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1 **ABSTRACT**

2

3 **Objective:** This study aims to determine whether a multi-component school-based
4 intervention can maintain children's fruit and vegetable intake post eligibility for free school
5 fruit and vegetables.

6 **Design:** A random sample of 54 English primary schools was randomised to receive the 10
7 month intervention *Project Tomato*, a multi-component theory based intervention or the
8 control. Each group consisted of 27 schools.

9 **Setting:** Children's intake of fruit and vegetables is below recommendations. The English
10 School Fruit and Vegetable Scheme has a short term impact on intake while children are
11 eligible for the scheme.

12 **Subjects:** Dietary measurements were collected from 658 Year 2 pupils aged 7 to 8 years at
13 baseline and at follow-up 20 months later.

14 **Results:** Following an intention to treat analysis, the intervention as delivered compared to
15 the control had no impact on intake of fruit and vegetables (2g, 95% confidence interval -23
16 to 26g), or the number of portions of fruit (0.0 portions, 95% CI -0.3 to 0.3) or vegetables
17 (0.0 portions, 95% CI -0.2 to 0.3) consumed by children. Intake of fruit and vegetables at
18 school and home dropped by approximately 100g and 50g respectively between baseline and
19 follow up in both the intervention and control groups.

20 **Conclusion:** Implementation of the intervention was low, with associated lack of impact on
21 fruit and vegetable consumption in children. Alternatives to the delivery of an intervention by
22 teachers and parents are needed to improve dietary intake of primary aged children.

23

24

25 INTRODUCTION

26 A diet rich in fruit and vegetables may decrease the risk of developing chronic disease such
27 as cardiovascular disease, stroke, obesity and several forms of cancer in adult life.¹⁻² For
28 some cancer sites the risk of developing cancer doubles with adult diets in the lowest quartile
29 of intake of fruit and vegetables compared with the upper quartile of intake.³ Good dietary
30 habits developed in childhood may persist and lead to improved diet and health in
31 adulthood.⁴⁻⁵

32

33 The recommended intake of fruit and vegetables for adults and children in the UK and other
34 Western countries is 400g. This is equivalent to five 80g portions of fruit and vegetables.² In
35 other countries recommendations are higher. In Australia the “Go for 2 & 5” campaign
36 recommends a daily intake of at least two pieces of fruit and five vegetables.⁶ Denmark
37 recommends 600g per day.⁷⁻⁸ Surveys indicate that children living in Western countries are
38 consuming considerably less than these recommendations.⁹⁻¹² A UK survey reported
39 children’s intake to be 2.5 portions of fruit and vegetables per day. In the USA and Australia
40 consumption is 3.6 portions per day.¹⁰⁻¹¹ The School Fruit and Vegetable Scheme (SFVS)
41 was launched in 2004 as part of the UK’s 5-A-Day strategy to improve children’s
42 consumption of fruit and vegetables.¹³ This scheme provides a free piece of fruit or vegetable
43 each school day to children from the age of four, for the first three years of school.¹⁴ The
44 scheme distributes approximately 440 million pieces of fruit and vegetables each year to over
45 two million children in 18,000 schools across England.¹⁵

46

47 Studies evaluating the SFVS suggest it increases children’s fruit and vegetable intake in the
48 short-term, while children receive the free fruit or vegetable, but this falls when children are
49 no longer eligible for the scheme. There appears to be no long term impact of this scheme on
50 fruit and vegetable intake of children.^{9, 16-17}

51

52 A number of school based multi-component intervention trials to improve fruit and vegetable
53 intake in children have been carried out which include elements to improve the school
54 curriculum as well as providing home based projects¹⁸⁻²⁵. The majority of these studies are
55 US based and also include components to improve the school environment. Two trials
56 reported in the literature are based in the UK; one in Dundee²⁴ and one in Leeds²⁵. The
57 former included improvements to the curriculum and communications with parents and
58 successfully improved fruit and vegetable consumption while the latter focused on improving

59 the curriculum and the school environment and reported little impact on fruit and vegetable
60 intake.

61

62 There is a need for a school based programme to maintain the increased intake of fruit
63 following children's participation in the SFVS during the first three years of school. Project
64 Tomato is a flexible multi-component, theory based, intervention designed to do just this.
65 The intervention is designed for children in school years three and four (aged seven to nine
66 years) who no longer receive free fruit and vegetables at school. It contains components
67 which aim to both improve the school curriculum and to engage parents and children at home
68 using a variety of home based projects.

69

70 This is the first cluster randomised controlled trial in the UK to study the maintenance of fruit
71 and vegetable intake post SFVS in a large number of schools across England.

