.230 to 0.235)		(-0.183 (0 0.190)	
N = 240 (n = 99,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 288 (n = 109, unadjusted)	29.13	33.60	26.90	28.70	4.878	0.001	1.054	0.019	1.262	0.066
N = 239 (n = 89,  partially adjusted)	(23.95–36.38)	(26.70-50.50)	(22.20–33.63)	(23.60–36.80)	(2.039 to 7.718)		(0.173 to 1.936)		(-0.084 to 2.609)	
N = 201 (n = 77,  fully adjusted)										
Body fat %										
N = 334 (n = 138, unadjusted)	21.24 (4.97)	21.95 (6.05)	19.81 (4.48)	19.89 (5.37)	2.060	< 0.001	0.283	0.644	0.413	0.561
N = 313 ( $n = 131$ , partially adjusted)					(0.330 (0 3.183)		(-0.917 (0 1.482)		(-0.980 (0 1.806)	
N = 242 ( $n = 101$ , fully adjusted)										

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 310 (n = 118, unadjusted)	6773	7116	6930	6959	375.273	0.208	251.091	0.186	297.274 ( 121.874 to 716.422)	0.165
N = 287 ( $n = 112$ , partially adjusted)	(5706–7748)	(6074-8333)	(5955-7946)	(5855–8170)	(-208.371 (0 958.916)		(-121.287 (0 623.469)		(-121.874 10 7 16.422)	
N = 244 ( $n = 100$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 256 ( $n = 102$ , unadjusted)	93.70 (21.54)	93.74 (24.96)	96.67 (24.93)	96.18 (26.68)	-2.979	0.390	-0.402	0.932	-5.920	0.175
N = 213 ( $n = 88$ , partially adjusted)					(-9.767 (0 3.810)		(-9.662 (0 8.858)		(-14.469 (0 2.629)	
N = 205 ( $n = 86$ , fully adjusted)										
PedsQL total score <sup>9</sup>										
N = 340 (n = 139, unadjusted)	73.91	78.26	73.91	76.09	-1.113 ( . 4.192 to . 1.956)	0.477	-1.441	0.473	-0.966	0.666
N = 320 ( $n = 134$ , partially adjusted)	(65.22-84.78)	(65.91–84.78)	(63.04–82.61)	(67.39-86.96)	(-4.182 to 1.956)		(-5.374 to 2.492)		(-5.359 to 3.426)	
N = 250 ( $n = 104$ , fully adjusted)										
CHU9D utility score										
N = 336 (n = 135, unadjusted)	0.85 (0.12)	0.86 (0.11)	0.84 (0.14)	0.86 (0.11)	0.017	0.246	0.018	0.239	0.007	0.679
N = 307 ( $n = 123$ , partially adjusted)					(-0.012 to 0.047)		(-0.012 to 0.049)		(-0.026 to 0.040)	
N = 238 ( $n = 94$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>valu</i> e
N = 337 (n = 138, unadjusted)	18 (11.84)	19 (13.77)	14 (6.97)	20 (10.05)	0.037	0.163	-0.061	0.001	-0.061	0.009
N = 318 ( $n = 133$ , partially adjusted)					(–0.012 to 0.114)		(–0.079 to –0.030)		(–0.083 to –0.020)	
N = 247 ( $n = 103$ , fully adjusted)										
										continued

#### TABLE 55 Adjusted differences for key variables between control and intervention groups at FU1: IMD score = 3–5 (less deprived) (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>®</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 337 (n = 138, unadjusted)	27 (17.76)	40 (28.99)	34 (16.92)	43 (21.61)	0.074	0.130	-0.042	0.461	-0.057	0.406
N = 318 ( $n = 133$ , partially adjusted)					(-0.018 to 0.208)		(-0.118 to 0.093)		(-0.138 to 0.111)	
N = 247 ( $n = 103$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 310 (n = 118, unadjusted)	67 (52.76)	67 (56.78)	129 (68.25)	111 (57.81)	-0.010	0.894	0.049	0.526	0.088	0.260
N = 287 ( $n = 112$ , partially adjusted)					(-0.142 to 0.161)		(-0.091 to 0.230)		(-0.058 to 0.274)	
N = 244 ( $n = 100$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 253 ( $n = 101$ , unadjusted)	38 (32.48)	53 (52.48)	85 (52.47)	78 (51.32)	-0.004	0.953	0.034	0.702	-0.076	0.227
N = 210 (n = 88,  partially adjusted)					(-0.133 to 0.167)		(–U.118 to U.246)		(-0.175 to 0.054)	

N = 202 (n = 86, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

j Adjusted for minutes of PA per 24 hours.

	<i>p</i> -value of interaction term						
Variable	Unadjusted model	Partially adjusted model <sup>a</sup>	Fully adjusted model <sup>b</sup>				
Continuous outcomes							
BMI-z	0.115	0.475	0.475				
Height (cm)	0.934	0.430	0.545				
Waist z-score	0.109	0.820	0.776				
Sum of four skinfolds (mm) <sup>c,d</sup>	0.003	0.316	0.445				
Body fat %	0.012	0.797	0.630				
Energy intake (kJ in 24 hours) <sup>e</sup>	0.113	0.176	0.076				
PA energy expenditure (kJ/kg/day)	0.214	0.990	0.952				
PedsQL total score <sup>f</sup>	0.769	0.689	0.884				
CHU9D utility score	0.927	0.804	0.590				
Binary outcomes							
Obese <sup>9</sup>	0.254	0.706	0.390				
Obese/overweight <sup>9</sup>	0.331	0.208	0.451				
Five or more portions of fruit and vegetables $^{\rm h}$	0.904	0.562	0.655				
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.587	0.901	0.829				

TABLE 56 Adjusted differences for key variables between control and intervention groups at FU1: IMD score – interaction terms

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

i Adjusted for minutes of PA per 24 hours.

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	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e
N = 252 ( $n = 124$ , unadjusted)	1.99 (0.81)	2.04 (0.82)	1.94 (0.73)	2.05 (0.75)	-0.001	0.989	-0.098	0.180	-0.129	0.130
N = 252 ( $n = 124$ , partially adjusted)					(-0.199 to 0.197)		(-0.240 to 0.045)		(–0.296 to 0.038)	
N = 169 (n = 89,  fully adjusted)										
Height (cm)										
N = 252 ( $n = 124$ , unadjusted)	121.72 (5.55)	131.07 (5.89)	120.74 (5.38)	130.14 (5.83)	0.924	0.179	-0.025	0.950	-0.654	0.104
N = 252 ( $n = 124$ , partially adjusted)					(-0.424 to 2.272)		(-0.792 to 0.742)		(-1.441 to 0.134)	
N = 169 (n = 89,  fully adjusted)										
Waist z-score										
N = 233 ( $n = 116$ , unadjusted)	2.33 (0.96)	2.60 (0.97)	2.41 (0.89)	2.62 (0.77)	-0.018	0.870	-0.045	0.562	-0.069	0.353
N = 220 ( $n = 109$ , partially adjusted)					(-0.238 to 0.201)		(-0.199 to 0.108)		(-0.215 to 0.077)	
N = 153 ( $n = 81$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 190 (n = 98, unadjusted)	43.40	55.53	44.75	55.88	-3.386	0.182	-0.197	0.767	0.256	0.784
N = 165 (n = 87,  partially adjusted)	(33.40–55.90)	(38.90–73.95)	(36.85–62.20)	(42.67-72.47)	(-8.362 to 1.589)		(-1.498 to 1.104)		(-1.576 to 2.088)	
N = 120 (n = 68,  fully adjusted)										
Body fat %										
N = 250 (n = 124, unadjusted)	27.93 (5.70)	29.28 (7.38)	28.06 (5.17)	29.63 (5.85)	-0.357	0.702	-0.885	0.157	-0.877	0.213
N = 248 (n = 123,  partially adjusted)					(-2.189 to 1.474)		(-2.110 to 0.341)		(–2.259 to 0.505)	
N = 167 (n = 89,  fully adjusted)										

**APPENDIX 60** 

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 224 (n = 111, unadjusted)	7386	7147	6851	7139	23.929 ( 551 127 to 508 084)	0.935	-12.946	0.959	158.159	0.482
N = 203 ( $n = 102$ , partially adjusted)	(6128-8339)	(5930-8351)	(5902-7975)	(5968-8308)	(-551.127 (0 598.984)		(-500.822 (0 474.929)		(-282.745 (0 599.063)	
N = 161 (n = 83,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 169 (n = 85, unadjusted)	94.95 (21.50)	90.41 (22.93)	89.86 (22.55)	90.49 (23.46)	-0.546	0.892	-0.282	0.943	-1.383	0.707
N = 142 ( $n = 71$ , partially adjusted)					(-8.398 (0 7.307)		(-7.968 (0 7.404)		(-8.609 (0 5.842)	
N = 129 (n = 67,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 246 (n = 118, unadjusted)	67.39	76.09	73.91	73.91	0.803	0.609	1.674	0.416	1.570	0.577
N = 244 ( $n = 118$ , partially adjusted)	(58.70–80.43)	(65.22-82.61)	(60.87-82.61)	(63.04–84.78)	(-2.278 to 3.884)		(-2.357 to 5.706)		(-3.942 to 7.082)	
N = 163 (n = 83,  fully adjusted)										
CHU9D utility score										
N = 241 (n = 116, unadjusted)	0.82 (0.14)	0.88 (0.10)	0.81 (0.13)	0.85 (0.11)	0.027	0.046	0.025	0.067	0.032	0.057
N = 232 ( $n = 112$ , partially adjusted)					(0.001 to 0.054)		(-0.002 to 0.052)		(-0.001 to 0.065)	
N = 154 ( $n = 78$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 252 (n = 124, unadjusted)	84 (57.93)	84 (67.74)	87 (58.00)	88 (68.75)	-0.010	0.818	-0.049	0.252	-0.018	0.729
N = 252 ( $n = 124$ , partially adjusted)					(–0.090 to 0.081)		(-0.125 to 0.037)		(–0.112 to 0.091)	
N = 169 (n = 89,  fully adjusted)										
										continued

#### TABLE 57 Adjusted differences for key variables between control and intervention groups at FU1: overweight only (continued)

	Arm			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 252 ( $n = 124$ , unadjusted)	145 (100)	105 (84.68)	150 (100)	116 (90.63)	-0.059	0.230	-0.074	0.154	-0.099	0.071
N = 252 ( $n = 124$ , partially adjusted)					(-0.148 to 0.040)		(-0.167 to 0.030)		(-0.194 to 0.009)	
N = 169 (n = 89,  fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 224 ( $n = 111$ , unadjusted)	85 (66.93)	57 (51.35)	75 (63.03)	51 (45.13)	0.062	0.412	0.021	0.782	0.094	0.191
N = 203 ( $n = 102$ , partially adjusted)					(-0.074 to 0.248)		(-0.109 to 0.198)		(-0.041 to 0.273)	
N = 161 (n = 83,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 171 (n = 86, unadjusted)	44 (40.74)	42 (48.84)	49 (47.12)	38 (44.71)	0.041	0.666	0.125	0.203	0.077	0.385
N = 145 ( $n = 72$ , partially adjusted)					(-0.120 to 0.282)		(-0.055 to 0.396)		(-0.080 to 0.309)	
N = 131 ( $n = 68$ , fully adjusted)										

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

- c Summary statistics presented are either mean (SD) or median (IQR).
- d Transformed via inverse.
- e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.
- f Transformed via natural logarithm.
- g Transformed via squaring.
- h Adjusted for baseline BMI-z.
- i Adjusted for total grams of fruit and vegetables consumed per day.
- j Adjusted for minutes of PA per 24 hours.

# TABLE 58 Adjusted differences for key variables between control and intervention groups at FU1: not overweight only

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
<i>N</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcome</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p-value
N = 945 (n = 432, unadjusted)	-0.26 (0.82)	-0.17 (1.00)	-0.32 (0.80)	-0.20 (0.93)	0.001	0.995	-0.062	0.273	-0.080	0.200
N = 945 ( $n = 432$ , partially adjusted)					(-0.176 to 0.177)		(-0.174 to 0.049)		(-0.202 to 0.042)	
N = 668 (n = 304,  fully adjusted)										
Height (cm)										
N = 946 (n = 432, unadjusted)	117.79 (5.31)	126.36 (5.80)	117.51 (5.18)	126.40 (5.49)	-0.043	0.903	-0.082	0.784	-0.119	0.684
N = 946 (n = 432,  partially adjusted)					(-0.744 to 0.657)		(-0.671 to 0.506)		(-0.696 to 0.457)	
N = 669 (n = 304,  fully adjusted)										
Waist z-score										
N = 870 (n = 396, unadjusted)	0.33 (0.92)	0.59 (1.10)	0.23 (0.89)	0.47 (1.05)	0.117	0.205	0.041	0.693	0.023	0.764
N = 847 (n = 380,  partially adjusted)					(-0.064 to 0.298)		(-0.165 to 0.248)		(-0.127 to 0.173)	
N = 643 (n = 287,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 815 (n = 373, unadjusted)	26.75	29.05	26.45	27.70	0.851	0.279	0.268	0.244	0.282	0.270
N = 737 (n = 334,  partially adjusted)	(21.95–31.60)	(22.85–36.75)	(22.20–32.00)	(22.50–34.40)	(-0.690 to 2.392)		(-0.183 to 0.720)		(-0.219 to 0.783)	
N = 563 (n = 255,  fully adjusted)										
Body fat %										
N = 936 (n = 432, unadjusted)	19.39 (3.20)	19.48 (4.44)	19.10 (3.28)	18.77 (4.33)	0.594	0.115	0.317	0.374	0.273	0.466
N = 921 ( $n = 430$ , partially adjusted)					(-0.145 to 1.333)		(-0.383 to 1.018)		(-0.461 to 1.008)	
N = 655 (n = 302,  fully adjusted)										
										continued

	Arm			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 840 (n = 379, unadjusted)	6841	7129	6961	7042	110.696	0.506	65.915	0.651	-52.801	0.729
N = 759 (n = 344,  partially adjusted)	(5782–7948)	(6107-8319)	(5767–8004)	(5938–8149)	(-215.404 to 436.797)		(-219.587 to 351.418)		(-351.824 to 246.221)	
N = 642 ( $n = 286$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 660 (n = 295, unadjusted)	96.84 (23.61)	92.32 (23.90)	95.03 (24.70)	91.61 (26.11)	0.176	0.944	-0.749	0.764	-2.060	0.379
N = 582 ( $n = 264$ , partially adjusted)					(-4.749 to 5.101)		(-5.648 to 4.151)		(-6.648 to 2.528)	
N = 529 (n = 243,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 933 (n = 418, unadjusted)	71.74	76.09	73.91	76.09	-1.157	0.364	-1.458	0.396	-1.165	0.515
N = 924 ( $n = 418$ , partially adjusted)	(60.87-82.61)	(65.22-84.78)	(60.87-82.61)	(65.22-84.78)	(-3.655 to 1.342)		(-4.824 to 1.909)		(-4.673 to 2.343)	
N = 654 ( $n = 292$ , fully adjusted)										
CHU9D utility score										
N = 923 (n = 416, unadjusted)	0.84 (0.13)	0.86 (0.11)	0.82 (0.15)	0.86 (0.10)	0.007	0.477	0.004	0.686	0.006	0.595
N = 895 ( $n = 405$ , partially adjusted)					(-0.013 to 0.028)		(-0.016 to 0.024)		(-0.016 to 0.028)	
N = 632 ( $n = 280$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>
N = 945 (n = 432, unadjusted)	0 (0.00)	4 (0.93)	0 (0.00)	11 (2.14)	-0.012	0.109	-0.013	0.081	-0.014	0.078
N = 945 ( $n = 432$ , partially adjusted)					(-0.018 to 0.004)		(-0.018 to 0.003)		(-0.019 to 0.003)	
N = 668 (n = 304,  fully adjusted)										

**APPENDIX 60** 

	Arm	rm			Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>6</sup>	
Obese/overweight <sup>h</sup>										
N = 945 (n = 432, unadjusted)	0 (0.00)	53 (12.27)	0 (0.00)	45 (8.77)	0.033	0.163	0.026	0.182	0.012	0.575
N = 945 ( $n = 432$ , partially adjusted)					(-0.011 to 0.100)		(-0.010 to 0.080)		(-0.025 to 0.071)	
N = 668 (n = 304,  fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 840 (n = 379, unadjusted)	247 (57.44)	176 (46.44)	317 (65.09)	231 (50.11)	-0.037	0.449	-0.031	0.528	-0.015	0.682
N = 759 (n = 344,  partially adjusted)					(-0.120 to 0.064)		(-0.114 to 0.071)		(-0.078 to 0.059)	
N = 642 ( $n = 286$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 656 (n = 295, unadjusted)	184 (48.04)	155 (52.54)	227 (50.11)	182 (50.42)	0.018 ( 0.087 to 0.140)	0.760	0.027	0.661	-0.022	0.673
N = 575 ( $n = 262$ , partially adjusted)					(-0.087 to 0.149)		(-0.065 (0 0.165)		(-0.115 (0 0.089)	

N = 523 (n = 242, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

- d Transformed via inverse.
- e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.
- f Transformed via natural logarithm.
- g Transformed via squaring.
- h Adjusted for baseline BMI-z.
- i Adjusted for total grams of fruit and vegetables consumed per day.
- j Adjusted for minutes of PA per 24 hours.

	<i>p</i> -value of interaction	term	
Variable	Unadjusted model	Partially adjusted model <sup>a</sup>	Fully adjusted <sup>b</sup>
Continuous outcomes			
BMI-z	0.838	0.580	0.639
Height (cm)	0.204	0.637	0.015
Waist z-score	0.276	0.334	0.454
Sum of four skinfolds (mm) <sup>c,d</sup>	0.094	0.752	0.958
Body fat %	0.320	0.046	0.102
Energy intake (kJ in 24 hours) <sup>e</sup>	0.642	0.710	0.347
PA energy expenditure (kJ/kg/day)	0.931	0.787	0.830
PedsQL total score <sup>f</sup>	0.297	0.189	0.368
CHU9D utility score	0.114	0.090	0.099
Binary outcomes			
Obese <sup>9</sup>	0.126	0.131	0.119
Obese/overweight <sup>g</sup>	0.075	0.075	0.193
Five or more portions of fruit and vegetables <sup>h</sup>	0.247	0.634	0.382
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.782	0.339	0.408

**TABLE 59** Adjusted differences for key variables between control and intervention groups at FU1: obese/ overweight – interaction terms

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

i Adjusted for minutes of PA per 24 hours.

