**Physical activity levels in adults and older adults 3-4 years after pedometer-based walking interventions:- long-term follow-up of participants from two randomised controlled trials in UK primary care**

**Short title: Long-term pedometer intervention effects**

Tess Harris\*1, Sally M Kerry2, Elizabeth S Limb1, Cheryl Furness1, Charlotte Wahlich1, Christina R Victor3, Steve Iliffe4, Peter H Whincup1, Michael Ussher1, Ulf Ekelund5,6, Julia Fox-Rushby7,8, Judith Ibison1, Stephen DeWilde1, Cathy McKay1, Derek G Cook1.

**Affiliations:** 1Population Health Research Institute, St George’s University of London, SW17 ORE. 2Pragmatic Clinical Trials Unit, Queen Mary’s University of London, E12AT. 3Gerontology and Health Services Research Unit, Brunel University, London UB8 3PH. 4Research Department of Primary Care & Population Health, University College, London, NW3 2PF. 5Department of Sport Medicine, Norwegian School of Sport Sciences, PO Box 4014, 0806, Oslo, Norway. 6MRC Epidemiology Unit, University of Cambridge, CB2 OQQ. 7Health Economics Research Group, Brunel, University of London, UB8 3PH, 8 Department of Population Science, King’s College London, SE1 1UK (current address).

\*Corresponding author

[tharris@sgul.ac.uk](mailto:tharris@sgul.ac.uk)

**Abstract**

**Background:** Physical inactivity is an important cause of non-communicable diseases. Interventions can increase short-term physical activity (PA), but health benefits require maintenance. Few interventions have evaluated PA objectively beyond 12 months. We followed up two pedometer interventions with positive 12-month effects, to examine objective PA levels at 3-4 years.

**Methods and Findings:** Long-term follow-up of 2 completed trials: PACE-UP 3-arm (postal, nurse-support, control) at 3 years; PACE-Lift 2-arm (nurse-support, control) at 4 years post-baseline. Randomly selected patients from 10 UK primary care practices were recruited (PACE-UP 45-75 years, PACE-Lift 60-75 years). Intervention arms received 12-week walking programmes (pedometer, handbooks, PA diaries) postally (PACE-UP) or with nurse-support (PACE-UP, PACE-Lift). Main outcomes were changes in 7-day accelerometer average daily step-counts and weekly time in moderate-to-vigorous PA (MVPA) in ≥10 minute bouts in intervention versus control groups, between baseline and 3 years (PACE-UP) and 4 years (PACE-Lift). PACE-UP 3-year follow-up was 67% (681/1023) (mean age 59, 64% female), PACE-Lift 4-year was 76% (225/298) (mean age 67, 53% female). PACE-UP 3-year intervention versus control comparisons were: additional steps/day postal +627 (95% CI 198-1056) p=0.004, nurse +670 (95% CI 237-1102) p=0.002; total weekly MVPA in bouts (minutes/week) postal +28 (95% CI 7-49) p=0.009, nurse +24 (95% CI 3-45) p=0.03. PACE-Lift 4-year intervention versus control comparisons were: +407 (95% CI -177 to 992) p=0.17 steps/day; and +32 (95% CI 5-60) p=0.02 minutes/week MVPA in bouts. Neither trial showed sedentary or wear-time differences. Main study limitation was incomplete follow-up, however, results were robust to missing data sensitivity analyses.

**Conclusions:** Intervention participants followed up from both trials demonstrated higher levels of objectively measured PA at 3-4 years than controls, similar to previously reported 12-month trial effects. Pedometer interventions, delivered by post or with nurse support, can help address the public health physical inactivity challenge.

**Trial Registrations:** PACE-UP isrctn.com ISRCTN98538934; PACE-Lift isrctn.com ISRCTN42122561.

Word count: 304

**Author summary**

**Why was this study done?**

Brisk walking for 30 minutes or more daily on most days of the week can help adults and older adults to achieve moderate-to-vigorous physical activity (MVPA) guidelines for health benefits, yet many do not achieve these levels.

Previous pedometer-based walking studies have shown positive effects on increased step-counts and time in MVPA for up to 12 months.

For sustained health benefits, increased physical activity levels need to be maintained, yet there is a lack of data from interventions assessed using objectively measured physical activity levels beyond 12 months.

**What did the researchers do and find?**

We followed up participants from two primary care 12-week pedometer-based walking trials, including both nurse supported and postal pedometer arms, to establish whether objectively measured physical activity increases seen at 12 months, were sustained at 3-4 years.

PACE-UP followed up 45-75 year olds 3 years post baseline and showed that both nurse-supported and postal pedometer interventions continued to have higher physical activity levels compared to the control group ( approximately an extra 28 and 24 minutes/week respectively of MVPA in bouts and an extra 670 and 630 steps/day respectively).

PACE-Lift results were very similar. In 60-75 year olds, followed up at 4 years post baseline, the nurse-supported pedometer intervention group spent about 33 minutes/week more time in MVPA in bouts compared to the control group. They also did about 407 steps/day more than controls; , whilst not a statistically significant result, this was consistent with the PACE-UP results.

**What do these findings mean?**

These findings suggest that adult and older adult participants receiving 12-week pedometer-based walking interventions, provided either by post or with nurse support, are still doing more physical activity3-4 years later**.** Pedometer interventions can help address the public health physical inactivity challenge

**Abbreviations**

BCTs behaviour change techniques

MAR missing at random

MNAR missing not at random

MVPA moderate-to-vigorous physical activity

PA physical activity

PROM patient reported outcome measure

**Introduction**

Strong evidence exists for the health benefits of physical activity (PA) for a wide range of conditions[1, 2]. Physical inactivity leads to high health service costs[1, 3] and is the fourth leading risk factor for global mortality[2]. Adult and older adult guidelines advise ≥150 minutes of moderate-to-vigorous PA (MVPA) weekly, or 75 minutes of vigorous PA, or a combination, in ≥10 minute bouts[1, 4], but any increase in PA for inactive people is valuable[5]. Many PA interventions, including pedometer-based, increase PA levels in the short-term[6-8], but long-term health effects require sustained PA changes[1] and evidence for maintenance is lacking. A meta-analysis of PA interventions (including pedometers) in 55-70 year olds[8], only identified 2 trials with objective PA data beyond 12 months[9, 10]. One showed a significant step-count effect 18 months post-baseline, but only 6 months post-intervention[10]; the other showed a significant increase in step-count in the lifestyle group 23 months post-baseline, but only 12 months post intervention[9]. The meta-analysis authors[8] repeated requests made by previous systematic reviews [11] [12] and guidelines [13] for trials to be conducted with longer follow-up periods and objective PA measures.

We previously conducted two pedometer-based walking interventions with adults and older adults, which increased step-count and MVPA in bouts at 12 months and provided longer-term follow-up opportunites [14][15]. Both trials recruited postally from primary care and delivered 12-week pedometer-based walking interventions incorporating behaviour change techniques (BCTs), through dedicated practice nurse PA consultations (3 in PACE-UP, 4 in PACE-Lift) or by post (PACE-UP only). PACE-UP recruited 1023 predominantly inactive 45-75 year olds. Average baseline daily step-count was 7479 (standard deviation (s.d.) 2,671), average time in MVPA in bouts was 94 (s.d. 102) minutes/week. PACE-Lift recruited 298 patients aged 60-75 years. Average baseline daily step-count was 7347 (s.d. 2839), average time in MVPA in bouts was 92 (s.d. 108) minutes/week. Despite age-group and intervention differences, both trials and all intervention groups showed increases in step-counts of approximately one-tenth and time in MVPA of over one-third between baseline and 12 months[14][15].

The study aim was to follow up both trial cohorts to examine objectively measured PA levels at 3 years in PACE-UP and 4 years in PACE-Lift. Given the different but overlapping age ranges, interventions which were similar but differed in intensity, and different lengths of follow-up, we analysed the two trials separately, using identical methods and present the results in parallel.

**Methods**

**Study design and participants**

*PACE-UP 3-year follow-up*

For the PACE-UP trial 3-year follow-up London, Hampstead, Research Ethics Committee (UK) granted approval (12L/LO/0219). Written informed consent was gained from all research participants. Trial methods are published [16]; the postal and nurse interventions are summarised in Table 1 and baseline findings are summarised in S1 Table. The handbook and diary are available [www.paceup.sgul.ac.uk/materials](http://www.paceup.sgul.ac.uk/materials). After 12-month follow-up 212/322 (66%) of controls were posted a pedometer, handbook and PA diary and 64/322 (20%) opted for a single nurse appointment where they also received these materials. No further follow-up was offered at that point (compared with the trial postal-intervention group who were telephoned to check materials had arrived and encouraged to return completed PA diaries). Three-year follow-up collected accelerometry and patient reported outcome measures (PROMs) by post. To minimise seasonal effects on PA levels, baseline, 12-month and 3-year outcomes were assessed in the same month. Follow-up ran from October 2015 to November 2016. The protocol including 3-year follow-up details is included (S1 Text). London, Hampstead, Research Ethics Committee granted approval (12L/LO/0219).

**Table 1: Components of interventions for PACE-UP and PACE-Lift trials**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PACE-UP** | | **PACE-Lift** |
|  | **Postal** | **Nurse** | **Nurse** |
| **Pedometer**  Yamax Digi-Walker (Tokyo, Japan) SW-200  Provides step-count, requires daily manual recording & re-setting | Posted with instructions for use a | Given with instructions by nurse at first appointment | Given with instructions by nurse at first appointment |
| **Dedicated practice nurse PA consultations** (including BCTs)b | Not applicable | 3 consultations,  Week 1 “First Steps” (approx. 30 mins)  Week 5 “Continuing the Changes” (approx. 20 mins)  Week 9 “Building Lasting Habits”(approx. 20 mins) | 4 consultations,  Week 1 “First Steps”(approx. 45 mins)  Week 3 “Continuing the Changes” (approx. 30 mins)  Week 7 “Keeping up the Changes” (approx. 30 mins)  Week 11 “Building Lasting Habits”(approx. 30 mins) |
| **Accelerometer feedback as part of intervention** | Not applicable | Not applicable | Actigraph GT3X+ (accelerometer) worn for 1 week prior to each nurse appointment. Nurse downloaded accelerometer data during consultation and provided immediate feedback on time spent in sedentary, light, moderate and vigorous PA levels in relation to activities recorded in PA diary. |
| **Handbookc**(including BCTs)b | Posteda | Given by nurse at first appointment | Given by nurse at first appointment |
| **Target-setting: step-count goals and PA goals and use of walking planner** | Blinded pedometer (Yamax DigiWalker CW200) worn for 7 days at baseline to calculate average daily baseline steps, used to set step-count targets. Use of 12‑week walking planner. Advised to add 1500 steps/day then 3000 steps/day to average baseline steps, in graded manner over 12-weeks.  “3000-steps-in-30-minutes” message for PA intensity. | Blinded pedometer (Yamax DigiWalker CW200) worn for 7 days at baseline to calculate average daily baseline steps, used to set step-count targets. Use of 12-week walking planner. Advised to add 1500 steps/day then 3000 steps/day to average baseline steps, in graded manner over 12-weeks. Targets could be adapted in discussion with nurse.  “3000-steps-in-30-minutes” message for PA intensity. | Nurses discussed appropriate step-count and PA goals with participants based on baseline step-count and weekly time in MVPA from accelerometry and any health issues. Participants encouraged to set both step-count and time in MVPA goals, encouraged to start-low-and-go-slow. Walking planner to help them plan when and where and with whom they planned to walk. Goals reviewed and re-set at each consultation. |
| **12-week physical activity and step-count diary** (including BCTs)b | Posteda and encouraged to return completed diary to researchers after 12‑week intervention. | Given by nurse at first appointment, reviewed by nurse at other appointments and encouraged to return completed diary to researchers after 12-week intervention. | Given by nurse at first appointment and reviewed at each nurse appointment. |

a Researcher telephoned 1 week later to check had arrived.

aBCTs for promoting lasting change in PA levels provided in nurse consultations, handbooks and PA diaries, categorised according to Michies taxonomy[17] and included: goal-setting, self-monitoring, feedback, boosting motivation, encouraging social support, addressing barriers, relapse anticipation etc.

cBoth PACE-Lift and PACE-UP patient handbooks were adapted from the NHS Health Trainer Handbook[18] and focused on changing PA levels

*PACE-Lift 4-year follow-up*

For the PACE-Lift trial 4-year follow-up Oxfordshire Research Ethics Committee C (UK) granted approval (11/H0606/2). Written informed consent was gained from all research participants. Trial methods are published[19]; the intervention is summarised in Table 1 and baseline findings are summarised in S1 Table. After 12-month follow-up, all control group participants were sent a pedometer and instructions, no support was offered. Four-year follow-up collected the accelerometry and PROMs by post, as in PACE-UP. Additionally, for PACE-Lift the opportunity to meet study participants face-to-face after postal return of accelerometers and questionnaires was offered, to measure anthropometric variables. For consistency with PACE-UP (where face-to-face contact was not offered) only postal outcomes (accelerometry and PROMs) are reported in this paper. Baseline, 12-month and 4-year outcomes were assessed in the same month. Follow-up ran from October 2015 to October 2016. The protocol including 4-year follow-up is included (S2 Text). Oxfordshire Research Ethics Committee C granted approval (11/H0606/2).

**Procedures**

Participants who had not withdrawn from either trial by 12 months were eligible. Practices excluded participants who had died, moved away or developed a terminal illness or dementia. Eligible participants were sent a trial follow-up letter, participant information sheet, consent form and freepost return envelope. Researchers telephoned participants to discuss any queries. Those interested returned signed consent forms. Participants and researchers were unmasked to intervention allocation.

Instruments, questionnaire measures and protocols were the same as during the trial. Participants were not asked to increase their PA levels, just to continue usual activity, so health limitations did not preclude participation. Participants were instructed to wear the accelerometer (Actigraph GT3X+) on a belt, over one hip, for 7 consecutive days, from getting up until going to bed. A diary (to record activities) questionnaire and freepost envelope were provided. If accelerometry recording did not result in ≥5 days with ≥540 minutes/day, participants were asked to re-wear monitors (re-wears were required for 20 PACE-UP and 1 PACE-Lift participants). Participants were posted a £10 gift voucher.

The Actigraph GT3X+ measures vertical accelerations in magnitudes from 0.05-2.0g sampled at 30Hz then summed over a 5s epoch time period, it can record PA continuously for up to 21 days. Actigraph data were reduced using Actilife software (V6.6.0) ignoring runs of ≥60 min of zero counts.[14, 15] Summary variables were as used in the trials[14, 15]: step-counts; accelerometer wear-time; time spent in total MVPA (≥1,952 Counts Per Minute, equivalent to ≥3 Metabolic Equivalents); time spent in ≥10 minute bouts of MVPA; and time spent sedentary (≤100 Counts Per Minute, equivalent to ≤1.5 Metabolic Equivalents). Only days with ≥540 minutes of registered time were used. To lessen attrition bias, main analyses of effect included all subjects with ≥1 satisfactory day of recording at 3 (or 4) years.

**Outcomes**

Outcomes focussed on changes between baseline measures and follow-up measures at 3-years (PACE-UP) or 4-years (PACE-Lift). For accelerometry we analysed: (i) change in average daily step-count; (ii) change in time spent weekly in MVPA in ≥10 minute bouts; (iii) change in weekly sedentary time.

Questionnaire PROMs were as for 3 and 12 month outcomes[16, 19]: quality of life[20]; exercise self-efficacy[21]; pain[22]; depression[23, 24]and anxiety[23, 25].

**Statistical analysis**

Analysis and reporting followed CONSORT guidelines (S7 Text, S8 Text). Primary analyses were conducted using STATA version 14.0 (StataCorp) with a two-step process to estimate change. In step 1, average daily step-counts at 3 years (PACE-UP) or 4 years (PACE-Lift) were computed from a random-effects model allowing for day of the week and day of wearing the accelerometer as fixed effects and participant as a random effect. In step 2, average daily step-count at 3 years (PACE-UP) or 4 years (PACE-Lift) was regressed on estimated baseline average daily step-count, with treatment group, age, gender, practice and month of baseline accelerometry as fixed effects and household as a random effect in a multi-level model. Identical analyses were carried out for MVPA in ≥10 minute bouts, sedentary time and wear time. Change in PROMs were estimated using step 2 only.

Primary analyses used 681 (PACE-UP) or 225 (PACE-Lift) participants who provided accelerometry data at 3 or 4 years respectively. Sensitivity analyses assessed the effect of missingness: 1) multiple imputation methods were used to impute outcome data for those missing at 3 or 4 years, assuming outcomes were missing at random (MAR), conditional on model variables and using the STATA procedure mi impute; 2) missing not at random (MNAR) analyses. The purpose of the MANAR analyses was to assess how extreme the missing data needed to be in order to explain away our positive effect estimates. To do this we used the Stata module rctmiss (Statistical Software Components (SSC) https://ideas.repec.org/s/boc/bocode.html)[26]. Essentially the rctmiss programme takes as its starting point MAR estimates for all subjects with missing data. It then adds or subtracts steps to the estimates before re-estimating the treatment effects. Thus we left the control group missing values at their MAR estimates and first subtracted 500 steps/day from the MAR estimates in the treatment groups; we then took a more extreme scenario where we subtracted 1000 steps/day for those in the treatment groups, again leaving the control group missing values at their MAR values.

**Results**

Of 1023 PACE-UP participants, 32 withdrew by 12-months, 2 died before 3-year follow-up, 1 was excluded, 681 provided ≥1 day of adequate accelerometry data. The 3-year follow-up rate was 69% (681/988), or 67% (681/1023) of initial trial participants, mean age 59 (s.d.7.9) and 64% (438/681) were female. Of 298 PACE-Lift participants, 15 withdrew by 12-months, 2 died before 4-year follow-up, 225 provided ≥1 day of adequate accelerometry data. The 4-year follow-up rate was 80% (225/281) or 76% (225/298) of original trial participants, mean age 67 (s.d.4.2) and 53% (120/225) were female. The CONSORT diagram (Figure 1) shows 3 and 4-year follow-up data by randomised groups. 92% (625/681) in PACE-UP and 93% (209/225) in PACE-Lift provided ≥5 days of accelerometry data at 3 and 4 years respectively (S2 Table and S3 Table).

**Figure 1 CONSORT diagrams for PACE-UP and PACE-Lift studies**

Accelerometry summary measures are shown for the three PACE-UP groups (S2 Table) and two PACE-Lift groups (S3 Table) at each time point. Figure 2 displays effect estimates for different groups from both trials at all time periods for step-counts and time in MVPA in bouts, respectively. Table 2 shows these estimates plus sedentary time and wear-time in tabular form. At 3 years in PACE-UP both intervention groups are doing more steps/day than controls, with no significant intervention group differences: postal +627 (95% CI 198, 1056); nurse +670 (95% CI 237, 1102). For PACE-Lift, at 4 years the intervention group is doing more steps/day than the control group, though the difference is not statistically significant +407 (95% CI -177, 992). For total weekly MVPA in ≥10 minute bouts (minutes/week) PACE-UP 3 year findings compared with control are: postal +28 (95% CI 7, 49); nurse +24 (95% CI (3, 45). For PACE-Lift at 4 years the intervention group is still doing significantly more MVPA in bouts (minutes/week) than the control group: +32 (95% CI 5, 60). Effect estimates for both steps per day and MVPA were stable when we limited analyses to subjects with at least 4 days of measurement at follow up (S4 Table).

In PACE-UP the 3-year treatment effects for steps/day were 98% (postal) (627/642) and 99% (nurse) (670/677) respectively of the 1 year estimates; in PACE-Lift the 4-year estimate was 67% (407/610) of the 1 year estimate. For minutes of MVPA in 10 minute bouts, PACE-UP estimates were 85% (postal) (28/33) and 69% (nurse) (24/35) respectively of the 1 year estimates, while the PACE-Lift estimate was 82% (32/39). Neither PACE-UP nor PACE-Lift showed differences between intervention and control groups at 3 and 4 years respectively for sedentary time or daily wear-time (Table 2). A PACE-UP sub-group analysis demonstrated similar effects for steps/day in 45-59 and 60-75 year olds (S1 Figure).

**Figure 2. PACE-UP and PACE-Lift studies. Effect estimates and 95% confidence intervals for change in a) average daily steps and b) total weekly minutes of MVPA in bouts at 3 months, 12 months, 3 years (PACE-UP) and 4 years (PACE-Lift).**

**Footnotes**

Effect sizes, 95% confidence intervals and *p-*values were obtained from multi-level linear regression models (see methods). 3 months: *p*<0.001 for all PACE-UP and PACE-Lift steps and MVPA intervention effects

12 months: *p*<0.001 for PACE-UP steps and PACE-UP MVPA; *p*=0.02 for PACE-Lift steps and *p*<0.001 for PACE-Lift MVPA

3 years: *p*<0.01 for PACE-UP steps and PACE-UP MVPA Postal group; *p*=0.03 for PACE-UP MVPA Nurse group

4 years: *p*=0.17 for PACE-Lift steps and *p*=0.02 for PACE-Lift MVPA

**Table 2. PACE-UP and PACE-Lift studies: Accelerometry outcomes at 3 months, 12 months, 3 years (PACE-UP) and 4 years (PACE-Lift).**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **PACE-UP study** | | |  | **PACE-UP study** | | |  | **PACE-Lift study** | | |
|  | **Postal vs Control** | | |  | **Nurse vs Control** | | |  | **Intervention vs Control** | | |
|  | **Effect** | **95% CI** | ***p*-value** |  | **Effect** | **95% CI** | ***p*-value** |  | **Effect** | **95% CI** | ***p*-value** |
| **Steps-counts** |  |  |  |  |  |  |  |  |  |  |  |
| **3 months** | 692 | (363, 1020) | <0.001 |  | 1173 | (844, 1501) | <0.001 |  | 1041 | (519, 1563) | <0.001 |
| **12 months** | 642 | (329, 955) | <0.001 |  | 677 | (365, 989) | <0.001 |  | 610 | (104, 1117) | 0.02 |
| **3 years** | 627 | (198, 1056) | 0.004 |  | 670 | (237, 1102) | 0.002 |  |  | | |
| **4 years** |  | | |  |  | | |  | 407 | (-177, 992) | 0.17 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **MVPA in ≥10 minute bouts** | |  |  |  |  |  |  |  |  |  |  |
| **3 months** | 43 | (26, 60) | <0.001 |  | 61 | (44, 78) | <0.001 |  | 63 | (40, 86) | <0.001 |
| **12 months** | 33 | (17, 49) | <0.001 |  | 35 | (19, 51) | <0.001 |  | 39 | (16, 62) | <0.001 |
| **3 years** | 28 | (7, 49) | 0.009 |  | 24 | (3, 45) | 0.03 |  |  | | |
| **4 years** |  | | |  |  | | |  | 32 | (5, 60) | 0.02 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Daily sedentary time (minutes)** | |  |  |  |  |  |  |  |  |  |  |
| **3 months** | -2 | (-12, 7) | 0.59 |  | -7 | (-16, 3) | 0.16 |  | -1 | (-13, 11) | 0.84 |
| **12 months** | 1 | (-8, 10) | 0.82 |  | 0 | (-9, 9) | 0.96 |  | 0 | (-15, 15) | 0.97 |
| **3 years** | -1 | (-12, 11) | 0.90 |  | -2 | (-14, 9) | 0.69 |  |  | | |
| **4 years** |  | | |  |  | | |  | 7 | (-9, 23) | 0.37 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Daily wear time (minutes)** | |  |  |  |  |  |  |  |  |  |  |
| **3 months** | 2 | (-8, 12) | 0.69 |  | 4 | (-6, 14) | 0.39 |  | 14 | (0, 28) | 0.06 |
| **12 months** | 9 | (-1, 19) | 0.08 |  | 9 | (-1, 19) | 0.07 |  | 5 | (-11, 22) | 0.51 |
| **3 years** | 8 | (-5, 20) | 0.23 |  | 7 | (-6, 19) | 0.32 |  |  | | |
| **4 years** |  | | |  |  | | |  | 9 | (-10, 28) | 0.35 |
|  |  |  |  |  |  |  |  |  |  |  |  |

**Footnotes**

Analyses using all available data at each follow-up.

PACE-UP study: N=954 at 3 months, 956 at 12 months and 681 at 3 years. PACE-Lift study: N=280 at 3 months, 273 at 12 months and 225 at 4 years.

All models include treatment group, practice, gender, age at randomisation, and month of baseline accelerometry as fixed effects and household as a random effect in a multi-level linear regression model. The results shown are the change in each Intervention group relative to the change in their Control group.

The effect estimates, 95% confidence intervals and *p*-values were obtained from the model output.

None of the interventions had significant effects on pain, depression, anxiety, or health related quality-of-life at 3 or 4 years, consistent with 3 and 12 month findings (S4 Table). In PACE-UP there was a persistent exercise self-efficacy effect for the nurse group at 3 years (also seen at 3 and 12 months) but not in PACE-Lift at 4 years (S5 Table).

Table 3 presents sensitivity analyses assuming that missing outcome data were MAR conditional on a variety of different predictors; analyses had little impact on the primary outcome step-count effect estimates and do not change interpretation. For the MNAR analyses we combined both intervention groups in PACE-UP to increase power and simplify presentation; separate analyses give a similar picture. The MNAR analyses (S2 Figure) make a bigger impact for both trials, but only when we assume there is a strong differential departure between the non-random effects in control and treatment groups (see solid lines in S2 Figure). For example, when we assume that the missing data in the treatment groups are 1000 steps below their MAR values, while the control group values are at their MAR values, the treatment effects for PACE-UP are no longer statistically significant; but even then the confidence interval is still largely positive.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **PACE-UP study** | | | |  | |  | |  | **PACE-Lift study** | | | |
|  |  | **Postal vs Control** | | | | | **Nurse vs Control** | | | | |  | **Intervention vs Control** | | | |
|  | **N** | **Effect** | **(95% CI)** | | ***p*-value** |  | **Effect** | | **(95% CI)** | | ***p*-value** |  | **N** | **Effect** | **(95% CI)** | ***p*-value** |
|  |  |  |  | |  |  |  | |  | |  |  |  |  |  |  |
| All participants with follow-up data | 681 | 627 | (198, 1056) | | 0.004 |  | 670 | | (237, 1102) | | 0.002 |  | 225 | 407 | (-177, 992) | 0.17 |
|  |  |  |  | |  |  |  | |  | |  |  |  |  |  |  |
| Imputed using treatment group, baseline steps, gender, age, practice, month baseline accelerometry | 1023 | 597 | (174, 1020) | | 0.006 |  | 679 | | (268, 1089) | | 0.001 |  | 298 | 429 | (-152, 1010) | 0.15 |
|  |  |  |  | |  |  |  | |  | |  |  |  |  |  |  |
| Imputed using treatment group, baseline steps, gender, age, practice, month baseline accelerometry, baseline deprivation, baseline self‑reported pain and baseline body fat mass† | 996 | 634 | (211, 1057) | | 0.003 |  | 735 | | (293, 1178) | | 0.001 |  | 292 | 437 | (-154, 1028) | 0.15 |
|  |  |  |  | |  |  |  | |  | |  |  |  |  |  |  |
| Imputed using treatment group, baseline steps, gender, age, practice, month baseline accelerometry and 12 month steps†† | 965 | 625 | (217, 1033) | | 0.003 |  | 683 | | (270, 1095) | | 0.001 |  | 280 | 367 | (-181, 916) | 0.19 |

**Table 3. PACE-UP and PACE-Lift studies: Imputation analyses for step-counts at 3-years (PACE-UP) and 4 years (PACE-Lift).**

**Footnotes**

Multiple imputations were carried out using the Stata commands *mi impute* followed by *mi estimate* in Stata V12, with three different sets of covariates as listed in the table. The results shown are the change in each Intervention group relative to the change in their Control group. The effect estimates, 95% confidence intervals and *p*-values were obtained from the model output.

† Imputed values were only available for 996 (PACE-UP) and 292 (PACE-Lift) when including baseline deprivation in the model (PACE-UP NS-SEC and PACE-Lift Index of Multiple Deprivation)

†† Imputed values only available for 965 (PACE-UP) and 280 (PACE-Lift) when including 12 month steps in the model

**Discussion**

To our knowledge these are the first population-based pedometer studies showing effects on objectively measured PA levels more than 12 months post-intervention. Intervention participants followed up from both PACE-UP and PACE-Lift trials showed significant increases in MVPA in bouts at 3 and 4-years compared to controls of approximately an extra 30 minutes weekly, with no difference between intervention groups in PACE-UP (as was also found at 12 months). PACE-UP showed a significant step-count increase of approximately 650 steps/day; PACE-Lift showed a similar, but non-significant, step-count increase. The increases seen in PA levels were similar to those seen at 12 months. No differences were seen in sedentary or wear-time.

This work’s main strength is its documentation of longer-term follow-up results beyond 12 months from trials with objective PA data relevant to guidelines. Both trials were based on population-based primary-care samples and achieved good follow-up. Sensitivity analyses demonstrated that effect estimates were robust, only extreme assumptions changed interpretation. We presented findings for two trials with overlapping but different age groups and slightly different intervention intensities and follow-up periods. However, the many similarities (recruited postally from primary care, 12-week pedometer-based interventions including nurse-support arms, accelerometer assessed main PA outcome measures beyond 12 months) meant there was considerable value in presenting the results together. Age was not an effect modifier in PACE-UP. Despite their differences, both trials show similar consistent long-term increased time in MVPA in bouts for intervention group participants.

The study also had a number of potential limitations. Long-term follow-up data was provided by 76% of PACE-Lift and 67% of PACE-UP original trial participants. Whilst only a small proportion of participants actively withdrew from each trial, reasons for withdrawal were not systematically collected. Whilst losing between a quarter and a third of subjects at follow-up could reduce the generalizability of the findings, we have directly addressed the risk of attrition bias through sensitivity analyses using appropriate imputation methods, and this gave robust results. Participants and researchers were unmasked to group, however, PA outcomes were assessed objectively by accelerometry and participants were blind to measurements. