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1 **Stand Out in Class: Restructuring the classroom environment to reduce sitting time**
2 **– findings from a pilot cluster randomised controlled trial**

3
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27 **Abstract**

28 **Background:** Excessive sedentary behaviour (sitting) is a risk factor for poor health in
29 children and adults. Incorporating sit-stand desks in the classroom environment has been
30 highlighted as a potential strategy to reduce children's sitting time. The primary aim of this
31 study was to examine the feasibility of conducting a cluster randomised controlled trial
32 (RCT) of a sit-stand desk intervention within primary school classrooms.

33 **Methods:** We conducted a two-armed pilot cluster RCT involving 8 primary schools in
34 Bradford, United Kingdom. Schools were randomised on a 1:1 basis to the intervention or
35 usual practice control arm. All children (aged 9-10 years) in participating classes were
36 eligible to take part. Six sit-stand desks replaced three standard desks (sitting 6 children)
37 in the intervention classrooms for 4.5-months. Teachers were encouraged to use a rotation
38 system to ensure all pupils were exposed to the sit-stand desks for >1 hour/day on
39 average. Trial feasibility outcomes (assessed using quantitative and qualitative measures)
40 included school and participant recruitment and attrition, intervention and outcome
41 measure completion rates, acceptability, and preliminary effectiveness of the intervention
42 for reducing sitting time. A weighted linear regression model compared changes in
43 weekday sitting time (assessed using the activPAL accelerometer) between trial arms.

44 **Results:** School and child recruitment rates were 33% (n=8) and 75% (n=176). At follow-
45 up, retention rates were 100% for schools and 97% for children. Outcome measure
46 completion rates ranged from 63–97%. A preliminary estimate of intervention effectiveness
47 revealed a mean difference in change in sitting of -30.6 minutes/day (95% CI: -56.42 to -
48 4.84) in favour of the intervention group, after adjusting for baseline sitting and wear time.
49 Qualitative measures revealed the intervention and evaluation procedures were
50 acceptable to teachers and children, except for some problems with activPAL attachment.

51 **Conclusion:** This study provides evidence of the acceptability and feasibility of a sit-stand
52 desk intervention and evaluation methods. Preliminary evidence suggests the intervention

53 showed potential in reducing children's weekday sitting but some adaptations to the desk
54 rotation system are needed to maximize exposure. Lessons learnt from this trial will inform
55 the planning of a definitive trial.

56 **Trial registration:** ISRCTN12915848 (registered: 09/11/16)

57

58 **Keywords**

59 Standing desks; sit-stand desks; primary/elementary school; sedentary behaviour;

60 Bradford; South Asian; children; health inequalities

61 **Background**

62 Advances in technology and changes to our environments have resulted in sedentary
63 behaviour becoming ubiquitous within all settings of daily life. Sedentary behaviour is
64 distinct from physical (in)activity and is defined as ‘any waking behaviour characterised by
65 an energy expenditure ≤ 1.5 metabolic equivalents (METs) while in a sitting, reclining or
66 lying posture’ [1]. In the UK, sitting is the most prevalent behaviour exhibited during waking
67 hours in children, typically accounting for over 65% (~7.5 hours/day) of waking time [2],
68 with some children reportedly sitting for over 10 hours/day [3]. Sedentary time is
69 associated with an increased risk of a number of chronic conditions in adults, including
70 cardiovascular disease, type 2 diabetes and all-cause mortality [4-7]. Whilst evidence of
71 the associations of sedentary time with increased risk of adiposity/weight gain and
72 clustered cardiometabolic risk in children is largely restricted to screen time [8], sedentary
73 behaviours have been shown to increase across key transitions in children’s lives (e.g.
74 from primary to secondary school) [9] and track into both adolescence [10] and adulthood
75 [11]. Reducing children’s sitting time may therefore be important for the primary prevention
76 of chronic diseases in adulthood [12].

77

78 The emergence of an increased cardiometabolic health risk profile in some population
79 groups is evident during the first decade of life [13]. For example, British South Asian
80 children have demonstrated higher glycated haemoglobin, fasting insulin and triglyceride
81 and lower high-density lipoprotein-cholesterol levels compared to white British children as
82 well as higher levels of fat mass percentage [14, 15]. Higher levels of sedentary behaviour
83 (ranging between an additional 28 to 39 minutes/day) have also been observed in South
84 Asian school-aged children (aged 6 – 11 years) in comparison to White British children
85 [16, 17]. Given the links between sedentary behaviour and cardiometabolic risk [8], early
86 interventions in such at risk groups may help reduce health inequalities later in life.

87

88 The environments and social norms that children are exposed to have dominant influences
89 on their activity behaviour [18]. Given children spend half of their waking hours at school, it
90 is plausible that the school environment may be a critical influence on their health
91 behaviour patterns [19-21] and be an appropriate setting for interventions [22], particularly
92 in relatively deprived locations with higher levels of health inequalities. Indeed, there has
93 been a growing interest in the use of sit-stand desks (desks which provide children with
94 the opportunity to alternate their posture between sitting and standing) within the
95 classroom environment as a tool to reduce sedentary behaviour. Classroom-based
96 interventions have the potential to target health inequalities because they are accessible to
97 all children [12].

98

99 Systematic and narrative reviews of sit-stand desk interventions within the classroom
100 environment have concluded that this approach shows promise as an effective tool for
101 reducing children's sitting time and increasing movement. However the majority of studies
102 included in these reviews have been feasibility trials or small-scale single-school pilot
103 studies [23-25]. Knowledge of the impact of sit-stand desks on sedentary behaviour,
104 markers of adiposity and pupil behaviour is currently limited by a lack of randomised
105 controlled trials (RCTs) [26, 27], and relatively small samples (median sample size across
106 studies: 45 [24, 26-30]). Furthermore, there has been a limited focus on the acceptability of
107 this intervention approach in the form of qualitative feedback from teachers and pupils, and
108 in understanding pupils' experiences and responses (for example, in-class behaviour) to
109 using sit-stand desks [26, 31, 32]. The above factors will be vital to establish prior to
110 schools agreeing to the longer-term adoption of this strategy [23, 24, 26]. Limited research
111 in this area has also been conducted within relatively deprived locations and/or higher-risk
112 populations, such as South Asian children.

113

114 We have previously demonstrated the feasibility of incorporating sit-stand desks in the
115 classroom environment over a 9-week period in a small non-randomised controlled study
116 conducted within one UK primary school with children aged 9-10 years [33]. In this novel
117 intervention, three standard desks (sitting six children) were replaced with six sit-stand
118 desks in one classroom. The teacher (who received training in intervention delivery)
119 rotated the children in the intervention classroom, using naturally occurring breaks
120 between lessons to do so, to ensure each child was exposed to the desks for at least one
121 hour/day. Children in a control group (within the same school) continued with their usual
122 practice, and no environmental changes were made to their classroom. Reductions in total
123 daily sitting time of 81 mins/day on weekdays (school days) after 9-weeks were seen in the
124 intervention group. As part of this feasibility work, changes in sitting observed in the
125 sample were compared to data from a related feasibility study conducted in a primary
126 school in Melbourne, Australia [33]. Within the Melbourne-based study, every child in the
127 intervention classroom had a sit-stand desk. No significant differences in reductions in
128 weekday total sitting time were observed between studies, demonstrating the potential of
129 this intervention, over the short-term, to reduce children's daily sitting time irrespective of
130 the different approaches to sit-stand desk provision employed.

