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**Dagger, RM, Davies, IG, Mackintosh, KA, Stone, GL, George, KP, Fairclough, SJ and Boddy, LM**

**The CHANGE! Project: Changes in body composition and cardiorespiratory fitness in 10-11 year old children after completing the CHANGE! Intervention**

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### Article

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1 PAPER AS ACCEPTED FOR PUBLICATION BY PEDIATRIC EXERCISE SCIENCE

2 **The CHANGE! Project: Changes in body composition and cardiorespiratory fitness in 10-11**  
3 **year old children after completing the CHANGE! Intervention**

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29

30 **Title: The CHANGE! Project: Changes in body composition and cardiorespiratory fitness in**  
31 **10-11 year old after completing the CHANGE! Intervention**

32 **Running Head:** Changes in body composition

33 **Abstract**

34 *Purpose:* To assess the effects of the Children's Health, Activity and Nutrition: Get Educated!  
35 intervention on body size, body composition and VO<sub>2</sub>peak in a sub-sample of 10-11 year old  
36 children.

37 *Method:* Sixty children were recruited from 12 schools (N= 6 intervention) to take part in the  
38 CHANGE! sub-sample study. Baseline, post intervention and follow measures were completed  
39 in October 2010, March-April 2011, and June-July 2011 respectively. Outcome measures were  
40 BMI z-score, waist circumference, body composition assessed using DEXA (baseline and  
41 follow up only), and VO<sub>2</sub>peak.

42 *Results:* Significant differences in mean trunk fat mass (control 4.72 kg, intervention 3.11 kg,  
43  $p = 0.041$ ) and trunk fat % (control 23.08%, intervention 17.75 %,  $p = 0.022$ ) between groups  
44 were observed at follow up. Significant differences in waist circumference change scores from  
45 baseline to follow up were observed between groups (control 1.3 cm, intervention -0.2 cm,  $p$   
46  $= 0.023$ ). Favourable changes in body composition were observed in the intervention group;  
47 however, none of these changes reached statistical significance. No significant differences in  
48 VO<sub>2</sub>peak were observed.

49 *Conclusion:* The results of the present study suggest the multicomponent curriculum  
50 intervention had small to medium beneficial effects on body size and composition health  
51 outcomes.

52

## 53 Introduction

54 Childhood obesity, poor nutritional intake, low cardiorespiratory fitness (CRF) and insufficient  
55 physical activity increase the risk of developing cardiometabolic disease (2, 3, 16). Over the  
56 last decade childhood obesity has increased (UK) (8, 40). Concurrently CRF, an independent  
57 risk factor for cardiometabolic (CM) disease, has decreased independent of changes in body  
58 size and other confounders such as maturation and deprivation (7, 8, 40).

59 Current UK guidelines recommend children participate daily in at least 60 minutes of  
60 moderate to vigorous intensity PA (MVPA) whilst engaging in vigorous PA (VPA) at least 3  
61 times per week (12). However, few children report meeting these guidelines (34, 36). Schools  
62 provide an ideal opportunity to implement an intervention designed to improve PA since  
63 children spend approximately half of their waking hours in school (15). Health promoting  
64 curriculum based interventions have been found to be successful in children, especially when  
65 utilising a multi-disciplinary approach, which combines PA and diet, and uses established  
66 behaviour change and social support processes (21, 43). Several intervention studies have  
67 aimed to increase PA, reduce sedentary time and improve nutritional intake in children in  
68 order to reduce CM disease risk, often reporting mixed levels of success (18, 30, 37, 38). These  
69 studies typically include measures of body size such as body mass index, skin fold thicknesses  
70 and waist circumference rather than composition. Furthermore the majority of studies  
71 assessed CRF in the field using the 20m multi-stage shuttle runs test, which although valid and  
72 reliable does not provide a direct assessment of peak oxygen uptake ( $VO_2$ peak). The  
73 Children's Health, Activity and Nutrition: Get Educated! (CHANGE!) intervention was designed  
74 to improve PA levels and healthy eating behaviours of 10-11 year old children using a school-  
75 based curriculum intervention delivered by in-service teachers (14). The main intervention

76 outcomes have been reported elsewhere (14). Briefly, significant differences between the  
77 control and intervention group were observed in waist circumference at post intervention  
78 and BMI z-scores and light intensity physical activity at follow up. As part of the CHANGE!  
79 study a sub-sample of children were invited to take part in some additional laboratory based  
80 measures, including treadmill assessed peak oxygen uptake ( $VO_{2peak}$ ) and DEXA scans to  
81 provide detailed information on body composition. This study reports outcomes from the  
82 sub-sample group who participated in these additional measures rather than the full  
83 CHANGE! pragmatic evaluation group. The aim of this analysis was to assess changes in  
84 measures of body size and  $VO_{2peak}$  between baseline and post intervention and baseline and  
85 10 week follow between the control and intervention group in the CHANGE! sub-sample. In  
86 addition, differences in pre-follow up DEXA assessed body composition between the control  
87 and intervention groups were also examined. This study extends the previous CHANGE!  
88 pragmatic evaluation study by examining changes on reference standard measures of body  
89 composition and cardiorespiratory fitness in the sub-sample participants.

