A pedometer-based physically active learning intervention: The importance of

2 using pre-intervention physical activity categories to assess effectiveness.

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12 Abstract

Purpose: To assess physical activity (PA) outcomes of a pedometer-based physically active learning
(PAL) intervention in primary school children.

Method: Six paired schools, were randomly allocated either to a six-week teacher-led pedometerbased PAL intervention or control (n=154, Female=60%, 9.9±0.3yrs). Accelerometers assessed total daily sedentary time, light PA (LPA) and moderate-to-vigorous PA (MVPA). Pre-intervention mean daily MVPA minutes grouped participants as Low Active (<45 minutes/day) and High Active (≥45 minutes/day).

20 **Results:** From the final sample size, the intervention (n=52) significantly improved LPA versus control 21 (n=31, p=0.04), by reducing sedentary time. More intervention (+10%) than control (+3%) pupils met 22 the 60 minutes/day guidelines. In both intervention subgroups pupils spent less time in LPA (p<0.05) 23 versus control. The greatest non-significant increase was found in the Low Active pupils MVPA levels. 24 **Conclusion:** Improvements in LPA were statistically significant in the intervention versus control 25 group. In subgroup analysis Low Active pupils in the intervention showed the greatest beneficial 26 effects and the Most Active pupils may have replaced MVPA and sedentary time with LPA. The 27 intervention group housed clusters of pupils showing variable responsiveness, justifying routine examination of subgroup variability in future studies. 28

29 Introduction

30 The beneficial effects of childhood physical activity (PA) are profound (22,44). Increased PA 31 has been associated with improvements in cardiovascular health (1), cardiometabolic risk factors 32 (4,14) and adiposity (19,23), as well as psychological health including depression (10), self-esteem and 33 reduced anxiety levels (3,27). Yet, in 38 countries around the world, including England, Canada, 34 Australia and America, less than 30% of children are sufficiently active to secure these benefits (23,43). 35 This is all-the-more alarming given the well documented adverse health outcomes for children who 36 lead inactive lifestyles (23,43). Moreover, inactivity is now considered an important global economic 37 problem due to escalating health care costs (13).

38 Overcoming high rates of physical inactivity is challenging, with no universal solution at 39 present. Given that behaviour is driven by a combination of individual, social and environmental 40 factors, children's responsiveness to PA interventions is widely variable (26,29). Although schools are 41 often a favoured environment for PA interventions targeted at children (11), data from contemporary 42 interventions continue to demonstrate limited effectiveness (46). Current national and international 43 guidelines recommend that children engage in at least 60 minutes of moderate-to-vigorous PA 44 (MVPA) each day (8,12,43,45), of which 30 minutes should be during the school day (21). Yet, school-45 based interventions typically display only small effects and short-term behavioural changes; clearly 46 some children respond powerfully, while others do not. This undermines any presumptions about 47 universal benefit arising from any provision and justifies looking at subgroup responsiveness within all intervention (11,25). In this regard, it is unhelpful that data pertaining to children have typically 48 49 utilised a single overall mean score, meaning that intervention effects may be attributed to high levels 50 of subgroup responsiveness rather than a universal intervention effect (24). Reliance on single 51 outcome averages may also conceal noteworthy detail about PA behaviour in the groups that require 52 most assistance and support (26), such as the most inactive children that are often overweight and 53 obese (41).

54 New interventions, especially those targeting lesson times - the most inactive period in a 55 child's day (2,18,34) - may offer further opportunities to improve PA. Physically active learning (PAL) provides one such avenue for intervention, whereby movement is combined with learning to replace 56 57 the typical traditional sedentary classroom lessons (35). Using a single mean outcome score, recent 58 systematic reviews and meta analyses revealed mixed success for PAL in increasing MVPA (35,45), 59 whereas a study using subgroup analyses found notable improvements in girls (36). While participant 60 variability has been identified as an important consideration when evaluating interventions (15,16), 61 subgroup analyses around PA behaviours are often overlooked (36) in favour of approaches that 62 identify 'universal' outcomes. To date, few studies have used subgroup approaches in PA and PAL research (36,40); no previous studies have conducted subgroup analyses on pre-intervention PA levels 63 64 to explore the differing effect of a PAL and pedometer-based intervention.