72

73 **METHODS**

74

75 **Sampling method and study design**

76

77 In 2006, a nationally representative sample of 130 primary schools across England formed a cross
78 sectional survey of children's fruit and vegetable intake. Schools were randomly sampled from
79 the National Foundation of Educational Research (NFER) database of all schools. Schools
80 were excluded if they had fewer than 15 pupils per class, did not have pupils in years 2 to 4,
81 were independent or special schools or were schools that had previously participated in SFVS
82 projects. All schools were stratified on the following background criteria to ensure the
83 sample was representative of English schools: Local Education Authority (LEA) type (e.g.
84 rural /metropolitan); school type (e.g. infant, primary); key stage one academic attainment
85 (percentage of pupils achieving level two on Standard Assessment Tasks (SATs)); percentage
86 of pupils eligible for free school meals (FSME); percentage of pupils defined as having
87 special educational needs (SEN) and percentage of pupils with English as an additional
88 language (EAL). From the sample of 130 schools assessed at baseline, a sub-set of 54 schools
89 were selected using a random allocation sequence generated by a computerized random number
90 generator and recruited to the Project Tomato cluster randomised controlled trial.

91

92 Eligible schools were sent a letter, additional information and a consent form inviting them to
93 take part in the study. Parents received a letter with information about the study two weeks
94 prior to the data collection date. The letter contained a self-completed reply slip providing the
95 parents or guardians the opportunity for their child not to take part in the study (opt-out
96 consent). Parents who did not wish their child to participate completed the reply slip, which
97 was then returned to the school. Ethics approval was obtained through the University of
98 Leeds Central Research Ethics Committee.

99 Fifty-four schools with 1031 children age 7 to 8 years (Year 2) were randomised by school to
100 either the intervention or control group. Block randomisation within strata was used (blocks
101 of 2) stratifying on ethnicity (percentage of pupils non-white British) and deprivation
102 (percentage of pupils eligible for free school meals) both split at the median. Baseline data
103 was collected between February and March 2007, and follow up data was collected between
104 September and October 2008 when these children were in Year 4.

105

106 **The intervention**

107

108 The intervention, Project Tomato, was designed using a framework of health maintenance
109 behaviour which included the following components: familiarising children with fruit and
110 vegetables through activities such as gardening and cooking; repeated exposure to eating fruit
111 and vegetables through tasting sessions and school meals; engaging children in activities
112 relating to these foods through science experiments and growing; encouraging adult and peer
113 modelling of desirable behaviours such as eating fruit and ensuring the environment of the
114 school promotes the eating of fruit and vegetables.^{15, 26-27} This approach was summarised by
115 the acronym FRAME (Familiarisation, Repetition, Activities, Modelling and Environment).

116 The duration of the intervention was 10 months from July 2007 to April 2008. All schools
117 received core intervention materials and activities consisting of a manual, 12 lesson plans,
118 two newsletters, advice for parents, 3 home activity bags, and instructions for setting up a
119 committee. In addition schools received customised modules of materials and activities
120 depending on their baseline level of activity in a number of key areas relating to promoting
121 fruit and vegetable consumption such as a cooking club or gardening club. For example if a
122 school did not have a gardening club, the head teacher was asked if they would like
123 information to help them set up a club for year 2 children in their school. The intervention
124 participants: teachers; parents and children were asked to complete questionnaires on the
125 intervention materials to identify aspects relating to implementation and appreciation of the

126 intervention. Baseline levels of school activity to promote fruit and vegetable consumption
127 was assessed by a questionnaire completed by a year three teacher.

128
129 The control schools received a ‘5-A-DAY’ booklet and healthy eating leaflets to distribute to
130 parents of Year two pupils.¹³

131 132 **Dietary Assessment**

133
134 Dietary intake was assessed using a validated 24 hour dietary assessment tool, the Child and
135 Diet Evaluation Tool (CADET) diary.²⁸ The CADET diary comprises of a list of 105
136 separate food and drink types, divided into 15 categories. The categories of foods are cereal
137 (5 items); sandwich/bread/cake/biscuit (10 items); spreads/sauces/soup (7 items); cheese/egg
138 (6 items); chicken/turkey (3 items); meat other (9 items); fish (5 items); vegetarian (3 items);
139 pizza/pasta/rice (8 items); desserts/puddings (3 items); sweets/crisps (4 items); vegetables and
140 beans (18 items); potato (2 items); fruit (13 items); drinks (9 items). Each item in the diary
141 has seven tick boxes related to different meal time options “morning break, lunch time,
142 afternoon break, before tea (after school), evening meal/tea, after tea/during night, and
143 breakfast/before school.” The diary is completed by a parent or guardian at home and by
144 trained field workers at school, they are required to tick each item consumed by the child,
145 under the appropriate meal time heading, within the 24-hour period. For this analysis the
146 National Foundation for Education Research (NFER) field workers completed the CADET
147 diary during school hours. Parents were asked to record what their child ate in the evening
148 and before school the next day.

149 **Statistical Analysis**

150
151 Twenty schools were required with 500 children per group to have 90% power to detect a 0.5
152 portion difference in fruit or vegetable intake. Further details on the sampling methodology
153 are reported elsewhere.¹⁵

154 Children who had no ticks in their diary for the home time periods were excluded from the
155 analysis. Children were also excluded if they had more than 40 ticks on their CADET diary
156 as this indicated that they were using the CADET diary incorrectly.