# Follow-up 2

TABLE 60 Adjusted differences for key variables between control and intervention groups at FU2: ethnicity – white only

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
N = total participants ( $n =$ number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR) <sup>c</sup>	Mean (SD) or	median (IQR)'	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 524 (n = 240,  unadjusted)	0.24 (1.03)	0.43 (1.17)	0.19 (1.07)	0.32 (1.18)	0.111	0.261	0.043	0.537	-0.005	0.945
N = 501 (n = 235,  partially adjusted)					(–0.082 to 0.304)		(-0.093 to 0.179)		(-0.137 to 0.128)	
N = 378 ( $n = 177$ , fully adjusted)										
Height (cm)										
N = 524 (n = 235, unadjusted)	118.07 (5.34)	134.63 (6.10)	117.50 (5.12)	134.44 (6.19)	0.209	0.732	0.008	0.983	-0.117	0.719
N = 501 (n = 235,  partially adjusted)					(–0.984 to 1.402)		(-0.730 to 0.746)		(–0.752 to 0.519)	
N = 378 (n = 177,  fully adjusted)										
Waist z-score										
N = 470 (n = 213, unadjusted)	0.81 (0.97)	1.15 (1.10)	0.72 (1.09)	0.88 (1.20)	0.257	0.032	0.190	0.044	0.108	0.252
N = 443 ( $n = 204$ , partially adjusted)					(0.022 to 0.493)		(0.005 to 0.374)		(–0.077 to 0.293)	
N = 361 (n = 168,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 404 (n = 182, unadjusted)	28.45	34.50	27.95	29.50	3.480	0.015	1.329	0.002	1.063	0.038
N = 347 (n = 162,  partially adjusted)	(23.90–34.20)	(26.15–48.75)	(22.75–34.15)	(23.80–43.00)	(0.670 to 6.290)		(0.487 to 2.172)		(0.061 to 2.066)	
N = 290 (n = 136,  fully adjusted)										
Body fat %										
N = 512 (n = 238, unadjusted)	20.61 (4.28)	21.46 (6.24)	20.26 (4.63)	20.42 (6.73)	1.028	0.080	0.674	0.148	0.321	0.529
N = 490 (n = 233,  partially adjusted)					(–0.123 to 2.178)		(–0.238 to 1.587)		(-0.677 to 1.319)	
N = 370 (n = 176,  fully adjusted)										
										continued

## TABLE 60 Adjusted differences for key variables between control and intervention groups at FU2: ethnicity – white only (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 469 (n = 209, unadjusted)	6912	7656	7031	7939	-398.197	0.046	-246.505	0.187	-224.534	0.325
N = 435 ( $n = 198$ , partially adjusted)	(5964–7868)	(6567–8966)	(6144–7964)	(6919–9256)	(-789.949 to -6.445)		(-612.762 to 119.753)		(-671.998 to 222.929)	
N = 361 (n = 167,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 324 (n = 140, unadjusted)	96.48 (20.69)	86.18 (23.15)	97.64 (24.08)	82.97 (21.68)	3.116	0.274	2.260	0.401	3.227	0.270
N = 276 ( $n = 125$ , partially adjusted)					(-2.466 to 8.698)		(-3.016 to 7.536)		(-2.505 to 8.958)	
N = 262 ( $n = 119$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 523 (n = 240, unadjusted)	73.91	82.61	73.91	82.61	2.520	0.131	2.768	0.178	2.924	0.171
N = 499 (n = 235,  partially adjusted)	(63.04–83.70)	(73.91–91.30)	(60.87-82.61)	(71.74–89.13)	(-0.753 to 5.792)		(-1.258 to 6.794)		(-1.264 to 7.113)	
N = 378 (n = 177,  fully adjusted)										
CHU9D utility score										
N = 518 (n = 238, unadjusted)	0.85 (0.12)	0.89 (0.09)	0.83 (0.14)	0.90 (0.09)	-0.002	0.847	-0.004	0.771	-0.006	0.666
N = 482 ( $n = 224$ , partially adjusted)					(-0.026 to 0.021)		(-0.029 to 0.022)		(-0.033 to 0.021)	
N = 363 (n = 168,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 524 (n = 240,  unadjusted)	26 (9.00)	40 (16.67)	33 (9.85)	44 (15.49)	0.012	0.703	0.030	0.302	0.023	0.408
N = 501 (n = 235,  partially adjusted)					(-0.040 to 0.088)		(-0.023 to 0.102)		(-0.027 to 0.091)	
N = 378 ( $n = 177$ , fully adjusted)										

ollow-up outcome variable:					Intervention vs. co	ntrol				
	Intervention		Control							
n = total participants n = number in intervention arm	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Dbese/overweight <sup>h</sup>										
= 524 ( <i>n</i> = 240, unadjusted)	49 (16.96)	78 (32.50)	69 (20.60)	69 (24.30)	0.082	0.049	0.100	0.043	0.073	0.07
l = 501 (n = 235, partially adjusted)					(0.000 to 0.191)		(0.003 to 0.236)		(-0.006 to 0.180)	
V = 378 (n = 177,  fully adjusted)										
ive or more portions of fruit and v	getables <sup>i</sup>									
V = 469 ( <i>n</i> = 209, unadjusted)	151 (59.22)	120 (57.42)	193 (64.33)	139 (53.46)	0.040	0.484	0.060	0.352	0.097	0.13
= 435 ( $n = 198$ , partially adjusted					(-0.065 to 0.167)		(-0.059 to 0.209)		(-0.026 to 0.251)	
V = 361 (n = 167,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
<i>I</i> = 327 ( <i>n</i> = 142, unadjusted)	87 (39.55)	47 (33.10)	133 (51.35)	60 (32.43)	0.007	0.909	0.036	0.608	0.081	0.30
V = 277 ( $n = 126$ , partially adjusted					(-0.091 to 0.145)		(-0.083 to 0.216)		(-0.059 to 0.301)	
V = 264 ( $n = 121$ , fully adjusted)										

0.075

0.132

0.304

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e	MD (95% CI)	p- <i>value</i>
N = 368 (n = 176, unadjusted)	-0.00 (1.42)	0.32 (1.51)	-0.03 (1.33)	0.24 (1.48)	0.082	0.581	-0.052	0.641	-0.007	0.956
N = 347 ( $n = 164$ , partially adjusted)					(-0.209 to 0.373)		(-0.273 to 0.168)		(-0.239 to 0.226)	
N = 244 ( $n = 115$ , fully adjusted)										
Height (cm)										
N = 369 (n = 164, unadjusted)	118.47 (5.79)	133.96 (7.02)	118.17 (5.23)	134.39 (6.41)	-0.433	0.458	-0.700	0.159	-0.799	0.142
N = 348 (n = 164,  partially adjusted)					(-1.577 (0 0.710)		(-1.673 to 0.273)		(-1.866 (0 0.268)	
N = 245 ( $n = 115$ , fully adjusted)										
Waist z-score										
N = 315 (n = 149, unadjusted)	0.50 (1.43)	1.07 (1.42)	0.49 (1.47)	0.80 (1.56)	0.254	0.200	0.025	0.856	-0.021	0.893
N = 287 (n = 132,  partially adjusted)					(-0.134 to 0.642)		(-0.245 to 0.295)		(-0.324 to 0.282)	
N = 212 ( $n = 98$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 262 (n = 124, unadjusted)	29.50	36.20	28.65	35.33	0.103	0.962	0.039	0.940	-0.056	0.890
N = 220 ( $n = 102$ , partially adjusted)	(22.95–37.40)	(25.32–56.23)	(23.20–38.35)	(25.45–53.25)	(-4.085 to 4.290)		(-0.988 to 1.067)		(-0.854 to 0.741)	
N = 167 (n = 80,  fully adjusted)										
Body fat %										
N = 357 (n = 171, unadjusted)	21.41 (5.89)	23.68 (8.47)	21.75 (5.46)	22.84 (7.44)	0.842	0.282	0.395	0.489	0.063	0.930
N = 329 (n = 157,  partially adjusted)					(-0.693 to 2.376)		(-0.725 to 1.515)		(-1.34/ to 1.4/4)	
N = 233 ( $n = 112$ , fully adjusted)										

**APPENDIX 60** 

	Arm				Intervention vs. contro	ol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 334 ( $n = 158$ , unadjusted)	6384	7710	6644	8034	-322.904	0.391	-250.883	0.491	-312.679	0.338
N = 278 ( $n = 126$ , partially adjusted)	(5307–8035)	(6282-9181)	(5303-7969)	(6592-9511)	(-1060.300 to 414.492)		(-964.647 (0 462.882)		(-952.135 (0 326.776)	
N = 231 ( $n = 107$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 229 (n = 108, unadjusted)	96.30 (23.05)	73.47 (18.86)	95.10 (25.21)	74.89 (23.41)	-1.414	0.601	-2.520	0.441	-2.723	0.373
N = 186 (n = 84,  partially adjusted)					(-6.707 (0 3.879)		(-8.923 (0 3.883)		(-8.718 (0 3.272)	
N = 166 (n = 79,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 361 (n = 168, unadjusted)	69.57	80.43	71.74	80.43	-1.373	0.316	-1.279	0.421	-1.100	0.529
N = 334 ( $n = 156$ , partially adjusted)	(57.61–80.43)	(68.48–89.13)	(58.70-80.43)	(/1./4–89.13)	(-4.056 to 1.310)		(-4.392 to 1.835)		(-4.525 to 2.325)	
N = 237 ( $n = 111$ , fully adjusted)										
CHU9D utility score										
N = 364 (n = 175, unadjusted)	0.83 (0.14)	0.89 (0.10)	0.79 (0.16)	0.91 (0.08)	-0.023	0.010	-0.026	0.006	-0.019	0.112
N = 333 ( $n = 162$ , partially adjusted)					(-0.040 (8 -0.006)		(-0.045 (0 -0.008)		(-0.043 (0 0.005)	
N = 234 ( $n = 113$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 368 (n = 176, unadjusted)	27 (12.73)	40 (22.99)	23 (10.95)	39 (20.31)	0.024	0.529	-0.009	0.799	0.053	0.211
N = 347 ( $n = 164$ , partially adjusted)					(-0.043 to 0.119)		(-0.065 to 0.070)		(-0.025 to 0.165)	
N = 244 ( $n = 115$ , fully adjusted)										
										continued

#### TABLE 61 Adjusted differences for key variables between control and intervention groups at FU2: ethnicity – South Asian only (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 368 (n = 176, unadjusted)	44 (21.15)	60 (34.09)	38 (18.10)	64 (33.33)	0.008	0.867	-0.037	0.465	0.009	0.872
N = 347 ( $n = 164$ , partially adjusted)					(-0.071 to 0.110)		(-0.117 to 0.073)		(-0.084 to 0.134)	
N = 244 ( $n = 115$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 334 (n = 158, unadjusted)	94 (54.65)	89 (56.33)	119 (65.75)	103 (58.52)	-0.022	0.667	0.017	0.768	0.011	0.854
N = 278 ( $n = 126$ , partially adjusted)					(-0.112 to 0.085)		(-0.085 to 0.139)		(-0.095 to 0.141)	
N = 231 ( $n = 107$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 232 ( $n = 109$ , unadjusted)	67 (44.08)	9 (8.26)	76 (46.06)	32 (26.02)	-0.178	< 0.001	-0.191	< 0.001	-0.200	< 0.001
N = 187 (n = 85,  partially adjusted)					(-0.214 to -0.114)		(-0.233 to -0.116)		(–U.241 to –U.122)	

N = 167 (n = 80, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

j Adjusted for minutes of PA per 24 hours.

#### TABLE 62 Adjusted differences for key variables between control and intervention groups at FU2: ethnicity – black African Caribbean only

Arm				Intervention vs. cor	ntrol					
Follow-up outcome variable:	Intervention		Control							
N = total participants ( $n =$ number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>®</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR)℃	Mean (SD) or	median (IQR)'	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e
N = 78 (n = 42,  unadjusted)	0.72 (1.36)	0.62 (1.28)	0.55 (1.05)	0.62 (1.30)	-0.002	0.995	-0.177	0.194	-0.613	0.006
N = 75 ( $n = 40$ , partially adjusted)					(–0.512 to 0.509)		(–0.443 to 0.090)		(-1.053 to -0.173)	
N = 37 ( $n = 15$ , fully adjusted)										
Height (cm)										
N = 78 ( $n = 41$ , unadjusted)	121.72 (5.89)	137.78 (7.29)	120.76 (5.51)	137.96 (6.17)	-0.205	0.899	-0.038	0.970	-2.759	0.000
N = 76 ( $n = 41$ , partially adjusted)					(-3.371 to 2.960)		(-2.008 to 1.933)		(-3.803 to -1.716)	
N = 37 ( $n = 15$ , fully adjusted)										
Waist z-score										
N = 57 (n = 27, unadjusted)	1.24 (1.52)	1.23 (1.27)	0.85 (1.00)	1.22 (1.25)	0.010 ( 0.647 to 0.666)	0.977	0.049	0.850	-1.029	< 0.001
N = 54 ( $n = 24$ , partially adjusted)					(-0.647 (0 0.666)		(-0.463 (0 0.562)		(-1.417 to -0.641)	
N = 31 ( $n = 11$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>de</sup>										
N = 55 (n = 25, unadjusted)	28.52	33.80 (22.70,45.45)	26.30	32.48	-0.946 ( 11 454 to 0 562)	0.860	-1.761	0.059	-3.485	0.001
N = 50 (n = 23,  partially adjusted)	(23.75-40.05)	(22.70-45.45)	(22.30-30.30)	(22.03-03.00)	(-11.454 (0 9.502)		(-3.390 to 0.008)		(-5.497 to -1.475)	
N = 30 ( $n = 11$ , fully adjusted)										
Body fat %										
N = 76 (n = 42,  unadjusted)	24.09 (6.53)	23.95 (8.53)	22.66 (4.65)	22.72 (7.41)	1.226 ( 2.184 to 4.627)	0.481	-1.266	0.254	-3.437	0.018
N = 72 ( $n = 40$ , partially adjusted)					(-2.184 (0 4.037)		(-3.439 (0 0.907)		(-0.269 (0 -0.383)	
N = 36 (n = 15,  fully adjusted)										
										continued

## TABLE 62 Adjusted differences for key variables between control and intervention groups at FU2: ethnicity – black African Caribbean only (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
<i>n</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 60 (n = 28, unadjusted)	7777	7555	7007	7412	115.763	0.726	21.388	0.936	751.522	0.382
N = 51 ( $n = 21$ , partially adjusted)	(0522-8511)	(6432-9043)	(5173-7964)	(6586-9074)	(-530.825 (0 762.350)		(-502.475 (0 545.250)		(-933.493 (0 2436.536)	
N = 33 ( $n = 12$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 39 (n = 16, unadjusted)	87.88 (27.15)	64.49 (15.70)	76.39 (17.45)	70.55 (18.58)	-6.052	0.169	-14.565	0.027	-15.800	0.027
N = 27 ( $n = 10$ , partially adjusted)					(-14.675 (0 2.570)		(-27.441 (0 -1.689)		(-29.817 (0 -1.782)	
N = 24 ( $n = 8$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 64 ( $n = 28$ , unadjusted)	69.57	80.43	73.91	78.26	-0.433	0.873	-0.297	0.934	4.672	0.238
N = 62 ( $n = 27$ , partially adjusted)	(58.70–80.43)	(65.22-86.96)	(60.87–84.78)	(66.30-84.78)	(-5.756 to 4.890)		(-7.375 to 6.780)		(-3.090 to 12.435)	
N = 35 ( $n = 13$ , fully adjusted)										
CHU9D utility score										
N = 77 (n = 41,  unadjusted)	0.81 (0.16)	0.89 (0.10)	0.83 (0.15)	0.87 (0.11)	0.022	0.414	0.030	0.282	-0.024	0.272
N = 74 ( $n = 39$ , partially adjusted)					(-0.031 to 0.075)		(-0.025 to 0.084)		(-0.068 to 0.019)	
N = 36 ( $n = 14$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n <i>(%)</i>		n <i>(%)</i>		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 78 ( $n = 42$ , unadjusted)	14 (23.33)	11 (26.19)	13 (25.49)	10 (27.78)	-0.016	0.861	-0.131	0.047	-0.243	0.085
N = 75 ( $n = 40$ , partially adjusted)					(-0.142 (0 0.227)		(-0.201 (0 -0.002)		(-0.281 (0 0.085)	
N = 37 (n = 15,  fully adjusted)										
	Arm				Intervention vs. control					
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Follow-up outcome variable:	Intervention	1	Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 78 ( $n = 42$ , unadjusted)	23 (38.33)	13 (30.95)	16 (31.37)	14 (38.89)	-0.079	0.424	-0.193	0.021	-0.349	0.017
N = 75 ( $n = 40$ , partially adjusted)					(-0.212 to 0.153)		(-0.282 to -0.038)		(-0.391 to -0.123)	
N = 37 (n = 15,  fully adjusted)										
Five or more portions of fruit and veg	etables <sup>i</sup>									
N = 60 (n = 28, unadjusted)	24 (55.81)	11 (39.29)	28 (65.12)	20 (62.50)	-0.232	0.064	-0.283	0.033	-0.502	0.009
N = 51 ( $n = 21$ , partially adjusted)					(-0.384 (0 0.017)		(-0.429 (0 -0.030)		(-0.593 (0 -0.204)	
N = 33 ( $n = 12$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 40 (n = 16, unadjusted)	22 (56.41)	4 (25.00)	15 (45.45)	9 (37.50)	-0.125	0.460	-0.004	0.985	-0.282	0.016
N = 27 ( $n = 10$ , partially adjusted)					(-0.290 to 0.358)		(-0.224 to 0.914)		(-0.293 to -0.130)	
N = 24 ( $n = 8$ , fully adjusted)										

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

**TABLE 63** Adjusted differences for key variables between control and intervention groups at FU2: ethnicity – interaction terms

	p-value of interaction term							
	Unadjuste	ed model	Partially adju	sted model <sup>a</sup>	Fully adju	sted <sup>b</sup>		
Variables	South Asian	African Caribbean	South Asian	African Caribbean	South Asian	African Caribbean		
Continuous outcomes								
BMI-z	0.867	0.693	0.434	0.112	0.807	0.132		
Height (cm)	0.427	0.834	0.538	0.873	0.699	0.246		
Waist z-score	0.849	0.551	0.208	0.483	0.276	0.070		
Sum of four skinfolds (mm) <sup>c,d</sup>	0.118	0.578	0.024	0.036	0.099	0.005		
Body fat %	0.817	0.900	0.573	0.127	0.778	0.366		
Energy intake (kJ in 24 hours) <sup>e</sup>	0.755	0.498	0.973	0.729	0.623	0.626		
PA energy expenditure (kJ/kg/day)	0.444	0.073	0.399	0.006	0.327	< 0.001		
PedsQL total score <sup>f</sup>	0.022	0.494	0.026	0.564	0.137	0.429		
CHU9D utility score	0.082	0.447	0.090	0.418	0.148	0.859		
Binary outcomes								
Obese <sup>g</sup>	0.885	0.715	0.670	0.505	0.822	0.598		
Obese/overweight <sup>g</sup>	0.202	0.110	0.008	0.003	0.111	0.028		
Five or more portions of fruit and vegetables <sup>h</sup>	0.388	0.044	0.664	0.029	0.406	0.152		
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.001	0.445	0.002	0.839	0.001	0.267		

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

## TABLE 64 Adjusted differences for key variables between control and intervention groups at FU2: fidelity score = 3 (higher fidelity)

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
<i>N</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p-value
N = 800 (n = 179, unadjusted)	0.18 (1.15)	0.37 (1.30)	0.15 (1.20)	0.31 (1.32)	0.045	0.554	-0.036	0.528	-0.064	0.231
N = 760 (n = 171,  partially adjusted)					(-0.103 to 0.193)		(-0.147 to 0.075)		(-0.168 to 0.040)	
N = 543 ( $n = 130$ , fully adjusted)										
Height (cm)										
N = 801 (n = 172, unadjusted)	118.64 (5.87)	135.08 (7.04)	118.18 (5.38)	134.86 (6.43)	0.205	0.684	-0.392	0.289	-0.460	0.140
N = 762 ( $n = 172$ , partially adjusted)					(-0.782 to 1.192)		(-1.117 to 0.333)		(-1.070 to 0.151)	
N = 544 ( $n = 130$ , fully adjusted)										
Waist z-score										
N = 691 (n = 147, unadjusted)	0.75 (1.22)	1.13 (1.21)	0.66 (1.25)	0.90 (1.35)	0.214	0.081	0.056	0.511	0.005	0.959
N = 644 ( $n = 135$ , partially adjusted)					(-0.027 to 0.454)		(-0.111 to 0.222)		(-0.181 to 0.191)	
N = 494 ( $n = 111$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 590 (n = 126, unadjusted)	26.35	32.98	28.10	31.93	0.430	0.729	0.978	< 0.001	0.744	0.035
N = 501 (n = 111,  partially adjusted)	(21.43–32.63)	(23.55–46.50)	(23.00–36.60)	(24.00–48.90)	(-2.000 to 2.860)		(0.475 to 1.480)		(0.053 to 1.436)	
N = 389 (n = 91,  fully adjusted)										
Body fat %										
N = 775 (n = 176, unadjusted)	20.92 (5.09)	22.52 (7.34)	20.95 (5.22)	21.58 (7.26)	0.946	0.066	0.694	0.052	0.309	0.421
N = 722 ( $n = 166$ , partially adjusted)					(-0.061 to 1.953)		(-0.007 to 1.395)		(-0.443 to 1.062)	
N = 519 ( $n = 126$ , fully adjusted)										
										continued

## TABLE 64 Adjusted differences for key variables between control and intervention groups at FU2: fidelity score = 3 (higher fidelity) (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
<i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 704 (n = 142,  unadjusted)	6936	7568	6911	7817	-72.826	0.783	22.890	0.921	-121.248	0.592
N = 628 (n = 134,  partially adjusted)	(5922-8098)	(6568–9342)	(5804–7964)	(6748–9212)	(-590.405 to 444.754)		(-431.282 to 477.061)		(-564.137 to 321.641)	
N = 508 (n = 110,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 480 (n = 95, unadjusted)	96.35 (21.87)	76.43 (21.20)	94.08 (24.38)	78.60 (22.43)	-2.693	0.438	-4.956	0.197	-4.706	0.179
N = 397 (n = 79,  partially adjusted)					(-9.495 to 4.108)		(-12.485 to 2.572)		(-11.564 to 2.152)	
N = 360 (n = 77,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 771 (n = 150, unadjusted)	71.74	82.61	73.91	80.43	1.597	0.442	2.274	0.333	2.785	0.080
N = 721 ( $n = 143$ , partially adjusted)	(58.70–80.43)	(71.74–89.13)	(60.87-82.61)	(/1./4–89.13)	(-2.4/7 to 5.6/1)		(-2.329 to 6.876)		(-0.328 to 5.898)	
N = 526 ( $n = 117$ , fully adjusted)										
CHU9D utility score										
N = 787 (n = 173, unadjusted)	0.83 (0.14)	0.90 (0.09)	0.82 (0.14)	0.90 (0.09)	0.899	< 0.001	0.219	0.001	0.298	< 0.001
N = 723 ( $n = 160$ , partially adjusted)					(0.878 to 0.920)		(0.084 to 0.354)		(0.182 to 0.415)	
N = 518 ( $n = 121$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 800 (n = 179, unadjusted)	26 (11.40)	32 (17.88)	87 (11.89)	112 (18.04)	-0.002	0.943	0.013	0.684	0.025	0.313
N = 760 (n = 171,  partially adjusted)					(-0.040 to 0.048)		(-0.043 to 0.091)		(-0.021 to 0.083)	
N = 543 ( $n = 130$ , fully adjusted)										

