1 Measuring change in trials of physical activity interventions: a comparison of self-report

2 questionnaire and accelerometry within the PACE-UP trial.

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50 Abstract

51 **Background**: Few trials have compared estimates of change in physical activity (PA) levels using 52 self-reported and objective PA measures when evaluating trial outcomes. The PACE-UP trial offered 53 the opportunity to assess this, using the self-administered International Physical Activity 54 Questionnaire (IPAQ) and waist-worn accelerometry.

Methods: The PACE-UP trial (N=1023) compared usual care (n=338) with two pedometer-based walking interventions, by post (n=339) or with nurse support (n=346). Participants wore an accelerometer at baseline and 12 months and completed IPAQ for the same 7-day periods. Main outcomes were weekly minutes, all in \geq 10 minute bouts as per UK PA guidelines of: i) accelerometer moderate-to-vigorous PA (Acc-MVPA) ii) IPAQ moderate+vigorous PA (IPAQ-MVPA) and iii) IPAQ walking (IPAQ-Walk). For each outcome, 12 month values were regressed on baseline to estimate change.

Results: Analyses were restricted to 655 (64%) participants who provided data on all outcomes at baseline and 12 months. Both intervention groups significantly increased their accelerometry MVPA minutes/week compared with control: postal group 42 (95% CI 22, 61), nurse group 43 (95% CI 24, 63). IPAQ-Walk minutes/week also increased: postal 57 (95% CI 2, 112), nurse 43 (95% CI -11, 97) but IPAQ-MVPA minutes/week showed non-significant decreases: postal -11 (95% CI -65, 42), nurse -34 (95% CI -87, 19).

68 **Conclusions:** Our results demonstrate the necessity of using a questionnaire focussing on the 69 activities being altered, as with IPAQ-Walk questions. Even then, the change in PA was estimated 70 with far less precision than with accelerometry. Accelerometry is preferred to self-report 71 measurement, minimising bias and improving precision when assessing effects of a walking 72 intervention.

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76 Keywords

Walking; Intervention; Primary Care; MVPA; Accelerometry; IPAQ; GPPAQ

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80 BACKGROUND

Adults who participate in regular physical activity (PA) and remain fit and active into later life have fewer chronic health conditions, and are better able to maintain a healthy weight [1]. WHO, UK and US aerobic PA guidelines for adults recommend at least 150 minutes weekly of moderate-tovigorous-physical-activity (MVPA) in bouts of at least 10 minutes, or 75 minutes of vigorous PA, or a combination. Brisk walking (3 miles/hr or 5 km/hr) counts as MVPA[2] and for most people approximates to 1000 steps in 10 minutes[3].

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Self-report questionnaires are a quick, easy way to assess PA. Population surveys such as the Health Survey for England (HSE)[4] and Sport England's "Active Lives Survey"[5] use self-completed questionnaires and report estimates that around 60% of participants aged 16+ meet PA guidelines. However, individuals often over-estimate their PA, particularly walking, on questionnaires compared with accelerometry measures of MVPA[6-8]. Self-report questionnaires can thus lead to inflated estimates of "active" individuals[9].

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The International Physical Activity Questionnaire (IPAQ) short form[10] assesses 7-day recall of PA in \geq 10 minute bouts based on intensity (separating vigorous, moderate and walking activity) and duration (days per week and minutes per day). The shorter General Practice Physical Activity Questionnaire (GPPAQ)[11] does not provide a continuous measure of PA, but categorises individuals as active or not. GPPAQ is used in the UK National Health Service (NHS) primary care cardiovascular health checks[12]. Individuals classified as less than "active" are assumed not to be meeting PA guidelines and are offered advice. In contrast, accelerometry is an objective PA measure, providing information on step-counts and time spent in different PA intensities and is increasingly
being used in cross-sectional studies to study PA[13, 14]. Although accelerometers e.g. Actigraph are
not a gold standard for measuring PA, they have been shown to correlate well with doubly labelled
water to measure activity energy expenditure[15]. For the Actigraph GT3X accelerometer, standard
cut-points for accelerometer counts per minute (CPM) for different PA intensity categories have also
been defined, thus leading to assessment of time spent in different PA intensities: light 101-1951
CPM; moderate 1952-5724 CPM; vigorous ≥5725 CPM[16].