157 To assess the impact of the intervention on changes in children’s fruit and vegetable intake an
158 intention to treat analysis was undertaken. Multilevel regression modelling was conducted

159 using MLwiN.²⁹ This model takes into consideration the hierarchical structure of the data
160 caused by cluster randomisation; school level and child level.¹⁵ This type of analysis is
161 appropriate as children within the same school are likely to be more similar to each other than
162 to others in a different school in terms of fruit and vegetable intake. A random intercepts
163 model was used with fruit total weight of fruit and vegetable, weight of fruit only and weight
164 of vegetables only used as the main outcomes. Weights were also converted to portions. To
165 determine the intervention effects baseline levels, age were included in the model as
166 covariates (fixed effects), together with intervention status and gender as dummy variables
167 (fixed effects). Results for school and home separately are reported as medians with inter-
168 quartile range due to the data not being normally distributed. Vitamin C and Vitamin A were
169 log transformed as they are not normally distributed based on previous research¹⁰.

170 171 RESULTS

172
173 54 schools were randomised into the trial. Fifty schools (26 control and 24 intervention)
174 completed the trial. Trial materials were allocated to 1080 children and 1031 received the
175 materials: 14 children were opted out by their parents; 31 were absent on the baseline
176 collection day; 4 children had left the school before data collection. CADET diaries were
177 returned from 781 (76% of those receiving materials) children who completed it at both
178 baseline and follow up. Data from 658 children (64% of those receiving materials: 347
179 control and 311 intervention) was used in the analysis. Poor completion of CADET resulted
180 in 123 children being excluded from the analysis. Reasons for the loss of children randomised
181 to the trial include: absence on the day of the survey; a move from the school between
182 baseline and follow up; withdrawal of schools entering special measures (See Figures 1 and
183 2).

184
185 (INSERT FIGURES 1 AND 2 HERE)

186
187 Table 1 shows baseline intake of fruit, vegetables and key nutrients in the control and the
188 intervention groups. Intake of food and key nutrients and energy are closely matched at
189 baseline across intervention and control groups. The combined fruit and vegetable intake is
190 similar in both groups (Control: 305g 95% CI 286 to 324 and Intervention: 309g 95%CI 287
191 to 332). Comparison of the characteristics of children in the control and intervention group at
192 baseline is shown in Table 1. There are also negligible differences in age, sex, height weight,

193 and deprivation however there are slightly more children from different ethnic groups in the
194 control compared to the intervention group (21.7, 95% CI 14.2 to 33.2 and 14.4, 95% CI 8.3
195 to 23.1). Slightly more children were eligible for free school meals in the control group
196 compared to the intervention group.

197 (INSERT TABLE 1 HERE)

198

199 The Project Tomato was evaluated by comparing fruit and vegetable intake in children in the
200 intervention group compared with the control group at follow up. Both groups were similar
201 in terms of fruit and vegetable intake (mean difference 2g 95% CI -23 to 26). This difference
202 was not statistically significant. There was no effect of the intervention as delivered on
203 portions of fruit (0.0, 95% CI -0.3 to 0.3) or vegetables consumed (0.0 95% CI -0.2 to 0.3).
204 Fruit intake was slightly higher than vegetable intake in both groups. There were no
205 differences between the two groups of children in terms of intake of key nutrients (Table 2).
206 Intake of fruit and vegetables combined fell by approximately 50g between baseline and
207 follow up in both groups.

208

209 (INSERT TABLE 2 HERE)

210

211 Table 3 shows median intakes of fruit and vegetables at home and school, at baseline and
212 follow up. Home intake of fruit and vegetables combined fell by about 50g in both groups.
213 The drop in fruit and vegetable intake at school is even more pronounced between baseline
214 and follow up. Fruit and vegetable intake fell by approximately 100g in both groups. (Table
215 3). Half of this drop in school fruit and vegetable intake was due to children not receiving
216 free school fruit or vegetables and the remaining drop was due to reduction at lunch time and
217 break time. At baseline the mean weight of fruit and vegetables from the FSFV was 56g,
218 while at follow up it was 0g.

219

220 (INSERT TABLE 3 HERE)

221

222 All 24 schools which completed the intervention also completed the process measures
223 questionnaires and 261 of the 311 children who completed the trial also completed the
224 process measures evaluation. Implementation of the intervention was low overall, with 21%
225 of school items and 56% of home items being used. 4 schools implemented the additional

226 materials to set up cooking and gardening clubs. Further details of the process evaluation are
227 presented elsewhere³⁰.

228

229 **DISCUSSION**

230

231 This is the first large, multi-component cluster randomised controlled trial designed to
232 improve fruit and vegetable intake involving primary schools across England. The
233 intervention was designed to prevent the fall in consumption of fruit and vegetables in year
234 three children, aged 8 to 9 years, when they are no longer eligible for free school fruit.

235 Despite an intensive programme of activities, the intervention, as delivered, failed to have an
236 impact on children's fruit and vegetable intake post SFVS. The decreased intake of fruit and
237 vegetables in these children was particularly notable during the school day where it dropped
238 by half. At baseline, children were receiving free school fruit and were eating more fruit than
239 vegetables at school. When eligibility for free fruit ends, it coincides with a drop in fruit and
240 vegetable intake. This is particularly marked at school and was not offset by the intervention.
241 The availability of fruit during the school day, through schemes such as the SFVS, may be a
242 key determinant of fruit intake of children. It appears difficult to make up for this loss of fruit
243 provided either at school or home.