Arm					Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 800 (n = 179, unadjusted)	46 (20.18)	57 (31.84)	150 (20.49)	187 (30.11)	0.017	0.480	0.030	0.423	-0.009	0.790
N = 760 ( $n = 171$ , partially adjusted)					(-0.028 to 0.071)		(-0.038 to 0.114)		(-0.067 to 0.063)	
N = 543 ( $n = 130$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 704 (n = 142, unadjusted)	129 (62.62)	76 (53.52)	405 (64.80)	317 (56.41)	-0.029	0.582	0.010	0.848	-0.009	0.835
N = 628 ( $n = 134$ , partially adjusted)					(-0.120 to 0.081)		(-0.085 to 0.124)		(-0.088 (0 0.083)	
N = 508 (n = 110,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 488 (n = 95, unadjusted)	87 (48.88)	17 (17.89)	276 (49.55)	120 (30.53)	-0.131	0.180	-0.141	0.166	-0.139	0.160
N = 400 (n = 79,  partially adjusted)					(-0.229 (0 0.090)		(-0.237 (0 0.089)		(-0.235 (0 0.082)	
N = 362 ( $n = 77$ , fully adjusted)										

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

TABLE 65 Adjusted differences for key variables between control and intervention groups at FU2: fidelity score = 2 (medium fidelity)

	Arm				Intervention vs. contr	ol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or r	nedian (IQR) <sup>c</sup>	Mean (SD) or r	nedian (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e	MD (95% CI)	p- <i>value</i>
<i>N</i> = 756 ( <i>n</i> = 135, unadjusted)	0.36 (1.21)	0.56 (1.33)	0.15 (1.20)	0.31 (1.32)	0.220	0.106	-0.030	0.711	-0.062	0.464
N = 721 ( $n = 132$ , partially adjusted)					(-0.047 (0 0.487)		(-0.187 (0 0.128)		(-0.229 (0 0.104)	
N = 513 ( $n = 100$ , fully adjusted)										
Height (cm)										
N = 757 (n = 132, unadjusted)	118.36 (5.50)	134.61 (6.54)	118.18 (5.38)	134.86 (6.43)	-0.242	0.638	-0.163	0.726	-0.566	0.190
N = 722 ( $n = 132$ , partially adjusted)					(-1.249 to 0.766)		(-1.074 to 0.748)		(-1.412 to 0.280)	
N = 514 ( $n = 100$ , fully adjusted)										
Waist z-score										
N = 667 (n = 123, unadjusted)	0.96 (1.17)	1.29 (1.25)	0.66 (1.25)	0.90 (1.35)	0.364	0.005	0.147	0.183	0.091	0.459
N = 624 ( $n = 115$ , partially adjusted)					(0.111 to 0.617)		(-0.069 to 0.362)		(-0.150 to 0.333)	
N = 474 ( $n = 91$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>de</sup>										
N = 574 (n = 110,  unadjusted)	31.55	35.05	28.10	31.93	3.150	0.109	0.552	0.085	0.330	0.320
N = 494 ( $n = 104$ , partially adjusted)	(25.63–38.55)	(26.40–51.75)	(23.00–36.60)	(24.00–48.90)	(-0.699 to 7.000)		(-0.076 to 1.179)		(-0.320 to 0.981)	
N = 381 (n = 83,  fully adjusted)										
Body fat %										
N = 733 ( $n = 134$ , unadjusted)	21.35 (5.15)	22.72 (7.04)	20.95 (5.22)	21.58 (7.26)	1.084	0.146	0.434	0.484	0.400	0.566
N = 688 (n = 132,  partially adjusted)					(–0.378 to 2.546)		(–U./82 to 1.650)		(–0.968 to 1.769)	
N = 493 ( $n = 100$ , fully adjusted)										

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>♭</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 689 (n = 127, unadjusted)	6808	7508	6911 (5804-7064)	7817	-448.925	0.092	-374.165	0.136	-530.508	0.085
N = 613 ( $n = 119$ , partially adjusted)	(5832-8064)	(6244–8835)	(5804–7964)	(6748–9212)	(-970.684 (0 72.835)		(-865.44510117.116)		(-1135.0511074.034)	
N = 493 ( $n = 95$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 474 ( $n = 89$ , unadjusted)	97.78 (23.58)	85.65 (23.97)	94.08 (24.38)	78.60 (22.43)	7.261	0.015	4.245	0.089	3.335 (	0.309
N = 395 ( $n = 77$ , partially adjusted)					(1.436 (0 13.086)		(-0.641 (0 9.132)		(-3.087 (0 9.758)	
N = 355 ( $n = 72$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 756 (n = 135, unadjusted)	71.74	80.43	73.91	80.43	0.751	0.595	1.265	0.425	-0.198	0.917
N = 710 (n = 132,  partially adjusted)	(60.87-82.61)	(71.74–89.13)	(60.87-82.61)	(71.74-89.13)	(-2.020 to 3.523)		(-1.842 to 4.372)		(-3.914 to 3.519)	
N = 509 (n = 100,  fully adjusted)										
CHU9D utility score										
N = 748 (n = 134, unadjusted)	0.83 (0.13)	0.89 (0.09)	0.82 (0.14)	0.90 (0.09)	0.893	< 0.001	0.152	0.002	0.179	< 0.001
N = 690 (n = 127,  partially adjusted)					(0.870 to 0.917)		(0.058 to 0.246)		(0.092 to 0.265)	
N = 493 ( $n = 96$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>valu</i> e
N = 756 (n = 135, unadjusted)	25 (14.79)	35 (25.93)	87 (11.89)	112 (18.04)	0.079	0.022	0.018	0.651	0.081	0.011
N = 721 ( $n = 132$ , partially adjusted)					(0.010 to 0.173)		(–0.049 to 0.119)		(0.016 to 0.167)	
N = 513 ( $n = 100$ , fully adjusted)										
										continued

#### TABLE 65 Adjusted differences for key variables between control and intervention groups at FU2: fidelity score = 2 (medium fidelity) (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 756 (n = 135, unadjusted)	41 (24.26)	51 (37.78)	150 (20.49)	187 (30.11)	0.077	0.079	0.009	0.822	0.083	0.030
N = 721 ( $n = 132$ , partially adjusted)					(-0.008 to 0.186)		(-0.062 to 0.101)		(0.007 to 0.178)	
N = 513 ( $n = 100$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 689 (n = 127, unadjusted)	96 (61.15)	69 (54.33)	405 (64.80)	317 (56.41)	-0.021	0.783	-0.000	0.997	0.081	0.320
N = 613 ( $n = 119$ , partially adjusted)					(-0.148 (0 0.146)		(-0.150 to 0.205)		(-0.068 (0 0.275)	
N = 493 ( $n = 95$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 483 (n = 90, unadjusted)	57 (43.18)	27 (30.00)	276 (49.55)	120 (30.53)	-0.005	0.923	0.058	0.351	0.077	0.266
N = 399 (n = 78,  partially adjusted)					(-0.095 (0 0.120)		(-0.055 to 0.216)		(-0.046 (0 0.262)	
N = 358 ( $n = 73$ , fully adjusted)										

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

## TABLE 66 Adjusted differences for key variables between control and intervention groups at FU2: fidelity score = 1 (lower fidelity)

-	-			-			-			
	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 831 (n = 210, unadjusted)	0.19 (1.33)	0.38 (1.39)	0.15 (1.20)	0.31 (1.32)	0.055	0.569	-0.023	0.801	0.001	0.993
N = 791 ( $n = 202$ , partially adjusted)					(-0.133 to 0.243)		(-0.199 to 0.154)		(-0.175 to 0.177)	
N = 542 ( $n = 129$ , fully adjusted)										
Height (cm)										
N = 832 (n = 202, unadjusted)	118.79 (5.44)	134.50 (6.48)	118.18 (5.38)	134.86 (6.43)	-0.361	0.544	-0.821	0.131	-0.873	0.084
N = 792 ( $n = 202$ , partially adjusted)					(-1.527 to 0.804)		(-1.885 to 0.243)		(-1.865 to 0.118)	
N = 543 ( $n = 129$ , fully adjusted)										
Waist z-score										
N = 720 (n = 176, unadjusted)	0.65 (1.30)	1.08 (1.28)	0.66 (1.25)	0.90 (1.35)	0.156	0.260	0.097	0.361	0.099	0.239
N = 673 ( $n = 164$ , partially adjusted)					(-0.116 to 0.428)		(-0.111 to 0.304)		(-0.066 to 0.264)	
N = 501 (n = 118,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 609 (n = 145, unadjusted)	28.38	35.60	28.10	31.93	2.261	0.116	0.550	0.271	0.766	0.210
N = 509 (n = 119,  partially adjusted)	(23.82–35.38)	(25.50–50.70)	(23.00–36.60)	(24.00–48.90)	(-0.561 to 5.084)		(-0.430 to 1.530)		(-0.432 to 1.964)	
N = 386 (n = 88,  fully adjusted)										
Body fat %										
N = 805 (n = 206, unadjusted)	21.58 (5.69)	22.39 (7.89)	20.95 (5.22)	21.58 (7.26)	0.753	0.300	-0.019	0.973	-0.068	0.917
N = 753 ( $n = 197$ , partially adjusted)					(-0.670 to 2.175)		(-1.124 to 1.086)		(-1.345 to 1.210)	
N = 521 ( $n = 128$ , fully adjusted)										
										continued

TABLE 66 Adjusted differences for key variables between control and intervention groups at FU2: fidelity score = 1 (lower fidelity) (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 746 (n = 184, unadjusted)	6926	7755	6911 (5004-7064)	7817	-135.158	0.561	-57.112	0.795	-164.351	0.449
N = 642 ( $n = 148$ , partially adjusted)	(5805-7971)	(6411–9153)	(5804–7964)	(6748–9212)	(-590.471 to 320.154)		(-488.917 to 374.694)		(-589.455 to 260.753)	
N = 524 ( $n = 126$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 506 (n = 121, unadjusted)	95.52 (24.15)	77.80 (21.06)	94.08 (24.38)	78.60 (22.43)	-0.903	0.729	-0.033	0.990	-0.698	0.783
N = 415 ( $n = 97$ , partially adjusted)					(-6.004 (0 4.199)		(-5.148 (0 5.082)		(-5.671 (0 4.275)	
N = 371 (n = 88,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 831 (n = 210, unadjusted)	71.74	82.61	73.91	80.43	0.732	0.653	0.548	0.772	1.827	0.175
N = 780 (n = 202,  partially adjusted)	(60.87-82.61)	(71.74-89.13)	(60.87-82.61)	(71.74-89.13)	(-2.454 (0 3.917)		(-3.166 (0 4.261)		(-0.811 (0 4.464)	
N = 538 ( $n = 129$ , fully adjusted)										
CHU9D utility score										
N = 824 (n = 210, unadjusted)	0.84 (0.13)	0.89 (0.09)	0.82 (0.14)	0.90 (0.09)	0.888	< 0.001	0.199	< 0.001	0.174	0.005
N = 762 ( $n = 199$ , partially adjusted)					(0.872 to 0.904)		(0.090 to 0.308)		(0.054 to 0.295)	
N = 524 ( $n = 127$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 831 (n = 210, unadjusted)	33 (12.55)	41 (19.52)	87 (11.89)	112 (18.04)	0.015	0.589	-0.030	0.249	-0.010	0.732
N = 791 ( $n = 202$ , partially adjusted)					(-0.034 to 0.080)		(-0.071 to 0.025)		(-0.057 to 0.054)	
N = 542 ( $n = 129$ , fully adjusted)										

Arm				Intervention vs. cont	rol				
Intervention		Control							
Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
58 (22.05)	68 (32.38)	150 (20.49)	187 (30.11)	0.023	0.518	-0.022	0.664	-0.027	0.567
				(-0.041 to 0.102)		(-0.103 to 0.091)		(-0.102 to 0.077)	
etables <sup>i</sup>									
111 (55.78)	108 (58.70)	405 (64.80)	317 (56.41)	0.023	0.642	0.023	0.645	-0.012	0.825
				(-0.068 to 0.130)		(-0.069 to 0.131)		(-0.107 to 0.103)	
84 (46.41)	26 (21.31)	276 (49.55)	120 (30.53)	-0.093	0.249	-0.109	0.201	-0.113	0.314
				(-0.191 to 0.088)		(-0.206 to 0.081)		(-0.228 to 0.167)	
	Arm Intervention Baseline 58 (22.05) 58 (22.05) tables <sup>i</sup> 111 (55.78) 84 (46.41)	Arm   Intervention   Baseline FU2   58 (22.05) 68 (32.38)   stables <sup>i</sup> 111 (55.78)   111 (55.78) 108 (58.70)   84 (46.41) 26 (21.31)	Arm Control   Intervention Control   Baseline FU2 Baseline   58 (22.05) 68 (32.38) 150 (20.49)   58 (22.05) 68 (32.38) 150 (20.49)   stables <sup>i</sup> 111 (55.78) 108 (58.70) 405 (64.80)   84 (46.41) 26 (21.31) 276 (49.55)	Arm   Control     Baseline   FU2   Baseline   FU2     58 (22.05)   68 (32.38)   150 (20.49)   187 (30.11)     stables <sup>i</sup> 111 (55.78)   108 (58.70)   405 (64.80)   317 (56.41)     84 (46.41)   26 (21.31)   276 (49.55)   120 (30.53)	Arm Intervention Control   Baseline FU2 Baseline FU2 Unadjusted   58 (22.05) 68 (32.38) 150 (20.49) 187 (30.11) 0.023 (-0.041 to 0.102)   stables' 111 (55.78) 108 (58.70) 405 (64.80) 317 (56.41) 0.023 (-0.068 to 0.130)   84 (46.41) 26 (21.31) 276 (49.55) 120 (30.53) -0.093 (-0.191 to 0.088)	Arm   Intervention vs. control     Intervention   Control     Baseline   FU2   Baseline   FU2   Unadjusted     58 (22.05)   68 (32.38)   150 (20.49)   187 (30.11)   0.023 (-0.041 to 0.102)   0.518 (-0.041 to 0.102)     stables'   111 (55.78)   108 (58.70)   405 (64.80)   317 (56.41)   0.023 (-0.068 to 0.130)   0.642 (-0.068 to 0.130)     84 (46.41)   26 (21.31)   276 (49.55)   120 (30.53)   -0.093 (-0.191 to 0.088)   0.249 (-0.191 to 0.088)	Arm   Intervention   Control     Baseline   FU2   Baseline   FU2   Unadjusted   Partially adjusted <sup>a</sup> 58 (22.05)   68 (32.38)   150 (20.49)   187 (30.11)   0.023 (-0.041 to 0.102)   0.518   -0.022 (-0.103 to 0.091)     stables'   111 (55.78)   108 (58.70)   405 (64.80)   317 (56.41)   0.023 (-0.068 to 0.130)   0.642   0.023 (-0.069 to 0.131)     84 (46.41)   26 (21.31)   276 (49.55)   120 (30.53)   -0.093 (-0.191 to 0.088)   0.249   -0.109 (-0.206 to 0.081)	Arm   Intervention   Control     Baseline   FU2   Baseline   FU2   Unadjusted   Partially adjusted <sup>a</sup> 58 (22.05)   68 (32.38)   150 (20.49)   187 (30.11)   0.023 (-0.041 to 0.102)   0.518   -0.022 (-0.103 to 0.091)   0.664     tables <sup>d</sup> Image: State	Arm   Intervention   Control     Baseline   FU2   Baseline   FU2   Unadjusted   Partially adjusted <sup>®</sup> Fully adjusted <sup>®</sup> 58 (22.05)   68 (32.38)   150 (20.49)   187 (30.11)   0.023 (-0.041 to 0.102)   0.518   -0.022 (-0.103 to 0.091)   0.664   -0.027 (-0.102 to 0.077)     trables'            111 (55.78)   108 (58.70)   405 (64.80)   317 (56.41)   0.023 (-0.068 to 0.130)   0.642   0.023 (-0.069 to 0.131)   0.645   -0.012 (-0.107 to 0.103)     84 (46.41)   26 (21.31)   276 (49.55)   120 (30.53)   -0.093 (-0.191 to 0.088)   0.249   -0.109 (-0.206 to 0.081)   0.201   -0.113 (-0.228 to 0.167)

N = 374 (n = 89, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

- d Transformed via inverse.
- e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.
- f Transformed via natural logarithm.
- g Transformed via squaring.
- h Adjusted for baseline BMI-z.
- i Adjusted for total grams of fruit and vegetables consumed per day.
- j Adjusted for minutes of PA per 24 hours.

TABLE 67 Adjusted differences for key variables between control and intervention groups at FU2: fidelity score – interaction terms

	<i>p</i> -value of interaction term										
	Unadjusted	model	Partially adjust	ed model <sup>a</sup>	el <sup>a</sup> Fully adjusted <sup>b</sup>						
Variable	Low fidelity	Medium fidelity	Low fidelity	Medium fidelity	Low fidelity	Medium fidelity					
Continuous outcomes											
BMI-z	0.897	0.116	0.818	0.907	0.611	0.624					
Height (cm)	0.383	0.425	0.464	0.658	0.527	0.919					
Waist z-score	0.713	0.259	0.685	0.413	0.349	0.573					
Sum of four skinfolds (mm) <sup>c,d</sup>	0.177	0.123	0.380	0.106	0.880	0.022					
Body fat %	0.815	0.837	0.205	0.687	0.439	0.614					
Energy intake (kJ in 24 hours) <sup>e</sup>	0.841	0.266	0.768	0.201	0.903	0.262					
PA energy expenditure (kJ/kg/day)	0.635	0.012	0.223	0.020	0.176	0.048					
PedsQL total score <sup>f</sup>	0.724	0.723	0.536	0.712	0.811	0.321					
CHU9D utility score	0.703	0.412	0.616	0.377	0.249	0.742					
Binary outcomes											
Obese <sup>9</sup>	0.571	0.025	0.774	0.463	0.670	0.458					
Obese/overweight <sup>9</sup>	0.863	0.141	0.704	0.772	0.868	0.693					
Five or more portions of fruit and vegetables <sup>h</sup>	0.384	0.920	0.555	0.905	0.756	0.166					
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.689	0.193	0.752	0.082	0.735	0.080					

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

#### TABLE 68 Adjusted differences for key variables between control and intervention groups at FU2: boys only

	-			-		-				
	Arm				Intervention vs. con	trol				
Follow-up outcome variable:	Intervention		Control							
n = 100 for a participants ( $n = 100$ number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR) <sup>c</sup>	Mean (SD) or	median (IQR) <sup>c</sup>	MD (95% CI)	p-value	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e
N = 589 (n = 255, unadjusted)	0.35 (1.36)	0.61 (1.44)	0.13 (1.25)	0.35 (1.35)	0.263	0.011	0.023	0.716	-0.038	0.560
N = 568 ( $n = 246$ , partially adjusted)					(0.061 to 0.464)		(-0.100 to 0.146)		(-0.167 to 0.090)	
N = 397 ( $n = 172$ , fully adjusted)										
Height (cm)										
N = 589 (n = 246, unadjusted)	119.32 (5.54)	135.48 (6.51)	118.86 (5.40)	135.42 (6.41)	0.061	0.907	-0.530	0.161	-0.615	0.094
N = 568 ( $n = 246$ , partially adjusted)					(-0.956 (0 1.078)		(-1.271 to 0.211)		(-1.334 to 0.104)	
N = 397 ( $n = 172$ , fully adjusted)										
Waist z-score										
N = 517 (n = 223, unadjusted)	0.77 (1.27)	1.12 (1.30)	0.61 (1.23)	0.82 (1.33)	0.300	0.021	0.071	0.409	0.012	0.893
N = 490 (n = 209,  partially adjusted)					(0.046 to 0.554)		(-0.098 to 0.241)		(-0.163 to 0.187)	
N = 367 ( $n = 156$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 469 (n = 198, unadjusted)	25.70	30.35	25.80	27.90	1.698	0.139	0.472	0.164	0.331	0.363
N = 408 ( $n = 176$ , partially adjusted)	(21.30–32.80)	(22.25–45.70)	(21.40–32.10)	(22.10–42.10)	(-0.553 to 3.949)		(-0.192 to 1.136)		(-0.382 to 1.043)	
N = 311 ( $n = 136$ , fully adjusted)										
Body fat %										
N = 575 ( $n = 251$ , unadjusted)	20.86 (5.19)	21.93 (8.41)	20.21 (4.72)	20.10 (7.16)	1.826	0.004	0.623	0.150	0.400	0.376
N = 544 ( $n = 240$ , partially adjusted)					(0.572 to 3.080)		(-0.224 to 1.471)		(-0.486 to 1.286)	
N = 386 (n = 170,  fully adjusted)										
										continued

## TABLE 68 Adjusted differences for key variables between control and intervention groups at FU2: boys only (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 527 (n = 226, unadjusted)	7151	7566	7119	7787	-347.761	0.097	-266.416	0.162	-307.410	0.161
N = 460 (n = 194,  partially adjusted)	(6126-8300)	(6255-9016)	(5998-8223)	(6728–9244)	(-/58.689 (0 63.167)		(-640.120 (0 107.289)		(-736.999 (0 122.178)	
N = 379 (n = 162,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 363 (n = 160, unadjusted)	103.42(23.84)	84.72 (24.04)	100.36(25.02)	85.28 (23.20)	0.671	0.826	-1.854	0.529	-2.038	0.505
N = 304 (n = 130,  partially adjusted)					(-5.300 10 6.643)		(-7.629 (0 3.921)		(-8.033 (0 3.957)	
N = 271 (n = 120,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 575 (n = 242, unadjusted)	70.65	81.52	73.91	81.82	-0.054	0.960	0.334	0.813	0.529	0.730
N = 548 (n = 233,  partially adjusted)	(59.98-82.01)	(71.74-89.13)	(60.87–84.78)	(69.57-89.13)	(-2.185 (0 2.077)		(-2.432 (0 3.100)		(-2.478 (0 3.537)	
N = 391 (n = 168,  fully adjusted)										
CHU9D utility score										
N = 581 (n = 251, unadjusted)	0.83 (0.14)	0.89 (0.09)	0.82 (0.15)	0.90 (0.09)	-0.007	0.403	-0.008	0.376	-0.005	0.592
N = 546 (n = 238,  partially adjusted)					(-0.024 (0 0.010)		(-0.025 to 0.010)		(-0.023 to 0.013)	
N = 384 (n = 166,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n <i>(%)</i>		n <i>(%)</i>		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 589 (n = 255, unadjusted)	50 (15.20)	67 (26.27)	51 (13.04)	66 (19.76)	0.059	0.019	0.000	0.990	0.048	0.085
N = 568 (n = 246,  partially adjusted)					(0.009-0.124)		(-0.030-0.040)			
N = 397 (n = 172,  fully adjusted)										

	Arm			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 589 (n = 255, unadjusted)	90 (27.36)	109 (42.75)	78 (19.95)	104 (31.14)	0.116	0.002	0.037	0.282	0.044	0.207
N = 568 (n = 246,  partially adjusted)					(0.037 to 0.213)		(-0.027 to 0.114)		(-0.022 to 0.123)	
N = 397 (n = 172,  fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 527 (n = 226, unadjusted)	157 (57.30)	115 (50.88)	206 (62.05)	154 (51.16)	-0.003	0.954	0.018	0.725	0.038	0.453
N = 460 (n = 194,  partially adjusted)					(-0.089 to 0.100)		(–0.076 to 0.134)		(-0.055 to 0.150)	
N = 379 (n = 162,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
<i>N</i> = 368 ( <i>n</i> = 162, unadjusted)	138 (56.10)	44 (27.16)	161 (54.76)	82 (39.81)	-0.116	0.129	-0.119	0.138	-0.117	0.130
N = 305 ( $n = 131$ , partially adjusted)					(-0.217 to 0.042)		(-0.224 to 0.048)		(-0.220 to 0.043)	

N = 272 (n = 122, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

## TABLE 69 Adjusted differences for key variables between control and intervention groups at FU2: girls only

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>valu</i> e	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 556 (n = 269, unadjusted)	0.11 (1.10)	0.24 (1.22)	0.16 (1.15)	0.27 (1.29)	-0.043	0.706	-0.023	0.731	-0.012	0.883
N = 526 ( $n = 259$ , partially adjusted)					(-0.266 to 0.180)		(-0.157 to 0.110)		(-0.173 (0 0.149)	
N = 375 ( $n = 187$ , fully adjusted)										
Height (cm)										
N = 557 (n = 260, unadjusted)	117.95 (5.59)	134.02 (6.79)	117.40 (5.25)	134.20 (6.41)	-0.167	0.794	-0.423	0.202	-0.601	0.065
N = 528 (n = 260,  partially adjusted)					(-1.419 to 1.086)		(-1.074 to 0.228)		(-1.239 to 0.037)	
N = 376 ( $n = 187$ , fully adjusted)										
Waist z-score										
N = 473 (n = 223, unadjusted)	0.76 (1.22)	1.18 (1.19)	0.71 (1.27)	0.98 (1.37)	0.174	0.239	0.145	0.126	0.148	0.155
N = 433 ( $n = 205$ , partially adjusted)					(-0.116 to 0.464)		(-0.041 to 0.331)		(-0.056 to 0.353)	
N = 336 ( $n = 164$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 376 (n = 183, unadjusted)	30.80	37.65	32.00	38.95	0.829	0.655	0.659	0.048	0.687	0.034
N = 316 ( $n = 158$ , partially adjusted)	(25.70–38.35)	(29.50–52.30)	(25.45–40.42)	(27.65–55.60)	(-2.807 to 4.466)		(0.005 to 1.314)		(0.053 to 1.320)	
N = 249 (n = 126,  fully adjusted)										
Body fat %										
$N = 540 \ (n = 265, \text{ unadjusted})$	21.72 (5.49)	23.08 (6.44)	21.79 (5.62)	23.32 (6.99)	-0.314	0.642	-0.210	0.659	-0.003	0.996
N = 507 (n = 255,  partially adjusted)					(-1.635 to 1.008)		(-1.142 to 0.722)		(-1.138 to 1.132)	
N = 361 (n = 184,  fully adjusted)										

**APPENDIX 60** 

	Arm				Intervention vs. conti	ol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 488 (n = 227, unadjusted)	6644	7814	6719	7856	-52.406	0.832	19.290	0.937	-187.707	0.419
N = 435 ( $n = 207$ , partially adjusted)	(5596-7772)	(0590-9250)	(5591-7639)	(6779-9165)	(-537.463 (0 432.651)		(-460.927 (0 499.506)		(-043.125 (0 207.711)	
N = 350 (n = 169,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 327 ( $n = 145$ , unadjusted)	89.38 (20.18)	74.09 (18.66)	86.98 (21.57)	71.15 (18.99)	2.900	0.243	3.939	0.093	2.931	0.181
N = 267 (n = 123,  partially adjusted)					(-1.969 to 7.769)		(-0.653 to 8.530)		(-1.366 to 7.229)	
N = 249 ( $n = 117$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 541 (n = 253, unadjusted)	71.74	82.61	71.74	80.22	1.498	0.359	1.724 ( .2.000 to F. 457)	0.365	1.553	0.329
N = 507 (n = 244,  partially adjusted)	(60.87-82.61)	(71.74–90.91)	(58.70-80.43)	(71.74–89.13)	(-1.702 to 4.698)		(-2.009 to 5.457)		(-1.567 to 4.672)	
N = 364 ( $n = 178$ , fully adjusted)										
CHU9D utility score										
N = 550 (n = 266, unadjusted)	0.84 (0.12)	0.89 (0.09)	0.81 (0.14)	0.90 (0.09)	-0.002	0.849	-0.006	0.605	-0.008	0.478
N = 503 ( $n = 248$ , partially adjusted)					(-0.022 to 0.018)		(-0.028 to 0.016)		(-0.029 to 0.014)	
N = 357 (n = 178,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>valu</i> e
N = 556 (n = 269, unadjusted)	34 (10.27)	41 (15.24)	36 (10.56)	46 (16.03)	-0.009	0.813	0.015	0.692	-0.007	0.866
N = 526 ( $n = 259$ , partially adjusted)					(-0.067 to 0.080)		(-0.050 to 0.111)		(-0.070 to 0.092)	
N = 375 ( $n = 187$ , fully adjusted)										
										continued

#### TABLE 69 Adjusted differences for key variables between control and intervention groups at FU2: girls only (continued)

Arm					Intervention vs. contro	ol				
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 556 (n = 269, unadjusted)	55 (16.62)	67 (24.91)	72 (21.11)	83 (28.92)	-0.040	0.318	-0.011	0.809	-0.027	0.538
N = 526 (n = 259,  partially adjusted)					(-0.103 to 0.045)		(-0.088 to 0.095)		(-0.097 to 0.069)	
N = 375 (n = 187,  fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 488 (n = 227, unadjusted)	179 (62.15)	138 (60.79)	199 (67.92)	163 (62.45)	-0.017	0.734	-0.007	0.898	-0.019	0.753
N = 435 ( $n = 207$ , partially adjusted)					(-0.104 to 0.085)		(-0.098 to 0.101)		(-0.124 to 0.108)	
N = 350 (n = 169,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 332 (n = 145, unadjusted)	90 (36.73)	26 (17.93)	115 (43.73)	38 (20.32)	-0.024	0.644	0.008	0.876	-0.010	0.852
N = 270 (n = 123,  partially adjusted)					(-0.099 to 0.104)		(-0.071 to 0.140)		(-0.085 to 0.120)	
N = 252 ( $n = 117$ , fully adjusted)										

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

TABLE 70	Adjusted d	ifferences for	key variable	s between	control and	d intervention	groups at	FU2: sex –
interactio	n terms							

	<i>p</i> -value of interaction term				
Variable	Unadjusted model	Partially adjusted model <sup>a</sup>	Fully adjusted <sup>b</sup>		
Continuous outcomes					
BMI-z	0.033	0.475	0.968		
Height (cm)	0.759	0.523	0.244		
Waist z-score	0.447	0.721	0.265		
Sum of four skinfolds (mm) <sup>c,d</sup>	0.310	0.960	0.638		
Body fat %	0.016	0.099	0.457		
Energy intake (kJ in 24 hours) <sup>e</sup>	0.261	0.311	0.592		
PA energy expenditure (kJ/kg/day)	0.440	0.095	0.161		
PedsQL total score <sup>f</sup>	0.298	0.395	0.743		
CHU9D utility score	0.595	0.749	0.731		
Binary outcomes					
Obese <sup>9</sup>	0.170	0.205	0.155		
Obese/overweight <sup>g</sup>	0.009	0.414	0.774		
Five or more portions of fruit and vegetables $^{\rm h}$	0.822	0.686	0.433		
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.493	0.283	0.488		

a Adjusted for baseline outcome.

 b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

## TABLE 71 Adjusted differences for key variables between control and intervention groups at FU2: IMD score of 1, 2 (more deprived)

	Arm			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
<i>N</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 816 (n = 384, unadjusted)	0.21 (1.30)	0.40 (1.40)	0.20 (1.28)	0.38 (1.38)	0.020	0.834	-0.032	0.605	-0.053	0.465
N = 785 ( $n = 371$ , partially adjusted)					(-0.170 to 0.210)		(-0.155 to 0.090)		(-0.194 to 0.089)	
N = 543 ( $n = 261$ , fully adjusted)										
Height (cm)										
N = 817 (n = 372, unadjusted) N = 787 (n = 372, partially adjusted) N = 544 (n = 261, fully adjusted)	118.58 (5.56)	134.54 (6.74)	118.21 (5.44)	134.91 (6.49)	-0.360 (-1.339 to 0.619)	0.471	–0.620 (–1.362 to 0.121)	0.101	–0.787 (–1.497 to –0.077)	0.030
Waist z-score										
N = 698 (n = 326, unadjusted) N = 656 (n = 305, partially adjusted) $N = 485 (n = 227, fully adjusted)$	0.71 (1.29)	1.13 (1.27)	0.72 (1.31)	0.96 (1.43)	0.154 (-0.092 to 0.400)	0.219	0.086 (-0.090 to 0.262)	0.337	0.056 (-0.139 to 0.250)	0.575
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 583 (n = 273, unadjusted) N = 510 (n = 245, partially adjusted) N = 383 (n = 188, fully adjusted)	28.45 (22.95–35.30)	34.10 (25.50–49.95)	29.25 (23.60–37.70)	33.70 (24.55–52.00)	0.316 (-2.547 to 3.179)	0.829	0.446 (-0.188 to 1.080)	0.168	0.319 (-0.389 to 1.027)	0.377
Body fat %										
N = 792 (n = 376, unadjusted) N = 750 (n = 363, partially adjusted) $N = 523 (n = 258, fully adjusted)$	21.28 (5.37)	22.49 (7.76)	21.42 (5.43)	22.13 (7.60)	0.343 (-0.749 to 1.435)	0.538	0.369 (-0.467 to 1.204)	0.387	0.075 (-0.919 to 1.068)	0.883

	Arm				Intervention vs. conti	rol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 713 (n = 331, unadjusted)	6978	7751	6895	7820	-83.395	0.707	-11.748	0.956	-120.351	0.585
N = 619 (n = 287,  partially adjusted)	(5887–8207)	(6486–9342)	(5730–7992)	(6704–9294)	(-518.854 to 352.064)		(-425.495 to 401.999)		(-552.310 to 311.608)	
N = 504 ( $n = 234$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 488 (n = 228, unadjusted)	97.05 (23.72)	77.60 (20.98)	93.05 (24.16)	77.01 (21.79)	0.605	0.767	-1.250	0.618	-1.557	0.458
N = 401 ( $n = 185$ , partially adjusted)					(-3.398 (0 4.609)		(-0.103 (0 3.003)		(-5.673 (0 2.559)	
N = 363 ( $n = 174$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 788 (n = 356, unadjusted)	71.74	82.61	73.91	78.26	1.349 ( 1.071 to 2.7(8)	0.275	1.622	0.258	1.127	0.372
N = 748 ( $n = 344$ , partially adjusted)	(58.70-82.61)	(71.74–89.13)	(60.87-82.61)	(69.57–88.04)	(-1.071 to 3.768)		(-1.187 to 4.430)		(-1.347 to 3.602)	
N = 526 ( $n = 248$ , fully adjusted)										
CHU9D utility score										
N = 804 (n = 378, unadjusted)	0.83 (0.14)	0.90 (0.09)	0.81 (0.15)	0.89 (0.09)	0.005	0.505	0.002	0.815	0.001	0.895
N = 750 (n = 359,  partially adjusted)					(-0.009 to 0.019)		(-0.014 to 0.017)		(-0.014 to 0.016)	
N = 521 ( $n = 253$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>valu</i> e
N = 816 (n = 384, unadjusted)	65 (13.18)	86 (22.40)	73 (13.96)	87 (20.14)	0.023	0.365	0.010	0.721	0.029	0.276
N = 785 ( $n = 371$ , partially adjusted)					(-0.023 to 0.080)		(-0.039 to 0.074)		(–0.021 to 0.093)	
N = 543 ( $n = 261$ , fully adjusted)										
										continued

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#### TABLE 71 Adjusted differences for key variables between control and intervention groups at FU2: IMD score of 1, 2 (more deprived) (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 816 (n = 384, unadjusted)	114 (23.12)	126 (32.81)	116 (22.18)	138 (31.94)	0.009	0.773	0.004	0.918	0.003	0.913
N = 785 ( $n = 371$ , partially adjusted)					(-0.046 (0 0.074)		(-0.057 (0 0.078)		(-0.052 (0 0.070)	
N = 543 ( $n = 261$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 713 (n = 331, unadjusted)	260 (61.47)	186 (56.19)	274 (63.57)	205 (53.66)	0.025	0.588	0.049	0.292	0.048	0.297
N = 619 (n = 287,  partially adjusted)					(-0.061 to 0.127)		(-0.039 to 0.152)		(-0.039 to 0.150)	
N = 504 ( $n = 234$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 497 (n = 229, unadjusted)	184 (50.55)	48 (20.96)	189 (48.59)	72 (26.87)	-0.057	0.294	-0.049	0.429	-0.043	0.488
N = 404 ( $n = 185$ , partially adjusted)					(-0.132 to 0.061)		(-0.135 to 0.092)		(-0.132 to 0.101)	

N = 367 (n = 175, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

## TABLE 72 Adjusted differences for key variables between control and intervention groups at FU2: IMD score of 3–5 (less deprived)

	Arm				Intervention vs. conti	rol				
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p-value	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 316 (n = 134, unadjusted)	0.29 (1.09)	0.45 (1.17)	-0.00 (1.01)	0.15 (1.17)	0.303	0.027	0.013	0.866	-0.023	0.842
N = 297 (n = 128,  partially adjusted)					(0.034 to 0.571)		(-0.135 to 0.160)		(-0.250 to 0.204)	
N = 229 (n = 98,  fully adjusted)										
Height (cm)										
N = 316 (n = 128, unadjusted)	118.84 (5.71)	135.18 (6.46)	118.09 (5.24)	134.81 (6.34)	0.373	0.545	0.075	0.860	0.146	0.653
N = 297 (n = 128,  partially adjusted)					(-0.836 to 1.582)		(-0.760 to 0.910)		(-0.491 to 0.783)	
N = 229 (n = 98,  fully adjusted)										
Waist z-score										
N = 281 (n = 115, unadjusted)	0.95 (1.10)	1.18 (1.17)	0.52 (1.07)	0.75 (1.15)	0.422	0.004	0.090	0.235	0.077	0.296
N = 257 (n = 104,  partially adjusted)					(0.131 to 0.713)		(-0.059 to 0.240)		(-0.068 to 0.222)	
N = 218 (n = 93,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 254 ( $n = 103$ , unadjusted)	29.13	36.40	26.90	29.40	5.263	0.000	0.973	0.012	1.083	0.015
N = 208 (n = 85,  partially adjusted)	(23.95–36.38)	(24.95–48.55)	(22.20–33.63)	(23.40–43.00)	(2.468 to 8.058)		(0.216 to 1.731)		(0.212 to 1.953)	
N = 177 (n = 74,  fully adjusted)										
Body fat %										
N = 310 (n = 134, unadjusted)	21.24 (4.97)	22.51 (6.67)	19.81 (4.48)	20.30 (6.32)	2.203	0.000	0.495	0.412	0.480	0.555
N = 290 (n = 126,  partially adjusted)					(1.015 to 3.392)		(-0.688 to 1.678)		(-1.113 to 2.073)	
N = 224 ( $n = 96$ , fully adjusted)										
										continued

## TABLE 72 Adjusted differences for key variables between control and intervention groups at FU2: IMD score of 3–5 (less deprived) (continued)

	<u>Arm</u>				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
<i>N</i> = 290 ( <i>n</i> = 117, unadjusted)	6773	7560	6930 (FOFF 704C)	7793	-525.078	0.020	-402.539	0.029	-334.060	0.071
N = 267 (n = 109,  partially adjusted)	(5706-7748)	(6280-8464)	(5955–7946)	(6899–9159)	(-966.21010-83.946)		(-764.021 t0 -41.057)		(-090.955 (0 28.835)	
N = 225 ( $n = 97$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 194 (n = 73, unadjusted)	93.70 (21.54)	85.48 (25.38)	96.67 (24.93)	82.30 (23.57)	3.085	0.475	3.588	0.293	1.770	0.616
N = 165 (n = 65,  partially adjusted)					(-5.382 to 11.551)		(-3.096 to 10.272)		(-5.144 to 8.684)	
N = 157 (n = 63,  fully adjusted)										
PedsQL total score <sup>9</sup>										
N = 316 (n = 134, unadjusted)	73.91	82.61	73.91	82.61	-0.000	0.999	-0.447	0.867	0.113	0.967
N = 296 (n = 128,  partially adjusted)	(65.22-84.78)	(71.74–89.13)	(63.04–82.61)	(73.91–89.13)	(-4.443 to 4.442)		(-5.664 to 4.770)		(-5.169 to 5.394)	
N = 229 (n = 98,  fully adjusted)										
CHU9D utility score										
N = 314 (n = 133, unadjusted)	0.85 (0.12)	0.88 (0.10)	0.84 (0.14)	0.91 (0.08)	-0.029	0.059	-0.031	0.050	-0.031	0.051
N = 287 (n = 121,  partially adjusted)					(-0.059 to 0.001)		(-0.063 to 0.000)		(-0.061 to 0.000)	
N = 220 ( $n = 91$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 316 (n = 134, unadjusted)	18 (11.84)	21 (15.67)	14 (6.97)	25 (13.74)	0.019	0.470	-0.062	0.021	-0.056	0.178
N = 297 (n = 128,  partially adjusted)					(-0.028 to 0.087)		(–0.093 to –0.012)		(-0.100 to 0.036)	
N = 229 (n = 98,  fully adjusted)										

	Arm				Intervention vs. control						
Follow-up outcome variable:	Intervention	Intervention		Control							
<i>N</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
Obese/overweight <sup>h</sup>											
N = 316 (n = 134, unadjusted)	27 (17.76)	46 (34.33)	34 (16.92)	45 (24.73)	0.096	0.047	-0.026	0.612	-0.050	0.424	
N = 297 ( $n = 128$ , partially adjusted)					(0.001 to 0.228)		(-0.105 to 0.094)		(-0.135 to 0.095)		
N = 229 ( $n = 98$ , fully adjusted)											
Five or more portions of fruit and veg	etables <sup>i</sup>										
N = 290 (n = 117, unadjusted)	67 (52.76)	64 (54.70)	129 (68.25)	109 (63.01)	-0.083	0.276	-0.066	0.417	-0.053	0.529	
N = 267 ( $n = 109$ , partially adjusted)					(-0.206 to 0.075)		(-0.200 to 0.107)		(-0.191 to 0.128)		
N = 225 ( $n = 97$ , fully adjusted)											
Achieving $\geq$ 60 minutes of PA <sup>i</sup>											
N = 195 (n = 74, unadjusted)	38 (32.48)	20 (27.03)	85 (52.47)	46 (38.02)	-0.109	0.208	-0.119	0.198	-0.070	0.463	
N = 165 ( $n = 66$ , partially adjusted)					(-0.219 to 0.078)		(–0.233 to 0.082)		(-0.200 to 0.153)		
N = 157 ( $n = 64$ , fully adjusted)											

Adjusted for baseling outcom

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

- d Transformed via inverse.
- e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.
- f Transformed via natural logarithm.
- g Transformed via squaring.
- h Adjusted for baseline BMI-z.
- i Adjusted for total grams of fruit and vegetables consumed per day.
- j Adjusted for minutes of PA per 24 hours.