The present study aims to evaluate the effectiveness of a PAL intervention on children's PA
levels using subgroup analysis to reveal stratified intervention effects highlighted by pre-intervention
PA levels.

68 Materials and Methods

69 Participants and Study Design

70 Participants (n=154, intervention: n=82, females=55%, age=9.98±0.31yrs, control, n=72, 71 females=52%, age=9.89±0.29yrs) were recruited from six year 5 classes across six schools (see figure 72 1 for CONSORT flow diagram). As directed by the local public health commissioner, the intervention 73 was directed to key stage two (years 3 to 6), however the evaluation was taken with year 5 due to 74 exam commitments of the other year groups. Prior to commencing, consent was obtained from 75 headteachers and parents; and assent was obtained from pupils. Ethical clearance was granted by the 76 Leeds Beckett University Ethics Committee (reference 37482). Schools were ranked and paired by 77 socioeconomic status (SES), determined by the proportion of children receiving free school meals

(2.39% to 31.79%, M=16.37±0.10%). One school per pair was randomly allocated, by coin toss, to a
six-week teacher-led pedometer-based PAL intervention or control condition. Data collection
commenced in January 2016.

81

[Insert figure 1 here]

82 Intervention Design

83 Pre-intervention, teachers received a one-to-one PAL training session from the local School 84 Games Organiser (SGO), a qualified teacher who organises inter-school sports participation and 85 competition for all and provides teacher training workshops. The intervention was commissioned by 86 the local authority and was practitioner designed and there was an absence of a theoretical 87 underpinnings. The training consisted of providing teachers with practical strategies to integrate 88 movement within their lessons both within and outside of the classroom environment. PAL lesson 89 ideas were shared amongst participants and further support was provided to assist with lesson plan 90 modification to facilitate teachers' incorporation of activities. One example of a lesson strategy 91 involved reinforcing spelling through active spelling relays in the playground. In addition, the SGO 92 modelled a PAL lesson with the teacher's class in the school hall, combining traditional PE activities 93 with subject specific learning outcomes and involving the students in an active story.

94 During the intervention period, participants wore pedometers (SW200 Digiwalker). These 95 were used to support the delivery of PAL lessons through (a) each school identified a target destination based on a number of steps they had to achieve over the six-week period (e.g., walk to the Olympic 96 97 stadium) and (b) incorporation of the outcome data into classroom activity (e.g., to develop bar charts 98 of the number of steps undertaken). Goal setting with the pedometers was also implemented with 99 the aim to increase step counts during the six-week step challenge. In the first week, children's 100 baseline step account was assessed using the pedometers, with an expectation this target would be 101 increased each week through school-based PA. Tracking sheets were provided to monitor pupils step

- 102 count progress. Control schools were instructed to maintain their current provision. There were no
- 103 perceived adverse events from the intervention.

104 Outcome Measures

105 Physical Activity Levels

The impact of the intervention on PA was assessed by GT1M uniaxial accelerometers (ActiGraph, Pensacola, FL, USA). Control and intervention participants wore the monitors for eight days' pre-intervention and for the final eight days of the intervention (final intervention week). The accelerometers were worn on the right hip; every day, all day except for sleeping and water-based activities. Monitors recorded from the second day to allow for reactivity on day one, resulting in seven days' data collection. Counts were recorded in 15-second epochs (31).