244 One reason for the lack of an intervention effect may be due to incomplete implementation.
245 Process measure questionnaires were taken throughout the intervention from teachers, parents
246 and children. The questionnaires measured implementation and appreciation of the
247 intervention materials. Implementation of the intervention was low with teachers
248 implementing only 21% of intervention materials even though they reported that they liked
249 the materials and activities that had been provided. Children implemented 56% of activities
250 provided in the take home activity kits. Parents implemented 35% of the activities related to
251 the intervention. Both child and parent appreciation of the intervention items was high³⁰. The
252 intervention was designed to be pragmatic, not relying on external agencies to deliver the
253 activities, however, it appears that despite commitment from the schools and appreciation of
254 the materials there was limited implementation.

255 The intervention was based on psychological constructs shown to promote behaviour change.
256 Research in the field of health psychology suggests the process of initiating health behaviour,
257 such as eating more fruit, may be different from maintaining the behaviour. Each type of
258 behaviour may need a separate and distinctive intervention strategy to support it.³¹ The

259 intervention was designed to address this hypothesis by mapping key psychological
260 constructs involved with maintenance behaviour to intervention activities.

261 The intervention *Project Tomato*, involved components aimed at teachers, parents and
262 children over a period of 10 months. It is important to note this intervention was designed to
263 be delivered by school staff and no additional personnel were deployed. *Project Tomato* was
264 also designed to be sustainable and to enable the schools to continue its delivery beyond the
265 evaluation stage. Multi-component interventions in this age group have been reported from
266 the US and shown improvements in fruit and vegetable intake of a third of a portion or more.
267 A recent pooled analysis of 7 studies in the USA showed an increase of 0.45 portions of fruit
268 and vegetables consumed post intervention³². However, not all of these studies were
269 randomised controlled trials. The studies included in the analysis were more intensive, of
270 longer duration and included additional personnel to deliver the interventions.^{23, 33-34} An
271 Icelandic study showed a 46% increase in fruit and vegetable intake in primary school
272 children following a school based intervention. That study was, however, characterised by
273 low intake of fruit and vegetables at baseline together with baseline imbalance between the
274 intervention and control groups.³⁵ One recent intervention in the UK had some success in
275 increasing fruit and vegetables in packed lunches at schools.³⁶

276 The age related decline in fruit and vegetables observed in this study is a cause for concern,
277 particularly as the intervention was designed to attenuate this. The impact of School Meal
278 Standards and the restriction on advertising of food high in fat, salt and sugar to children
279 which were introduced after this intervention may help to increase children's intake of fruit
280 and vegetables.³⁷⁻³⁸ The introduction of food-based standards for school meals in 2006 has
281 moderately improved the nutrient content of school meals, slightly widening the nutritional
282 gap between children consuming school meals compared to packed lunches.³⁹ However,
283 packed lunches fall behind with only 19% of packed lunches containing vegetables and 54%
284 containing fruit for children in this age group.⁴⁰

285 Powerful socio-cultural influences drive children's eating behaviour towards a more
286 processed diet, low in fruit and vegetables with adolescents consuming less than younger
287 children, particularly boys¹⁰. This may be hard to offset without the continued availability of
288 free fruit during the school day. The combined fruit and vegetable intake of about 300g in
289 this study appears relatively high in comparison to other UK data. Findings of the National
290 Diet and Nutrition Survey found the median intake of fruit for children aged 4 to 10 years
291 was 88g and intake of cooked and raw vegetables including salad was 74g⁹⁻¹⁰ a total of 162g

292 of fruit and vegetables combined. The fall in fruit intake at school in year 3, shown in this
293 study may provide some evidence to support the continuation of the SFVS throughout
294 primary school. However more work is needed to confirm this. Some other studies have
295 reported similar small or no improvements in fruit and vegetable intake following an
296 intervention⁴¹⁻⁴² although others have been successful.⁴³⁻⁴⁴

297

298 Strengths of this study include the strong study design, the random sampling to include all
299 primary schools in England and the multi-level analysis using MLwiN which took into
300 account the clustering of children within schools. A validated dietary assessment tool was
301 used.

302 There were some limitations to this study. Four schools (approximately 120 pupils) were lost
303 following randomisation. Reasons for school withdrawal include the school entering special
304 measures or undergoing an inspection. This could have led to biased results if the schools that
305 withdrew were different from schools that remained in the trial. In addition, the children in
306 the intervention and control groups could have been unmatched in terms of social
307 deprivation. Although attempts were made to match schools, measures of deprivation at the
308 individual level were not included in the model. Parents were asked for their postcode to
309 determine IMD score for each child but a large number of families did not provide this data.
310 Therefore, including IMD in the analysis would have greatly reduced the number of children
311 included in the final model leading to bias if there were inherent differences between families
312 who provided this information and those who did not.