131

132 This paper reports the findings of a pilot cluster RCT, conducted in a relatively socially
133 deprived location within the UK. Rapid increases in sedentary time have been observed in
134 children aged 11 years and above [34]. This study therefore targeted year 5 classrooms
135 and involved children aged 9-10 years, with the goal of mitigating the typical rise in
136 sedentary time seen during the transition into adolescence [9]. The aim of this study was
137 to examine the feasibility of a protocol for a cluster RCT of a sit-stand desk intervention
138 within primary school classrooms. If deemed feasible, a fully powered cluster RCT could

139 provide valuable evidence on the effectiveness and cost-effectiveness of a sit-stand desk
140 intervention within primary school classrooms, incorporating device-based measures of
141 sitting and activity and a range of health and behaviour-related outcomes. The breadth and
142 findings of the present study are essential to inform a full trial and the potential longer-term
143 adoption of sit-stand desks in primary schools. Objectives of this pilot trial included: 1)
144 evaluating the feasibility and acceptability of recruiting schools and children into the trial; 2)
145 determining attrition in the trial (schools and children); 3) evaluating the acceptability of the
146 intervention and randomisation to teachers and children; 4) determining the acceptability
147 and completion rates of the outcome measures; 5) monitoring the occurrence of any
148 adverse events of the intervention (or a sit-stand desk); and 6) exploring the potential of
149 the intervention to reduce children's device-based measurement (activPAL) of weekday
150 sitting time (the proposed primary outcome in a full trial), and describing the proposed
151 secondary outcome measures collected at baseline and follow-up (device-based
152 measurement of physical activity, adiposity, blood pressure, in-class behaviour, and
153 learning engagement).

154

155 **Methods**

156 ***Design***

157 The detailed protocol for this pilot trial has been reported elsewhere [12]. The study was a
158 school-based, two-armed pilot cluster RCT. Individuals (children aged 9-10 years) were
159 the unit of analysis and schools (clusters) were stratified according to predominant pupil
160 ethnicity (either >50% White British pupils, or >% South Asian pupils) and randomly
161 assigned to one of two conditions: 1) six manually adjustable sit-stand desks incorporated
162 into the classroom environment (intervention condition), or 2) current practice (control
163 condition). Given the intervention was delivered at the classroom level, rather than
164 individual level, a cluster design was considered appropriate. Baseline measurements

165 (November 2016) preceded randomisation (December 2016), and the sit-stand desks were
166 installed into the intervention classrooms following this (February 2017, remaining until
167 July 2017). An identical set of outcome measurements were taken from all participants
168 approximately 7-months after baseline testing at the end of the year 5 school term (July
169 2017). The reporting of this trial follows the CONSORT extension statement for cluster
170 trials [35] and the CONSORT checklist is provided as supplementary material.

171

172 ***Study setting***

173 The study was conducted in primary schools in Bradford, a northern city in England,
174 chosen as the study location given its ethnic composition (predominantly South Asian and
175 White British) and high levels of deprivation, health inequalities and childhood morbidity
176 [36]. Half of all babies born in Bradford are of South Asian origin and 60% are born into the
177 poorest 20% of the population [36]. The study setting was deemed fundamental in
178 addressing the important issue of health inequalities, with classroom-based interventions
179 being accessible to all children [12].

180

181 ***Sample size***

182 A recruitment target of eight primary schools, each with at least 15 child participants per
183 class (approximately 50% of a typical class size) was set, giving a minimum total sample
184 of 120. This exceeds the target minimum sample size recommended for pilot trials [37]. It
185 was also assumed that this sample size should be sufficient to provide clear estimates of
186 recruitment and follow-up to inform a full RCT [12].

187

188 ***School and participant recruitment and eligibility criteria***

189 Government-funded primary schools located in the City of Bradford were invited to
190 participate in the study. Private and designated special educational needs schools and

191 schools with fewer than 25 pupils in year 5 (ages 9-10 years) were not eligible. The aim
192 was to recruit four schools with predominantly South Asian pupils (>50%) and four with
193 predominantly White British pupils (>50%). Information on the ethnic composition of the
194 schools' pupil population was determined using local school census data [12].

195

196 The following three-stage recruitment process was adopted for schools: 1) head
197 teachers/senior teachers were sent an email detailing the study, which included a copy of
198 an Information Sheet for Schools; 2) two days after sending the email, the schools were
199 contacted via telephone and the reception team were asked to confirm receipt of the email;
200 3) a follow-up telephone call was made to establish the schools' interest or otherwise in
201 participating in the study. A designated lead teacher was identified for each interested
202 school who was then given full details of the study and what their involvement would entail.

203

204 Consenting schools were asked to nominate a year 5 class and were provided with
205 invitation packs for the parents/guardians of children within these classes. All children
206 within participating classes were eligible to take part in the evaluation. The invitation pack
207 contained a detailed Information Sheet for Parents/Guardians, an opt-in consent form for
208 the parent/guardian to complete and return if they were happy for their child to participate
209 in the evaluation, and an Information Sheet for Children. Completed consent forms were
210 returned by pupils to their teacher, who informed the research team of the children who
211 were to be involved in the evaluation measures. At the beginning of the baseline
212 measurement session, all methods were fully explained to children by a member of the
213 research team at which time they were asked to provide verbal and written assent. This
214 was requested again at the start of the follow-up measurement sessions.

215

216

217 ***The 'Stand Out in Class' intervention***

218 Six height-adjustable sit-stand desks (LearnFit, Ergotron Inc, USA) were placed in a year 5
219 classroom (replacing three standard desks sitting 6 children) in each intervention school
220 for two school terms, spanning 4.5 months. The research team supported teachers in the
221 development of a classroom rotation plan to ensure all children in their class were exposed
222 to the sit-stand desks for at least one hour/day on average across the week. Stools or
223 chairs remained in the classroom and while children were free to choose whether they sat
224 or stood when using the sit-stand desks, they were encouraged to stand by teachers, as
225 well as through the use of nudge prompts displayed on the desks and standing champions
226 (i.e. one child in a class who was given the responsibility of reminding the teacher about
227 the rotation plan) (see Figure 1)[12].

228

229 Teachers and pupils in the intervention classrooms received training on sit-stand desk use
230 by the research team and teachers also received a 'Professional Development Manual'
231 containing information on the health benefits of reducing prolonged sitting and on correct
232 posture when standing at the desks. The teacher manual and training focussed on
233 encouraging adoption of the intervention, targeting key barriers and facilitators to sit-stand
234 desk use. These were identified from: our previous work [33, 38]; the Capability,
235 Opportunity, and Motivation to perform a Behaviour (COM-B) model within the Behaviour
236 Change Wheel [39]; and the Theoretical Domains Framework [40] (e.g. self-efficacy,
237 motivation and knowledge). Standardised behaviour change techniques (e.g. goal setting,
238 instruction) [41] were also used during the training with teachers and pupils [12]. Further
239 details of the intervention, including an overview of the intervention components and
240 potential barriers, solutions, and hypothesised mediating processes informed by the above
241 theoretical frameworks are reported elsewhere [12]. A logic model for the Stand Out in
242 Class intervention, applicable for a definitive trial, is presented in Figure 1.