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TABLE 73 Ad	ljusted differences for	key variables between	n control and interv	vention groups at	FU2: IMD score –
interaction te	erms				

	<i>p</i> -value of interaction term						
Variable	Unadjusted model	Partially adjusted model <sup>a</sup>	Fully adjusted <sup>b</sup>				
Continuous outcomes							
BMI-z	0.094	0.680	0.874				
Height (cm)	0.407	0.218	0.321				
Waist z-score	0.182	0.892	0.672				
Sum of four skinfolds (mm) <sup>c,d</sup>	0.012	0.166	0.372				
Body fat %	0.017	0.823	0.752				
Energy intake (kJ in 24 hours) <sup>e</sup>	0.158	0.084	0.066				
PA energy expenditure (kJ/kg/day)	0.575	0.121	0.076				
PedsQL total score <sup>f</sup>	0.453	0.420	0.693				
CHU9D utility score	0.015	0.021	0.040				
Binary outcomes							
Obese <sup>9</sup>	0.905	0.145	0.975				
Obese/overweight <sup>9</sup>	0.102	0.151	0.346				
Five or more portions of fruit and vegetables $^{\rm h}$	0.221	0.176	0.203				
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.730	0.646	0.736				

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

## TABLE 74 Adjusted differences for key variables between control and intervention groups at FU2: obese/overweight – overweight only

	Arm			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
N = total participants ( $n =$ number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>®</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or	median (IQR) <sup>c</sup>	Mean (SD) or	median (IQR)⁰	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e
N = 229 (n = 108, unadjusted)	1.99 (0.82)	1.99 (0.83)	1.94 (0.73)	2.06 (0.75)	-0.080	0.497	-0.084	0.345	-0.170	0.083
N = 229 ( $n = 108$ , partially adjusted)					(-0.510 (0 0.151)		(-0.260 to 0.091)		(-0.363 to 0.022)	
N = 154 ( $n = 77$ , fully adjusted)										
Height (cm)										
N = 229 (n = 108, unadjusted)	121.72 (5.55)	138.71 (6.63)	120.74 (5.37)	138.71 (6.43)	-0.001	0.999	-0.600	0.150	-1.026	0.012
N = 229 ( $n = 108$ , partially adjusted)					(-1.761 to 1.759)		(-1.419 to 0.218)		(-1.828 to -0.225)	
N = 154 ( $n = 77$ , fully adjusted)										
Waist z-score										
N = 200 (n = 95, unadjusted)	2.33 (0.96)	2.46 (0.89)	2.41 (0.89)	2.59 (0.77)	-0.147	0.289	-0.135	0.249	-0.207	0.104
N = 190 (n = 89,  partially adjusted)					(-0.419 (0 0.125)		(-0.365 (0 0.095)		(-0.457 (0 0.042)	
N = 135 ( $n = 68$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 156 (n = 75, unadjusted)	43.40	62.95	44.75	66.50	-4.940	0.237	0.183 ( 1.545 to 1.012)	0.835	-0.010	0.993
N = 138 ( $n = 70$ , partially adjusted)	(33.40-55.90)	(40.80–82.35)	(30.85-62.20)	(48.80–79.60)	(-13.134 (0 3.255)		(-1.545 (0 1.912)		(-2.311 (0 2.292)	
N = 99 (n = 55,  fully adjusted)										
Body fat %										
N = 223 (n = 107, unadjusted)	27.93 (5.70)	30.34 (7.90)	28.06 (5.17)	31.25 (6.04)	-0.954	0.357	-0.799	0.323	-1.085	0.163
N = 222 ( $n = 106$ , partially adjusted)					(-2.984 (0 1.077)		(-2.384 (0 0.787)		(-2.609 (0 0.440)	
N = 150 (n = 76,  fully adjusted)										
										continued

## TABLE 74 Adjusted differences for key variables between control and intervention groups at FU2: obese/overweight – overweight only (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 211 (n = 99, unadjusted)	7386	7487	6851 (F002, 707F)	7782	-467.059	0.097	-368.871	0.202	-566.272	0.165
N = 191 (n = 91,  partially adjusted)	(6128-8339)	(6080–9142)	(5902-7975)	(6795-9228)	(-1017.963 (0 83.844)		(-935.829 (0 198.086)		(-1364.981 (0 232.437)	
N = 150 (n = 73,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 134 (n = 68, unadjusted)	94.95 (21.50)	80.40 (21.46)	89.86 (22.55)	76.68 (20.36)	3.719	0.301	3.575	0.276	2.182	0.439
N = 110 (n = 53,  partially adjusted)					(-3.334 (0 10.773)		(-2.861 (0 10.012)		(-3.338 (0 7.701)	
N = 100 (n = 51,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 222 ( $n = 102$ , unadjusted)	67.39	81.52	73.91	78.26	2.385	0.216	3.121	0.184	4.021	0.094
N = 220 ( $n = 102$ , partially adjusted)	(56.70-60.45)	(71.74-09.15)	(00.07-02.01)	(07.39-69.13)	(-1.394 (0 0.104)		(-1.482 (0 7.724)		(-0.082 (0 8.724)	
N = 150 (n = 74,  fully adjusted)										
CHU9D utility score										
N = 227 (n = 107, unadjusted)	0.82 (0.14)	0.89 (0.09)	0.81 (0.13)	0.89 (0.10)	0.006	0.560	0.002	0.884	-0.003	0.794
N = 219 (n = 104,  partially adjusted)					(-0.015 (0 0.028)		(-0.022 (0 0.025)		(-0.029 (0 0.022)	
N = 146 (n = 73,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		N (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 229 (n = 108, unadjusted)	84 (57.93)	75 (69.44)	87 (58.00)	85 (70.25)	-0.008	0.893	-0.011	0.838	-0.025	0.682
N = 229 ( $n = 108$ , partially adjusted)					(-0.113 (0 0.116)				(-0.134 (0 0.104)	
N = 154 ( $n = 77$ , fully adjusted)										

	Arm				Intervention vs. control						
Follow-up outcome variable:	Intervention		Control								
n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
Obese/overweight <sup>h</sup>											
N = 229 (n = 108, unadjusted)	145 (100)	91 (84.26)	150 (100)	110 (90.91)	-0.067	0.175	-0.065	0.172	-0.109	0.026	
N = 229 ( $n = 108$ , partially adjusted)					(-0.154 to 0.031)		(-0.151 to 0.030)		(-0.194 (0 -0.014)		
N = 154 ( $n = 77$ , fully adjusted)											
Five or more portions of fruit and vege	etables <sup>i</sup>										
N = 211 (n = 99, unadjusted)	85 (66.93)	50 (50.51)	75 (63.03)	67 (59.82)	-0.093	0.260	-0.128	0.138	-0.122	0.150	
N = 191 (n = 91,  partially adjusted)					(-0.222 to 0.080)		(-0.258 to 0.048)		(-0.251 to 0.051)		
N = 150 (n = 73,  fully adjusted)											
Achieving $\geq$ 60 minutes of PA <sup>i</sup>											
N = 139 (n = 70, unadjusted)	44 (40.74)	16 (22.86)	49 (47.12)	17 (24.64)	-0.021	0.811	0.010	0.913	0.063	0.691	
N = 114 (n = 55,  partially adjusted)					(-0.137 (0 0.218)	(-0.119 (0 0.279)		(-0.144 (0 0.731)			

N = 104 (n = 53, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

- d Transformed via inverse.
- e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.
- f Transformed via natural logarithm.
- g Transformed via squaring.
- h Adjusted for baseline BMI-z.
- i Adjusted for total grams of fruit and vegetables consumed per day.
- j Adjusted for minutes of PA per 24 hours.

TABLE 75 Adjusted differences for key variables between control and intervention groups at FU2: obese/overweight – not overweight only

			Intervention vs. control							
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 865 (n = 397, unadjusted)	-0.26 (0.82)	-0.04 (1.10)	-0.32 (0.80)	-0.11 (1.03)	0.055	0.491	-0.004	0.939	-0.024	0.717
N = 865 (n = 397,  partially adjusted)					(-0.102 (0 0.212)		(–0.118 to 0.109)		(-0.155 (0 0.107)	
N = 618 (n = 282,  fully adjusted)										
Height (cm)										
N = 866 (n = 397, unadjusted)	117.79 (5.31)	133.68 (6.36)	117.52 (5.18)	134.09 (6.10)	-0.417	0.358	-0.444	0.192	-0.585	0.082
N = 866 (n = 397,  partially adjusted)					(-1.306 to 0.472)		(-1.110 to 0.222)		(-1.244 to 0.075)	
N = 619 (n = 282,  fully adjusted)										
Waist z-score										
N = 748 (n = 335, unadjusted)	0.33 (0.92)	0.74 (1.06)	0.23 (0.89)	0.50 (1.09)	0.229	0.025	0.156	0.043	0.146	0.081
N = 732 ( $n = 324$ , partially adjusted)					(0.028 to 0.429)		(0.005 to 0.308)		(-0.018 to 0.311)	
N = 568 (n = 252,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 652 (n = 292, unadjusted)	26.75	31.52	26.45	29.05	1.350	0.201	0.447	0.042	0.408	0.120
N = 586 (n = 264,  partially adjusted)	(21.95–31.60)	(23./3–42./5)	(22.20–32.00)	(23.20–39.88)	(-0.720 to 3.420)		(0.017 to 0.877)		(-0.106 to 0.922)	
N = 461 (n = 207,  fully adjusted)										
Body fat %										
N = 844 (n = 391, unadjusted)	19.39 (3.20)	20.20 (5.57)	19.10 (3.28)	19.26 (5.33)	0.931	0.021	0.617	0.094	0.576	0.216
N = 829 (n = 389,  partially adjusted)					(0.140 to 1.722)		(-0.106 to 1.341)	(-0.	(-U.336 TO 1.488)	
N = 597 (n = 278,  fully adjusted)										

	Arm				Intervention vs. cont	rol					
Follow-up outcome variable:	Intervention		Control								
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
Energy intake (kJ in 24 hours) <sup>f</sup>											
<i>N</i> = 757 ( <i>n</i> = 337, unadjusted)	6841	7729	6961	7820	-161.071	0.439	-72.351	0.692	-234.859	0.208	
N = 687 (n = 307,  partially adjusted)	(5782–7948)	(6538-9117)	(5767-8004)	(6716-9303)	(-569.019 to 246.878)		(-429.873 to 285.171)		(–600.153 to 130.435)		
N = 579 (n = 258,  fully adjusted)											
PA energy expenditure (kJ/kg/day)											
N = 524 ( $n = 225$ , unadjusted)	96.84 (23.61)	80.01 (22.47)	95.03 (24.70)	79.59 (22.78)	0.663	0.788	-0.667	0.781	-1.300	0.553	
N = 461 ( $n = 200$ , partially adjusted)					(-4.171 (0 5.497)		(-5.366 (0 4.031)		(-5.591 to 2.992)		
N = 420 ( $n = 186$ , fully adjusted)											
PedsQL total score <sup>g</sup>											
<i>N</i> = 844 ( <i>n</i> = 375, unadjusted)	71.74	82.61	73.91	80.43	0.560	0.657	0.654	0.665	0.566	0.681	
N = 835 ( $n = 375$ , partially adjusted)	(60.87-82.61)	(71.74-89.13)	(60.87-82.61)	(71.74–89.13)	(-1.912 (0 3.032)		(-2.306 10 3.613)		(-2.135 (0 3.266)		
N = 605 (n = 272,  fully adjusted)											
CHU9D utility score											
N = 853 (n = 391, unadjusted)	0.84 (0.13)	0.89 (0.09)	0.82 (0.15)	0.90 (0.09)	-0.007	0.435	-0.008	0.327	-0.009	0.326	
N = 829 ( $n = 381$ , partially adjusted)					(-0.023 (0 0.010)		(-0.025 (0 0.008)		(-0.027 to 0.009)		
N = 595 ( $n = 271$ , fully adjusted)											
<b>Binary outcomes</b> Obese <sup>h</sup>	n <i>(%)</i>		n <i>(%)</i>		RD (95% CI)	p-value	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>valu</i> e	
N = 865 (n = 397, unadjusted)	0 (0.00)	26 (6.55)	0 (0.00)	24 (5.13)	0.014	0.397	0.008	0.604	0.014	0.501	
N = 865 ( $n = 397$ , partially adjusted)					(-0.014 to 0.064)		(-0.017 to 0.053)		(-0.019 to 0.079)		
N = 618 (n = 282,  fully adjusted)											
										continued	

#### TABLE 75 Adjusted differences for key variables between control and intervention groups at FU2: obese/overweight – not overweight only (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 865 (n = 397, unadjusted)	0 (0.00)	74 (18.64)	0 (0.00)	70 (14.96)	0.034	0.280	0.019	0.465	0.014	0.649
N = 865 (n = 397,  partially adjusted)					(-0.023 to 0.117)		(-0.028 to 0.085)		(-0.038 to 0.089)	
N = 618 (n = 282,  fully adjusted)										
Five or more portions of fruit and vegetables										
N = 757 (n = 337, unadjusted)	247 (57.44)	195 (57.86)	317 (65.09)	231 (55.00)	0.029	0.538	0.049	0.296	0.052	0.273
N = 687 (n = 307,  partially adjusted)					(-0.058 to 0.130)		(-0.040 to 0.153)		(-0.038 to 0.157)	
N = 579 (n = 258,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 529 (n = 225, unadjusted)	184 (48.04)	53 (23.56)	227 (50.11)	99 (32.57)	-0.090	0.084	-0.088	0.109	-0.085	0.127
N = 461 (n = 199,  partially adjusted)					(-0.162 to 0.014)		(–0.163 to 0.024)		(-0.162 to 0.029)	
N = 420 (n = 186,  fully adjusted)										
a Adjusted for baseline outcome										

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

	<i>p</i> -value of interaction term						
Variable	Unadjusted model	Partially adjusted model <sup>a</sup>	Fully adjusted <sup>b</sup>				
Continuous outcomes							
BMI-z	0.349	0.473	0.214				
Height (cm)	0.612	0.895	0.437				
Waist z-score	0.014	0.022	0.011				
Sum of four skinfolds (mm) <sup>c,d</sup>	0.081	0.846	0.546				
Body fat %	0.066	0.167	0.118				
Energy intake (kJ in 24 hours) <sup>e</sup>	0.408	0.331	0.508				
PA energy expenditure (kJ/kg/day)	0.388	0.159	0.254				
PedsQL total score <sup>f</sup>	0.315	0.325	0.236				
CHU9D utility score	0.215	0.316	0.552				
Binary outcomes							
Obese <sup>9</sup>	0.386	0.426	0.338				
Obese/overweight <sup>9</sup>	0.115	0.115	0.337				
Five or more portions of fruit and vegetables $^{\mbox{\tiny h}}$	0.247	0.634	0.382				
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.446	0.362	0.620				

**TABLE 76** Adjusted differences for key variables between control and intervention groups at FU2: obese/overweight – interaction terms

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

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# **Appendix 61** Exploratory subgroup analyses

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## TABLE 77 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention arm at FU1 in G1

	Arm				Intervention vs. contr	ol				
Follow-up outcome variable:	Intervention		Control							
<i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
$N = 560 \ (n = 267, \text{ unadjusted})$	0.29 (1.24)	0.35 (1.32)	0.28 (1.12)	0.53 (1.16)	-0.176	0.084	-0.233	< 0.001	-0.258	< 0.001
N = 536 (n = 258,  partially adjusted)					(-0.375 to 0.024)		(–0.345 to –0.122)		(–0.355 to –0.160)	
N = 407 (n = 195,  fully adjusted)										
Height (cm)										
N = 561 (n = 258, unadjusted)	118.95 (5.74)	127.33 (6.09)	118.75 (5.60)	126.99 (5.95)	0.338	0.423	0.460	0.085	0.501	0.030
N = 537 (n = 258,  partially adjusted)					(-0.489 to 1.166)		(-0.063 to 0.984)		(0.049 to 0.952)	
N = 408 (n = 195,  fully adjusted)										
Waist z-score										
N = 554 (n = 263, unadjusted)	0.86 (1.17)	0.99 (1.39)	0.92 (1.14)	1.05 (1.30)	-0.064	0.503	-0.061	0.698	-0.046	0.679
N = 513 ( $n = 237$ , partially adjusted)					(-0.253 to 0.124)		(–0.370 to 0.248)		(-0.264 to 0.172)	
N = 389 (n = 180,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 499 (n = 243, unadjusted)	29.02	32.05	30.55	31.50	-0.431	0.735	0.265	0.515	0.481	0.307
N = 409 (n = 198,  partially adjusted)	(24.48–35.65)	(24.70–43.65)	(24.45–40.10)	(25.23–45.72)	(-2.927 to 2.064)		(-0.534 to 1.065)		(-0.442 to 1.405)	
N = 316 (n = 152,  fully adjusted)										
Body fat %										
N = 552 (n = 267, unadjusted)	21.33 (5.19)	22.00 (6.83)	21.18 (5.21)	22.01 (6.70)	-0.076	0.910	-0.807	0.052	-0.869	0.029
N = 527 (n = 257,  partially adjusted)		55 (5.13) 22.00 (0.85) 21			(-1.394 to 1.241)		(-1.621 to 0.006)		(–1.648 to –0.090)	
N = 402 ( $n = 195$ , fully adjusted)										
	Arm				Intervention vs. conti	rol				
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Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 535 (n = 249, unadjusted)	6907	7292	7071	7213	78.698	0.750	32.129	0.863	16.142	0.935
N = 460 (n = 218,  partially adjusted)	(5858-7964)	(6258-8491)	(5948–8038)	(6306-8520)	(-404.798 (0 562.194)		(-332.899 (0 397.157)		(-371.590 to 403.874)	
N = 394 ( $n = 182$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 453 ( $n = 214$ , unadjusted)	93.07 (21.69)	93.90 (24.55)	91.82 (22.42)	89.68 (26.59)	2.979	0.387	3.363	0.339	1.565 ( 4.218 to 7.448)	0.602
N = 388 (n = 183,  partially adjusted)					(-3.763 (0 9.721)		(-3.537 to 10.263)		(-4.318 (0 7.448)	
N = 346 ( $n = 167$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 561 (n = 268, unadjusted)	72.83	78.26	73.91	76.09	0.173	0.919	-0.098	0.964	0.012	0.997
N = 536 ( $n = 259$ , partially adjusted)	(63.04–84.78)	(05.22-85.87)	(63.04–82.61)	(67.39-84.78)	(-3.100 (0 3.513)		(-4.396 (0 4.200)		(-6.068 (0 6.093)	
N = 409 (n = 196,  fully adjusted)										
CHU9D utility score										
N = 550 (n = 264, unadjusted)	0.84 (0.13)	0.88 (0.10)	0.82 (0.14)	0.86 (0.09)	0.027	0.039	0.026	0.056	0.031	0.050
N = 510 (n = 245,  partially adjusted)					(0.001 to 0.054)		(-0.001 to 0.053)		(0.000 to 0.062)	
N = 388 (n = 183,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 560 (n = 267, unadjusted)	39 (13.36)	45 (16.85)	43 (13.15)	52 (17.75)	-0.009	0.674	-0.056	0.035	-0.037	0.076
N = 536 ( $n = 258$ , partially adjusted)					(-0.045 to 0.037)		(–0.092 to –0.005)		(-0.069 to 0.004)	
N = 407 ( $n = 195$ , fully adjusted)										
										continued

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### TABLE 77 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention arm at FU1 in G1 (continued)

	<u>Arm</u>			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 560 (n = 267, unadjusted)	67 (22.95)	72 (26.97)	67 (20.49)	82 (27.99)	-0.010	0.757	-0.048	0.110	-0.043	0.173
N = 536 (n = 258,  partially adjusted)					(-0.067 to 0.061)		(-0.095 to 0.012)		(-0.093 to 0.021)	
N = 407 (n = 195,  fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 535 (n = 249, unadjusted)	160 (60.61)	132 (53.01)	207 (72.13)	150 (52.45)	0.006	0.915	0.017	0.767	0.011	0.772
N = 460 (n = 218,  partially adjusted)					(-0.089 to 0.121)		(-0.087 to 0.146)		(-0.060 to 0.093)	
N = 394 ( $n = 182$ , fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 453 (n = 214, unadjusted)	88 (36.36)	124 (57.94)	133 (47.00)	122 (51.05)	0.069	0.290	0.098	0.148	0.108	0.280
N = 385 ( $n = 181$ , partially adjusted)					(-0.052 to 0.222)		(-0.031 to 0.263)		(-0.079 to 0.337)	