313 The dietary assessment tool could also be a limitation. The portion size of some of the
314 different fruits and vegetables may have been over-estimated using this method. Accurately
315 assessing diet remains a difficult problem and the issues with 24 hour-recalls such as CADET
316 is that participants may over-estimate intake compared with weighed diaries where
317 participants are more likely to under-estimate consumption. Although efforts were made to
318 exclude children who used the assessment tool as a food frequency questionnaire by ticking
319 all the fruits and vegetables that they ever ate, it is possible that some pupils were included
320 contributing to an over estimation of fruit and vegetables consumption. The estimated daily
321 amounts in this study are higher than for the NDNS where weighed diaries were used which
322 may be due to overestimation of this tool or underestimation of NDNS data. Moreover, the
323 diary was only completed for one day and fruit and vegetable consumption could vary
324 considerably from day to day for each child. These issues are unlikely to have had an impact

325 on the results of the trial as fruit and vegetable consumption would have been over-estimated
326 in both groups to the same degree.

327 This large randomised controlled trial provides a unique opportunity to explore whether a
328 multi-component school based intervention could increase children's consumption of fruit
329 and vegetables. The results showed the intervention as delivered had no positive effect on
330 children's intake of these foods. Rather there was a marked decline following the end of the
331 SFVS, particularly during the school day. However, the implementation of the intervention
332 by teachers, pupils and parents was low. This raises important issues regarding how long
333 national interventions such as the SFVS should be maintained in schools; what the effects of
334 withdrawing an interventions may be and the challenges facing the implementation of dietary
335 interventions during the busy school day. These findings suggest further work is required to
336 improve the delivery and implementation of school based interventions to improve fruit and
337 vegetables and to prevent the age related decline in fruit and vegetable intake.

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What this paper adds

What is already known on this subject?

Children's intake of fruit and vegetables is low and this may have serious adverse effects on health. As children progress through school there is an age related decline in fruit and vegetable intake. This is partly reduced by the School Fruit and Vegetable Scheme (SFVS).

What does this study add?

Following the end of the SFVS in year 3 there is a marked decline in intake of fruit and vegetables. The decline was particularly **evident** during the school day. **A school based, multi-component** intervention to prevent this decline had no impact on children's intake of these foods. **However, implementation of the intervention was low.** Implementation rates of school based dietary interventions need to be improved. The SFVS should be

364 **References**

- 365 [1] World Health Organization. Global strategy on diet, physical activity and health.
366 World Health Assembly, 2004.
- 367 [2] World Cancer Research Fund & the American Institute for Cancer Research. Food,
368 Nutrition and Physical Activity and the Prevention of Cancer: a Global Perspective.
369 Washington DC: World Cancer Research Fund & the American Institute for Cancer
370 Researched, 2007.
- 371 [3] Block G, Patterson B, Sumar A. Fruit, vegetables, and cancer prevention: a review of
372 the epidemiological evidence. *Nutrition and Cancer*. 1992 **18**: 1-29.
- 373 [4] Maynard M, Gunnell D, Emmett P, Frankel S, Smith G. Fruit and vegetables and
374 antioxidants in childhood and risk of adult cancer: the Boyd Orr Cohort. *Journal of*
375 *Epidemiology and Community Health*. 2003 **57**: 218-25.
- 376 [5] Fisher J, Mitchell D, Smiciklas-Wright H, Birch L. Parental influences on young girls'
377 fruit and vegetable, micronutrient, and fat intakes. *Journal of the American Dietetic*
378 *Association*. 2002 **102**: 58-64.
- 379 [6] Horticulture Australia. Go for 2 & 5. ed.
- 380 [7] Eriksen K, Haraldsdottir J, Pederson R, Flyger HV. Effect of a fruit and vegetable
381 subscription in Danish schools. *Public Health Nutrition*. 2003 **6**: 57-63.
- 382 [8] Appleton KM, Rogers PJ, Blundell JE. Effects of a sweet and a nonsweet lunch on
383 short-term appetite: differences in female high and low consumers of sweet/low-energy
384 beverages. *JHumNutrDiet*. 2004 **17**: 425-34.

- 385 [9] Ransley J, Greenwood D, Cade J, Blenkinsop S, Schagen I, Teeman D, et al. Does the
386 school fruit and vegetable scheme improve children's diet? A non-randomised controlled
387 trial. *J Epidemiol Community Health*. 2007 **61**: 699-703.
- 388 [10] Gregory J, Lowe S, Bates C, Prentice A, Jackson L, Smithers G. *National diet and*
389 *nutrition survey: young people aged 4 to 18 years*. London: The Stationary Office, 2001.
- 390 [11] Magarey A, Daniels LA, Smith A. Fruit and vegetable intakes of Australians aged 2-
391 18 years: an evaluation of the 1995 National Nutrition Survey data. *Aust NZ J Pub Health*.
392 2001 **25** 155-61.
- 393 [12] Krebs-Smith SM, Cook A, Subar AF, Cleveland L, Friday J, LL K. Fruit and
394 vegetable intakes of children and adolescents in the United States. *Arch Pediatr Adolesc Med*.
395 1996 **150**: 81-6.
- 396 [13] Department of Health. *5 A Day introduction*. London: Department of Health, 2003.
- 397 [14] Department of Health. *Information for schools: School Fruit and Vegetable Scheme*.
398 London: The Department for Health, 2002.
- 399 [15] Kitchen MS, Ransley JK, Greenwood DC, Clarke GP, Conner MT, Jupp JE. Study
400 protocol: a cluster randomised controlled trial of a school based fruit and vegetable
401 intervention - Project Tomato. *BMC Health Services Research*. 2009 **9**.
- 402 [16] Wells L, & Nelson M, The National School Fruit Scheme produces short-term but not
403 longer-term increases in fruit consumption in primary school children. *Br J Nutr*. 2005 **93**:
404 537-42.