243 *Insert Figure 1 about here*

244 ***The usual practice control arm***

245 To compare the effects of the intervention against usual practice (i.e. the provision of
246 standard classroom desks), schools assigned to the control arm were requested to
247 continue with their usual practice and lesson delivery; no environmental changes were
248 made to their classrooms [12].

249

250 ***Allocation to treatment groups***

251 Schools were stratified based on the ethnic composition of their pupils. Following baseline
252 measurements, schools within each stratum were randomised into the two study arms
253 using an allocation ratio of 1:1, employing a randomisation list in SAS software, by an
254 independent statistician at the Leicester Clinical Trials Unit (CTU). Two schools with
255 predominantly South Asian pupils (>50%) and two schools with predominantly White
256 British pupils (>50%) were randomised into the intervention and control arms (4 schools in
257 each arm).

258

259 ***Outcome measurements***

260 The primary outcomes of this pilot trial were the feasibility and acceptability of the research
261 procedures (including recruitment, data collection, randomisation, acceptability of the
262 intervention, retention, and the presence of any adverse events) to inform the planning of a
263 full RCT. A detailed process evaluation describing teachers' and children's experiences of
264 the intervention is reported elsewhere [42]. Study uptake was monitored by recording the
265 number of schools and pupils approached, and the number agreeing to participate
266 (objective 1). Withdrawal rates of schools and children were recorded (objective 2). The
267 acceptability of recruitment (objective 1), the intervention and randomisation (objective 3),
268 and the acceptability of outcome measures (objective 4) were determined via focus groups

269 with children and interviews with teachers. Furthermore, completion rates of the outcome
270 measures were recorded (objective 4), along with the occurrence of any study-related
271 adverse events (objective 5).

272

273 Interviews with teachers and focus groups with children from both trial arms were
274 conducted approximately 1 month following randomisation to explore the acceptability of
275 recruitment (example question: *'What did you think about the way that you were asked to*
276 *take part in the Stand Out in Class Study?'*), randomisation (example question: *'What did*
277 *you think about being randomised to one of the 2 school groups in the study*
278 *[control/intervention]?'*), and the measurement instruments (example question to children:
279 *'What was your view about wearing the thigh worn device for 7 days?'*). The acceptability
280 of the intervention was determined through a further set of interviews (with teachers) and
281 focus groups (with children) from the 4 intervention schools during the final month of the
282 intervention. An example question to intervention teachers and children included: *'What*
283 *has been your experience so far of the sit-stand desks being part of your classroom?'*

284

285 Four male (3 control group, 1 intervention) and 4 female (1 control, 3 intervention)
286 teachers participated in the study. A total of 43 children, 22 boys and 21 girls, took part in
287 the focus groups following randomisation (8 focus groups were conducted, 1 per school)
288 and 24 children, 10 boys and 14 girls, participated in the focus groups towards the end of
289 the trial (4 intervention schools only). Teachers selected children in their class for
290 participation in the focus groups. Within the intervention classes, there may have been
291 some overlap between children participating in the first and second focus groups (at the
292 end of the trial). All interviews and focus groups, across both phases, used semi-structured
293 topic guides to ensure consistency. The focus group topic guides were written in child
294 friendly language. All interviews and focus groups were audio-recorded digitally.

295

296 Device-based sitting was measured for 7 consecutive days during each measurement
297 period using the activPAL3 micro accelerometer (PAL Technologies, UK). This device has
298 been shown to provide a valid measure of posture in children [43]. All activPALs were
299 initialised and downloaded using manufacturer proprietary software (activPAL Professional
300 v.7.2.32) and data were processed using the freely available ProcessingPAL Software
301 (<https://github.com/UOL-COLS/ProcessingPAL>, version 1.1, University of Leicester,
302 (Leicester UK)). The activPAL3 was waterproofed (using a nitrile sleeve and
303 hypoallergenic Hypafix [BSN Medical] dressing) and participants were requested to wear
304 the device continuously (24 hours/day) on the anterior aspect of their right thigh. The
305 device was attached using Hypafix dressing. Participants were provided with a brief diary
306 during each monitoring period in which they were requested to document time in bed and
307 any periods of non-wear [12]. Periods of prolonged non-wear and time in bed were
308 removed from the data using the default algorithm rules within Processing PAL [44].
309 Briefly, the algorithm searches within event files (created in the activPAL Professional
310 software) to identify prolonged bouts of behaviour (sitting, standing) within a noon-noon
311 period. If they meet the criteria they are coded as time in bed/non-wear (no distinction). To
312 accommodate fragmented sleep patterns, the algorithm searches around these identified
313 bouts for other prolonged bouts of behaviour occurring after brief upright activity. If they
314 meet the criteria, the identified bouts and the upright activity are also coded as time in
315 bed/non-wear. Once time in bed and non-wear were excluded, a day was considered
316 valid if it consisted of ≥ 8 hours of waking wear data, $< 95\%$ of time spent in any one
317 behaviour (e.g., sitting, standing, or stepping) and ≥ 500 single leg steps (i.e., ≥ 1000 steps)
318 [44]. Due to the exploratory nature of this study, children were included in the analysis
319 relating to objective 6 (exploring the potential of the intervention to reduce children's

320 weekday sitting time) if they had worn the activPAL for at least 8 hours on at least 1
321 weekday at baseline and follow-up.

322

323 Proposed secondary outcomes for a future full trial included device-based measured
324 physical activity, using the ActiGraph GT3X+ accelerometer (ActiGraph, Pensacola, FL)
325 worn on an elasticated belt at the waist continuously (24 hours/day) for 7 consecutive
326 days, concurrently with the activPAL. The feasibility of collecting ActiGraph data, in
327 addition to activPAL data, was examined to inform a full trial, where this device could be
328 used as a secondary outcome to examine any positive or negative (i.e. compensatory)
329 effects of the intervention on physical activity either during or after school hours.

330 ActiGraphs were initialised to record data at 60 Hz. The devices were initialised and
331 downloaded using ActiLife version 6.13.3, and the data (reintegrated into 15 second
332 epochs) were processed using specifically developed and commercially available software
333 (KineSoft version 3.3.20, Loughborough UK). Time spent in light (26 – 573 counts per 15
334 second epoch) and moderate-to-vigorous intensity (≥ 574 counts per 15 second epoch)
335 activity were determined using the Evenson cut-points [45]. Due to the 24-hour wear
336 protocol of the ActiGraphs, a blanket removal of sleep time between 11pm and 5.59am
337 was undertaken when processing these data. However, to identify periods of sleep and/or
338 non-wear occurring outside of this time period (i.e. after 6am and before 11pm), the 3-axis
339 acceleration data from the ActiGraph were used to detect periods of no movement. If these
340 periods exceeded 20 minutes of zero counts, then this additional period was excluded as
341 non-wear/sleep time. The same wear time criteria as applied to the activPAL data (a
342 minimum of 8 hours of wear on at least one weekday) was also applied to the ActiGraph
343 data.

344

345 At each measurement point children's height and body mass (without shoes) were
346 measured directly using standard procedures by trained research staff. Body composition
347 was assessed using bio-impedance analysis scales, suitable for use with children (Tanita
348 DC-360S). Blood pressure was measured from the left arm after at least a five minute
349 period of quiet sitting using a semi-automated recorder (Omron HEM-907) with a
350 paediatric cuff, in accordance with current recommendations [46]. Three assessments
351 were taken with each measurement separated by a two-minute rest period and the mean
352 systolic and diastolic blood pressures recorded from the second and third assessments
353 were calculated.

354

355 The impact of the intervention on participants' behaviour was assessed using the
356 Strengths and Difficulties questionnaire [47], a measure of pro-social behaviour, emotional
357 symptoms, conduct problems, hyperactivity and peer problems, completed by teachers at
358 baseline and follow-up. The questionnaire consists of 25 items, with five items per scale,
359 which receive a score from 0 to 2. A total difficulties score is calculated by summing the
360 scores from the first four scales, with higher scores indicating increased behavioural
361 difficulties [47]. In addition, children self-reported their engagement and disaffection with
362 their own learning via the Engagement Versus Disaffection with Learning questionnaire
363 [48]. This questionnaire assesses behavioural engagement and behavioural disaffection,
364 using five items each, along with emotional engagement, using five items, and emotional
365 disaffection, using 12 items. Each item is scored on a 1 to 4 scale, with higher values
366 indicating increased levels of engagement and reduced disaffection. Mean scores are
367 calculated across the two engagement and disaffection categories to provide an overall
368 indication of engagement and disaffection levels [49].

369

370 Children furthermore completed the Paediatric Quality of Life Inventory (PEDS-QL) [50]
371 and EuroQol 5-dimension Youth (EQ-5D-Y) [51] at each measurement point to provide a
372 measure of self-reported quality of life to inform an economic analysis in a full trial. Basic
373 demographic information (sex, age, ethnicity) were reported by children at baseline. Full
374 details of all measurement instruments, along with information on their validity has been
375 reported elsewhere [12].

376

377 ***Quantitative and qualitative analyses***

378 *Trial feasibility and acceptability*

379 As this was a pilot trial, the primary analyses (the purpose of which was to assess the
380 feasibility of conducting a cluster RCT of a sit-stand desk intervention within primary
381 school classrooms) mainly utilised descriptive statistics summarising: the number of
382 schools approached, the number agreeing to participate, and the proportion of children
383 within each school with parental/guardian consent, and giving their assent, to participate in
384 the study evaluation (objective 1); retention rates (schools and children) (objective 2);
385 outcome measure completion rates and compliance (objective 4); and the documentation
386 of any study-related adverse events (objective 5).

387

388 The acceptability of recruitment (objective 1), randomisation and the intervention (objective
389 3), along with the acceptability of the outcome measures (objective 4) were determined
390 through qualitative analyses of the pupil focus groups and teacher interview data. Audio
391 recordings were transcribed verbatim with anonymisation of all personal data. To address
392 the objects within the present paper, sample quotes which reflect common responses
393 across the questions asked are provided (a detailed process evaluation is reported
394 elsewhere[42]). Extracts from the focus groups and interviews are labelled to indicate the

395 participant (Child/Teacher), group (I = intervention, C = control) and school (number 1-4
396 within each trial arm).

397

398 *The potential of the intervention to reduce children's weekday sitting time, and a summary*
399 *of the proposed secondary outcomes for inclusion in a full trial (objective 6)*

400 An objective of this study was to examine the potential of the intervention to reduce
401 children's weekday sitting time (the proposed primary outcome in a full trial). As the
402 number of clusters was low, cluster summary statistics were used rather than multi-level
403 modelling [52, 53]. A weighted linear regression model compared the change in mean
404 weekday sitting time between follow-up and baseline between control and intervention arm
405 participants. The model was adjusted for baseline total daily sitting time on school days
406 and average weekday wear time across the two measurement points. Subsequent models
407 adjusted for the season in which the baseline and follow-up measures were taken. Since
408 the variables in the regression model reflect cluster means rather than individual
409 observations, an analytically weighted least squares method of estimation was used,
410 where cluster sizes were the weights. The results from this analysis should, however, be
411 treated as preliminary and interpreted with caution given the lack of statistical power [54,
412 55]. Statistical analyses were undertaken using Stata version 15.1 (StataCorp, Texas,
413 USA), and were validated by an independent trial statistician at the Leicester CTU.

414

415 Descriptive statistics were calculated to summarise the proposed secondary outcomes
416 (device-based measured time spent in light intensity and moderate-to-vigorous intensity
417 activity on weekdays, adiposity, blood pressure, behaviour, and learning engagement)
418 measured at baseline and follow-up.

419

420

421 **Results**

422 ***Trial feasibility and acceptability***

423 Twenty-four eligible schools were approached and of these the target number of eight
424 schools consented to participate, with the overall recruitment rate being 33% (95% CI: 16
425 to 55%). Twelve schools did not consent to join the study (50%) and four did not respond
426 to the initial email (17%). All eight participating schools completed the trial (100%
427 retention). Data from the 2016-2017 school census [56] show that the proportion of
428 children eligible for free school meals was similar across the recruited schools and the
429 declined schools (mean: 17.1% [range: 2.3%, 26.4%] vs. 17.4% [9.6%, 28.5%]), with these
430 values being higher than the national average of 14.8% in 2016-2017.

431

432 The proportion of pupils at the eight schools with parental consent to participate in the trial
433 evaluation was 75% (176 out of 234), exceeding the target minimum sample of 120 [12].

434 At follow-up, retention of participating children was 97% (170 out of 176). A CONSORT
435 flow diagram is shown in Figure 2. Two pupils in the control group were unable to provide
436 follow-up measures as they were absent from school on the days they were taken. Three
437 children (1 control, 2 intervention) moved away from the area during the study and hence
438 changed schools. One control group participant withdrew their assent prior to the follow-up
439 measures. The demographic characteristics of the participating children at baseline are
440 shown in Table 1.

441 *Insert Figure 2 about here*

442

443

444

445

446 **Table 1.** Demographic characteristics of the participating children, by group and total
 447 sample.

| | | Control | Intervention | Overall |
|------------------|---------------|------------|--------------|------------|
| | | (n = 90) | (n = 86) | (n = 176) |
| Sex, n (%) | Male | 50 (55.6%) | 48 (55.8%) | 98 (55.7%) |
| | Female | 44 (44.4%) | 38 (44.2%) | 78 (44.3%) |
| Ethnicity, n (%) | White British | 18 (20.0%) | 45 (52.3%) | 63 (35.8%) |
| | South Asian | 59 (65.6%) | 26 (30.2%) | 85 (48.3%) |
| | Other | 13 (14.4%) | 15 (17.4%) | 28 (15.9%) |
| Age | Mean (SD) | 9.3 (0.5) | 9.3 (0.4) | 9.3 (0.5) |

448

449

450 Completion rates of the proposed outcome measures for inclusion in a full RCT at baseline
 451 and follow-up are shown in Table 2. The table also displays the proportion of children
 452 providing valid activPAL and ActiGraph data on at least 1, 2, 3, 4 and all 5 weekdays.