112 Accelerometer data were downloaded using ActiLife 6, and analysed in KineSoft (v3.3.75, 113 Loughborough, UK). A period of non-wear time used the criterion of greater \geq 20-minutes of consecutive zero counts. A minimum of 480 minutes/day identified a valid day. Spurious values were 114 115 identified as ≥30,000 counts and omitted from the final data analysis. A valid profile required a minimum of three-school days (5,30). Evenson's cut-points were used, determining time spent in 116 sedentary (0-25 counts 15⁻¹), light (26-573 counts 15⁻¹), moderate (574-1002 counts 15⁻¹) and vigorous 117 118 activity (\geq 1003 counts 15⁻¹) (17). Individual accelerometer profiles were independently screened to 119 validate wear time and remove incomplete data.

120 Anthropometrics and Biological Maturation

On the day when accelerometers were fitted – the week before the intervention started participants height and weight were also collected, using Seca 217 Stadiometer (Seca, Germany) and Seca 875 Digital Weighing Scales (Seca, Germany). Participants wore their school uniform but removed jumpers and shoes. BMI and BMI SDS (standard deviation scores) were calculated and classified against British 1990 growth reference (UK90) distribution (9). Biological maturation was calculated

- using gender specific equations to predict children's age from on peak height velocity (32). This
- 127 method has been commonly used with children in similar studies (42).

128 Statistical Analysis

Average daily minutes spent sedentary, light PA (LPA) and MVPA were converted into percentages based on the average total day. Change in percentage from pre to final intervention week, and percentage of participants meeting the MVPA guidelines (60 minutes/day) were also calculated to explore pre to final intervention week differences in the intervention versus control. Analysis of Covariance tests (ANCOVA) using SPSS (Version 24) identified any significant intervention effects on sedentary time, LPA and MVPA. Covariates entered in the model were maturity offset, BMI SDS, gender and the appropriate pre activity category.

Two subgroups were created using initial accelerometery data on MVPA levels; (i) Low Active (e.g. achieved less than 45 minutes/day MVPA), and (ii) High Active (e.g. achieved more than 45 minutes/day of MVPA, including children achieving 60 minutes/day fulfilling the PA guidelines). ANCOVA tests were conducted to identify main interactions with the addition of the subgroups on sedentary time, LPA and MVPA and using the same covariates previously described. Post hoc analysis was conducted using a Bonferroni correction to look at the differences between subgroups for sedentary time, LPA and MVPA.

To determine statistical significance, α was set at p<0.05. This study did not include an a priori power calculation due to the nature of the recruitment process. As a result, the sample size was determined using a non-probability purposive sample. Nevertheless, a post hoc power calculation indicated that the study achieved 8% power. To achieve 80% power, a sample size of 128 participants would have been required (1-beta probability =0.80, alpha error probability =0.05, effect size *f*=0.25, number of groups =4, number of covariates =4).

149 Results

Eighty-three participants met the inclusion criteria (intervention: n=52, females=61.5%, age=9.92 \pm 0.34yrs, control: n=31, females=56.3%, age=9.95 \pm 0.26yrs); 69 were removed for providing (3 days of valid data at both time points (*n*Intervention=29, *n*Control=40), and 2 were removed due to missing data (*n*Intervention=1, *n*Control=1). Table 1 details characteristics for the intervention and control conditions, identifying no significant differences (p>0.05).

Main effects revealed intervention participants improved time spent in LPA (2.03±4.63% vs. -0.04±4.32%) and found a trend towards significant improvements for sedentary time (-2.33±5.90% vs. -0.14±5.60%) versus control. A significant time by group interaction was observed for LPA (p=0.04, η^2_p =0.05, 95% CI: 0.12, 4.27). No significant time by group interaction effects were observed for MVPA (p=0.65, η^2_p =0.05) or sedentary time (p=0.06, η^2_p =0.04). A seven percent greater increase was observed in the proportion of intervention participants (17% to 27%) who met the daily MVPA guidelines compared to controls (16% to 19%).