N = 343 (n = 166, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

# TABLE 78 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention arm at FU1 in G2

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
<i>N</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>®</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p <i>-value</i>	MD (95% CI)	p- <i>value</i>
N = 689 (n = 307, unadjusted)	0.19 (1.24)	0.33 (1.35)	0.04 (1.26)	-0.00 (1.31)	0.331	0.001	0.079	0.353	0.136	0.097
N = 661 (n = 298,  partially adjusted)					(0.128 to 0.534)		(-0.088 to 0.246)		(-0.025 to 0.297)	
N = 430 (n = 198,  fully adjusted)										
Height (cm)										
N = 690 (n = 300, unadjusted)	118.37 (5.48)	127.41 (6.10)	117.73 (5.15)	127.06 (5.60)	0.357	0.433	-0.583	0.195	-0.991	0.027
N = 663 (n = 300,  partially adjusted)					(-0.536 to 1.249)		(–1.463 to 0.298)		(-1.867 to -0.115)	
N = 430 (n = 198,  fully adjusted)										
Waist z-score										
N = 597 (n = 265, unadjusted)	0.69 (1.30)	1.12 (1.33)	0.41 (1.29)	0.72 (1.32)	0.401	0.002	0.118	0.235	0.074	0.285
N = 556 (n = 253,  partially adjusted)					(0.151 to 0.650)		(-0.077 to 0.313)		(-0.062 to 0.210)	
N = 407 (n = 188,  fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 549 (n = 245, unadjusted)	27.55	30.90	26.75	28.00	2.563	0.001	0.379	0.303	0.450	0.283
N = 493 ( $n = 223$ , partially adjusted)	(22.13–35.30)	(24.20–43.65)	(22.15–34.05)	(22.18–38.38)	(1.026 to 4.100)		(-0.342 to 1.099)		(-0.372 to 1.273)	
N = 367 (n = 171,  fully adjusted)										
Body fat %										
N = 684 (n = 307, unadjusted)	21.27 (5.49)	21.61 (6.65)	20.76 (5.22)	20.01 (5.86)	1.589	0.001	0.900	0.118	1.280	0.024
N = 642 ( $n = 296$ , partially adjusted)					(0.622 to 2.556)		(-0.230 to 2.029)		(0.171 to 2.389)	
N = 420 ( $n = 196$ , fully adjusted)										
										continued

# TABLE 78 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention arm at FU1 in G2 (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
<i>N</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 577 (n = 258, unadjusted)	6894	6975	6739	6916	142.566	0.510	79.212	0.687	62.958	0.739
N = 518 ( $n = 231$ , partially adjusted)	(5871–8098)	(5903–8209)	(5700-7830)	(5692–7999)	(-281.248 to 566.380)		(-306.631 to 465.055)		(-307.891 to 433.808)	
N = 409 (n = 187,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 415 (n = 181, unadjusted)	99.73 (24.11)	89.10 (22.46)	96.40 (26.08)	92.89 (24.12)	-3.828		-6.010	0.019	-5.620	0.052
N = 336 ( $n = 152$ , partially adjusted)					(-9.190 (0 1.534)	0.162	(-11.033 (0 -0.986)		(-11.290 to 0.049)	
N = 312 ( $n = 143$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 670 (n = 286, unadjusted)	69.57	73.91	71.74	73.91	-1.386	0.270	-0.897	0.618	0.018 ( 2.752 to 2.788)	0.990
N = 635 ( $n = 279$ , partially adjusted)	(50.52-80.43)	(63.04-82.61)	(60.87-82.61)	(63.04–84.78)	(-3.849 (0 1.077)		(-4.419 (0 2.624)		(-2.752 (0 2.788)	
N = 408 ( $n = 179$ , fully adjusted)										
CHU9D utility score										
N = 665 (n = 286, unadjusted)	0.83 (0.14)	0.85 (0.12)	0.81 (0.15)	0.85 (0.11)	-0.004	0.757	-0.005	0.702	-0.006	0.664
N = 620 ( $n = 274$ , partially adjusted)					(-0.028 to 0.021)		(-0.030 to 0.020)		(-0.035 to 0.022)	
N = 398 (n = 175,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>
N = 689 (n = 307, unadjusted)	45 (12.23)	48 (15.64)	44 (10.86)	48 (12.57)	0.031	0.202	-0.022	0.428	0.016	0.635
N = 661 (n = 298,  partially adjusted)					(-0.014 to 0.093)		(-0.063 to 0.042)		(–0.039 to 0.104)	
N = 430 ( $n = 198$ , fully adjusted)										

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 689 (n = 307, unadjusted)	78 (21.20)	93 (30.29)	83 (20.49)	85 (22.25)	0.080	0.012	0.014	0.743	0.083	0.121
N = 661 (n = 298,  partially adjusted)					(0.016 to 0.163)		(-0.059 to 0.118)		(-0.018 to 0.232)	
N = 430 ( $n = 198$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 577 (n = 258, unadjusted)	176 (59.06)	112 (43.41)	198 (58.58)	147 (46.08)	-0.024	0.681	-0.044	0.479	0.002	0.964
N = 518 ( $n = 231$ , partially adjusted)					(-0.122 to 0.103)		(-0.145 to 0.089)		(-0.078 to 0.099)	
N = 409 (n = 187,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 413 ( $n = 182$ , unadjusted)	140 (56.22)	83 (45.60)	143 (52.19)	112 (48.48)	-0.044	0.540	-0.025	0.745	-0.112	0.348
N = 335 ( $n = 153$ , partially adjusted)					(-0.159 (0 0.112)		(-0.151 (0 0.149)		(-0.509 (0 0.138)	

N = 311 (n = 144, fully adjusted)

a Summary statistics presented are either mean (SD) or median (IQR).

b Adjusted for baseline outcome.

c Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

# TABLE 79 Interaction term for group: FU1

	<i>p</i> -value of interaction term					
Variable	Unadjusted model	Partially adjusted model <sup>a</sup>	Fully adjusted <sup>b</sup>			
Continuous outcomes						
BMI-z	< 0.001	0.001	< 0.001			
Height (cm)	0.976	0.053	0.006			
Waist z-score	0.004	0.323	0.333			
Sum of four skinfolds (mm) <sup>c,d</sup>	0.027	0.741	0.430			
Body fat %	0.050	0.014	0.003			
Energy intake (kJ in 24 hours) <sup>e</sup>	0.820	0.835	0.757			
PA energy expenditure (kJ/kg/day)	0.112	0.031	0.085			
PedsQL total score <sup>f</sup>	0.471	0.791	0.953			
CHU9D utility score	0.092	0.119	0.119			
Binary outcomes						
Obese <sup>9</sup>	0.196	0.200	0.658			
Obese/overweight <sup>g</sup>	0.042	0.025	0.044			
Five or more portions of fruit and vegetables $^{\rm h}$	0.677	0.323	0.797			
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.354	0.334	0.169			

a Adjusted for baseline outcome.

 b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

# TABLE 80 Fixed-term effect for group: FU1 (G1 vs. G2)

	Unadjusted model		Partially adjusted model <sup>a</sup>		Fully adjusted model <sup>b</sup>		
Continuous outcome variables	Group effect (95% Cl)	<i>p</i> -value	Group effect (95% Cl)	<i>p</i> -value	Group effect (95% Cl)	<i>p</i> -value	
BMI-z	0.529 (0.302 to 0.756)	< 0.001	0.212 (0.075 to 0.349)	0.002	0.294 (0.148 to 0.440)	< 0.001	
Height (cm)	-0.068 (-0.699 to 0.564)	0.834	-1.410 (-1.948 to -0.871)	< 0.001	-1.656 (-2.204 to -1.108)	< 0.001	
Waist z-score	0.334 (0.148 to 0.519)	< 0.001	-0.126 (-0.365 to 0.114)	0.304	0.003 (-0.202 to 0.207)	0.980	
Sum of four skinfolds (mm) <sup>c,d</sup>	3.643 (1.290 to 5.997)	0.002	0.079 (-0.530 to 0.688)	0.800	0.232 (-0.586 to 1.049)	0.579	
Body fat %	1.968 (0.637 to 3.299)	0.004	1.462 (0.526 to 2.397)	0.002	1.773 (0.818 to 2.728)	0.000	
Energy intake (kJ in 24 hours) <sup>e</sup>	465.178 (34.084 to 896.272)	0.034	335.853 (-14.911 to 686.617)	0.061	299.770 (–23.999 to 623.539)	0.070	
PA energy expenditure (kJ/kg/day)	-2.158 (-9.792 to 5.477)	0.580	-0.922 (-8.218 to 6.375)	0.804	–0.798 (–7.125 to 5.529)	0.805	
PedsQL total score <sup>f</sup>	0.970 (–2.035 to 3.974)	0.527	1.140 (-2.912 to 5.192)	0.581	0.450 (-4.008 to 4.907)	0.843	
CHU9D utility score	0.003 (-0.020 to 0.027)	0.783	0.003 (-0.020 to 0.027)	0.784	-0.001 (-0.026 to 0.024)	0.957	

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

# TABLE 81 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention arm at FU2 in G1

	Arm				Intervention vs. contr	ol				
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 524 (n = 252,  unadjusted)	0.29 (1.24)	0.44 (1.32)	0.28 (1.12)	0.54 (1.25)	-0.100	0.361	-0.167	0.055	-0.182	0.036
N = 499 (n = 242,  partially adjusted)					(-0.315 to 0.115)		(-0.339 to 0.004)		(–0.352 to –0.012)	
N = 376 (n = 182,  fully adjusted)										
Height (cm)										
N = 524 ( $n = 242$ , unadjusted) N = 499 ( $n = 242$ , partially adjusted) N = 376 ( $n = 182$ , fully adjusted)	118.95 (5.74)	134.87 (6.83)	118.75 (5.60)	135.37 (6.45)	-0.469 (-1.763 to 0.826)	0.478	-0.206 (-1.112 to 0.701)	0.656	-0.329 (-1.222 to 0.563)	0.469
Waist z-score										
N = 493 ( $n = 235$ , unadjusted) N = 459 ( $n = 215$ , partially adjusted) N = 349 ( $n = 166$ , fully adjusted)	0.86 (1.17)	1.28 (1.24)	0.92 (1.14)	1.22 (1.30)	0.064 (-0.151 to 0.279)	0.558	0.066 (–0.153 to 0.286)	0.553	0.040 (-0.131 to 0.210)	0.649
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 458 (n = 214, unadjusted) N = 373 (n = 179, partially adjusted) N = 288 (n = 139, fully adjusted)	29.02 (24.48–35.65)	35.65 (25.60–51.00)	30.55 (24.45–40.10)	34.60 (25.05–58.83)	-0.079 (-3.059 to 2.901)	0.959	0.677 (-0.126 to 1.480)	0.099	0.690 (-0.186 to 1.566)	0.123
Body fat %										
N = 511 (n = 249, unadjusted) N = 485 (n = 238, partially adjusted) N = 368 (n = 181, fully adjusted)	21.33 (5.19)	22.49 (7.65)	21.18 (5.21)	22.34 (7.53)	0.125 (-1.399 to 1.649)	0.872	-0.655 (-1.746 to 0.435)	0.239	-0.709 (-1.817 to 0.398)	0.209

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 506 (n = 246, unadjusted)	6907 (FRER 70C4)	7566	7071	7869	-341.251	0.093	-248.531	0.193	-327.334	0.092
N = 431 ( $n = 214$ , partially adjusted)	(5858-7964)	(0359–8903)	(5948–8038)	(6794–9337)	(-739.918 to 57.416)		(-622.397 (0 125.336)		(-707.974 (0 53.306)	
N = 367 (n = 179,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 332 (n = 150, unadjusted)	93.07 (21.69)	81.78 (24.16)	91.82 (22.42)	78.03 (22.96)	3.648	0.210	2.391	0.347	1.904	0.405
N = 282 ( $n = 124$ , partially adjusted)					(-2.052 (0 9.348)		(-2.595 (0 7.376)		(-2.577 10 6.385)	
N = 250 ( $n = 113$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 524 ( $n = 252$ , unadjusted)	72.83	84.78	73.91	78.26	3.674	0.011	4.142	0.013	3.675	0.009
N = 497 (n = 242,  partially adjusted)	(63.04–84.78)	(73.91–91.30)	(63.04–82.61)	(71.74–89.13)	(0.848 to 6.500)		(0.889 to 7.395)		(0.931 to 6.420)	
N = 376 ( $n = 182$ , fully adjusted)										
CHU9D utility score										
N = 519 (n = 251, unadjusted)	0.84 (0.13)	0.90 (0.09)	0.82 (0.14)	0.89 (0.09)	0.010	0.142	0.006	0.443	0.013	0.127
N = 480 (n = 233,  partially adjusted)					(-0.003 to 0.024)		(-0.010 to 0.022)		(-0.004 to 0.029)	
N = 360 (n = 173,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 524 ( $n = 252$ , unadjusted)	39 (13.36)	55 (21.83)	43 (13.15)	60 (22.06)	-0.002	0.943	-0.037	0.253	-0.011	0.719
N = 499 (n = 242,  partially adjusted)					(-0.058 to 0.072)		(-0.086 to 0.031)		(-0.060 to 0.054)	
N = 376 ( $n = 182$ , fully adjusted)										
										continued

### TABLE 81 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention arm at FU2 in G1 (continued)

	Arm			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 524 (n = 252, unadjusted)	67 (22.95)	81 (32.14)	67 (20.49)	86 (31.62)	0.005	0.901	-0.030	0.461	-0.029	0.423
N = 499 (n = 242,  partially adjusted)					(-0.068 (0 0.101)		(-0.097 (0 0.057)		(-0.088 (0 0.046)	
N = 376 ( $n = 182$ , fully adjusted)										
Five or more portions of fruit and vege	etables <sup>i</sup>									
N = 506 (n = 246, unadjusted)	160 (60.61)	134 (54.47)	207 (72.13)	152 (58.46)	-0.040	0.501	-0.034	0.599	-0.062	0.236
N = 431 ( $n = 214$ , partially adjusted)					(-0.141 to 0.085)		(-0.143 to 0.103)		(-0.151 to 0.045)	
N = 367 (n = 179,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 337 (n = 151, unadjusted)	88 (36.36)	43 (28.48)	133 (47.00)	52 (27.96)	0.004	0.945	0.009	0.897	-0.024	0.875
N = 283 ( $n = 124$ , partially adjusted)					(-0.095 to 0.156)		(-0.097 to 0.174)		(-0.260 to 0.363)	

N = 252 (n = 114, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

# TABLE 82 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention arm at FU2 in G2

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
N = total participants ( $n =$ number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>®</sup>		Fully adjusted <sup>6</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR) <sup>c</sup>	Mean (SD) or i	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 621 (n = 272, unadjusted)	0.19 (1.24)	0.40 (1.36)	0.04 (1.26)	0.14 (1.35)	0.262	0.003	0.092	0.168	0.111	0.075
N = 595 ( $n = 263$ , partially adjusted)					(0.088 to 0.436)		(–0.039 to 0.224)		(-0.011 to 0.234)	
N = 396 (n = 177,  fully adjusted)										
Height (cm)										
N = 622 (n = 264, unadjusted)	118.37 (5.48)	134.60 (6.56)	117.73 (5.15)	134.46 (6.40)	0.141	0.781	-0.787	0.099	-1.060	0.004
N = 597 (n = 264,  partially adjusted)					(-0.855 to 1.137)		(-1.722 to 0.148)		(-1.782 to -0.339)	
N = 397 (n = 177,  fully adjusted)										
Waist z-score										
N = 497 (n = 211, unadjusted)	0.69 (1.30)	1.01 (1.25)	0.41 (1.29)	0.61 (1.33)	0.404	0.000	0.134	0.141	0.128	0.125
N = 464 ( $n = 199$ , partially adjusted)					(0.201 to 0.608)		(-0.044 to 0.313)		(-0.035 to 0.291)	
N = 354 ( $n = 154$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
<i>N</i> = 387 ( <i>n</i> = 167, unadjusted)	27.55	33.50	26.75	29.50	3.222	0.010	0.463	0.215	0.569	0.185
N = 351 (n = 155,  partially adjusted)	(22.13–35.30)	(24.45–46.90)	(22.15–34.05)	(22.68–42.20)	(0.773 to 5.672)		(-0.268 to 1.194)		(-0.273 to 1.411)	
N = 272 ( $n = 123$ , fully adjusted)										
Body fat %										
N = 604 (n = 267, unadjusted)	21.27 (5.49)	22.55 (7.33)	20.76 (5.22)	20.99 (6.99)	1.561 (0.51c to 0.607)	0.003	1.233	0.006	0.989	0.035
N = 566 (n = 257,  partially adjusted)					(0.516 to 2.607)		(0.352 to 2.113)		(0.068 to 1.910)	
N = 379 (n = 173,  fully adjusted)										
										continued

# TABLE 82 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention arm at FU2 in G2 (continued)

	Arm			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
<i>N</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 509 (n = 207, unadjusted)	6894	7763	6739	7722	-82.686	0.773	0.378	0.999	-226.061	0.466
N = 464 ( $n = 187$ , partially adjusted)	(5871–8098)	(6528–9311)	(5700-7830)	(6622-9108)	(-645.495 to 480.123)		(-518.071 to 518.828)		(-833.751 to 381.629)	
N = 362 ( $n = 152$ , fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 358 (n = 155, unadjusted)	99.73 (24.11)	77.61 (20.12)	96.40 (26.08)	79.11 (21.99)	-1.004	0.768	-2.127	0.543	-0.157	0.954
N = 289 ( $n = 129$ , partially adjusted)					(-7.681 (0 5.673)		(-8.978 (0 4.724)		(-5.498 (0 5.185)	
N = 270 ( $n = 124$ , fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 592 (n = 243, unadjusted)	69.57	80.43	71.74	81.82	-1.945	0.235	-2.006	0.321	-2.211 ( C 184 to 1 7C2)	0.275
N = 558 (n = 235,  partially adjusted)	(50.52-80.43)	(07.39-89.13)	(60.87-82.61)	(69.57-89.13)	(-5.157 to 1.267)		(-5.965 (0 1.953)		(-0.184 (0 1.762)	
N = 379 (n = 164,  fully adjusted)										
CHU9D utility score										
N = 612 (n = 266, unadjusted)	0.83 (0.14)	0.89 (0.10)	0.81 (0.15)	0.91 (0.09)	-0.019	0.124	-0.020	0.136	-0.029	0.031
N = 569 (n = 253,  partially adjusted)					(-0.044 to 0.005)		(-0.045 to 0.006)		(-0.055 to -0.003)	
N = 381 ( $n = 171$ , fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n <i>(%)</i>		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>
N = 621 (n = 272, unadjusted)	45 (12.23)	53 (19.49)	44 (10.86)	52 (14.90)	0.046	0.061	0.023	0.392	0.055	0.141
N = 595 ( $n = 263$ , partially adjusted)					(-0.002 to 0.109)		(-0.026 to 0.091)		(–0.015 to 0.158)	
N = 396 ( $n = 177$ , fully adjusted)										

	Arm				Intervention vs. control						
Follow-up outcome variable:	Intervention		Control								
(n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
Obese/overweight <sup>h</sup>											
N = 621 (n = 272, unadjusted)	78 (21.20)	95 (34.93)	83 (20.49)	101 (28.94)	0.060	0.093	0.033	0.435	0.062	0.213	
N = 595 ( $n = 263$ , partially adjusted)					(-0.009 (0 0.140)		(–0.044 to 0.134)		(-0.031 to 0.189)		
N = 396 ( $n = 177$ , fully adjusted)											
Five or more portions of fruit and veg	etables <sup>i</sup>										
N = 509 (n = 207, unadjusted)	176 (59.06)	119 (57.49)	198 (58.58)	165 (54.64)	0.029	0.598	0.056	0.314	0.060	0.325	
N = 464 ( $n = 187$ , partially adjusted)					(-0.070 to 0.148)		(–0.048 to 0.183)		(-0.054 to 0.201)		
N = 362 ( $n = 152$ , fully adjusted)											
Achieving $\geq$ 60 minutes of PA <sup>i</sup>											
N = 363 (n = 156, unadjusted)	140 (56.22)	27 (17.31)	143 (52.19)	68 (32.85)	-0.156	0.059	-0.142	0.110	-0.249	0.066	
N = 292 ( $n = 130$ , partially adjusted)			(		(-0.240 to 0.008)		(-0.230 10 0.045)		(-0.404 (0 0.022)		

# N = 272 (n = 125, fully adjusted)

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

- d Transformed via inverse.
- e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.
- f Transformed via natural logarithm.
- g Transformed via squaring.
- h Adjusted for baseline BMI-z.
- i Adjusted for total grams of fruit and vegetables consumed per day.
- j Adjusted for minutes of PA per 24 hours.