- 405 [17] Fogarty AW, Antoniak M, Venn AJ, Davies L, Goodwin A, Salfield N, et al. Does
406 participation in a population-based dietary intervention scheme have a lasting impact on fruit
407 intake in young children? *Int J Epidemiol.* 2007 **36**: 1080-5.
- 408 [18] Baranowski T, Davis M, Resnicow K, Baranowski J, Doyle C, Lin LS, et al. Gimme 5
409 fruit, juice, and vegetables for fun and health: outcome evaluation. *Health Educ Behav.* 2000
410 **27**: 96-111.
- 411 [19] Gortmaker SL, Cheung LW, Peterson KE, Chomitz G, Cradle JH, Dart H, et al.
412 Impact of a school-based interdisciplinary intervention on diet and physical activity among
413 urban primary school children: eat well and keep moving. *ArchPediatrAdolescMed.* 1999
414 **153**: 975-83.
- 415 [20] Gortmaker SL, Peterson K, Wiecha J, Sobol AM, Dixit S, Fox MK, et al. Reducing
416 obesity via a school-based interdisciplinary intervention among youth: Planet Health.
417 *ArchPediatrAdolescMed.* 1999 **153**: 409-18.
- 418 [21] Bere E, Veierod MB, Bjelland M, Klepp KI. Outcome and process evaluation of a
419 Norwegian school-randomized fruit and vegetable intervention: Fruits and Vegetables Make
420 the Marks (FVMM). *Health Educ Res.* 2006 **21**: 258-67.
- 421 [22] Taylor RW, McAuley KA, Barbezat W, Strong A, Williams SM, Mann JI. APPLE
422 Project: 2-y findings of a community-based obesity prevention program in primary school
423 age children. *Am J Clin Nutr.* 2007 **86**: 735-42.
- 424 [23] Reynolds KD, Franklin FA, Binkley D, Raczynski JM, Harrington KF, Kirk KA, et
425 al. Increasing the fruit and vegetable consumption of fourth-graders: results from the high 5
426 project. *Prev Med.* 2000 **30**: 309-19.

- 427 [24] Anderson A, Porteous L, Foster E, Higgins C, Stead M, Hetherington M, et al. The
428 impact of a school-based nutrition education intervention on dietary intake and cognitive and
429 attitudinal variables relating to fruits and vegetables. *Public Health Nutrition*. 2005 **8**: 650-6.
- 430 [25] Sahota P, Rudolf MC, Dixey R, Hill AJ, Barth JH, Cade J. Randomised controlled
431 trial of primary school based intervention to reduce risk factors for obesity. *BMJ*. 2001 **323**:
432 1029-32.
- 433 [26] Knai C, Pomerleau J, Lock K, McKee M, Pomerleau J, Lock K, et al. Getting children
434 to eat more fruit and vegetables: a systematic review. *Prev Med*. 2006 **42**: 85-95.
- 435 [27] Conner M, Sparks P. The theory of planned behaviour and health behaviour. In:
436 Conner M, Norman P, eds. *Predicting Health behaviour*. Buckingham: Open University
437 Pressed, 2005:170-222.
- 438 [28] Cade JE, Frear L, Greenwood DC, Cade JE, Frear L, Greenwood DC. Assessment of
439 diet in young children with an emphasis on fruit and vegetable intake: using CADET (Child
440 and Diet Evaluation Tool). *Public Health Nutrition*. 2006 **9**: 501-8.
- 441 [29] Rasbash J, Steele F, Browne WJ, Prosser B. *A User's guide to MLwiN, Version 2.0*.
442 London: Institute of Education, 2004.
- 443 [30] Christian MS, Evans CE, Ransley JK, Greenwood DC, Thomas JD, Cade JE. Process
444 evaluation of a cluster randomised controlled trial of a school-based fruit and vegetable
445 intervention: Project Tomato. *Public Health Nutr*. 2011: 1-7.
- 446 [31] Armitage C, Conner M. Social cognition models and health behaviour: A structured
447 review. *Psychology and Health*. 2000 **15**: 173-89.