90

## 91 **Materials and Methods**

### 92 **Participants and Study Design**

93 After receiving institutional ethical approval 12 primary schools from the Wigan Borough in  
94 North West England were recruited to participate within the clustered randomized controlled  
95 pilot trial, registered with Current Controlled Trials (ISRCTN03863885). All children within  
96 Year 6 (10 - 11.9 y) were invited to take part in the CHANGE! study from each school (N = 420).  
97 At baseline informed parental consent and participant assent was received from 318  
98 participants (75.7% participation rate), the results of the whole sample are reported

99 elsewhere (14). A stratified random sub-sample of sixty participants (5 participants from each  
100 participating school), were invited to take part in these additional study measures, and are  
101 reported here. The sample size was based on feasibility of data collection and the resources  
102 available to the research team. If the selected children did not wish to participate in the sub-  
103 ample measures another participant was randomly selected from the volunteers in the school  
104 using the random number generator function in SPSS V.17 (SPSS Inc., Chicago, IL.) This  
105 sampling approach was completed until parental consent and participant assent was received  
106 for 60 participants to take part in the subsample measures. The number of children invited to  
107 take part in the subsample vs the number agreeing to participate were not recorded.  
108 Approximately 95% of the children were of white British ethnicity, which is representative of  
109 the school age population in Wigan (45). Schools were randomised to an intervention (N = 6  
110 schools) or control condition (N = 6 schools) prior to baseline measures being completed in  
111 October 2010. Randomisation occurred prior to baseline measures to allow enough time for  
112 the teacher training sessions to take place, and was completed using the random number  
113 generator function in SPSS v17 (SPSS Inc., Chicago IL). Post intervention measures were  
114 completed after the 20 week intervention period in March and April 2011 for all measures  
115 with the exception of DEXA assessed body composition, which was assessed at baseline and  
116 follow up only. Follow up laboratory measures were taken 8 to 10 weeks after the  
117 intervention ended, prior to the school summer holidays in June-July 2011. One intervention  
118 school withdrew from the CHANGE! project shortly after baseline measurements leaving a  
119 subsample of 30 children in the control group, and 25 in the intervention group (total N = 55,  
120 N = 24 boys, 31 girls).

## 121 **Intervention Design**

122 The CHANGE! Intervention including details on lesson topics has been described elsewhere  
123 (14). Briefly the CHANGE! Intervention was designed and adapted from the Planet Health  
124 resources that have been used in the USA (19). The adaptations were made following  
125 formative work which has been described elsewhere (9, 29). The CHANGE! topics were  
126 aligned with the UK Healthy Schools programme and were cross-referenced to English  
127 National Curriculum objectives in Personal Social Health and Economic Education (PSHE) PE,  
128 Maths, Science, ICT, English, Geography and History (35). In total the CHANGE! Intervention  
129 consisted of 20 lesson plans which included worksheets, and other resources, and were also  
130 supported by homework tasks which involved the whole family, since the formative work  
131 emphasised the importance of family support. The CHANGE! lesson themes, titles and  
132 content summary have been published previously (14). Briefly themes such as energy  
133 balance, reducing sedentary time, what physical activity is and where children are active were  
134 amongst the topics covered.

135

## 136 **Outcome Measures**

### 137 **Anthropometrics**

138 Stature and sitting stature were measured to the nearest 0.1 cm and body mass to the  
139 nearest 0.1 kg using a stadiometer (Seca, Bodycare, Birmingham, UK) and calibrated  
140 electronic scales (Seca, Bodycare, Birmingham, UK) using standard techniques (28). Body  
141 Mass Index (BMI) was calculated using the equation  $\text{body mass (kg)} \div \text{height (m)}^2$ . Waist  
142 Circumference (WC) was measured using a non-elastic anthropometric tape. Measurements

143 were taken at the narrowest point between the bottom of the ribs and the iliac crest by one  
144 researcher.

### 145 **Body Composition**

146 Body composition was assessed at baseline and follow up using fan beam dual energy x-ray  
147 absorptiometry (DEXA) (Hologic QDR series, Delphi A, Bedford, Massachusetts, USA) in the  
148 whole body scan mode. Participants were scanned in a supine position in lightweight clothing  
149 and without shoes. All scans were carried out by the same qualified researcher and were  
150 analysed using Hologic QDR software for Windows version 11.2. All scans were completed in  
151 accordance with standard operating procedures and after completing the necessary quality  
152 control checks including daily calibration. Key variables assessed from the whole body scan  
153 were absolute (kg) fat mass and lean tissue mass, and relative (%) body fat. Segmental analysis  
154 was also carried out to assess the distribution of body fat and the key variables of interest  
155 were trunk fat mass, and relative (%) trunk fat, peripheral (arms and legs) fat mass (PFM), and  
156 relative (%) peripheral fat.

157

### 158 **Somatic Maturation**

159 Somatic maturation was estimated using the sex specific regression equations (32) by  
160 determining years from peak height velocity. This method has been used previously in similar  
161 paediatric populations (20, 25) and shows acceptable agreement with skeletal age (32).

162

### 163 **Estimation of Deprivation**

164 To account for the known associations between deprivation and health outcomes, postcodes  
165 for the primary address of each participant were collected and indices of multiple deprivation



166 score (IMD) were calculated using Geoconvert (<http://geoconvert.mimas.ac.uk/>) which uses  
167 data from the National Statistics Postcode Database November 2010. The IMD score was then  
168 retained for analysis.

169

### 170 **Cardiorespiratory Fitness (VO<sub>2</sub>peak)**

171 Peak oxygen uptake (VO<sub>2</sub>peak) was assessed using an individually calibrated continuous  
172 incremental treadmill (H P Cosmos, Traunstein, Germany) test to volitional exhaustion, under  
173 ambient conditions, using an online gas analysis system (Jaeger Oxycon Pro, Viasys Health  
174 Care, Warwick, UK). All participants wore an accelerometer (Actigraph GT1M, ActiGraph LLC,  
175 Pensacola, FL, USA) on the right hip and a heart rate monitor (Polar, Kempele, Finland)  
176 throughout the test. In order to account for individual variation in limb length, the VO<sub>2</sub>peak  
177 test speeds were calibrated individually by setting treadmill speeds to set Froude (Fr)  
178 numbers. Dynamic similarity theory suggests that geometrically, individuals will have similar  
179 gait dynamics if the Fr number is kept constant (1). According to this theory optimum walking  
180 speed will be at Fr 0.25, with the transition between walking and running occurring close to  
181 Fr 0.5 regardless of variations in body size (31). Therefore treadmill speeds were calculated  
182 individually using the equation:

$$183 \quad Fr = v^2 / (g \times l)$$

184 [Where v is speed of movement (m/sec), g is gravity, l is leg length (m)]

185 The protocol involved 2 minute incremental stages; stage 1 was programmed to individual  
186 walking speed equivalent to Fr 0.25; stage 2 was programmed to a speed equivalent of Fr 0.5;  
187 subsequent stage increments were based on researcher judgement using respiratory  
188 exchange ratio (RER) and heart rate (HR) of participant as a guide and either involved an

189 increase in speed, determined by the difference in speed for stages one and two  
190 (approximately 1 to 2 km/h), or by an increase in gradient.  $VO_{2peak}$  was determined as the  
191 highest 15-s averaged oxygen uptake achieved during the test when participants exhibited  
192 subjective indicators of peak effort that were confirmed by a  $RER \geq 1.05$  and/or  $HR \geq 195$   
193  $beats \cdot min^{-1}$ . This protocol has been used previously in similar paediatric studies (10, 24).

194

### 195 **Statistical Analysis**

196 All analyses were conducted using SPSS V.17 (SPSS Inc., Chicago, IL.). Participant  
197 characteristics were compared at baseline using multivariate analysis of covariance  
198 (MANCOVA) controlling for sex and IMD. Differences in mean waist circumference, BMI Z-  
199 scores, body composition measures and  $VO_{2peak}$  between participants in the intervention  
200 and control groups at each time point were assessed using MANCOVA with somatic  
201 maturation, IMD and sex as covariates. Change scores between baseline and post  
202 intervention and baseline and follow up were calculated for waist circumference, BMI Z-  
203 scores, body composition measures (baseline and follow up only) and  $VO_{2peak}$ . Group  
204 differences between mean change scores were assessed using MANCOVA with sex, somatic  
205 maturity at baseline, IMD, and baseline measure value as covariates. This method has been  
206 recommended for use in randomised control trials (RCTs), and generally has greater statistical  
207 power than other methods when analysing the effects of RCTs (44). Partial eta squared ( $\eta^2$ )  
208 values provide estimates of effect sizes for the main analyses where partial  $\eta^2 \geq 0.01$ , 0.09  
209 and 0.25 classified as small, medium and large effect sizes respectively (33).

210

### 211 **Results**

212 Participant characteristics are presented for the control and intervention groups in Table 1.  
213 Groups were well matched at baseline. Table 2 shows adjusted means (SD) for measures at  
214 baseline, post intervention and follow up. For the comparison of mean values between  
215 groups, there were no significant differences for any values at post intervention. There were  
216 also no significant differences for any values with the exception of significantly lower trunk  
217 fat mass (control group 4.7 kg, intervention group 3.1 kg,  $p = 0.041$ , partial  $\eta^2 = 0.098$ , medium  
218 effect size) and trunk fat mass % in the intervention group in comparison to the control group  
219 at follow up (control group 23.08%, intervention group 17.75%,  $p = 0.022$ , partial  $\eta^2 = 0.122$ ,  
220 medium effect size). Table 3 displays adjusted mean change scores between baseline and post  
221 intervention, and between baseline and follow up, when controlling for baseline values, sex,  
222 maturity, and IMD. For the change score analysis there were no significant differences  
223 between groups for baseline to post intervention change scores. A significant difference  
224 between groups for waist circumference change between baseline and follow up was  
225 observed after controlling for sex, maturity, baseline values, and IMD (control waist  
226 circumference change: 0.013 cm, intervention change score: -0.002cm,  $p=0.023$ , partial  $\eta^2=$   
227 0.166, medium effect size) (Table 3). There were no other statistically significant differences  
228 between groups for changes between baseline and follow up for any of the other measures.  
229  
230 The adjusted body composition (DEXA) measures showed favourable improvements in the  
231 intervention group in comparison to the control group in a range of measures (Tables 2 and  
232 3); however, none of these changes with the exception of mean trunk fat and trunk fat%  
233 reached statistical significance ( $p > 0.05$ ). Whole body fat mass decreased by 0.31 kg in the  
234 intervention group and increased by 1.84 kg in the control group (partial  $\eta^2 = 0.096$  medium  
235 effect size), and whole body fat % reduced in the intervention group by 0.68 %, whereas the

236 control group increased by 2.04 % (partial  $\eta^2 = 0.095$ , medium effect). There was a slight  
237 decrease in trunk fat mass of 0.26 kg in the intervention group, and an increase of 1.02 kg in  
238 the control group (partial  $\eta^2 = 0.024$ , small effect). Trunk fat % reduced in the intervention  
239 group by 1.32 % and increased by 2.6 % in the control group, however this change score trend  
240 did not reach statistical significance ( $p = 0.091$ , partial  $\eta^2 = 0.022$ , small effect). Peripheral fat  
241 mass also decreased slightly in the intervention group (0.04 kg) and a small increase was  
242 observed in the control group (0.80 kg, partial  $\eta^2 = 0.008$ , negligible effect). Peripheral fat  
243 mass % decreased by 0.33% in the intervention group and increased by 2.22% in the control  
244 group (partial  $\eta^2 = 0.042$ , small effect). Whole body lean mass % increased in the intervention  
245 group slightly (0.68%) in comparison to a small decline in the control group (-2.04%), however  
246 this trend was not statistically significant ( $p = 0.268$ , partial  $\eta^2 = 0.012$ , small effect). Between  
247 baseline and post intervention the control group exhibited greater changes in  $VO_2$ peak (4.1  
248 ml/kg/min) than the intervention group (2.37 ml/kg/min). Despite this, the intervention  
249 group exhibited a greater increase in  $VO_2$ peak between baseline and follow up (5.25  
250 ml/kg/min) in comparison to the control group (2.87 ml/kg/min) however this difference did  
251 not reach statistical significance ( $p=0.410$ , partial  $\eta^2 = 0.042$ , small effect).

252

## 253 **Discussion**

254 This cluster randomised study aimed to assess the effects of the school-based CHANGE! PA  
255 and healthy eating intervention on body composition and cardiorespiratory fitness in a sub-  
256 sample of 10 to 11 year old children. A significant intervention effect was detected at follow  
257 up for adjusted mean waist circumference change scores, mean trunk fat mass and trunk  
258 fat %. Furthermore, there were also favourable improvements in body composition (DEXA)  
259 measures in the intervention group in comparison to the control group (Tables 2 and 3);

260 however, none of these changes reached statistical significance ( $p > 0.05$ ), which may be due  
261 to the small sample size involved in the sub-sample cohort. Despite the lack of statistically  
262 significant findings, medium and small effect sizes were observed that suggested the  
263 intervention may have been beneficial.

264

265 The results of the present study add a degree of support to the existing evidence of the  
266 effectiveness of combined curriculum based PA and nutrition interventions on lifestyle-  
267 related health outcomes. The changes observed in mean trunk fat (mass and %) and waist  
268 circumference suggest reductions in central adiposity in the intervention group. Waist  
269 circumference and DEXA assessed trunk fat predict visceral fat (11, 41) and are positively  
270 associated with cardiometabolic risk factors in children (5, 39). The small to medium  
271 improvements in central adiposity observed, equating to a change score difference of 1.5cm  
272 between the control and intervention group at follow up, may be associated with reduced  
273 disease risk therefore representing an important intervention effect. Significant differences  
274 in waist circumference were also observed between the intervention and control groups in  
275 the main CHANGE! trial, however these improvements were statistically significant at post  
276 intervention only. Other physical activity and dietary intervention studies have reported  
277 improvements in waist circumference, for example the Lekker Fit! (26) study conducted with  
278 9-12 year old children reported significant improvements in waist circumference in the  
279 intervention group, however their reported decrease in waist circumference was greater at  
280 0.71 cm (26). Unlike the main CHANGE! study, no significant changes in BMI Z-scores were  
281 observed between the intervention and control groups either at post intervention or follow  
282 up, though the intervention group exhibited smaller Z-score changes between baseline and  
283 follow up (0.01 Z-score units) than the control group (0.48 Z-score units, partial  $\eta^2 = 0.056$ ,

284 small effect), suggesting favourable changes in the intervention group in overall body size,  
285 though these did not reach statistical significance. Other intervention studies have  
286 demonstrated significant improvements in BMI z-scores, with significant decreases in  
287 intervention children's BMI z-scores (0.2 units) observed after two years follow-up in the  
288 APPLE Project (42), and in the Planet Health intervention study obesity prevalence  
289 significantly reduced in girls (19). Any reduction in BMI z-scores is thought to be clinically  
290 meaningful (6), reducing the risk of cardiometabolic disease (22, 23), therefore despite the  
291 lack of statistical significance the medium effects observed for BMI z-scores may have been  
292 meaningful in our study.

293

294 Despite differences in other measures of body size and body composition failing to reach  
295 statistical significance small and medium effect sizes demonstrate potentially beneficial  
296 changes in total body fat and peripheral fat mass between groups at follow up. These findings  
297 suggest that the CHANGE! intervention may have improved body composition, but that the  
298 sub-sample study was not suitably powered to detect changes. Future studies should aim to  
299 include larger sample sizes in all key outcome measures to better examine the effect of the  
300 intervention on body composition. Despite this recommendation, the use of DEXA in  
301 children's studies on a large scale is not always feasible, due to a lack of facilities and resources  
302 available.

303

304 When assessing change in  $VO_{2peak}$  from baseline to follow up the control group slightly  
305 increased  $VO_{2peak}$  (adjusted mean (SE) change = 2.87 (1.7) [95% CI -2.8, 4.2] ml/kg/min),  
306 whereas the intervention group increased  $VO_{2peak}$  by over 5 ml/kg/min. The difference in  
307  $VO_{2peak}$  between groups did not reach statistical significance ( $p = 0.410$ ). Other studies have

308 demonstrated greater increases in fitness immediately following multi-disciplinary curriculum  
309 based interventions (27, 30, 38), however, fitness was assessed using different methods to  
310 CHANGE!. The small improvement in VO<sub>2</sub>peak in the intervention group between baseline  
311 and follow up equates to an increase of 2.8%, representing a small effect size. In a review of  
312 22 aerobic training studies, there was an average improvement in VO<sub>2</sub>peak of 5-6%, and  
313 greatest improvements were evident where training intensity exceeded 80% HR max (4). In  
314 light of this, the improvement in the present study is low, and suggests that any changes in  
315 physical activity were not of sufficient intensity or duration to stimulate significantly improved  
316 fitness. Despite the minor intervention effects observed, cross sectional studies have  
317 demonstrated the negative relationship between clustered cardiometabolic risk and VO<sub>2</sub>peak  
318 (3, 10, 17) and therefore the small improvement in VO<sub>2</sub>peak observed in the current study, if  
319 sustained, may be physiologically beneficial.

320

321 The CHANGE! intervention was underpinned by a programme of formative work (9, 29) as  
322 well as reviews of empirical evidence related to school-based physical activity and nutrition  
323 interventions. Empirical evidence consistently reported that multi-component studies stood  
324 the best chance of success and formative work highlighted key issues of importance to the  
325 target population. The theoretically underpinned curriculum intervention that was adjusted  
326 to the needs of the population involved (9, 29) in combination with homework tasks to  
327 promote family engagement (13) may have created an environment conducive to behaviour  
328 change, thus accounting for the changes observed in body composition and body size  
329 observed. In the absence of a thorough process evaluation it is difficult to establish which  
330 components of the CHANGE! intervention were successful or unsuccessful, therefore future

331 studies should build-in thorough process evaluation measures to provide this important  
332 information going forwards.

333

#### 334 *Strengths and Limitations*

335 Over 75% of children invited to take part in the main CHANGE! study consented to take part,  
336 and the subsample was randomly invited to participate from this group, therefore reducing  
337 the risk of sampling bias. Despite this, records were not kept to examine how many  
338 participants declined to participate in the subsample groups, so recruitment rates cannot be  
339 calculated. Randomisation into treatment groups was by school therefore reducing risk of  
340 intervention contamination to control group children, however randomization occurred prior  
341 to baseline measures. The intervention content was informed by opinions and beliefs of the  
342 participants and stakeholders and was relevant to the local context. Furthermore, the  
343 intervention was a sustainable approach since existing class teachers delivered the lessons,  
344 which were able to be integrated into the existing curriculum. Randomisation into treatment  
345 group was limited to clusters (by school) and therefore allows for the possibility of clustering  
346 of outcome observations within schools. However, at baseline control and intervention  
347 participants were well matched and analysis of the main CHANGE! intervention study found  
348 no significant influence of clustering on outcomes. Statistical analysis presented within the  
349 present study controlled for baseline results, as well as sex, deprivation (IMD), and maturation  
350 therefore accounting for the influence of these covariates within analyses.

351

352 Teachers received training on how to deliver the intervention lessons; however, there were  
353 no on-going procedures in place to monitor progress or to evaluate delivery of lessons,  
354 therefore intervention fidelity is unknown. The study used reference standard measurement



355 techniques to assess body composition (DEXA), and CRF (individually calibrated treadmill  
356 based VO<sub>2</sub>peak protocol). In larger scale studies the combination of such high quality  
357 measures are rarely utilised. However, the sample size for the subsample was relatively small.  
358 This would have therefore reduced statistical power and may account for some between  
359 group and time-point differences failing to reach statistical significance; furthermore, due to  
360 the small sample size and narrow age range of participants, the results may not be generalised  
361 to a wider population. This study demonstrates that conducting reference standard measures  
362 in children is possible and feasible, however a larger sample size is needed in future to obtain  
363 the necessary statistical power to detect any changes in health outcomes. A strength of the  
364 study was that it included a follow up investigation period. However, this was relatively short  
365 (8 to 10 weeks) and a longer term follow up is required to determine whether any intervention  
366 effects were maintained long-term.

367

### 368 *Conclusions*

369 The present study demonstrated short-term positive intervention effects with statistically  
370 significant improvements in waist circumference, mean trunk fat mass and mean trunk fat  
371 mass % at follow up. Given the association between central adiposity and disease risk, these  
372 changes are likely to be beneficial. The study also demonstrated some small to medium  
373 improvements in other markers including whole body fat %, lean mass % and VO<sub>2</sub>peak at  
374 follow up. Since the CHANGE! intervention focused mainly on behaviour change, it is possible  
375 that any behavioural changes may not have clinical influence immediately after intervention.  
376 Therefore a similar study involving a greater number of participants and longer term follow  
377 up is required in order to establish if behaviour can transition into clinical health benefits  
378 using the CHANGE! intervention approach.