# TABLE 83 Interaction term for group: FU2

	<i>p</i> -value of interaction term					
Outcomes	Unadjusted model	Partially adjusted model <sup>a</sup>	Fully adjusted <sup>b</sup>			
Continuous outcomes						
BMI-z	0.010	0.020	0.016			
Height (cm)	0.448	0.380	0.365			
Waist z-score	0.023	0.678	0.505			
Sum of four skinfolds (mm) <sup>c,d</sup>	0.052	0.956	0.839			
Body fat %	0.133	0.009	0.023			
Energy intake (kJ in 24 hours) <sup>e</sup>	0.465	0.433	0.623			
PA energy expenditure (kJ/kg/day)	0.297	0.268	0.272			
PedsQL total score <sup>f</sup>	0.009	0.015	0.009			
CHU9D utility score	0.031	0.059	0.038			
Binary outcomes						
Obese <sup>9</sup>	0.174	0.170	0.615			
Obese/overweight <sup>g</sup>	0.319	0.110	0.132			
Five or more portions of fruit and vegetables $^{\rm h}$	0.389	0.411	0.121			
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.111	0.168	0.170			

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode),
 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll),
 percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjusted for baseline BMI-z.

h Adjusted for total grams of fruit and vegetables consumed per day.

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# TABLE 84 Fixed-effect term for group: FU2 (G1 vs. G2)

	Unadjusted model		Partially adjusted model <sup>a</sup>		Fully adjusted <sup>b</sup>		
Continuous outcome variables	Group effect (95% Cl)	<i>p</i> -value	Group effect (95% Cl)	<i>p</i> -value	Group effect (95% Cl)	<i>p</i> -value	
BMI-z	0.396 (0.188 to 0.605)	< 0.001	0.113 (-0.043 to 0.268)	0.156	0.211 (0.057 to 0.366)	0.007	
Height (cm)	0.886 (-0.302 to 2.074)	0.144	–0.553 (–1.353 to 0.247)	0.176	-0.634 (-1.451 to 0.182)	0.128	
Waist z-score	0.612 (0.414 to 0.810)	< 0.001	0.165 (-0.053 to 0.383)	0.137	0.245 (0.021 to 0.469)	0.032	
Sum of four skinfolds (mm) <sup>c,d</sup>	5.778 (2.877 to 8.679)	< 0.001	-0.006 (-0.702 to 0.690)	0.987	0.184 (-0.713 to 1.081)	0.688	
Body fat %	1.348 (0.053 to 2.642)	0.041	1.019 (0.042 to 1.996)	0.041	1.448 (0.517 to 2.379)	0.002	
Energy intake (kJ in 24 hours) <sup>e</sup>	9.909 (-441.449 to 461.268)	0.966	-91.553 (-501.930 to 318.824)	0.662	-106.208 (-557.510 to 345.095)	0.645	
PA energy expenditure (kJ/kg/day)	-0.185 (-6.143 to 5.773)	0.952	0.118 (-5.871 to 6.107)	0.969	-0.066 (-6.181 to 6.050)	0.983	
PedsQL total score <sup>f</sup>	-1.252 (-4.269 to 1.765)	0.416	-1.518 (-5.276 to 2.240)	0.428	-1.707 (-5.176 to 1.761)	0.335	
CHU9D utility score	-0.021 (-0.040 to -0.002)	0.026	-0.019 (-0.039 to 0.000)	0.054	-0.025 (-0.044 to -0.005)	0.015	

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

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# Appendix 62 Sensitivity analyses

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# **Multiple imputation**

	Intervention vs. control					
Follow-up outcome variable	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Continuous outcomes	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e
BMI-z	0.081 (-0.083 to 0.244)	0.334	-0.048 (-0.170 to 0.074)	0.439	-0.057 (-0.182 to 0.068)	0.370
Height (cm)	0.561 (-0.069 to 1.192)	0.081	-0.011 (-0.619 to 0.596)	0.971	-0.172 (-0.793 to 0.449)	0.587
Waist z-score	0.189 (0.008 to 0.369)	0.040	0.057 (-0.144 to 0.258)	0.578	0.032 (-0.129 to 0.192)	0.701
Sum of four skinfolds (mm) <sup>c,d</sup>	0.944 (-1.308 to 3.196)	0.409	0.486 (-0.266 to 1.237)	0.202	0.460 (-0.375 to 1.294)	0.276
Body fat %	0.749 (-0.180 to 1.678)	0.114	0.207 (-0.622 to 1.036)	0.623	0.162 (-0.671 to 0.995)	0.703
Energy intake (kJ in 24 hours) <sup>e</sup>	646.049 (-687.396 to 1979.495)	0.340	571.985 (-630.065 to 1774.036)	0.348	518.404 (-572.128 to 1608.935)	0.349
PA energy expenditure (kJ/kg/day)	0.950 (–3.679 to 5.579)	0.687	0.356 (-3.979 to 4.690)	0.872	0.069 (-4.275 to 4.413)	0.975
PedsQL total score <sup>f</sup>	-0.554 (-3.43 to 2.325)	0.705	-0.710 (-5.247 to 3.828)	0.758	-0.402 (-5.255 to 4.450)	0.871
CHU9D total score	0.012 (-0.009 to 0.033)	0.272	0.009 (-0.012 to 0.031)	0.404	0.014 (-0.009 to 0.036)	0.236
Binary outcomes	RD (95% CI)	p-value	RD (95% CI)	p-value	RD (95% CI)	p- <i>valu</i> e
Obese <sup>9</sup>	0.025 (-0.016 to 0.076)	0.248	0.014 (-0.034 to 0.076)	0.612	-0.006 (-0.049 to 0.051)	0.813
Obese/overweight <sup>9</sup>	0.049 (-0.005 to 0.109)	0.078	0.037 (-0.035 to 0.123)	0.338	0.010 (-0.058 to 0.092)	0.786
Eating five or more portions of fruit and vegetables <sup>h</sup>	0.030 (-0.053 to 0.112)	0.484	0.017 (-0.060 to 0.093)	0.667	0.016 (-0.054 to 0.086)	0.652
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.015 (–0.081 to 0.111)	0.760	0.015 (–0.085 to 0.115)	0.774	-0.017 (-0.114 to 0.082)	0.732

TABLE 85 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU1, with multiple imputation included

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on role at baseline), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjustments were made for baseline BMI-z.

h Adjustments were made for total grams of fruit and vegetables consumed per day.

	Intervention vs. control					
Follow-up outcome variable	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Continuous outcomes	MD (95% CI)	p- <i>valu</i> e	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
BMI-z	0.114 (-0.036 to 0.264)	0.137	-0.013 (-0.128 to 0.102)	0.824	-0.039 (-0.162 to 0.085)	0.538
Height (cm)	0.162 (-0.635 to 0.960)	0.69	-0.46 (-1.112 to 0.191)	0.166	-0.626 (-1.228 to -0.024)	0.041
Waist z-score	0.291 (0.051 to 0.532)	0.018	0.176 (-0.011 to 0.362)	0.065	0.119 (-0.068 to 0.306)	0.21
Sum of four skinfolds (mm) <sup>c,d</sup>	1.808 (-1.020 to 4.636)	0.208	0.785 (-0.043 to 1.614)	0.063	0.635 (-0.121 to 1.391)	0.099
Body fat %	1.067 (0.125 to 2.009)	0.027	0.432 (-0.386 to 1.251)	0.298	0.255 (-0.625 to 1.136)	0.569
Energy intake (kJ in 24 hours) <sup>e</sup>	170.2378 (758.431 to 1098.906)	0.718	158.583 (-711.427 to 1028.593)	0.720	13.69412 (-765.471 to 792.860)	0.972
PA energy expenditure (kJ/kg/day)	0.979 (-4.114 to 6.072)	0.704	0.266 (-4.573 to 5.105)	0.913	0.282 (-4.359 to 4.924)	0.904
PedsQL total score <sup>f</sup>	1.886 (-0.807 to 4.578)	0.169	0.775 (-0.089 to 1.639)	0.078	0.628 (-0.201 to 1.456)	0.136
CHU9D total score	-0.0042673 (-0.022 to 0.014)	0.643	-0.0063602 (-0.025 to 0.012)	0.501	-0.006 (-0.025 to 0.012)	0.499
Binary outcomes	RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p-value
Obese <sup>9</sup>	0.036 (-0.012 to 0.094)	0.153	0.026 (-0.031 to 0.096)	0.402	0.019 (-0.038 to 0.089)	0.551
Obese/overweight <sup>9</sup>	0.046 (-0.010 to 0.106)	0.110	0.026 (-0.048 to 0.109)	0.504	0.007 (-0.067 to 0.091)	0.869
Eating five or more portions of fruit and vegetables <sup>h</sup>	0.034 (-0.055 to 0.118)	0.449	0.052 (-0.039 to 0.141)	0.264	0.042 (-0.052 to 0.129)	0.377
Achieving $\geq$ 60 minutes of PA <sup>i</sup>	0.015 (-0.081 to 0.111)	0.760	0.014 (-0.080 to 0.115)	0.774	-0.017 (-0.114 to 0.082)	0.732

TABLE 86 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU2, with multiple imputation included

a Adjusted for baseline outcome.

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on role at baseline), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Transformed via inverse.

d Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

e Transformed via natural logarithm.

f Transformed via squaring.

g Adjustments were made for baseline BMI-z.

h Adjustments were made for total grams of fruit and vegetables consumed per day.

# **Different levels of clustering**

TABLE 87 Adjusted differences for key anthropometric, diet and PA variables between control and intervention groups at FU1, with nested clustering

Arm					Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
<i>n</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR)'	Mean (SD) or i	median (IQR)'	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>valu</i> e
N = 1249 (n = 574, unadjusted)	0.23 (1.24)	0.34 (1.34)	0.15 (1.20)	0.23 (1.27)	0.120	0.170	-0.074	0.184	-0.063	0.291
N = 1197 (n = 556, partially adjusted)					(-0.051 to 0.292)		(-0.183 to 0.035)		(-0.181 to 0.054)	
N = 837 (n = 393,  fully adjusted)										
Height (cm)										
N = 1251 (n = 575, unadjusted) N = 1200 (n = 558, partially adjusted) N = 837 (n = 392, fully adjusted)	118.63 (5.60)	127.37 (6.09)	118.18 (5.38)	127.03 (5.75)	0.346 (-0.255 to 0.947)	0.259	-0.064 (-0.641 to 0.514)	0.829	-0.194 (-0.795 to 0.408)	0.528
Waist z-score										
N = 1151 (n = 528, unadjusted) N = 1069 (n = 490, partially adjusted) $N = 796 (n = 368, fully adjusted)$	0.77 (1.24)	1.05 (1.36)	0.66 (1.25)	0.87 (1.32)	0.186 (0.010 to 0.361)	0.038	0.067 (-0.108 to 0.243)	0.453	0.028 (-0.115 to 0.172)	0.697
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 1048 (n = 488, unadjusted) N = 902 (n = 421, partially adjusted) $N = 683 (n = 323, fully adjusted)$	28.55 (23.30–35.43)	31.48 (24.57–43.65)	28.10 (23.00–36.60)	29.40 (23.63–41.67)	1.349 (-0.178 to 2.876)	0.083	0.317 (-0.181 to 0.816)	0.212	0.364 (-0.233 to 0.961)	0.232
Body fat %										
N = 1236 (n = 574, unadjusted) N = 1169 (n = 553, partially adjusted) N = 822 (n = 391, fully adjusted)	21.30 (5.35)	21.79 (6.73)	20.95 (5.22)	20.87 (6.30)	0.841 (-0.040 to 1.722)	0.061	0.044 (-0.703 to 0.792)	0.908	0.051 (-0.747 to 0.849)	0.900

	Arm				Intervention vs. cont	rol				
Follow-up outcome variable:	Intervention		Control							
(n = number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 1112 (n = 507, unadjusted)	6904 (5005 - 005 4)	7152	6911 (5004-7064)	7074	122.507	0.488	30.825	0.841	6.568 ( 200 C15 to 201 752)	0.965
N = 978 ( $n = 449$ , partially adjusted)	(5865–8054)	(6107-8376)	(5804–7964)	(5963–8233)	(-223.935 to 468.949)		(-270.606 to 332.256)		(-288.615 to 301.752)	
N = 803 (n = 369,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 868 (n = 395, unadjusted)	96.43 (23.16)	91.70 (23.71)	94.08 (24.38)	91.27 (25.42)	-0.207	0.926	-0.866	0.708	-1.691	0.422
N = 724 ( $n = 335$ , partially adjusted)					(-4.552 to 4.137)		(-5.389 to 3.658)		(-5.821 to 2.440)	
N = 658 (n = 310,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 1231 (n = 554, unadjusted)	71.74	76.09	73.91	76.09	-0.662	0.545	-0.630	0.665	-0.437	0.769
N = 1171 (n = 538,  partially adjusted)	(60.87-82.61)	(65.22-84.78)	(60.87-82.61)	(65.22-84.78)	(-2.805 to 1.481)		(-3.487 to 2.227)		(-3.354 to 2.481)	
N = 817 (n = 375,  fully adjusted)										
CHU9D total score										
N = 1215 (n = 550, unadjusted)	0.84 (0.13)	0.87 (0.11)	0.82 (0.14)	0.86 (0.10)	0.012	0.228	0.009	0.323	0.012	0.265
N = 1130 (n = 519,  partially adjusted)					(-0.007 to 0.030)		(-0.009 to 0.028)		(-0.009 to 0.032)	
N = 786 (n = 358,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p- <i>value</i>	RD (95% CI)	p- <i>value</i>
N = 1249 (n = 574, unadjusted)	84 (12.73)	93 (16.20)	87 (11.89)	100 (14.81)	0.015	0.381	-0.034	0.084	-0.006	0.753
N = 1197 (n = 556, partially adjusted)					(-0.017 to 0.055)		(-0.064 to 0.005)		(-0.036 to 0.033)	
N = 837 (n = 393,  fully adjusted)										
										continued

# TABLE 87 Adjusted differences for key anthropometric, diet and PA variables between control and intervention groups at FU1, with nested clustering (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n =  number in intervention arm)	Baseline	FU1	Baseline	FU1	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Obese/overweight <sup>h</sup>										
N = 1249 (n = 574, unadjusted)	145 (21.97)	165 (28.75)	150 (20.49)	167 (24.74)	0.043	0.076	-0.010	0.720	0.002	0.958
N = 1197 (n = 556,  partially adjusted)							(-0.059 to 0.051)		(-0.050 to 0.066)	
N = 837 (n = 393,  fully adjusted)										
Five or more portions of fruit and vegetables <sup>i</sup>										
N = 1112 (n = 507, unadjusted)	336 (59.79)	244 (48.13)	405 (64.80)	297 (49.09)	-0.010	0.820	-0.014	0.753	0.004	0.900
N = 978 (n = 449,  partially adjusted)					(-0.085 to 0.080)		(-0.090 to 0.077)		(-0.057 to 0.074)	
N = 803 (n = 369,  fully adjusted)										
Achieving $\geq$ 60 minutes of PA <sup>i</sup>										
N = 866 (n = 396, unadjusted)	228 (46.44)	207 (52.27)	276 (49.55)	234 (49.79)	0.015	0.762	0.057	0.320	0.017	0.729
N = 720 (n = 334,  partially adjusted)					(-0.076 to 0.126)		(-0.049 to 0.188)		(-0.072 to 0.125)	
N = 654 ( $n = 310$ , fully adjusted)										
a Adjusted for baseline outcome										

b Adjusted for baseline outcome, baseline pupil-level covariates [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake (PA energy expenditure)] and baseline school-level covariates [size (number of pupils on roll), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Summary statistics presented are either mean (SD) or median (IQR).

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjusted for baseline BMI-z.

i Adjusted for total grams of fruit and vegetables consumed per day.

# TABLE 88 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU2, with nested clustering

	Arm			Intervention vs. control						
Follow-up outcome variable:	Intervention		Control							
<i>N</i> = total participants ( <i>n</i> = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>6</sup>	
<b>Continuous outcomes</b> BMI-z	Mean (SD) or i	median (IQR)'	Mean (SD) or	median (IQR) <sup>c</sup>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p- <i>value</i>
N = 1145 (n = 524, unadjusted)	0.23 (1.24)	0.42 (1.34)	0.15 (1.20)	0.31 (1.32)	0.107	0.175	-0.002	0.973	-0.028	0.660
N = 1094 ( $n = 505$ , partially adjusted)					(-0.048 to 0.262)		(-0.105 to 0.101)		(-0.152 to 0.097)	
N = 772 ( $n = 359$ , fully adjusted)										
Height (cm)										
N = 1146 (n = 524, unadjusted)	118.63 (5.60)	134.73 (6.68)	118.18 (5.38)	134.86 (6.43)	-0.135	0.744	-0.427	0.198	-0.642	0.046
N = 1096 (n = 506,  partially adjusted)					(-0.945 to 0.675)		(-1.079 to 0.224)		(-1.273 to 0.011)	
N = 773 ( $n = 359$ , fully adjusted)										
Waist z-score										
N = 990 (n = 446, unadjusted)	0.77 (1.24)	1.15 (1.25)	0.66 (1.25)	0.90 (1.35)	0.279	0.005	0.143	0.056	0.083	0.300
N = 923 ( $n = 414$ , partially adjusted)					(0.085 to 0.473)		(-0.003 to 0.290)		(-0.074 to 0.240)	
N = 703 ( $n = 320$ , fully adjusted)										
Sum of four skinfolds (mm) <sup>d,e</sup>										
N = 845 (n = 381, unadjusted)	28.55	34.70	28.10	31.93	2.156	0.077	0.649	0.015	0.501	0.094
N = 724 ( $n = 334$ , partially adjusted)	(23.30–35.43)	(25.50–49.95)	(23.00–36.60)	(24.00–48.90)	(-0.235 to 4.548)		(0.129 to 1.170)		(-0.085 to 1.086)	
N = 560 (n = 262,  fully adjusted)										
Body fat %										
N = 1115 (n = 516, unadjusted)	21.30 (5.35)	22.52 (7.48)	20.95 (5.22)	21.58 (7.26)	0.975	0.044	0.452	0.242	0.222	0.627
N = 1051 (n = 495,  partially adjusted)					(0.025 to 1.925)		(-0.306 to 1.210)		(-0.674 to 1.119)	
N = 747 (n = 354,  fully adjusted)										
										continued

TABLE 88 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU2, with nested clustering (continued)

	Arm				Intervention vs. control					
Follow-up outcome variable:	Intervention		Control							
n = number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>	
Energy intake (kJ in 24 hours) <sup>f</sup>										
N = 1015 (n = 453, unadjusted)	6904 (FRCF ROF 4)	7656	6911 (F804 7064)	7817	-272.925	0.118	-186.728	0.253	-330.700	0.053
N = 895 ( $n = 401$ , partially adjusted)	(5865–8054)	(6436-9118)	(5804–7964)	(6748–9212)	(-615.526 to 69.675)		(-507.225 to 133.769)		(-666.100 to 4.700)	
N = 729 (n = 331,  fully adjusted)										
PA energy expenditure (kJ/kg/day)										
N = 690 (n = 305, unadjusted)	96.43 (23.16)	79.66 (22.26)	94.08 (24.38)	78.60 (22.43)	1.167	0.603	0.001	0.999	-0.076	0.968
N = 571 (n = 253,  partially adjusted)					(-3.226-5.560)		(-4.3/1-4.3/3)		(-3.770-3.018)	
N = 520 (n = 237,  fully adjusted)										
PedsQL total score <sup>g</sup>										
N = 1116 (n = 495, unadjusted)	71.74	82.61	73.91	80.43	1.002	0.390	1.248	0.365	1.263	0.287
N = 1055 ( $n = 477$ , partially adjusted)	(60.87-82.61)	(71.74–89.13)	(60.87-82.61)	(71.74–89.13)	(-1.283 to 3.286)		(-1.453 to 3.948)		(-1.062 to 3.588)	
N = 755 (n = 346,  fully adjusted)										
CHU9D total score										
N = 1131 (n = 517, unadjusted)	0.84 (0.13)	0.89 (0.09)	0.82 (0.14)	0.90 (0.09)	-0.004	0.615	-0.006	0.472	-0.006	0.396
N = 1049 (n = 486,  partially adjusted)					(-0.018 to 0.011)		(-0.021 to 0.010)		(-0.021 to 0.008)	
N = 741 (n = 344,  fully adjusted)										
<b>Binary outcomes</b> Obese <sup>h</sup>	n (%)		n (%)		RD (95% CI)	p- <i>value</i>	RD (95% CI)	p-value	RD (95% CI)	p- <i>value</i>
N = 1145 (n = 524, unadjusted)	84 (12.73)	108 (20.61)	87 (11.89)	112 (18.04)	0.026	0.227	-0.004	0.837	0.020	0.336
N = 1094 ( $n = 505$ , partially adjusted)			(-	(-0.014 (0 0.076)		(-0.040 (0 0.041)		(-0.019 (0 0.069)		
N = 772 (n = 359,  fully adjusted)										

	Arm				Intervention vs. control						
Follow-up outcome variable:	Intervention		Control								
n =  number in intervention arm)	Baseline	FU2	Baseline	FU2	Unadjusted		Partially adjusted <sup>a</sup>		Fully adjusted <sup>b</sup>		
Obese/overweight <sup>h</sup>											
N = 1145 (n = 524, unadjusted)	145 (21.97)	176 (33.59)	150 (20.49)	187 (30.11)	0.035	0.201	0.002	0.948	0.004	0.892	
N = 1094 (n = 505,  partially adjusted)					(-0.017 to 0.096)		(-0.053 to 0.069)		(-0.047 to 0.065)		
N = 772 ( $n = 359$ , fully adjusted)											
Five or more portions of fruit and vege	etables <sup>i</sup>										
N = 1015 (n = 453, unadjusted)	336 (59.79)	253 (55.85)	405 (64.80)	317 (56.41)	-0.006	0.890	0.011	0.790	0.002	0.953	
N = 895 ( $n = 401$ , partially adjusted)					(-0.079 to 0.079)		(-0.068 to 0.103)		(-0.074 to 0.091)		
N = 729 (n = 331,  fully adjusted)											
Achieving $\geq$ 60 minutes of PA <sup>i</sup>											
N = 700 (n = 307, unadjusted)	228 (46.44)	70 (22.80)	276 (49.55)	120 (30.53)	-0.077	0.127	-0.068	0.215	-0.067	0.219	
N = 575 (n = 254,  partially adjusted)					(-0.149 to 0.026)		(-0.147 to 0.048)		(-0.146 to 0.049)		
N = 524 ( $n = 239$ , fully adjusted)											
<ul> <li>a Method 3: considers participan</li> <li>b Method 1: indicates the origina</li> <li>c Method 2: adjustments are mad</li> <li>d Transformed via inverse.</li> </ul>	it-level and clu al methodolog ide for individu	ster-level associa y. Here adjustm ials' baseline ou	ation using ind ent is made for tcome and clus	ividuals' baselir r individuals' ba ster-level baseli	ne outcome, cluster-le aseline outcome only. ne mean outcome.	evel mean c	outcome and grand m	ean outcor	ne.		