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110 Longitudinal studies and trials which examine PA changes over time need valid, reliable PA 111 assessment methods. Both IPAQ-Short and accelerometry have been used separately to measure PA change over time, [17-20] but only a few small studies have used both and compared change in 112 minutes of PA[21, 22]. Other studies have compared self-report PA minutes with either pedometer 113 114 steps[23, 24] or accelerometry counts[25] which are not directly comparable. The PACE-UP trial offers the opportunity to directly compare change in PA minutes from accelerometry and IPAO within 115 116 a large trial dataset. This study had the following objectives: to compare the trial treatment effects at 12 months (difference between intervention and control groups in the change in PA) using (i) 117 accelerometry minutes of MVPA and IPAQ minutes of moderate+vigorous activity and walking; (ii) 118 the percentage of "active" individuals classified by accelerometry, IPAQ and GPPAQ. 119

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121 METHODS

122 Background to the PACE-UP study

The PACE-UP study is a three-arm parallel groups randomised controlled trial comparing a 3-month pedometer-based walking intervention, delivered by post or with nurse support, to usual care[26].
Ethical approval was given by the London Research Ethics Committee (Hampstead) (12L/LO/0219),
trial registration ISRCTN 98538934. Adults aged 45-75 years from seven South-West London (UK)
General Practices (family practices) who self-reported as inactive were invited to take part. Following

a baseline assessment to assess eligibility, 1023 participants gave informed written consent and were 128 randomised into one of three groups: the Control group (n=338) received usual care; the Postal group 129 130 (n=339) received a pedometer, a 12-week personalised walking plan including behaviour change 131 techniques (e.g. goal setting, self-monitoring) designed to increase their walking and a step-count diary through the post; the Nurse group (n=346) received these and were additionally offered three 132 individual practice nurse PA consultations. Randomisation was carried out at household level 133 allowing couples to take part together. The main trial outcomes were changes in accelerometry 134 135 measured average daily step-count and total weekly time in MVPA in ≥10 minute bouts between 136 baseline and 12 months. 956/1023 (93%) provided at least one day of accelerometry data at 12 137 months, >90% provided at least 5 days wear. The postal and nurse groups both significantly increased their objective PA levels (step count and time in MVPA) compared with the control group, with no 138 difference between intervention groups at 12 months[27]. 139

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Participants wore a sealed accelerometer (GT3X, Actigraph LLC) over their hip for 7 consecutive 141 142 days at baseline, prior to randomization, and 12 months post-randomization. They also completed the IPAQ Short form[10] and GPPAQ[11], both designed for self-completion, for the same 7-day periods 143 as they wore the accelerometer. Actilife software (v 6.6.0) was used to extract and reduce the 144 Actigraph data, ignoring runs of ≥ 60 minutes of zero counts[26], to provide daily steps counts and 145 time spent in ≥ 10 minute bouts of MVPA (≥ 1952 counts per minute, equivalent to ≥ 3 Metabolic 146 Equivalents (METs))[16]. When assessing ≥ 10 minute bout, the default "drop time" of 2 minutes was 147 148 used, which allows for a 2 minute interruption in bout activity. At baseline, all participants provided \geq 5 days of \geq 540 minutes accelerometer wear-time. To limit attrition bias, those providing \geq 1 day of 149 \geq 540 minutes accelerometer wear time at 12 months were included in analyses. IPAQ questions focus 150 151 on time spent being physically active in the previous seven days in at least 10 minute bouts, including PA at work, home, travelling and leisure. For each of vigorous and moderate PA and walking, there 152 are questions on the number of days and the duration on each of these days. GPPAQ questions ask 153

about PA at work and the type and weekly duration of leisure PA (physical exercise/sport, cycling, walking, housework/childcare and gardening/DIY). Duration categories are None, <1 hour, 1-3 hours, ≥ 3 hours.

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158 Study outcomes

159 Accelerometry: The main accelerometry outcome was total weekly minutes of MVPA in ≥10 minute 160 bouts; a secondary outcome was total weekly minutes of MVPA, including MVPA in <10 minute 161 bouts. Binary variables were generated for each MVPA outcome to indicate 150 minutes of activity. 162 IPAQ: Total weekly minutes spent in each of vigorous PA, moderate PA and walking were calculated, 163 capped at a maximum of 3 hours/day or 21 hours/week, as recommended by the IPAQ coding guidelines[28]. Two self-report PA measures were derived: total weekly minutes of vigorous + 164 moderate PA in bouts of >10 minutes, excluding walking (IPAO-MVPA) and total weekly minutes 165 of walking in bouts of ≥ 10 minutes (IPAQ-Walk). We also report an additional outcome, IPAQ-Total 166 (IPAQ-MVPA + IPAQ-Walk), conceptually the same construct as accelerometry MVPA in ≥ 10 167 168 minute bouts. Binary variables were generated for each of these to indicate 150 minutes or more per week of activity. 169

GPPAQ: The GPPAQ Physical Activity Index is a 4-level index ranging from "Inactive" through to 170 "Active". "Active" individuals are achieving ≥ 3 hours (180 minutes) of MVPA per week including 171 work PA and leisure PA from physical exercise and cycling, but not including PA from walking, 172 housework/childcare or gardening. We defined a binary outcome, GPPAQ, to identify those 173 174 individuals classified as "Active" by the GPPAQ score. However, adults who are retired or not working and who do no sport or cycling can never be classified as active, although they may achieve 175 MVPA guidelines through walking. Thus, a modified index, GPPAQ-Walk, was also derived, where 176 177 those who reported walking briskly for at least 3 hours per week were classified as "active". . Previous analysis of GPPAQ showed this modified index had improved sensitivity at identifying active 178 179 individuals compared with accelerometry data, but lower specificity in adults aged 60-75 years[29].

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181 Statistical analyses

182 Analyses were carried out using Stata 14[30]. Multi-level regression models estimated treatment 183 effects for accelerometer, IPAQ and GPPAQ outcomes. The 12-month outcome was regressed on baseline value, treatment group, age, gender, practice and month of baseline accelerometry as fixed 184 185 effects and household as a random effect in the multi-level model. (i) Linear regression was used for 186 weekly minutes of accelerometer MVPA, IPAQ-MVPA, IPAQ-Walk and IPAQ-Total; (ii) logistic 187 regression was used for the binary variables "active" from accelerometry, IPAQ and GPPAQ. The 188 distributions of change in PA for the four continuous outcomes were reasonably normally distributed, 189 as were the distributions of residuals from the models, allowing this method of analysis. Analyses 190 were restricted to those with complete data for all outcomes being compared: 833 at baseline and 655 for the longitudinal regression models. This ensured direct comparisons of the same group of 191 192 participants for each outcome. Sensitivity analyses used ≥ 180 minutes of accelerometer MVPA and IPAQ outcomes, as the GPPAQ outcome is based on \geq 180 minutes per week. 193

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195 **RESULTS**

At baseline, accelerometry data were available on all participants and 989 (97%) returned IPAQ and 196 GPPAQ questionnaires. At 12 months, 956 (93%) participants provided at least one day of 197 accelerometry and 942 (92%) returned IPAQ and GPPAQ questionnaires. However, incomplete 198 answers on IPAQ and GPPAQ questions reduced the sample size to 833 at baseline and to 655 for 199 200 analyses of changes between baseline and 12 months. Study groups were balanced at baseline for the 833 with complete data with respect to age, gender, ethnicity and different health measures (Table 1). 201 202 One third of participants were male and two thirds were overweight or obese (Body Mass Index 203 \geq 25kg/m²). Mean weekly minutes of accelerometer-MVPA were 317 (sd 151) for total MVPA and 98 (sd 103) for MVPA in \geq 10 minute bouts. Self-reported mean weekly minutes were 174 (sd 279) 204 for IPAQ-MVPA, 315 (sd 310) for IPAQ-Walk, similar to total accelerometry MVPA and 489 (sd 205

453) for IPAQ-Total. Accelerometry data classified 23% of participants at baseline as "Active" i.e. achieving \geq 150 minutes of MVPA per week in \geq 10 minute bouts (Table 1). In contrast, 35%, 66% and 84% of participants self-reported \geq 150 minutes per week of IPAQ-MVPA, IPAQ-Walk and IPAQ-Total respectively. GPPAQ classified 12% of participants as active which increased to 28% when walking was included.

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212 i) Comparison of estimated treatment effects using minutes of physical activity

213 Both intervention groups showed statistically significant increases in accelerometer-MVPA, both in 214 bouts and total, compared with controls. Increases in accelerometer-MVPA bouts: postal group 42 215 minutes/week (95% CI 22 to 61), nurse group 43 (95% CI 24 to 63) (Table 2 and Figure 1a); increases for total accelerometry MVPA were almost identical to accelerometer-MVPA in bouts but with wider 216 confidence intervals (Table 2 and Figure 1). Repeating the analysis using the IPAO outcomes, IPAO-217 Walk showed positive increases, similar in magnitude to accelerometer-MVPA in the nurse group, 218 but with wider confidence intervals indicating less precision: postal group 57 minutes (95% CI 2 to 219 220 112), nurse group 43 (95% CI -11 to 97). IPAQ-MVPA showed non-significant decreases and IPAQ-Total showed non-significant increases. The distribution of residuals from the regression models were 221 222 normally distributed for MVPA in bouts[27] and IPAQ outcomes (data not shown).

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ii) Comparison of estimated treatment effects using the binary variable "active"

Similar patterns were found for the binary variable "active" for the different outcomes. Odds ratios (ORs) for being "active" at 12 months (achieving \geq 150 weekly minutes of MVPA in \geq 10 minute bouts) conditional on baseline "active" status were statistically significant for accelerometry-MVPA: postal group 3.7 (95% CI 1.8 to 7.5) and nurse group 2.9 (95% CI 1.5 to 5.7) (Table 3). IPAQ-Walk showed statistically significant OR for the postal group, 2.1 (95% CI 1.2 to 4.0) and borderline for the nurse group, 1.7 (95% CI 1.0 to 3.0). Results were inconclusive for IPAQ-MVPA and IPAQ-Total had increased ORs for both intervention groups, but only statistically significant for the nurse group ORs for the two GPPAQ outcomes were close to 1.0 suggesting that GPPAQ was unable to identify changes in the proportion classified as "active" (Table 3). Sensitivity analyses using ≥ 180 minutes of the accelerometer and IPAQ outcomes gave similar results.

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236 **DISCUSSION**

237 The PACE-UP study was a walking intervention designed to increase individuals' PA through a 3-238 month programme, in particular MVPA in \geq 10 minute bouts in line with current UK, WHO and US 239 PA guidelines[31-33]. We found statistically significant increases between baseline and 12 months 240 in accelerometer measured MVPA in ≥ 10 minute bouts for both intervention groups compared with 241 control. IPAQ-Walk showed a significant increase in the postal group and a non-significant increase in the nurse group compared with control, but with less precision than with accelerometry. 242 IPAO-MVPA showed non-significant decreases and IPAO-Total non-significant increases in 243 intervention groups compared with controls. When considering the proportion of "active" individuals, 244 only accelerometry showed statistically significant increases for both intervention groups versus 245 246 controls. IPAQ-Walk and IPAQ-Total showed statistically significant increases for one intervention group compared with controls (postal for IPAQ-Walk and nurse for IPAQ-Total), but borderline 247 effects for the other intervention group compared with controls. Neither IPAQ-MVPA nor GPPAQ 248 identified any change in the proportions categorised as "active" in intervention versus control groups. 249 Therefore, in terms of overall construct validity for assessing change in walking in a walking 250 intervention study, accelerometry has the greatest validity, followed by IPAQ-Walk. The other 251 measures have considerable disadvantages: IPAQ-MVPA and GPPAQ have very poor construct 252 validity; IPAQ-Total is measured with substantial imprecision and is unsuitable for assessing a 253 254 walking intervention as it includes IPAQ-MVPA.

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Our study had several strengths. It was based on a large population-based sample of adults from seven
 south-west London (UK) general practices (family practices), predominantly classified as inactive at

258 baseline. Accelerometry is an objective PA measure and measures walking accurately. We used standard cut-points to define the different intensities of accelerometry activity and were thus able to 259 260 identify those bouts of walking which can be classified as MVPA. The main PACE-UP analysis[27] 261 showed that the increase in weekly steps in intervention groups relative to control group was equivalent to the increase in weekly minutes of MVPA and this was all in ≥ 10 minute bouts, thus 262 demonstrating the effectiveness of the PACE-UP walking intervention. The two self-completed 263 264 questionnaires, IPAQ and GPPAQ, are standard questionnaires used to assess PA, and were 265 completed for the same seven days as for accelerometry, thus providing directly comparable estimates of effect. The study achieved 93% accelerometry follow-up at 12 months, >90% of these with ≥ 5 266 267 days wear-time. Total weekly minutes of MVPA and total weekly minutes of walking (not including MVPA) were easy to extract from IPAQ and provided a direct comparison with minutes of 268 accelerometer-MVPA. The increases in IPAQ-Walk minutes are similar to those for accelerometer-269 MVPA suggesting that IPAQ can identify changes in walking minutes, although the wider confidence 270 intervals show the loss of precision from using IPAQ. At baseline, average IPAQ-Walk minutes were 271 similar to average total accelerometer-MVPA minutes rather than accelerometer-MVPA in ≥ 10 272 minute bouts. This is perhaps unsurprising, as the IPAQ walking questions ask for number of days 273 walking and duration on each day, and people may find it easier to report walking minutes as a 274 rounded number e.g. 30 or 45 minutes per day and which may include relative short walks of <10275 minutes. GPPAQ is commonly used in UK general practice to assess an individual's PA. However, 276 it can underestimate PA amongst those not working or those whose main PA is walking, and this 277 study provided a further opportunity to evaluate our modified GPPAQ-Walk index[29]. We were 278 also able to estimate how well GPPAQ could identify individuals moving from "not active" to 279 "active" (assumed to be achieving PA guidelines). Finally, our method of analysis, regressing 280 281 outcome at 12 months on baseline values focusses on individual changes in activity while allowing for regression to the mean. Cross-sectionally, the distributions of accelerometer-MVPA and IPAQ 282 measures are highly skewed leading many to present medians and interquartile ranges of activity at 283

different time points. However, change in activity is usually symmetric and reasonably normally distributed, which our approach exploits. We were thus able to present mean changes in activity and associated confidence intervals for both accelerometry and questionnaire measures, thus allowing for a more informative comparison.

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The study also had some important limitations. All of the PA measures (accelerometry, IPAQ and 289 290 GPPAQ) only measured PA levels for 7 days and it may be that participants were more likely to be 291 active or report being active in the week that their PA was being assessed, rather than at other times. However, any such tendency would potentially affect all of the PA measures and would be true for 292 293 control participants as well as for those in the intervention group. IPAQ is difficult to complete and thus unreliable if an individual's PA varies by day across the week. Although we had high return rates 294 at baseline and 12 months for the IPAQ and GPPAQ, 97% and 92% respectively, each IPAQ outcome 295 at baseline and 12 months had 20-25% missing or incomplete answers. Participants' comments on 296 the questionnaires described their confusion over how to interpret and answer the questions and many 297 questions were left blank. This reduced our sample size to 655 for comparisons with accelerometry 298 although this is still large compared with other studies [21-23]. The proportions of missing data were 299 similar across the three groups, but those with missing IPAQ data had lower mean 300 accelerometry-MVPA at baseline and 12 months than those with complete data. The accelerometry 301 effect sizes reported here (42-43 minutes) are also larger than for the full cohort (33-35 minutes)[27]. 302 The limited options on GPPAQ for duration of PA, led to using ≥ 3 hours (180 minutes) for GPPAQ 303 304 "active" whereas the PA guidelines are \geq 150 minutes. However, ORs from sensitivity analyses using \geq 180 minutes for accelerometry and IPAQ outcomes were similar to those using \geq 150 minutes. 305 306 Although neither of our methods of measuring PA are considered a gold-standard, accelerometry has 307 the advantage of providing an objective time-stamped record of PA that does not rely on recall. It has been validated as a measure of activity energy expenditure using doubly labelled water[15] and we 308 used standard cut-points in counts per minute to define MVPA.[16] Our findings that 309

accelerometer-MVPA and IPAQ-Walk provide similar estimates of change clearly support results
from the PACE-UP intervention which is aimed at increasing walking, but it is unknown if these
findings would be generalisable to other PA interventions.

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Participants in the postal and nurse intervention groups were encouraged to increase their MVPA through walking and the nurse group in particular were taught to recognise and classify different PA intensities – vigorous, moderate, light, and sedentary. Thus they may have been more likely to accurately report their PA on IPAQ at follow-up i.e. with less over-estimation of their PA levels, which could explain the non-significant decreases in the treatment groups for IPAQ-MVPA from the modelling.

320

321 **Comparison with other studies**

Our baseline data agree with other studies that individuals tend to over-estimate their PA on self-322 report questionnaires compared with objective accelerometry, both time spent being physically 323 active[6] and proportions achieving PA guidelines[7]. Studies which have found better 324 correspondence between IPAQ and accelerometry cross-sectionally[34] have used total 325 accelerometer MVPA rather than MVPA in ≥ 10 minute bouts and a similar pattern is seen in our data 326 where baseline total accelerometer-MVPA minutes are similar to IPAQ-Walk minutes. However, 327 IPAQ questions ask about vigorous and moderate PA in ≥10 minute bouts and UK, WHO and US PA 328 guidelines are based on \geq 150 minutes of MVPA per week in \geq 10 minute bouts. In our trial, whilst 329 330 total accelerometry MVPA was much higher than accelerometry MVPA in \geq 10 minute bouts, changes in both measures were almost identical. 331

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To our knowledge, this is the largest population-based trial to make direct comparisons of accelerometry and self-report questionnaires to assess an individual's change in minutes of PA after an intervention. All five studies we identified [21-25] which have attempted to compare longitudinal 336 changes in PA measured using IPAQ compared to objective measures have limitations. Three studies recruited less than 100 subjects[21-23]. One study was observational[21], one had no control 337 group[22] and one was a weight loss intervention rather than PA intervention[24]. One study was 338 339 comparing IPAQ with pedometer steps[23] and another with accelerometer counts[25] making direct comparison of minutes of physical activity between IPAQ and accelerometry difficult. Whilst our 340 study compares measures using different constructs, we were able to compare time spent in MVPA 341 and time spent walking, both in minutes per week. Three studies present distribution of PA measures 342 343 at baseline and follow-up, but provided no estimate of the distribution of change[21, 24, 25] Our 344 findings do agree with two of the small studies. Nicaise et al[22] followed up one group of women, 345 but with no control group, and found median changes in IPAQ Walking minutes were similar to median changes in accelerometer MVPA minutes. Baker et al[23] compared IPAQ PA minutes with 346 pedometer steps, and argue that the increase in step counts in the intervention group was comparable 347 to the increase in leisure time walking reported on IPAQ, although they report mean differences for 348 pedometer steps and median differences for IPAQ data. 349

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GPPAQ is used in UK primary care to help identify those not achieving PA guidelines during UK 351 NHS Health Checks [12]. GPPAQ guidance recommends repeating it annually on those at increased 352 cardiovascular risk [11], however our study suggests that it is poor at identifying those individuals 353 who have increased their PA to current guideline levels. In addition, the binary nature of this outcome 354 fails to recognise modest, but important, increases in PA made by inactive individuals. We have also 355 confirmed our previous findings [29] that, compared with objective accelerometry, GPPAQ 356 underestimates the proportion of "active" individuals and our modified index GPPAQ-Walk classifies 357 358 slightly more as "active".

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360 CONCLUSIONS

361 We have demonstrated that neither GPPAQ nor IPAQ-MVPA provide a valid estimate of change in a walking intervention trial compared with accelerometry measures. Moreover, we have shown that 362 although IPAQ-Walk produces an estimate of change comparable with that from accelerometry 363 364 MVPA in ≥ 10 minute bouts, the IPAQ-Walk estimate had considerably less precision. Missing data were also an issue with the self-report IPAQ. This has implications for future trials. Studies may need 365 to use IPAQ to assess changes in walking if they are not able to use accelerometry. If this is the case, 366 367 they should focus particularly on the walking questions and will need to be larger to be adequately 368 powered, although they will still lack information on intensity of any changes that occur. In conclusion, accelerometry is preferred to self-report measures in assessing the effects of a walking 369 370 intervention, as it avoids recall bias and improves precision.

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372 LIST OF ABBREVIATIONS

- 373 PA: Physical Activity
- 374 MVPA: Moderate-to-vigorous physical activity
- 375 IPAQ: International Physical Activity Questionnaire
- 376 GPPAQ: General Practice Physical Activity Questionnaire
- 377 NHS: UK National Health Service
- 378 95% CI: 95% Confidence Interval
- 379 sd: Standard deviation
- 380 OR: Odds ratio
- 381
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- 383 **DECLARATIONS**

384 **Ethics approval and consent**

385 Ethics approvals were obtained from NRES Committee London - Hampstead REC reference:

386 12/LO/0219. Written consent was obtained from all participants.

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388	Consent for publication
389	Not applicable
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391	Availability of data
392	There are restrictions on the availability of the data for this study due to the signed consent agreements
393	around data security, which only allow access to external researchers for research monitoring
394	purposes. Requestors wishing to access the data for the purposes of replicating or checking analyses
395	can apply to Research Data Management at St George's University of London
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397	
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407	
408	
409	Author Contributions
410	TH, DGC, ESL and SA conceived the idea for the paper. TH, DGC, SMK, CRV, PHW, MU, SI, UE
411	and JFR were trial investigators and designed and were awarded funding for the trial. TH was trial
412	Principal Investigator and had overall responsibility for the execution of the project. II and SDW

413 recruited general practices to the trial. CF was trial manager and oversaw data collection for the trial.

414 ESL and DGC designed the analyses and ESL conducted the analyses for this paper. The manuscript

415 was prepared by TH, ESL and DGC with input from all of the other authors. All of the author team

416 reviewed and approved the manuscript prior to submission.

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427 The results of the study are presented clearly, honestly and without fabrication, falsification or428 inappropriate data manipulation.

429

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521	Figur	re captions
522	Figure	e 1. Treatment effects and 95% confidence intervals for change in minutes of physical activity
523	measu	ared by accelerometry, IPAQ-MVPA, IPAQ-Walk and IPAQ-Total.
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Table 1. Demographic, health, physical characteristics and physical activity at baseline.

	All groups		Cor	trol	Pos	stal	Nurse		
	(N=8	333)	(N=	279)	(N=	270)	(N=284)		
	n	(%)	n	(%)	n	(%)	n	(%)	
Age at randomisation									
45-54 years	280	(34%)	87	(31%)	94	(35%)	99	(35%)	
55-64 years	315	(38%)	111	(40%)	98	(36%)	106	(37%)	
65-75 years	238	(29%)	81	(29%)	78	(29%)	79	(28%)	
Sex: Male	304	(36%)	98	(35%)	104	(39%)	102	(36%)	
Ethnicity									
White	654	(81%)	212	(79%)	222	(85%)	220	(80%)	
Black / African / Caribbean / Black British	77	(10%)	25	(9%)	21	(8%)	31	(11%)	
Asian / Asian British	54	(7%)	21	(8%)	14	(5%)	19	(7%)	
Other, incl mixed	19	(2%)	10	(4%)	4	(2%)	5	(2%)	
General health: Very good or good	679	(83%)	223	(81%)	230	(88%)	226	(82%)	
Chronic diseases									
None	321	(39%)	109	(39%)	112	(42%)	100	(36%)	
1-2	436	(53%)	153	(55%)	133	(50%)	150	(54%)	
≥3	61	(7%)	14	(5%)	20	(8%)	27	(10%)	
Self-reported pain: Yes	566	(69%)	185	(67%)	191	(72%)	190	(69%)	
Limiting long-standing illness	174	(21%)	60	(22%)	55	(21%)	59	(21%)	
Townsend Disability score									
None (0)	491	(60%)	159	(58%)	158	(59%)	174	(62%)	
Slight or some disability (1-6)	305	(37%)	103	(37%)	104	(39%)	98	(35%)	
Appreciable or severe disability (7-18)	24	(3%)	13	(5%)	4	(2%)	7	(3%)	

Physical characteristics	n	(%)	n	(%)	n	(%)	n	(%)
Overweight/obese: BMI≥25kg/m ²	544	(65%)	184	(66%)	173	(64%)	187	(66%)
	Mean	(sd)	Mean	(sd)	Mean	(sd)	Mean	(sd)
Fat mass (kg)	26	(11)	26	(10)	26	(11)	26	(11)
Accelerometry data	Mean	(sd)	Mean	(sd)	Mean	(sd)	Mean	(sd)
Adjusted baseline step count per day	7550	(2670)	7528	(2685)	7480	(2583)	7638	(2744)
Total weekly mins MVPA in ≥ 10 min bouts	98	(103)	91	(100)	97	(94)	106	(113)
Total weekly mins MVPA	317	(151)	316	(152)	311	(145)	322	(154)
Daily wear time (minutes)	79	2 (79)	79	1 (73)	78	9 (79)	79	6 (84)
International Physical Activity Questionnai	re (IPA)	Q)						
IPAQ-MVPA: Weekly mins of moderate PA	174	(279)	194	(310)	159	(266)	167	(259)
+ vigorous PA in ≥10 min bouts								
IPAQ-Walk: Weekly minutes of walking in	315	(310)	323	(327)	316	(326)	307	(275)
$\geq 10 \text{ min bouts}$								
IPAQ-Total: Weekly minutes of moderate	489	(453)	518	(501)	475	(457)	474	(395)
PA+vigorous PA+walking in >-10 min bouts								
Proportions of "active" individuals ¹	n	(%)	n	(%)	n	(%)	n	(%)
Accelerometry								
150 weekly mins MVPA in \geq 10 min bouts	190	(23%)	57	(21%)	58	(22%)	75	(27%)
International Physical Activity Questionnai	re (IPA	Q)						
150 weekly mins of IPAQ-MVPA	286	(35%)	99	(36%)	86	(32%)	101	(36%)
150 weekly mins of IPAQ-Walk	540	(66%)	176	(64%)	173	(65%)	191	(68%)
150 weekly mins of IPAQ-Total	690	(84%)	227	(82%)	226	(85%)	237	(84%)
General Practice Physical Activity Question	nnaire (C	GPPAQ))					
GPPAQ: "Active" ≥180 mins PA per week	101	(12%)	38	(14%)	33	(12%)	30	(11%)

GPPAQ-Walk: "Active" ≥180 mins PA per 229 (28%) 82 (30%) 71 (27%) 76 (27%)

week including walking at brisk/fast pace

- 533
- 534 Footnotes
- 535 1 Proportions of "active" individuals are based on 276, 265 and 281 participants in Control, Postal and Nurse
- 536 groups respectively

Table 2. Physical activity outcomes (total weekly minutes) at baseline and 12 months for accelerometry and IPAQ

			Group su	mmary data				Treatmen	t effects	
	Control gro	oup (n=231)	Postal grou	up (n=207)	Nurse gro	oup (n=217)	Postal v	Postal vs Control		Control
	Baseline 12 months		Baseline 12 months		Baseline	Baseline 12 months		Effect <i>p</i> -value		<i>p</i> -value
	Mean (sd)	Mean (sd)	Mean (sd)	Mean (sd)	Mean (sd)	Mean (sd)	(95% CI)		(95% CI)	
Accelerometry outcom	es									
Daily step count	7572 (2738)	7402 (2724)	7691 (2560)	8233 (3076)	7487 (2738)	8146 (3224)	804	< 0.001	837	< 0.001
							(426, 1181)		(463, 1211)	
MVPA in ≥10 min	95 (103)	97 (101)	107 (95)	144 (128)	107 (114)	146 (149)	42	< 0.001	43	< 0.001
bouts (weekly minutes)							(22, 61)		(24, 63)	
Total MVPA (weekly	319 (155)	330 (160)	329 (143)	377 (173)	317 (157)	367 (189)	43	< 0.001	41	< 0.001
minutes)							(20, 65)		(18, 63)	
IPAQ outcomes										
IPAQ-MVPA (weekly	188 (300)	222 (343)	171 (285)	200 (288)	165 (249)	180 (300)	-11	0.68	-34	0.21
minutes)							(-65, 42)		(-87, 19)	
IPAQ-Walk (weekly	336 (332)	356 (335)	331 (336)	398 (332)	286 (262)	365 (309)	57	0.04	43	0.12
minutes)							(2, 112)		(-11, 97)	

IPAQ-Total (weekly	525 (494)	578 (520)	502 (481)	598 (479)	450 (365)	545 (456)	46	0.26	14	0.74
minutes)							(-34, 126)		(-66, 93)	

	Group summary data Control group (n=228) Postal group (n=205) Baseline 12 months Baseline 12 months N (%) N (%) N (%) N (%) 54 (24%) 47 (21%) 53 (26%) 83 (40%) 199 (87%) 200 (88%) 180 (88%) 185 (90%) 81 (36%) 90 (39%) 68 (33%) 89 (43%) 148 (65%) 156 (68%) 136 (66%) 161 (79%) 190 (83%) 189 (83%) 177 (86%) 182 (89%)				Treatment effects					
	Control gro	oup (n=228)	Postal grou	Postal group (n=205) Nurse grou			Postal v	rs Control	Nurse v	s Control
	Baseline	12 months	Baseline	12 months	Baseline	12 months	OR	<i>p</i> -value	OR	<i>p</i> -value
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	(95% CI)		(95% CI))
Accelerometry										
MVPA bouts: 150 minutes	54 (24%)	47 (21%)	53 (26%)	83 (40%)	55 (26%)	79 (37%)	3.7	< 0.001	2.9	0.002
							(1.8, 7.5)		(1.5, 5.7)	
MVPA total: 150 minutes	199 (87%)	200 (88%)	180 (88%)	185 (90%)	183 (86%)	193 (91%)	1.7	0.24	1.7	0.24
							(0.7, 3.9)		(0.7, 3.8)	
IPAQ										
IPAQ-MVPA: 150 minutes	81 (36%)	90 (39%)	68 (33%)	89 (43%)	77 (36%)	76 (36%)	1.4	0.38	0.6	0.27
							(0.6, 3.3)		(0.3, 1.4)	
IPAQ-Walk: 150 minutes	148 (65%)	156 (68%)	136 (66%)	161 (79%)	137 (64%)	162 (76%)	2.1	0.01	1.7	0.05
							(1.2, 4.0)		(1.0, 3.0)	
IPAQ-Total: 150 minutes	190 (83%)	189 (83%)	177 (86%)	182 (89%)	178 (84%)	194 (91%)	1.8	0.07	2.3	0.02
							(0.9, 3.5)		(1.1, 4.6)	
GPPAQ										

539 Table 3. Physical activity outcomes ("active") at baseline and 12 months for accelerometry, IPAQ and GPPAQ

PA Index: Active ≥180 mins	28 (12%)	37 (16%)	31 (15%)	37 (18%)	24 (11%)	28 (13%)	1.1	0.83	0.8	0.50
PA per week							(0.6, 2.1)		(0.4, 1.6)	
PA Index incl walking:	66 (29%)	77 (34%)	62 (30%)	74 (36%)	59 (28%)	70 (33%)	1.1	0.66	1.0	0.89
Active ≥180 mins PA per							(0.7, 1.9)		(0.6, 1.8)	
week including walking at										
brisk/fast pace										
							1			