- 448 [32] Howerton MW, Bell BS, Dodd KW, Berrigan D, Stolzenberg-Solomon R, Nebeling
449 L. School-based nutrition programs produced a moderate increase in fruit and vegetable
450 consumption: meta and pooling analyses from 7 studies. *J Nutr Educ Behav.* 2007 **39**: 186-
451 96.
- 452 [33] Perry CL, Bishop DB, Taylor G, Murray DM, Mays RW, Dudovitz BS. Changing
453 fruit and vegetable consumption among children: the 5-a-Day Power Plus program in St.
454 Paul, Minnesota. *Am J Public Health* 1998 **88**: 603-9.
- 455 [34] Cullen KW, Watson K, Baranowski T, Baranowski JH, Zakeri I, Cullen KW, et al.
456 Squire's Quest: intervention changes occurred at lunch and snack meals. *Appetite.* 2005 **45**:
457 148-51.
- 458 [35] Kristjansdottir A, Johannsson E, Thorsdottir I. Effects of a school based intervention
459 on adherence of 7-9 year olds to food based dietary guidelines and intake of nutrients. *Public*
460 *Health Nutrition.* 2010 **13**: 1151-61.
- 461 [36] Evans CE, Greenwood DC, Thomas JD, Cleghorn CL, Kitchen MS, Cade JE.
462 SMART lunch box intervention to improve the food and nutrient content of children's packed
463 lunches: UK wide cluster randomised controlled trial. *J Epidemiol Community Health.* 2010
464 **64**: 970-6.
- 465 [37] School Food Trust. School Food Standards. ed.
- 466 [38] Office of Communications. Update on impact of restrictions on food and drink
467 advertising to children. ed.

468 [39] Evans CE, Cleghorn CL, Greenwood DC, Cade JE. A comparison of British school
469 meals and packed lunches from 1990 to 2007: meta-analysis by lunch type. *Br J Nutr*. 2010
470 **104**: 474-87.

471 [40] Evans CE, Greenwood DC, Thomas JD, Cade JE. A cross-sectional survey of
472 children's packed lunches in the UK: food- and nutrient-based results. *J Epidemiol*
473 *Community Health*. 2010 **64**: 977-83.

474 [41] Bere E, Veierod MB, Klepp K-I. The Norwegian School Fruit Programme: evaluating
475 paid vs. no-cost subscriptions. *Prev Med*. 2005 **41**: 463-70.

476 [42] Te Velde SJ, Brug J, Wind M, Hildonen C, Bjelland M, Perez-Rodrigo C, et al.
477 Effects of a comprehensive fruit and vegetable promoting school based intervention in three
478 European countries: the Pro Children Study. *British Journal of Nutrition*. 2008 **99**: 893-903.

479 [43] Ciliska D, Miles E, O'Brien MA, Turl C, Tomasik HH, Donovan U. Effectiveness of
480 community-based interventions to increase fruit and vegetable consumption. *Journal of*
481 *Nutrition Education and Behavior*. 2000 **32**: 341-52.

482 [44] Auld G, C. O, Endinger E, Ambudgem M. Outcomes from a school-based nutrition
483 education program using resource teachers and cross-disciplinary models. . *J Nutr Educ*.
484 1998 **30**: 268-80.

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Table 1: Balance at baseline of foods, nutrients, pupil and school characteristics, for the 658 children with complete data at baseline and follow up

Food	Control (n=347)		Intervention (n=311)	
	mean or median	95% CI or IR	mean or median	95% CI or **IR
Fruit (g)	195	177 to 214	202	185 to 218
Vegetables (g)	110	95 to 124	108	94 to 122
Fruit & vegetables (g)	305	286 to 324	309	287 to 332
Fruit & vegetables (g)**	300	195 to 398	288	198 to 387
Energy (KJ)	6729	6496 to 6962	6634	6385 to 6883
Energy (kcal)	1598	1543 to 1653	1575	1516 to 1634
Total fat (g)	57.3	54.7 to 59.9	57.1	54.3 to 59.8
Saturated fat (g)	20.3	19.3 to 21.3	20.3	19.2 to 21.3
Total CHO (g)	230.4	222.5 to 238.3	225.6	217.1 to 234.1
Total sugar (g)	124.3	118.9 to 129.7	119.4	113.6 to 125.2
NSP (g)	11.7	11.2 to 12.2	12.3	11.7 to 12.8
Sodium (mg)	2051	1961 to 2141	2098	2002 to 2194
Folate (µg)	191.6	183 to 200.2	191.8	182.6 to 201
Iron (mg)	9.2	8.9 to 9.6	9.3	8.9 to 9.6
Zinc (mg)	6.2	6 to 6.4	6.1	5.8 to 6.3
*carotene (µg)	1552	1252 to 1923	1464	1165 to 1840
*Vitamin C (mg)	90.5	83 to 98.3	90.2	82.2 to 98.5
pupil				
Age (years)	7.0	n/a	7.0	n/a
Sex (% male)	48.1	42.6 to 52.5	51.4	45 to 57.4
Ethnicity (% non-white)	21.7	14.2 to 33.2	14.4	8.3 to 23.1
Height (cm)	122.9	122.3 to 123.5	122.7	122.1 to 123.3
Weight (kg)	25.1	24.6 to 25.5	24.7	24.2 to 25.1
BMI (kg/m ²)	16.5	16.3 to 16.7	16.3	16.1 to 16.5
Standardised BMI	0.4	0.3 to 0.5	0.3	0.2 to 0.4
IMD† score	**17.6	**8.7 to 30.3	**15.4	**8.4 to 25.9
school				
% FSME†† (median)	**12.0	**4 to 27	**9.0	**3 to 15
% White British	**92.1	**70.8 to 96.6	**93.5	**86.8 to 97.1

*Natural log

**Median and interquartile range (IR) for single level model

† IMD = index of multiple deprivation

†† FSME = free school meal eligibility

Table 2: Follow up levels of foods and nutrients of the 658 children with trial data analysed; and intervention effects adjusted for age, gender and baseline results

Food	Control mean	Control 95% CI	Intervention mean	Intervention 95% CI	Intervention effect mean	95% CI	P value
Fruit (weight in g)	134	118 to 149	133	119 to 148	0	-20 to 20	1.0
Fruit (portions)	1.7	1.5 to 1.9	1.7	1.5 to 1.9	0	-0.3 to 0.3	1.0
Vegetables (weight in g)	119	107 to 132	122	109 to 135	2	-15 to 19	0.8
Vegetables (portions)	1.5	1.3 to 1.7	1.5	1.3 to 1.7	0	-0.2 to 0.3	0.8
Fruit & vegetables (weight in g)	253	234 to 273	255	237 to 273	2	-23 to 26	0.9
Fruit & vegetables (portions)	3.2	2.9 to 3.4	3.2	2.9 to 3.4	0	-0.3 to 0.3	0.9
Fruit & vegetables (g)**	228	135 to 335	238	144 to 343	10	n/a	n/a
Energy (KJ)	7103	6827 to 7379	7239	6958 to 7520	136.4	-194 to 467	0.42
Energy (kcal)	1687	1621 to 1753	1719	1652 to 1786	32.4	-46.2 to 110.9	0.42
Total fat (g)	63.3	60.1 to 66.4	64.45	61.2 to 67.7	1.2	-2.8 to 5.1	0.56
Saturated fat (g)	22.4	21.2 to 23.6	22.4	21.1 to 23.6	0	-1.5 to 1.5	1.00
Total CHO (g)	235.5	226.8 to 244.2	237.4	228.6 to 246.2	1.9	-8.2 to 12	0.72
Total sugar (g)	110.4	104.8 to 116	111.5	105.8 to 117.2	1.1	-5.5 to 7.6	0.75
NSP (g)	12.3	11.6 to 13	12.4	11.7 to 13.1	0.1	-0.7 to 0.9	0.79
Sodium (mg)	2334	2207.1 to 2460.9	2460	2328.6 to 2591.4	126	-35.6 to 287.4	0.13
Folate (µg)	200.5	190.5 to 210.5	205.3	195 to 215.6	4.8	-7.3 to 17	0.44
Iron (mg)	10.3	9.7 to 10.9	10.6	9.9 to 11.2	0.3	-0.4 to 1	0.44
Zinc (mg)	6.9	6.4 to 7.3	7.3	6.8 to 7.8	0.4	-0.2 to 1	0.16
*carotene (µg)	1397	1169 to 1669	1474	1227 to 1772	77.9	-221 to 453	0.64
*Vitamin C (mg)	69.4	63.5 to 75.9	67.7	61.8 to 74.2	-1.7	-8.7 to 6	0.65

*Natural log

**Median and IR (single level model)

Table 3: Median intakes of fruit and vegetables at home and school at baseline and follow up

	Control				Intervention				
	Food	Baseline median	IR	Follow up median	IR	Baseline median	IR	Follow up median	IR
HOME	Fruit (g)	63	0 to 97	0	0 to 95	66	0 to 113	11	0 to 95
	Vegetables (g)	104	0 to 222	57	0 to 125	98	0 to 224	69	0 to 146
	Fruit & vegetables (g)	184	80 to 301	124	46 to 203	190	85 to 286	142	57 to 219
	Control				Intervention				
	Food	Baseline median	IR	Follow up median	IR	Baseline median	IR	Follow up median	IR
SCHOOL	Fruit (g)	94	67 to 182	61	0 to 95	126	71 to 174	61	0 to 96
	Vegetables (g)	40	0 to 158	0	0 to 64	46	0 to 152	0	0 to 57
	Fruit & vegetables (g)	193	101 to 291	91	40 to 155	189	126 to 288	90	21 to 160

The medians in table 1 and 2 I think are fine, but in table 3 where the data is split between home and school the medians are now skewing the data. The median difference between table 1 and 2 for fruit and veg is approximately 50g, the combined totals from table 3 is approximately 150g. This is a big difference for the same data and is confusing to which is the more likely difference. (I would say difference between table 1 and 2 is more reliable). The text uses the difference based on table 3, if this is considered the most appropriate information to use this should be explained in the discussion. Otherwise table 3 should be removed.

Figure Legends:

Figure 1 Flow diagram of schools entering and completing the trial

Figure 2 Flow diagram of pupils entering and completing the trial