Subgroup analysis revealed no significant main interaction between subgroups and conditions 162 for MVPA (p=0.899, η^2_p =0.003), LPA (p=0.644, η^2_p =0.000) or sedentary behaviour (p=0.568, η^2_p =0.004). 163 On closer inspection, the Low Active intervention subgroup revealed a significant improvement in 164 165 percentage of time spent in LPA (2.09 \pm 5.05%, vs. 1.10 \pm 4.05, p=0.04, η^2_p =0.118) and the greatest non-166 significant improvement in time spent in MVPA (1.27±2.11% vs. 0.79±2.23, p=0.728) and sedentary time (-3.36±6.16%, vs. -1.89±4.96, p=0.08). The High Active intervention subgroup revealed the 167 greatest significant increase in time spent in LPA versus control ($1.96 \pm 4.23\%$, vs. -0.95±4.31, p=0.052, 168 η^2_p =0.099). Whilst improvements were in seen in the High Active intervention subgroup for sedentary 169 170 time, this was not statistically significant versus control (p=0.199). The High Active subgroup in both 171 the intervention and the control conditions demonstrated a small non-significant decrease in MVPA 172 levels (table 2 and figure 2).

173 When assessing the change in the proportion of participants meeting the PA guidelines of 60 174 minutes/day, stratified by the subgroups, an increase was identified in both the Low Active

intervention (+3 participants, 11%) and control subgroup (+2 participants, 15%). The High Active
intervention subgroup revealed a greater increase in participants meeting the guidelines with an
increase of 13% (+2 participants) versus a decrease of 6% (-1 participant) in the control.

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[Insert figure 2 here]

179 Discussion

180 This in-school pedometer-based PAL intervention identified statistically significant increases in LPA versus the control. The improved PA profiles indicate that LPA displaced sedentary time and 181 MVPA in the intervention group. In line with previous school-based interventions (38), this 182 183 intervention resulted in significant increases in LPA but not MVPA, and reductions in time spent being 184 sedentary. These findings are noteworthy as some international PA guidelines for children now 185 include recommendations for LPA alongside MVPA (6). Recommendations for LPA have been 186 supported by the epidemiological evidence indicating the potential benefits of increasing LPA, 187 including associations with reduced systolic blood pressure (21), diastolic blood pressure and HDL-188 cholesterol levels (7). Indeed, all intensities of PA above sedentary activity have significant beneficial associations with such cardiometabolic biomarkers (21). This reinforces the beneficial effects of the 189 190 current study for increasing LPA levels through a PAL intervention.

A further purpose of this study was to undertake a preliminary PA subgroup analysis, given few studies have explored similar subgroup analysis methods (36,40). Although we found statistically significant improvements in LPA at the group level, the standard universal approach masked behavioural differences between subgroups and incorrectly presumed all participants reacted in the same way to the intervention (26,29). Refined analysis revealed small, but varied responses to the intervention: first, the least active pupils benefitted most, an effect supported by previous literature (39). Second, both intervention subgroups revealed a significant increase in time spent in LPA (p<0.05),

however the High Active subgroup showed decreases in percentage of time spent in MVPA, suggestingthe possibility of some form of 'compensation'.

200 This compensation may be due to the subtle decline in time spent in MVPA and sedentary 201 behaviour that allowed an increase in LPA. This may suggest the beneficial effects of the intervention 202 were not as unified for High Active as the beneficial effects for the Low Active subgroup. This stratified 203 examination of the current data, using subgroup analysis, revealed varied response to the intervention 204 in groups identified as different using baseline figures. Using conventional reporting of a single value 205 of the intervention effect would overlook the distinctive responsiveness of these groups. While the 206 current study provides an interesting insight, these findings do need to be treated with some caution. 207 The small sample size may have produced an estimate for the benefits of PAL that are too imprecise 208 to be useful for planning and intervention.