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464 **Table 2.** Total sample outcome measure compliance and completion rates at baseline and
 465 follow-up

| | Baseline | Follow-up | Both baseline and follow-up |
|--|----------|-----------|-----------------------------|
| activPAL data on weekdays* | | | |
| ≥1 valid day | 80.1% | 76.1% | 63.1% |
| ≥2 valid days | 74.4% | 66.5% | 51.7% |
| ≥3 valid days | 65.3% | 53.4% | 39.2% |
| ≥4 valid days | 54.5% | 42.6% | 27.3% |
| 5 valid days | 18.2% | 16.5% | 5.7% |
| ActiGraph data on weekdays* | | | |
| ≥1 valid day | 94.3% | 87.5% | 83.5% |
| ≥2 valid days | 89.8% | 78.4% | 73.3% |
| ≥3 valid days | 85.2% | 65.3% | 58.0% |
| ≥4 valid days | 75.0% | 50.0% | 42.6% |
| 5 valid days | 25.6% | 11.4% | 5.1% |
| Anthropometric measures | | | |
| Body composition | 98.9% | 94.9% | 93.8% |
| Blood pressure | 77.8% | 89.8% | 70.5% |
| Engagement vs Disaffection with Learning (child reported) | 97.7% | 96.0% | 93.8% |
| Strength and Difficulties questionnaire (teacher reported) | 91.5% | 94.9% | 90.3% |
| PEDS-QL | 83.0% | 93.2% | 83.0% |
| EQ-5D-Y | 94.6% | 94.6% | 94.6% |

466 *A valid day for the activPAL and ActiGraph constituted at least 8 hours of wear on a
 467 weekday

468

469 No serious adverse events were reported throughout the duration of the trial. Specifically,
470 there were no adverse effects associated with the intervention that related to
471 musculoskeletal discomfort and/or disruption to the classroom or to reported learning.

472

473 All eight teachers expressed high satisfaction with the recruitment protocol, with all stating
474 the study had been clearly explained:

475 *“Yeah, it was very well explained and the ideas and the concept behind what you*
476 *were doing, so I had no hesitation accepting really.”* (Teacher, C1)

477

478 Teachers also commented that the recruitment approach was appropriate and suitable for
479 children:

480 *“It worked well. I think you got quite a good uptake...as a class, so obviously what*
481 *you were sending out and the conversations you were having with the children got*
482 *them quite enthused. I think with them, with the children they’re doing something*
483 *scientific because they all sort of really love science, the idea of doing something*
484 *scientific with scientists is like “yay!” So they jumped on that.”* (Teacher, C2).

485

486 Children across all focus groups reported that recruitment had been positive for them, the
487 study made clear, and that everyone had a choice to participate:

488 *“It was good because once I got the letter, I didn’t understand what it was.*

489 *[Researchers] told us about the letter and our teachers told us about it and told us*
490 *to tell our mum if we want to go or not because you first need permission off your*
491 *mum, and that’s why it was a good process because you got told three times.”*

492 (Child, I1).

493

494 *"It's more like you get to choose to take part and if you don't want to then it doesn't*
495 *matter."* (Child, I3).

496

497 When asked about the acceptability of randomisation, all teachers and children expressed
498 a clear understanding of why randomisation had occurred. Whilst control group teachers
499 and children were disappointed not to have worked with the sit-stand desks, they
500 considered their participation in the trial to be positive and important:

501 *"Well, I completely understand why you need to have a control. You know, we teach*
502 *the children, that certain investigations need a control, you need something to*
503 *compare it against..."* (Teacher, C3).

504

505 *"Because then you can look at the schools that have the tables and the schools that*
506 *didn't and look at the difference on health."* (Child, I3).

507

508 With regards to the acceptability of the activPAL (as a primary outcome measure for a full
509 trial), the most common theme identified from the responses related to issues with the
510 medical dressing used (Hypafix® transparent) to attach the monitor. This reportedly caused
511 a minority of children to suffer from itchiness, soreness and discomfort, and led to some
512 class disruption:

513 *"Yeah, it was a bit faffy. Some of the children did complain about getting a bit of a*
514 *rash, but they like to complain anyway, so it was a bit... I don't want to use the word*
515 *chaotic, but that was more to do with the fact that the kids were constantly*
516 *interested by them so they were focused on them..."* (Teacher, I1)

517

518 However, other teachers did not perceive the medical dressing to be particularly
519 problematic as only a few children had been affected:

520 *“...there were only a few complaints [about the dressing]...”, (Teacher, C2)*

521

522 *“Only a couple of them had a little reaction to it.” (Teacher, I4)*

523

524 During the focus groups with children, 10 out of 43 reported feeling some discomfort
525 related to the activPAL:

526 *“When you tried to take it off it really hurt.” (Child, C3)*

527

528 *“When I took it off I had a bit of like a little rash or a few spots, from the underneath
529 because my leg got quite sweaty.” (Child, C1).*

530

531 In contrast to the activPAL, the ActiGraph was regarded as a more acceptable device for
532 children to wear by all teachers and most children (38/43):

533 *“It didn’t really annoy me at all and it felt like nothing was even there.” (Child, C4)*

534

535 The focus groups and interviews with intervention children and teachers conducted
536 towards the end of the study period revealed that the intervention was generally well
537 accepted by children and teachers. All teachers expressed that the desks had become
538 part of their classroom, and that any initial concerns they had had regarding the desks
539 causing a distraction had not materialised:

540 *“Yeah, well for me I’m now used to them so before, I think for the first month or so, I
541 was kind of looking at them as to how would they work, how well would they work
542 with the children, would it just be a distraction for them, but now it’s, it’s kind of just
543 the norm for the children, and we’re kind of, we’re used to them and every week
544 when we rotate round we, we just do it steadily.” (Teacher, I2).*

545

546 The children felt having the desks in their classroom had been very positive, with key
547 themes including changing behaviour for the better, liking having the option to stand, and
548 appreciating the increased personal working space afforded by the desks:

549 *“they really change boys’ behaviours because some boys, not me, are fidgety so it’s*
550 *good for them to stand up.”* (Child 14)

551

552 *“I like it because, like, every time you don’t feel comfortable while sitting down, you*
553 *could just stand up and then you might feel more comfortable.”* (Child, 13).

554

555 *“It’s like it’s a lot better than our tables because when we do our work, sometimes*
556 *Miss says, sit down to do our work but then now with the stand-up-sit-down tables*
557 *we can stand up more because I like working when I stand up especially when it’s*
558 *stuff like art and stuff like that where you have to draw.”* (Child, 14).

559

560 *“I liked it because it was only for one person to sit on, for each table. Because*
561 *normally, when we have to share a table, there’s not enough space.”* (Child, 12).

562

563 ***The potential of the intervention to reduce children’s weekday sitting time***

564 An objective of this pilot trial was to examine preliminary evidence of the effectiveness of
565 the intervention in changing mean weekday sitting time, as the intervention was school
566 based. Total school day/weekday sitting time was chosen as this encompasses school
567 hours and out of school hours, and factors in any potential compensatory effects of the
568 intervention (i.e. increases in sitting after school). Table 3 displays the descriptive statistics
569 for all activPAL variables recorded throughout waking hours on weekdays for the control
570 and intervention groups.