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjustments were made for baseline BMI-z.

i Adjustments were made for total grams of fruit and vegetables consumed per day.

	Unadjusted ICC		ICC adjusted for tre	atment arm	Partially adjusted I	CCª	Fully adjusted ICC <sup>b</sup>	
Outcome	School-level ICC	Class-level ICC	School-level ICC	Class-level ICC	School-level ICC	Class-level ICC	School-level ICC	Class-level ICC
Continuous outcomes								
BMI-z	0.0211	0.0211	0.0193	0.0193	0.0840	0.0869	0.0805	0.0805
	(0.0074 to 0.0590)	(0.0074 to 0.0590)	(0.0063 to 0.0577)	(0.0063 to 0.0577)	(0.0449 to 0.1519)	(0.0497 to 0.1475)	(0.0441 to 0.1423)	(0.0441 to 0.1423)
Height	0.0000	0.0000	0.0000	0.0000	0.2700	0.3045	0.3672	0.3795
	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.1840 to 0.3775)	(0.2223 to 0.4013)	(0.2708 to 0.4755)	(0.2857 to 0.4833)
Waist z-score	0.0136	0.0136	0.0089	0.0089	0.1443	0.1552	0.1067	0.1099
	(0.0027 to 0.0650)	(0.0027 to 0.0650)	(0.0010 to 0.0772)	(0.0010 to 0.0772)	(0.0795 to 0.2478)	(0.0963 to 0.2405)	(0.0522 to 0.2058)	(0.0621 to 0.1872)
Sum of four skinfolds	0.0051	0.0051	0.0029	0.0029	0.0879	0.1831	0.0671	0.1596
	(0.0001 to 0.1813)	(0.0001 to 0.1813)	(0.0000 to 0.5995)	(0.0000 to 0.5995)	(0.0312 to 0.2235)	(0.1223 to 0.2648)	(0.0178 to 0.2222)	(0.1018 to 0.2414)
Body fat %	0.0252	0.0252	0.0208	0.0208	0.0984	0.1061	0.1059	0.1059
	(0.0101 to 0.0616)	(0.0101 to 0.0616)	(0.0074 to 0.0572)	(0.0074 to 0.0572)	(0.0541 to 0.1724)	(0.0634 to 0.1720)	(0.0620 to 0.1752)	(0.0620 to 0.1752)
Energy intake	0.0443	0.0658	0.0436	0.0649	0.0305	0.0513	0.0212	0.0450
(kJ in 24 hours)	(0.0177 to 0.1067)	(0.0342 to 0.1231)	(0.0173 to 0.1057)	(0.0336 to 0.1220)	(0.0076 to 0.1144)	(0.0233 to 0.1092)	(0.0024 to 0.1651)	(0.0193 to 0.1010)
PA energy expenditure	0.0493	0.0493	0.0493	0.0493	0.0819	0.0819	0.0468	0.0572
(kJ/kg/day)	(0.0220 to 0.1068)	(0.0220 to 0.1068)	(0.0220 to 0.1068)	(0.0220 to 0.1068)	(0.0410 to 0.1570)	(0.0410 to 0.1570)	(0.0053 to 0.3130)	(0.0226 to 0.1376)
PedsQL total score	0.0403	0.0403	0.0395	0.0395	0.0394	0.0394	0.0176	0.0176
	(0.0189 to 0.0839)	(0.0189 to 0.0839)	(0.0184 to 0.0829)	(0.0184 to 0.0829)	(0.0181 to 0.0839)	(0.0181 to 0.0839)	(0.0037 to 0.0799)	(0.0037 to 0.0799)
CHU9D total score	0.0535	0.0599	0.0513	0.0581	0.0407	0.0654	0.0335	0.0710
	(0.0224 to 0.1226)	(0.0304 to 0.1145)	(0.0208 to 0.1209)	(0.0294 to 0.1118)	(0.0105 to 0.1456)	(0.0343 to 0.1213)	(0.0046 to 0.2064)	(0.0361 to 0.1348)
Binary outcomes								
Obese <sup>c</sup>	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)
Obese/overweight <sup>c</sup>	0.0000	0.0000	0.0000	0.0000	0.0192	0.0192	0.0040	0.0040
	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0052 to 0.0684)	(0.0052 to 0.0684)	(0.000 to 0.6448)	(0.000 to 0.6448)
Five or more portions of fruit and vegetables <sup>d</sup>	0.0371	0.0396	0.0371	0.0396	0.0233	0.0314	0.0000	0.0072
	(0.0110 to 0.1175)	(0.0168 to 0.0906)	(0.0110 to 0.1182)	(0.0168 to 0.0906)	(0.0038 to 0.1310)	(0.0103 to 0.0916)	(0.0000 to 0.0000)	(0.0002 to 0.2466)

# TABLE 89 Estimates of school- and class-level ICCs at FU1, point estimate (95% CI)

a Adjusted for treatment arm and baseline value of the outcome.

b Adjusted for treatment arm, baseline value of the outcome, baseline pupil-level [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake PA energy expenditure] and baseline school level [size (number of pupils on role at baseline), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Adjustments were made for baseline BMI-z.

d Adjustments were made for total grams of fruit and vegetables consumed per day.

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# TABLE 90 Estimates of school- and class-level ICCs at FU2, point estimate (95% CI)

	Unadjusted ICC		ICC adjusted for treatment arm		Partially adjusted ICC <sup>a</sup>		Fully adjusted ICC <sup>b</sup>	
Outcome	School-level ICC	Class-level ICC	School-level ICC	Class-level ICC	School-level ICC	Class-level ICC	School-level ICC	Class-level ICC
Continuous outcomes								
BMI-z	0.0046	0.0056	0.0000	0.0047	0.0000	0.0480	0.0000	0.0375
	(0.0000 to 0.5444)	(0.0001 to 0.2975)	(0.0000 to 0.0000)	(0.0000 to 0.4389)	(0.0000 to 0.0000)	(0.0180 to 0.1215)	(0.0000 to 0.0000)	(0.0122 to 0.1090)
Height	0.0066	0.0066	0.0066	0.0066	0.0962	0.2097	0.0845	0.1607
	(0.0004 to 0.0971)	(0.0004 to 0.0971)	(0.0004 to 0.0972)	(0.0004 to 0.0972)	(0.0375 to 0.2253)	(0.1442 to 0.2946)	(0.0314 to 0.2077)	(0.1005 to 0.2470)
Waist z-score	0.0252	0.0444	0.0075	0.0368	0.0291	0.0796	0.0335	0.0682
	(0.0050 to 0.1174)	(0.0185 to 0.1027)	(0.0000 to 0.6311)	(0.0139 to 0.0936)	(0.0029 to 0.2376)	(0.0428 to 0.1436)	(0.0050 to 0.1929)	(0.0319 to 0.1401)
Sum of four skinfolds	0.0288	0.0467	0.0230	0.0455	0.0000	0.0721	0.0000	0.0806
	(0.0055 to 0.1361)	(0.0184 to 0.1135)	(0.0028 to 0.1655)	(0.0180 to 0.1105)	(0.0000 to 0.0000)	(0.0334 to 0.1488)	(0.0000 to 0.0000)	(0.0372 to 0.1660)
Body fat %	0.0115	0.0149	0.0042	0.0129	0.0040	0.0705	0.0053	0.0667
	(0.0011 to 0.1057)	(0.0022 to 0.0938)	(0.0000 to 0.7345)	(0.0016 to 0.0980)	(0.0000 to 0.9998)	(0.0370 to 0.1301)	(0.0000 to 0.9995)	(0.0313 to 0.1367)
Energy intake	0.0045	0.0908	0.0000	0.0889	0.0000	0.1083	0.0000	0.0879
(kJ in 24 hours)	(0.0000 to 0.9899)	(0.0530 to 0.1512)	(0.0000 to 0.0000)	(0.0518 to 0.1485)	(0.0000 to 0.0000)	(0.0648 to 0.1754)	(0.0000 to 0.0000)	(0.0481 to 0.1551)
PA energy expenditure	0.0515	0.0573	0.0520	0.0568	0.0753	0.0753	0.0000	0.0601
(kJ/kg/day)	(0.0076 to 0.2794)	(0.0227 to 0.1369)	(0.0080 to 0.2723)	(0.0224 to 0.1365)	(0.0329 to 0.1634)	(0.0329 to 0.1634)	(0.0000 to 0.0000)	(0.0225 to 0.1510)
PedsQL total score	0.0708	0.0720	0.0697	0.0715	0.0674	0.0674	0.0428	0.0467
	(0.0326 to 0.1466)	(0.0386 to 0.1304)	(0.0316 to 0.1470)	(0.0383 to 0.1293)	(0.0355 to 0.1240)	(0.0355 to 0.1240)	(0.0114 to 0.1481)	(0.0186 to 0.1124)
CHU9D total score	0.0438	0.0466	0.0428	0.0458	0.0481	0.0554	0.0526	0.0526
	(0.0158 to 0.1153)	(0.0215 to 0.0980)	(0.0151 to 0.1152)	(0.0209 to 0.0973)	(0.0160 to 0.1357)	(0.0268 to 0.1112)	(0.0226 to 0.1174)	(0.0226 to 0.1174)
Binary outcomes								
Obese <sup>c</sup>	0.0000	0.0000	0.0000	0.0000	0.0033	0.0033	0.0000	0.0000
	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.0000)	(0.0000 to 0.6713)	(0.0000 to 0.6713)	(0.0000 to 0.0000)	(0.0000 to 0.0000)
Obese/overweight <sup>c</sup>	0.0000	0.0014	0.0000	0.0012	0.0190	0.0358	0.0143	0.0143
	(0.0000 to 0.0000)	(0.0000 to 1.0000)	(0.0000 to 0.0000)	(0.0000 to 1.0000)	(0.0011 to 0.2607)	(0.0140 to 0.0885)	(0.0020 to 0.0967)	(0.0020 to 0.0967)
Five or more portions of fruit and vegetables <sup>d</sup>	0.0000	0.0516	0.0000	0.0516	0.0000	0.0589	0.0000	0.0313
	(0.0000 to 0.0000)	(0.0244 to 0.1057)	(0.0000 to 0.0000)	(0.0244 to 0.1055)	(0.0000 to 0.0000)	(0.0271 to 0.1232)	(0.0000 to 0.0000)	(0.0094 to 0.0992)
Achieving $\geq$ 60 minutes of PA <sup>e</sup>	0.0459	0.0976	0.0391	0.0901	0.0394	0.0992	0.0457	0.0902
	(0.0043 to 0.3501)	(0.0498 to 0.1823)	(0.0025 to 0.4006)	(0.0442 to 0.1749)	(0.0019 to 0.4739)	(0.0485 to 0.1922)	(0.0031 to 0.4230)	(0.0397 to 0.1917)

a Adjusted for treatment arm and baseline value of the outcome.

b Adjusted for treatment arm, baseline value of the outcome, baseline pupil-level [sex, ethnicity, deprivation (IMD score for home postcode), 24-hour total energy intake PA energy expenditure] and baseline school level [size (number of pupils on role at baseline), percentage of school population South Asian, percentage of school population black African Caribbean, percentage of free school meal eligibility].

c Adjustments were made for baseline BMI-z.

d Adjustments were made for total grams of fruit and vegetables consumed per day.

# Alternative methods for baseline adjustment

Follow-up outcome variable	Method 1 <sup>ª</sup>		Method 2 <sup>b</sup>			Method 3 <sup>c</sup>	
Continuous outcomes	MD (95% CI)	p- <i>value</i>	MD (95% CI)	p-value		MD (95% CI)	p-value
BMI-z	-0.075 (-0.183 to 0.033)	0.175	0.026 (-0.098 to 0.151)	0.680		-0.069 (-0.175 to 0.037)	0.201
Height (cm)	-0.073 (-0.652 to 0.505)	0.804	0.163 (-0.406 to 0.731)	0.575		0.151 (-0.341 to 0.644)	0.547
Waist z-score	0.026 (-0.168 to 0.220)	0.794	0.140 (-0.001 to 0.280)	0.051		0.074 (-0.086 to 0.233)	0.367
Sum of four skinfolds (mm) <sup>d,e</sup>	0.366 (-0.157 to 0.890)	0.170	0.459 (-0.178 to 1.096)	0.158		1.111 (-0.421 to 2.643)	0.155
Body fat %	0.040 (-0.707 to 0.786)	0.917	0.651 (-0.146 to 1.448)	0.109		0.129 (-0.592 to 0.849)	0.727
Energy intake (kJ in 24 hours) <sup>f</sup>	61.531 (-217.772 to 340.834)	0.666	59.017 (-263.384 to 381.418)	0.720		59.017 (-263.384 to 381.418)	0.720
PA energy expenditure (kJ/kg/day)	-0.866 (-5.389 to 3.658)	0.708	-0.547 (-4.665 to 3.570)	0.794		-0.764 (-5.223 to 3.696)	0.737
PedsQL total score <sup>9</sup>	-0.630 (-3.487 to 2.227)		0.665	-0.546 (-2.961 to 1.868)	0.657	-0.546 (-2.961 to 1.868)	0.657
CHU9D total score	0.010 (-0.009 to 0.029)		0.300	0.010 (-0.007 to 0.028)	0.255	0.012 (-0.006 to 0.030)	0.197
Binary outcomes	RD (95% CI)		p-value	RD (95% CI)	p- <i>valu</i> e	RD (95% CI)	p-value
Obese <sup>h</sup>	-0.036 (-0.066 to 0.004)		0.074	-0.057 (-0.106 to 0.009)	0.083	-0.035 (-0.065 to 0.005)	0.083
Obese/overweight <sup>h</sup>	-0.013 (-0.061 to 0.048)		0.655	-0.009 (-0.060 to 0.055)	0.748	-0.009 (-0.060 to 0.055)	0.748
Five or more portions of fruit and vegetables <sup>i</sup>	-0.014 (-0.090 to 0.077)		0.753	0.001 (-0.055 to 0.064)	0.975	0.013 (-0.059 to 0.097)	0.742
Achieving $> 60$ minutes of PA <sup>j</sup>	0.041 (-0.058 to 0.163)		0.446	0.014 (-0.042 to 0.077)	0.645	0.004 (-0.054 to 0.071)	0.889

TABLE 91 Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU1, with adjustment for cluster-level means

a Method 1: indicates the original methodology. Here adjustment is made only for individuals' baseline outcome.

b Method 2: adjustments are made for individuals' baseline outcome and cluster-level baseline mean outcome.

c Method 3: considers participant- and cluster-level association using individuals' baseline outcome, cluster-level mean outcome and grand mean outcome.

d Transformed via inverse.

e Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

f Transformed via natural logarithm.

g Transformed via squaring.

h Adjustments were made for baseline BMI-z.

i Adjustments were made for total grams of fruit and vegetables consumed per day.

**TABLE 92** Adjusted differences for key anthropometric, diet, PA and psychological variables between control and intervention groups at FU1, with the inclusion of a random effect for individual vs. original model

Follow-up outcome variable	Original model, MD (95% Cl)ª	Including random effect for individual, MD (95% Cl)
Continuous outcomes		
BMI-z	-0.075 (-0.183 to 0.033)	-0.045 (-0.163 to 0.073)
Height	-0.073 (-0.652 to 0.505)	0.004 (-0.611 to 0.619)
Waist z-score	0.026 (-0.168 to 0.220)	0.030 (-0.144 to 0.203)
Sum of four skinfolds <sup>b,c</sup>	0.366 (-0.157 to 0.890)	0.539 (–0.975 to 2.054)
Body fat %	0.040 (-0.707 to 0.786)	0.268 (-0.537 to 1.074)
Energy intake (kJ in 24 hours) <sup>d</sup>	61.531 (-217.772 to 340.834)	109.053 (-390.752 to 608.858)
PA energy expenditure (kJ/kg/day)	-0.866 (-5.389 to 3.658)	-1.180 (-6.045 to 3.685)
PedsQL total score <sup>e</sup>	-0.630 (-3.487 to 2.227)	–0.379 (–3.574 to 2.815)
CHU9D total score	0.010 (-0.009 to 0.029)	-0.011 (-0.039 to 0.018)
Binary outcomes	RD (95% CI)	RD (95% CI)
Obese <sup>f</sup>	-0.036 (-0.066 to 0.004)	-0.002 (-0.030 to 0.033)
Obese/overweight <sup>f</sup>	-0.013 (-0.061 to 0.048)	0.019 (-0.029 to 0.078)
Five or more portions of fruit and vegetables <sup>9</sup>	-0.014 (-0.090 to 0.077)	0.032 (-0.062 to 0.146)
Achieving $\geq 60$ minutes of PA <sup>h</sup>	0.041 (-0.058 to 0.163)	0.059 (-0.072 to 0.232)

a Adjustments made for baseline covariate.

b Transformed via inverse.

c Sum of four skinfolds comprised summation of biceps, subscapular, suprailiac and triceps measurements.

d Transformed via natural logarithm.

e Transformed via squaring.

f Adjustments were made for baseline BMI-z.

g Adjustments were made for total grams of fruit and vegetables consumed per day.

h Adjusted for minutes of PA per 24 hours.

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# Treatment by cluster heterogeneity

TABLE 93 Intracluster correlation coefficients that vary over treatment arm, estimated using FU1 measurements

		Mixed model with separate random effect	
FU1 measurements: outcome	Overall ICC <sup>a</sup>	Treatment	Control
BMI-z	0.0193	0.0000	0.0461
Height	0.0000	0.0065	0.0000
Waist z-score	0.0089	0.0089	0.0089
Sum of four skinfolds	0.0029	0.0000	0.0137
Body fat %	0.0208	0.0000	0.0415
Energy intake (kJ in 24 hours)	0.0525	0.0619	0.0445
PA energy expenditure (kJ/kg/day)	0.0493	0.0000	0.0990
PedsQL total score	0.0395	0.0380	0.0407
CHU9D total score	0.0559	0.0733	0.0399
Obese	0.0000	0.0000	0.0000
Obese/overweight	0.0000	0.0000	0.0066
Five or more portions of fruit and vegetables	0.0390	0.0456	0.0325
Achieving $\geq$ 60 minutes of PA	0.0642	0.0460	0.0776
a ICC is estimated with the inclusion of the treatr	ment arm as a covaria	ate.	

# TABLE 94 Intracluster correlation coefficients that vary over treatment arm: estimated using FU2 measurements

		Mixed model with separate random effe	
FU2 measurements: outcome	Overall ICC <sup>a</sup>	Treatment	Control
BMI-z	0.0025	0.0000	0.0198
Height	0.0066	0.0000	0.0150
Waist z-score	0.0258	0.0031	0.0466
Sum of four skinfolds	0.0369	0.0113	0.0547
Body fat %	0.0086	0.0032	0.0136
Energy intake (kJ in 24 hours)	0.0480	0.0525	0.0444
PA energy expenditure (kJ/kg/day)	0.0565	0.0444	0.0651
PedsQL total score	0.0712	0.0794	0.0644
CHU9D total score	0.0450	0.0451	0.0450
Obese	0.0000	0.0000	0.0000
Obese/overweight	0.0000	0.0000	0.0099
Five or more portions of fruit and vegetables	0.0443	0.0395	0.0478
Achieving $\geq$ 60 minutes of PA	0.0793	0.0891	0.0712

a ICC is estimated with the inclusion of the treatment arm as a covariate.

# EME HS&DR HTA PGfAR PHR

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