209 Although a single mean statistical difference was found using traditional data analysis 210 methods, unpicking the data with subgroup analysis revealed the scale and direction of the variable 211 responses generated by a pedometer-based PAL intervention. These profiles can be used to inform 212 future interventions, on which children, to target greatest benefits. The current study is supported by 213 previous evidence on PAL interventions showing mixed success and small changes at the group level 214 (35,36). Varied responsiveness has previously been demonstrated by Oliver et al. (36) who found that 215 least active girls benefited most from a PAL intervention, whereas a whole-group analysis showed no 216 benefit. Moreover, a recent systematic review identified the scarcity of studies providing evidence on 217 a range of equity effects on interventions beyond gender (26), resulting in a lack of understanding of 218 subgroups and their varied intervention responses. The current results support the use of subgroup 219 analysis, while offering new insights into the responsiveness of a pedometer-based PAL intervention 220 based on pre-intervention PA characteristics.

One of the most important findings from our data relates to the stratified responsiveness of participants to the intervention. While there were several positive significant subgroup improvements in activity levels in the intervention, a decrease in MVPA and increase in sedentary time in the High

Active was also evident. Although this may seem negative, overall PA levels in this subgroup were still higher than all other intervention subgroups. Furthermore, these differences could be attributed from day-to-day variability, environmental influences or individual behaviours (29,37). These effects should be addressed in future research using tightly controlled designs.

228 The present study, in part, aims to encourage schools and policymakers to address the issue 229 of traditional didactic teaching methods promoting sedentary behaviour and limiting time to be 230 physically active (39). Moreover, it also endorses deploying analyses that can illustrate variations in 231 intervention effect when the intervention occurs in a confined classroom space. While the conclusions 232 emerging from these data, based on traditional analysis methods, provide some positive outcomes, further analysis exploring subgroups provides a more in-depth understanding of the intervention, 233 234 which otherwise, might have been overlooked. Acknowledging that few PA interventions will provide 235 a 'universal' fix for inactive children, analytical approaches are available to investigate individual and 236 stratified responsiveness (37). Subsequently, these individual responses need to be considered in 237 future interventions to ensure greater returns and associated benefits. The challenge for policymakers 238 and practitioners is to correctly identify intervention impact across groups with diverse baseline PA profiles, which can be used for tailored context and population implementation. 239

Several strengths are encompassed within the current study including the use of a randomised control design balanced by SES. An objective assessment of PA was also used; this is rare in schoolbased pedometer interventions (26,28). However, there was a high non-return rate resulting in a small sample size, which limits the external validity, especially for subgroup analysis. Statistical conclusions drawn from the subgroup analysis should be considered with caution, with an emphasis on the potential possibilities subgroups analysis can provide for a more in-depth analysis of PA behaviour, especially in relation to field-based studies.

This pilot study would benefit from being replicated with a sample of sufficient statistical power to support subgroup analysis that can be directly related to policy (20). Future studies expanding on the current studies analysis techniques with a sufficient sample size, would warrant

250 using more subgroups that can be aligned more appropriately to the PA guidelines and provide greater 251 public health relevance (e.g., Subgroup 1 'Non-Achievers' = achieved less than 30minutes/day MVPA, 252 Subgroup 2 'Non-Achievers' = 30-44 minutes/day, Subgroup 3 'Near-Achievers' = 45-59 minutes/day 253 and Subgroup 4 'Achievers' = more than 60minutes/day). Finally, recent conclusions around the 254 success of school-based PA interventions states that they can be successful without visible changes in 255 PA behaviour, where other potential benefits may be revealed (33). The present study assessed LPA, 256 MVPA and sedentary behaviour, future studies may include further outcome measures, including 257 psychological changes such as motivation and enjoyment (33) to explain changes in PA behaviours.