571

572 **Table 3.** Descriptive statistics for the activPAL variables measured throughout waking
 573 hours on weekdays.

| Waking hours on weekdays | Baseline | | Follow-up | | Change | |
|--|---------------------|--------------------------|---------------------|--------------------------|---------------------|--------------------------|
| | Control (n = 57) | Intervention (n = 52) | Control (n = 57) | Intervention (n = 52) | Control (n = 57) | Intervention (n = 52) |
| Wear time (min/day) | 836.3 (88.5) | 843.8 (47.8) | 830.9 (78.6) | 835.4 (64.2) | -3.7 (121.6) | -8.4 (62.3) |
| Time spent sitting (mins/day) | 520.1 (83.6) | 514 (61.5) | 504.4 (94.0) | 472.0 (73.5) | -15.2 (107.5) | -42.0 (76.6) |
| Time spent standing (mins/day) | 179.9 (58.6) | 195.4 (38.7) | 176.5 (45.7) | 197.1 (49.4) | -3.0 (50.2) | 1.6 (52.0) |
| Time spent stepping (min/day) | 136.3 (44.9) | 134.4 (30.4) | 150.0 (42.1) | 166.4 (41.9) | 14.4 (44.8) | 32.0 (41.1) |
| Percentage of wear time spent sitting (%) | 62.4 (8.8) | 60.9 (5.9) | 60.5 (8.6) | 56.5 (8.2) | -2.0 (8.7) | -4.3 (8.6) |
| Percentage of wear time spent standing (%) | 21.4 (6.3) | 23.2 (4.5) | 21.5 (6.1) | 23.6 (5.7) | 0.1 (5.9) | 0.4 (5.8) |
| Percentage of wear time spent stepping (%) | 16.2 (4.7) | 15.9 (3.5) | 18.1 (4.8) | 19.9 (4.6) | 1.9 (4.6) | 3.9 (4.6) |
| Number of sit to stand transitions | 102.5 (28.7) | 106.4 (23.6) | 104.1 (26.5) | 106.2 (21.4) | 1.6 (25.0) | 0.2 (20.5) |
| Number of days worn | 3.7 (1.3) | 3.5 (0.9) | 3.2 (1.2) | 3.5 (1.4) | -0.5 (1.4) | 0.0 (1.8) |

574 Data are presented as the mean (SD). This table includes data from participants who wore
 575 the activPAL device with a minimum valid wear time of 8 hours each day on at least one
 576 weekday at baseline and at 7-months follow-up.

577

578 The weighted linear regression model applied revealed the mean difference in change in
579 sitting time was -30.6 minutes/day (95% CI: -56.42 to -4.83) for the intervention group,
580 relative to the control group. The addition of baseline season of activPAL data collection to
581 the weighted linear regression model did not affect the difference in sitting time between
582 groups. When follow-up season was included in the model the adjusted difference in sitting
583 time between groups was -26.64 minutes/day (95% CI: -73.08 to 19.79).

584

585 Table 4 displays the descriptive statistics for all ActiGraph variables recorded throughout
586 waking hours on weekdays for the control and intervention groups. Both groups
587 demonstrated small changes in light intensity physical activity and moderate-to-vigorous
588 intensity physical activity (MVPA) over the follow-up period. Descriptive statistics for the
589 anthropometric, blood pressure and questionnaire measures (Engagement and
590 Disaffection with Learning and the Strengths and Difficulties questionnaire) collected from
591 participants at baseline and follow-up are shown in Table 5. The changes seen in the
592 anthropometric measurements over the follow-up period are reflective of typical growth-
593 related changes in children of this age. There were no noticeable between-group
594 differences in the mean changes in learning engagement and disaffection scores over the
595 trial period, and a small decrease in the total difficulties score (indicating improved
596 behaviour) in the intervention group relative to the control group over the follow-up period.

597

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603 **Table 4.** Descriptive statistics for the ActiGraph variables measured throughout waking
 604 hours on weekdays.

| Waking hours on weekdays | Baseline | | Follow-up | | Change | |
|---|---------------------|--------------------------|---------------------|--------------------------|---------------------|--------------------------|
| | Control (n = 74) | Intervention (n = 72) | Control (n = 74) | Intervention (n = 72) | Control (n = 74) | Intervention (n = 72) |
| Wear time (min/day) | 885.1 (90.5) | 882.6 (84.5) | 827.7 (134.1) | 852.9 (106.8) | -57.4 (125.9) | -29.7 (118.0) |
| Time spent in light PA (mins/day) | 378.2 (61.9) | 383.5 (68.6) | 364.3 (81.2) | 392.7 (70.8) | -13.9 (74.4) | 9.3 (78.3) |
| Time spent in MVPA (min/day) | 40.0 (20.5) | 37.4 (17.9) | 40.7 (30.9) | 45.7 (24.7) | 0.7 (24.5) | 8.3 (20.0) |
| Percentage of wear time spent in light PA (%) | 43 (6.4) | 43.4 (6.2) | 44.0 (6.9) | 46.0 (6.0) | 1.1 (5.5) | 2.6 (5.6) |
| Percentage of wear time spent in MVPA (%) | 4.6 (2.3) | 4.3 (2.1) | 5.0 (3.8) | 5.4 (2.7) | 0.5 (2.8) | 1.1 (2.2) |
| Number of days worn | 3.8 (1.4) | 3.6 (1.3) | 2.8 (1.5) | 3.2 (1.6) | -1.0 (1.3) | -0.4 (1.3) |

605 Data are presented as the mean (SD). This table includes data from participants who wore
 606 the ActiGraph device with a minimum valid wear time of 8 hours each day on at least one
 607 weekday at baseline and at 7 months follow-up.

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615 **Table 5.** Anthropometric, blood pressure and questionnaire measurements

| | Baseline | | Follow-up | | Change | |
|---|---------------------|--------------------------|---------------------|--------------------------|---------------------|--------------------------|
| | Control (n = 90) | Intervention (n = 84) | Control (n = 85) | Intervention (n = 83) | Control (n = 85) | Intervention (n = 81) |
| Height (cm) | 140.5 (6.6) | 138.3 (6.2) | 144.0 (6.8) | 141.3 (6.4) | 3.3 (1.7) | 2.9 (1.0) |
| Body mass (kg) | 36.3 (9.5) | 35.0 (7.8) | 39.2 (10.6) | 37.7 (8.7) | 3.0 (1.7) | 2.7 (1.7) |
| Percent body fat – Girls [§] | 24.4 (8.4) | 23.6 (8.1) | 23.7 (9.1) | 25.0 (8.3) | -0.7 (2.1) | 0.5 (2.8) |
| Percent body fat - Boys [§] | 20.6 (8.9) | 19.9 (6.9) | 20.7 (8.9) | 19.0 (6.6) | 0.4 (2.6) | -0.9 (2.4) |
| BMI (kg/m ²) | 18.2 (4.0) | 18.2 (3.3) | 18.7 (4.1) | 18.8 (3.5) | 0.6 (0.8) | 0.6 (0.7) |
| Systolic blood pressure (mmHg)* | 102.5 (11.8) | 102.8 (15.2) | 107.3 (11.7) | 110.5 (11.2) | 5.1 (15.8) | 10.2 (17.8) |
| Diastolic blood pressure (mmHg)* | 66.1 (10.2) | 67.3 (14.1) | 66.3 (9.5) | 68.4 (9.7) | 0.2 (12.1) | 2.4 (16.2) |
| Engagement and Disaffection with Learning questionnaire sub-scale scores (child reported) | | | | | | |
| | Control (n = 90) | Intervention (n = 82) | Control (n = 86) | Intervention (n = 83) | Control (n = 86) | Intervention (n = 80) |
| Overall Engagement | 3.4 (0.5) | 3.4 (0.5) | 3.3 (0.6) | 3.3 (0.5) | -0.1 (0.6) | -0.1 (0.5) |
| Overall Disaffection | 3.1 (0.7) | 3.1 (0.7) | 3.2 (0.7) | 3.1 (0.6) | 0.1 (0.7) | 0.0 (0.6) |
| Strengths and Difficulties questionnaire (teacher reported) | | | | | | |
| | Control (n = 83) | Intervention (n = 78) | Control (n = 83) | Intervention (n = 84) | Control (n = 81) | Intervention (n = 78) |
| Total difficulties score | 6.2 (5.7) | 9.2 (7.6) | 6.9 (6.0) | 7.8 (6.6) | 0.6 (4.6) | -1.3 (4.5) |

616 Data are reported as the mean (SD). [§]Percent body fat sample sizes: girls, control n = 40,

617 intervention n = 35; boys, control n = 50; intervention n = 49. *The sample size for the

618 change in blood pressure measurements reduced to 54 control participants and 49
619 intervention participants.

620

621 **Discussion**

622 The purpose of this study was to undertake a pilot cluster RCT to test the feasibility and
623 acceptability of conducting and evaluating a school-based sit-stand desk intervention. The
624 findings confirmed that recruitment and attrition rates were acceptable to support
625 progression to a full trial, most outcome measures were acceptable, and the intervention
626 was well received. However, improvements to compliance with protocols for assessing the
627 proposed primary outcome (activPAL-determined sitting time) are needed. Furthermore,
628 preliminary evidence demonstrated the potential of the intervention in reducing children's
629 weekday sitting time, although the changes observed were not as large as those seen
630 previously within the same setting within a 9-week non-randomised controlled study
631 conducted in just one school [33].

632

633 The uptake into the study by schools (33% of those approached) is similar to recruitment
634 rates seen in other primary school-based interventions located in the same region [57] and
635 elsewhere in England [58]. Whilst all eight recruited schools were located predominantly in
636 urban areas within the Bradford metropolitan district, the study was effective in recruiting a
637 diverse range of schools in terms of the ethnic composition of their pupils within a relatively
638 deprived setting. Within the participating schools, parental consent and pupil assent to
639 participate was obtained for 75% (n = 176) of eligible pupils, exceeding our target
640 minimum sample size (120 participants) [12]. Furthermore, school and participant retention
641 rates within the trial were high (100% and 97% respectively). Overall, these findings
642 demonstrate the feasibility of recruiting and retaining schools and participants into a
643 school-based sit-stand desk RCT and suggest good interest and recognition of the

644 importance of the study by participating schools. Whilst schools have been identified as
645 important environments for health promoting interventions [22], the challenges of recruiting
646 schools and children, particularly via opt-in consent procedures (as adopted herein), and in
647 retaining participants, have been highlighted [59].

648

649 Most outcome measures were regarded as acceptable by children and teachers. Of the
650 physiological measures, lower compliance rates were seen for blood pressure, with some
651 children stating during the assessments that they found this measure uncomfortable.
652 Whilst modest (63%), the proportion of children providing valid activPAL data in the
653 present study is higher than that observed previously in the same study setting [33], and
654 similar to that in a recent sit-stand desk RCT in Belgian children [26]. The main issue faced
655 was with the medical dressing (Hypafix [BSN Medical]) used to attach the activPAL, with
656 this reportedly causing irritation on the leg for some children. In the present study we
657 adopted a 24-hour wear protocol with the anticipation that the hypoallergenic dressing
658 would stay on the skin for a number of days, and not require children to frequently remove
659 the device (and dressing), with the purpose of reducing participant burden. However, this
660 did not prove to be very effective as a number of children requested additional medical
661 dressing throughout the monitoring periods to enable them to re-attach the activPAL after
662 removal. Other researchers have enclosed the activPAL in a small pocket in an adjustable
663 elasticised belt worn at the mid-anterior position of the thigh throughout waking hours only,
664 removing it for water-based activities. This approach has been used successfully (85%
665 compliance) in cross-sectional research [60] and is worth exploring ahead of a full trial.
666 Evidently, further research is needed on the attachment options for the activPAL in
667 children to improve compliance. In comparison to the activPAL, compliance rates for the
668 waist-worn ActiGraph were higher (83%) and this device was reasonably well accepted by
669 children.

670

671 The intervention was well received by teachers and children, and towards the end of the
672 intervention teachers commented on how the desks were regarded as part of the norm
673 within their classrooms. This positive finding suggests teachers are both prepared and
674 capable of adapting their teaching style and willing to make modifications to their
675 classroom environments. Some children reported that they felt the desks improved
676 behaviour within the classroom. These findings are consistent with others who have
677 concluded that sit-stand desks can be introduced into the classroom environment without
678 having a negative impact on student learning, behaviour, musculoskeletal comfort, or
679 causing classroom disruption [28, 29, 31, 61, 62]. The absence of any negative impacts of
680 sit-stand desks on these outcomes are likely to be of particular interest to schools
681 considering adopting these desks in the future. Further, the potential positive effects
682 observed within this study on pupil behaviour and increases in pupil autonomy (having the
683 choice of sitting or standing) are even more encouraging and support further testing of this
684 intervention.

685

686 Preliminary analyses demonstrated the potential of the intervention in reducing children's
687 weekday sitting time, with the intervention group reducing their total weekday sitting time
688 by more than 30 minutes/day relative to the control group. No data currently exist in
689 children to inform the magnitude of a reduction in sitting time needed to bring about
690 changes in health markers. This information will be vital in the future to inform public health
691 messaging. Data from adults however have indicated that reallocating just 30 minutes of
692 sedentary time per day to light movement is associated with a 2–4% improvement in
693 cardiometabolic biomarkers [63]. An earlier meta-analysis of RCTs and non-RCTs
694 delivered in the school or home environment reported an overall decrease in children's
695 sedentary behaviour of 18 mins/day [64]. The preliminary findings from this study hold

696 promise, therefore, and support the need for further RCTs examining the impact of sit-
697 stand desks in the classroom environment. The reduction in sitting time observed in the
698 current pilot RCT is also greater than that reported in a recent sit-stand desk RCT
699 conducted in primary school children in Belgium where, relative to the control group, the
700 intervention group experienced a reduction in daily sitting of 13.5 minutes/day over the 8-
701 12 week intervention period [26]. In the Belgian study however, only three sit-stand desks
702 were placed in the intervention classrooms and pupils were exposed to these desks for an
703 average of 60 minutes/week, which likely explains the differences in findings.

704

705 When a bank of sit-stand desks are included within the classroom environment, as in the
706 present study, the Belgian study [26] and in our earlier study [33], the creation and
707 successful implementation of a regular rotation plan is important in order to maximise pupil
708 exposure to the sit-stand desks. In our previous small study, the teacher was very effective
709 in rotating pupils daily around the classroom to ensure equal exposure to the desks of
710 approximately one hour/day on average, and this led to a large reduction in mean
711 weekday sitting time (81 mins/day). In the present study, our intervention instructed
712 teachers to rotate children daily, however some intervention teachers trialled different
713 rotation options which may have reduced the overall exposure to the desks and the
714 subsequent impact of the intervention and explain the differences between our study
715 findings. This has been explored further as part of the process evaluation (reported
716 elsewhere) [42]. It was observed in the present study that daily sitting time appeared to be
717 replaced predominately with stepping time, as opposed to standing time, in the
718 intervention group at follow-up. This finding contrasts to that seen in adult samples within
719 RCTs implementing sit-stand desks in the workplace, where sitting time is predominately
720 replaced with standing time [65, 66]. A possible explanation for this finding could be that
721 children may be less likely to stand still when using a sit-stand desk, and hence some

722 stepping movement could be recorded by the activPAL. Furthermore, rotating children
723 around the class to facilitate their exposure to the sit-stand desks may also increase
724 overall movement levels.

725

726 ***Study limitations and strengths***

727 Delays experienced at the start of the study meant that the duration of the intervention was
728 shorter than originally proposed (2 school terms as opposed to 3 terms). Nevertheless, the
729 overall duration was deemed appropriate to provide evidence of the feasibility and
730 acceptability of the study protocol to inform the planning of a full trial. A further limitation
731 was the relatively poor compliance to the activPAL protocol. Despite schools being
732 stratified by their pupils ethnicity (either >50% South Asian pupils, or >50% White British
733 pupils) with two schools from each stratum being randomised into the intervention and
734 control arms, the balance between South Asian and White British participants across the
735 two arms was not equal. This discrepancy was likely due to the ethnic composition of
736 children in the individual classes involved in the trial, and discrepancies in consent from
737 the individuals rather than an overall imbalance across the schools.

738

739 A key strength of this study includes the multi-method approach which enabled a thorough
740 evaluation of all trial procedures. Other strengths are that the intervention was based on a
741 theoretical framework, and its development was informed by the literature [23-25], our
742 early work [33, 38], and public involvement (including focus groups with children and
743 interviews with teachers and head teachers during the planning stages, along with ongoing
744 consultation with teachers throughout the trial). The study setting, in terms of its location,
745 associated demographics and school context, was a further strength of the trial. As noted
746 earlier, Bradford was purposely chosen as the study location given its ethnic composition
747 (predominantly South Asian and White British) and high levels of deprivation, health

748 inequalities and childhood morbidity [36]. The characteristics of the participating schools
749 suggest they were largely representative of schools within the Bradford metropolitan
750 district which enabled us to pilot this intervention under challenging circumstances. The
751 acceptability and feasibility findings of this study therefore suggest that this trial would
752 likely be feasible within other schools. The accessibility of the classroom-based setting to
753 all children is furthermore important for addressing health inequalities. Forty-eight percent
754 of the present sample were of South Asian ethnic origin. With the emergence of an
755 increased cardiometabolic health risk profile observed in British South Asian children, in
756 comparison to white British children [15], early health promotion interventions like this in
757 such higher-risk groups, could be an important strategy for reducing ethnicity-related
758 health inequalities later in life.

759

760 ***Conclusions and recommendations***

761 The present study demonstrated that recruitment and retention rates were adequate, and
762 randomisation, the measurement procedures and intervention were generally acceptable
763 to participants. Some modifications to the protocol are needed to ensure the successful
764 conduct of a future RCT, particularly around improvements to the activPAL wear protocol.
765 Preliminary evidence from this study has demonstrated the potential of the intervention to
766 reduce children's weekday sitting time but more work is needed with teachers to create an
767 acceptable classroom rotation plan to ensure pupil exposure to the sit-stand desks is
768 maximised. The findings from this pilot cluster RCT therefore support the conduct of a full
769 trial designed to evaluate the effectiveness and cost-effectiveness of a sit-stand desk
770 intervention within the primary school setting on children's sedentary behaviour, markers
771 of health and behavioural outcomes. As suggested elsewhere [26, 31], a full trial should be
772 conducted over a minimum of one academic year. Such a trial could provide novel and
773 robust evidence of the longer-term health and education impacts of this intervention.

774

775 **List of abbreviations**

776 RCT - randomised controlled trial; CI – confidence interval; METs - metabolic equivalents;

777 UK - United Kingdom; CONSORT - Consolidated Standards of Reporting Trials; USA –

778 United States of America; COM-B - Capability, Opportunity, and Motivation to perform a

779 Behaviour; CTU - Clinical Trials Unit; Hz – Hertz; PEDS-QL - Paediatric Quality of Life

780 Inventory; EQ-5D-Y - EuroQol 5-dimension Youth; SD – Standard deviation; MVPA -

781 moderate-to-vigorous physical activity; cm – centimetres; kg – kilograms; BMI – body

782 mass index.

783

784 **Declarations**

785 ***Ethics approval and consent to participate***

786 Ethical approval for the research was obtained from Loughborough University’s Ethical

787 Advisory Committee (reference: R16-P027). Head teachers, or a nominated senior

788 teacher, provided written informed consent for their school to participate in the study.

789 Teachers provided written informed consent for their participation, parents/guardians

790 provided written informed consent for their child to participate in the trial evaluation, and

791 participating children provided verbal and written assent.

792

793 ***Consent for publication***

794 Not applicable

795

796 ***Availability of data and materials***

797 Data supporting the results reported in this paper are stored at Loughborough University

798 and are available upon request by contacting the first author.

799

800 ***Competing interests***

801 The sit-stand desks used in this study were supplied via an in-kind donation from Ergotron
802 Inc, USA. The company played no role in the study design, data collection or data
803 analyses, or in the preparation of this paper. The company have no relevant
804 interests/rights in terms of project outcomes and uses. JS notes that she has a potential
805 conflict of interest as her husband owns a business to manufacture height-adjustable
806 desks for schools. These desks were not used in this research, and she was not involved
807 in the data analysis. The remaining authors declare no other competing interests.

808

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814 Healthy Families theme. The views expressed are those of the authors and not necessarily
815 those of the NHS, the NIHR or the Department of Health and Social Care.

816

817 ***Authors' contributions***

818 SC, SaB, CE, RME, LC, KT, GR, MF and StB obtained funding for the research, JS and
819 DD were named collaborators on the funding application and supported the study
820 throughout. DB, NP and YLC were the trial Research Associates. NBJ was the trial
821 statistician and JA and GR undertook the health economics component of the study. All
822 authors contributed to the development of the intervention and study methods, and all
823 contributed to the reviewing and editing of the manuscript. All authors accept full
824 responsibility for and have read and approved the final version of the manuscript.

825

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836

837 **List of Figures**

838 Figure 1. A Logic model for the Stand Out in Class intervention, applicable for a definitive
839 trial.

840 Figure 2. A CONSORT Diagram for the Stand Out in Class pilot cluster RCT

841

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