379 **References**

- 380 1. Alexander RM. Optimization and gaits in the locomotion of vertebrates. *Physiol Rev.*  
381 1989;69:1199-227.
- 382 2. Andersen LB, Harro M, Sardinha LB, et al. Physical activity and clustered cardiovascular  
383 risk in children: a cross-sectional study (The European Youth Heart Study) *Lancet.*  
384 2006;368(9532):229-304.
- 385 3. Andersen LB, Sardinha LB, Froberg K, Riddoch CJ, Page AS, Andersen SA. Fitness,  
386 fatness and clustering of cardiovascular risk factors in children from Denmark, Estonia and  
387 Portugal: The European Youth Heart Study. *International Journal of Pediatric Obesity.*  
388 2008;3:58-66.
- 389 4. Baquet G, van Praagh E, Berthoin S. Endurance training and aerobic fitness in young  
390 people. *Sports Medicine.* 2003;33(15):1127-43. PubMed PMID: 14719981. Epub 2004/01/15.  
391 eng.
- 392 5. Bassali R, Waller JL, Gower B, Allison J, Davis CL. Utility of waist circumference  
393 percentile for risk evaluation in obese children. *Int J Pediatr Obes.* 2010;5(1):97-101. PubMed  
394 PMID: 19606372. PMCID: 2851850. Epub 2009/07/17. eng.
- 395 6. Bell LM, Byrne S, Thompson A, et al. Increasing body mass index z-score is continuously  
396 associated with complications of overweight in children, even in the healthy weight range. *J*  
397 *Clin Endocrinol Metab.* 2007 Feb;92(2):517-22. PubMed PMID: 17105842. Epub 2006/11/16.  
398 eng.
- 399 7. Boddy LM, Fairclough SJ, Atkinson G, Stratton G. Changes in cardiorespiratory fitness  
400 in 9-10.9 year old children: SportsLinx 1998-2010. *Medicine and Science in Sports and*  
401 *Exercise.* 2012 Aug 3. PubMed PMID: 21814150. Epub 2011/08/05. Eng.
- 402 8. Boddy LM, Hackett AF, Stratton G. Changes in fitness, body mass index and obesity in  
403 9-10 year olds. *Journal of Human Nutrition and Dietetics* 2010;23(3):254-9.
- 404 9. Boddy LM, Knowles ZR, Davies IG, et al. Using formative research to develop the  
405 healthy eating component of the CHANGE! school-based curriculum intervention. *BMC Public*  
406 *Health.* 2012;12:710. PubMed PMID: 22931457. PMCID: 3548762. Epub 2012/08/31. eng.
- 407 10. Boddy LM, Murphy MH, Cunningham C, et al. Physical activity, cardiorespiratory  
408 fitness, and clustered cardiometabolic risk in 10- to 12-year-old school children: The REACH  
409 Y6 study. *American journal of human biology : the official journal of the Human Biology*  
410 *Council.* 2014 Jul;26(4):446-51. PubMed PMID: 24599609.
- 411 11. Brambilla P, Bedogni G, Moreno LA, et al. Crossvalidation of anthropometry against  
412 magnetic resonance imaging for the assessment of visceral and subcutaneous adipose tissue  
413 in children. *Int J Obes (Lond).* 2006 Jan;30(1):23-30. PubMed PMID: 16344845.
- 414 12. Department of Health. Start Active, Stay Active: A report on physical activity for health  
415 from the four home countries' Chief Medical Officers. 2011.
- 416 13. Duncan S, McPhee JC, Schluter PJ, Zinn C, Smith R, Schofield G. Efficacy of a  
417 compulsory homework programme for increasing physical activity and healthy eating in  
418 children: the healthy homework pilot study. *Int J Behav Nutr Phys Act.* 2011;8:127. PubMed  
419 PMID: 22085440. PMCID: 3256102. Epub 2011/11/17. eng.
- 420 14. Fairclough SJ, Hackett AF, Davies IG, et al. Promoting healthy weight in primary school  
421 children through physical activity and nutrition education: a pragmatic evaluation of the  
422 CHANGE! randomised intervention study. *BMC Public Health.* 2013 Jul 2;13(1):626. PubMed  
423 PMID: 23819701. Epub 2013/07/04. Eng.

- 424 15. Fox KR, Cooper A, McKenna J. The school and promotion of children's health  
425 enhancing physical activity: perspectives from the United Kingdom. *Journal of School Health*.  
426 2004;2:338-58.
- 427 16. Freedman DS, Mei Z, Srinivasan SR, Berenson GS, Dietz WH. Cardiovascular risk factors  
428 and excess adiposity among overweight children and adolescents: the Bogalusa Heart Study.  
429 *Journal of Pediatrics* 2007;150(1):12-7 e.
- 430 17. Gobbi RM, Davies IG, Fairclough SJ, et al. Clustered Cardiometabolic Risk,  
431 Cardiorespiratory fitness and Physical Activity in 10-11 year old children. The CHANGE! Project  
432 Baseline." *Archives of Exercise in Health and Disease* 2012;3(3):207-13.
- 433 18. Gorely T, Nevill ME, Morris JG, Stensel DJ, Nevill A. Effect of a school-based  
434 intervention to promote healthy lifestyles in 7-11 year old children. *Int J Behav Nutr Phys Act*.  
435 2009;6:5. PubMed PMID: 19154622. PMCID: 2637227.
- 436 19. Gortmaker SL, Peterson K, Wiecha J, et al. Reducing obesity via a school-based  
437 interdisciplinary intervention among youth: Planet Health. *Archives of Pediatrics and*  
438 *Adolescent Medicine*. 1999 Apr;153(4):409-18. PubMed PMID: 10201726. Epub 1999/04/14.  
439 eng.
- 440 20. Graves LEF, Ridgers ND, Atkinson G, Stratton G. The effect of active video gaming on  
441 children's physical activity, behaviour preferences and body composition. *Pediatric Exercise*  
442 *Science*. 2010;22:535-46.
- 443 21. Greaves CJ, Sheppard KE, Abraham C, et al. Systematic review of reviews of  
444 intervention components associated with increased effectiveness in dietary and physical  
445 activity interventions. *BMC Public Health*. 2011;11:119. PubMed PMID: 21333011. PMCID:  
446 3048531. Epub 2011/02/22. eng.
- 447 22. Hobkirk JP, King RF, Davies I, et al. The metabolic inter-relationships between changes  
448 in waist circumference, triglycerides, insulin sensitivity and small, dense low-density  
449 lipoprotein particles with acute weight loss in clinically obese children and adolescents.  
450 *Pediatr Obes*. 2014 Jun;9(3):209-17. PubMed PMID: 23616363.
- 451 23. Hobkirk JP, King RF, Gately P, et al. The predictive ability of triglycerides and waist  
452 (hypertriglyceridemic waist) in assessing metabolic triad change in obese children and  
453 adolescents. *Metab Syndr Relat Disord*. 2013 Oct;11(5):336-42. PubMed PMID: 23758076.
- 454 24. Hopkins ND, Stratton G, Maia J, et al. Heritability of Arterial Function, Fitness, and  
455 Physical Activity in Youth: A Study of Monozygotic and Dizygotic Twins. *Journal of Pediatrics*  
456 2010;157:943-8.
- 457 25. Hopkins ND, Stratton G, Tinken TM, et al. Relationships between measures of fitness,  
458 physical activity, body composition and vascular function in children. *Atherosclerosis*.  
459 2009;204(1):244-9.
- 460 26. Jansen W, Borsboom G, Meima A, et al. Effectiveness of a primary school-based  
461 intervention to reduce overweight. *International Journal of Pediatric Obesity*. 2011;6(2):e70-  
462 e7.
- 463 27. Jansen W, Borsboom G, Meima A, et al. Effectiveness of a primary school-based  
464 intervention to reduce overweight. *International journal of pediatric obesity*. 2011 Jun;6(2-  
465 2):e70-7. PubMed PMID: 21609245. Epub 2011/05/26. eng.
- 466 28. Lohman T, Roche AF, Martorell R. Anthropometric standardization reference manual.  
467 Kinetics H, editor. Champaign, Illinois 1991.
- 468 29. Mackintosh KA, Knowles ZR, Ridgers ND, Fairclough SJ. Using formative research to  
469 develop CHANGE!: a curriculum-based physical activity promoting intervention. *BMC Public*  
470 *Health*. 2011;11:831. PubMed PMID: 22032540. PMCID: 3214189. Epub 2011/10/29. eng.

- 471 30. Manios Y, Moschandreas J, Hatzis C, Kafatos A. Health and nutrition education in  
472 primary schools of Crete: changes in chronic disease risk factors following a 6-year  
473 intervention programme. *Br J Nutr.* 2002 Sep;88(3):315-24. PubMed PMID: 12207842.
- 474 31. Minetti AE. Walking on other planets. *Nature* 2001;409:467-8.
- 475 32. Mirwald R, Baxter-Jones A, Bailey D, Beunen G. An assessment of maturity from  
476 anthropometric measurements. *Medicine and Science in Sports and Exercise.* 2002;34(4):689-  
477 94.
- 478 33. MRC Cognition and Brain Sciences Unit. Rules of thumb on magnitudes of effect sizes  
479 [20.02.206]. Available from: <http://imaging.mrc-cbu.cam.ac.uk/statswiki/FAQ/effectSize>
- 480 34. Ness AR, Leary SD, Mattocks C, et al. Objectively Measured Physical Activity and Fat  
481 Mass in a Large Cohort of Children *PLoS Med.* 2007;4(3):e97.
- 482 35. Qualifications and Curriculum Authority. Personal, social and health education key  
483 stage 2. Non-statutory content. 1999.
- 484 36. Riddoch CJ, Mattocks C, Deere K, et al. Objective measurement of levels and patterns  
485 of physical activity. *Archives of Disease in Childhood.* 2007 Nov;92(11):963-9. PubMed PMID:  
486 17855437. PMCID: 2083612. Epub 2007/09/15. eng.
- 487 37. Rosenbaum M, Nonas C, Weil R, et al. School-based intervention acutely improves  
488 insulin sensitivity and decreases inflammatory markers and body fatness in junior high school  
489 students. *Journal of clinical endocrinology and metabolism.* 2007 Feb;92(2):504-8. PubMed  
490 PMID: 17090635. Epub 2006/11/09. eng.
- 491 38. Slawta JN, DeNeui D. Be a Fit Kid: nutrition and physical activity for the fourth grade.  
492 *Health Promot Pract.* 2010 Jul;11(4):522-9. PubMed PMID: 19129432.
- 493 39. Steene-Johannessen J, Kolli, Bo Andersen L, Anderssen SA. Adiposity, aerobic fitness,  
494 muscle fitness, and markers of inflammation in children. *Medicine and Science in Sports and*  
495 *Exercise.* 2013;45(4):714-21.
- 496 40. Stratton G, Canoy D, Boddy LM, Taylor SR, Hackett AF, Buchan IE. Cardiorespiratory  
497 fitness and body mass index of 9-11-year-old English children: a serial cross-sectional study  
498 from 1998 to 2004. *International Journal of Obesity.* 2007;31(7):1172-8.
- 499 41. Taylor RW, Jones IE, Williams SM, Goulding A. Evaluation of waist circumference,  
500 waist-to-hip ratio, and the conicity index as screening tools for high trunk fat mass, as  
501 measured by dual-energy X-ray absorptiometry, in children aged 3-19 y. *Am J Clin Nutr.* 2000  
502 Aug;72(2):490-5. PubMed PMID: 10919946.
- 503 42. Taylor RW, McAuley KA, Barbezat W, Strong A, Williams SM, Mann JI. APPLE Project:  
504 2-y findings of a community-based obesity prevention program in primary school age  
505 children. *The American Journal of Clinical Nutrition.* 2007 Sep;86(3):735-42. PubMed PMID:  
506 17823440. Epub 2007/09/08. eng.
- 507 43. van Sluijs EM, McMinn AM, Griffin SJ. Effectiveness of interventions to promote  
508 physical activity in children and adolescents: systematic review of controlled trials. *BMJ.* 2007  
509 Oct 6;335(7622):703. PubMed PMID: 17884863. PMCID: 2001088. Epub 2007/09/22. eng.
- 510 44. Vickers AJ, Altman DG. Analysing controlled trials with baseline and follow up  
511 measures. *BMJ.* 2001;323:1123-4.
- 512 45. Wigan Council. Equality information and objectives 2011 [cited 2016 29th February].  
513 Available from: [http://www.wigan.gov.uk/Council/Strategies-Plans-and-Policies/Equality-](http://www.wigan.gov.uk/Council/Strategies-Plans-and-Policies/Equality-and-Diversity/Equality-information-and-objectives.aspx)  
514 [and-Diversity/Equality-information-and-objectives.aspx](http://www.wigan.gov.uk/Council/Strategies-Plans-and-Policies/Equality-and-Diversity/Equality-information-and-objectives.aspx).

516 **Tables**

517 Table 1. Participant characteristics at baseline adjusted for sex and IMD

	<b>Control N= 27</b>		<b>Intervention N= 26</b>	
	mean	(SE)	mean	(SE)
Age	10.62	(0.06)	10.64	(0.06)
Somatic Maturation (Years)	-1.99	(0.08)	-1.99	(0.08)
Stature (m)	1.46	(0.01)	1.45	(0.01)
Sitting Stature (m)	0.72	(0.007)	0.73	(0.007)
Mass (kg)	39.9	(1.5)	37.5	(1.5)
BMI (kg/m <sup>2</sup> )	18.5	(0.53)	17.82	(0.54)
BMI z-scores	0.43	(0.2)	0.24	(0.2)
Waist circumference (cm)	63	(0.01)	62	(0.01)

518

519 BMI = Body mass index

520 Table 2 Adjusted mean (SE) and partial  $\eta^2$  for waist circumference, BMI Z-score, and VO<sub>2</sub>peak at  
 521 baseline, post intervention and follow up (where available), controlling for somatic maturation, IMD  
 522 and sex

Variable	Time point	Control N= 24		Intervention N= 22		P Value	Partial $\eta^2$
		mean	(SE)	mean	(SE)		
Waist Circumference (CM)	Baseline	63.8	0.01	61.5	0.02	.286	0.028
	Post intervention	65	0.01	61.3	0.01	.074	0.076
	Follow Up	64.7	0.01	62.1	0.01	.212	0.038
BMI Z-score	Baseline	0.44	0.21	0.27	0.22	.581	0.008
	Post intervention	0.49	0.22	0.26	0.22	.459	0.013
	Follow Up	0.48	0.2	0.01	0.21	.128	0.056
VO <sub>2</sub> peak (ml/kg/min)	Baseline	41.41	1.96	44.4	2.06	.320	0.024
	Post Intervention	46.49	1.12	45.66	1.17	.620	0.006
	Follow Up	44.61	1.7	49.26	1.78	.076	0.075
Whole Body Fat Mass (kg)	Baseline	11.34	0.88	9.62	0.93	.202	0.039
	Follow Up	12.69	1.11	9.84	1.16	.093	0.067
Whole Body Fat %	Baseline	26.34	1.29	24.3	1.35	.30	0.026
	Follow Up	27.98	1.42	24.05	1.49	.073	0.076
Trunk Fat Mass (kg)	Baseline	4.02	0.42	3.02	0.44	.117	0.059
	<b>Follow Up</b>	<b>4.72</b>	<b>0.51</b>	<b>3.11</b>	<b>0.53</b>	<b>0.041*</b>	<b>0.098</b>
Trunk Fat %	Baseline	21.04	1.35	18.13	1.42	.159	0.048
	<b>Follow Up</b>	<b>23.08</b>	<b>1.49</b>	<b>17.75</b>	<b>1.56</b>	<b>.022*</b>	<b>0.122</b>
Peripheral Fat Mass (kg)	Baseline	6.52	0.48	5.82	0.5	.334	0.023
	Follow Up	7.17	0.61	5.95	0.63	.187	0.042
Peripheral Fat %	Baseline	32.03	1.68	30.17	1.76	.462	0.013
	Follow Up	34.01	1.81	30.11	1.90	.159	0.048

Whole Lean Body Mass (kg)	Baseline	2.93	0.46	2.88	0.48	.470	0.013
	Follow Up	3.01	0.94	2.88	0.48	.935	0.000
Whole Lean Body Mass %	Baseline	73.67	1.29	75.70	1.35	.300	0.026
	Follow Up	72.03	1.42	75.95	1.49	.073	0.076

523

524 \* denotes significant difference between control and intervention groups

525 Table 3. Change scores (SE) and partial  $\eta^2$  between groups at all time points, controlling for sex,  
 526 somatic maturation (baseline), IMD and baseline values

Variable	Time point	Control N= 24		Intervention N= 22		P Value	Partial $\eta^2$
		Change Score	(SE)	Change Score	(SE)		
Waist Circumference (cm)	Baseline to Post	1.1	0.5	0.4	0.5	.355	0.030
	<b>Baseline to Follow Up</b>	<b>1.3</b>	<b>0.4</b>	<b>-0.2</b>	<b>0.4</b>	<b>.023*</b>	<b>0.166</b>
BMI Z-score	Baseline to Post	0.042	0.097	0.001	0.102	.792	0.002
	Baseline to Follow Up	0.042	0.096	0.002	.102	.796	0.002
VO <sub>2</sub> peak (ml/kg/min)	Baseline to Post	4.10	0.90	2.37	0.95	.239	0.052
	Baseline to Follow Up	2.87	1.77	5.25	1.87	.410	0.042
Whole Body Fat Mass (kg)	Baseline to Follow Up	1.84	1.06	-0.31	1.12	.219	0.096
Whole Body Fat %	Baseline to Follow Up	2.04	1.50	-0.68	1.58	.268	0.095
Trunk Fat Mass (kg)	Baseline to Follow Up	1.02	0.45	-0.26	0.48	.090	0.024
Trunk Fat %	Baseline to Follow Up	2.60	1.5	-1.32	1.58	.091	0.022
Peripheral Fat Mass (kg)	Baseline to Follow Up	0.80	0.61	-0.04	0.65	.402	0.008
Peripheral Fat %	Baseline to Follow Up	2.22	1.96	-3.30	2.07	.425	0.042
Whole Lean Body Mass (kg)	Baseline to Follow Up	1.36	0.99	0.57	1.05	.623	0.000
Whole Lean Body Mass %	Baseline to Follow Up	-2.04	1.50	0.68	1.58	.268	0.012
BMC (kg)	Baseline to Follow Up	0.07	0.04	0.06	0.04	.925	0.024
BMD (g/cm <sup>2</sup> )	Baseline to Follow Up	0.017	0.013	0.005	0.014	.565	0.048

527

528 \*denotes significant difference between control and intervention group