258 Conclusions

259 The current findings confirm statistically significant improvements in time spent in LPA for the 260 intervention versus control. On closer inspection, subgroup analysis identified statistical improvements in both intervention subgroups versus control, which for the Low Active subgroup may 261 262 be compensated due to decreases in sedentary behaviour, yet the more active subgroup may have 263 increased LPA due to a combination of decreased time spent in MVPA and time spent sedentary. 264 Rather than expecting universal effects from generic interventions, researchers can use subgroup 265 analysis to explore individual variability to establish the many ways children may respond to schoolbased PA interventions. Once this is established, research can move towards understanding how to 266 267 appropriately tailor intervention methods to identify and reproduce more sustainable and widespread 268 improvements.

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	Intervention (n=52)	Control (n=31)	p
Gender (Girls/Boys)	31/21	18 / 13	
Age	9.92 (0.34)	9.95 (0.26)	0.69
Maturity Offset	-2.23 (0.66)	-2.29 (0.67)	0.70
BMI	18.69 (3.47)	17.85 (2.74)	0.25
BMI SDS	0.64 (1.13)	0.37 (1.11)	0.29
Weight Category (%)			
Normal Weight	67%	68%	
Overweight	33%	32%	

388	Table 1:	Descriptive	characteristics	of the	intervention	and contro	ol conditions.

390 Table 2: Average pre-total daily percentage of time spent in MVPA and LPA and time spent being sedentary and change in percentage, stratified by condition

391 *and pre-activity group.*

	MVPA (SD)		Change in Time Spent in MVPA (SD)		LPA (SD)		Change in Time Spent in LPA (SD)		Sedentary Time (SD)		Change in Sedentary		
											Time (SD)		
	Pre %	FIW %	%	Minutes	Pre %	FIW %	%	Minutes	Pre %	FIW %	%	Minutes	
Intervention		-	-			-	-	-	-	-	-	-	
Low Active	4.32	5.59	1.27	10.35	29.93	32.02	2.09	17.47	65.75	62.40	-3.36	-16.59	
(n =27)	(0.92)	(1.94)	(2.11)	(16.15)	(3.92)	(4.75)	(5.05)	(42.97)	(4.34)	(5.91)	(6.16)	(78.61)	
High Active	7.97	7.23	-0.74	-4.86	29.66	31.62	1.96	16.91	62.38	61.16	-1.22	-7.92	
(n =25)	(1.86)	(2.08)	(2.86)	(20.21)	(4.27)	(3.92)	(4.23)	(49.00)	(5.44)	(4.47)	(5.50)	(77.31)	
TOTAL (n=52)	6.07	6.38	0.30	3.04	29.80	31.83	2.03	17.20	64.13	61.80	-2.33	-12/42	
	(2.31)	(2.15)	(2.65)	(19.60)	(4.01)	(4.34)	(4.59)	(45.51)	(5.09)	(5.26)	(5.84)	(77.35)	

	Control												
	Low Active	4.85	5.65	0.79	6.75	27.48	28.57	1.10	14.43	67.67	65.78	-1.89	2.21
	(n =13)	(1.47)	(2.72)	(2.23)	(15.98)	(4.36)	(3.34)	(4.05)	(35.72)	(5.23)	(4.19)	(4.96)	(55.19)
	High Active	8.18	7.80	-0.38	-2.13	31.84	30.90	-0.95	-6.61	59.99	61.31	1.33	3.10
	(n =18)	(2.33)	(2.34)	(2.45)	(16.40)	(7.12)	(4.55)	(4.31)	(32.72)	(8.17)	(5.76)	(5.66)	(52.76)
		6.72	6.85	0.13	1.75	29.93	29.88	-0.05	2.59	63.35	63.27	-0.08	2.71
101AL (N=32)	TOTAL (N=32)	(2.55)	(2.70)	(2.35)	(16.57)	(6.27)	(4.18)	(4.19)	(35.14)	(7.82)	(5.54)	(5.52)	(52.95)

392 NB: FIW Final Week Intervention, SD Standard Deviation. Low Active: Children active for less than 45 minutes/day; High Active: Children active for 45

393 minutes/day or more.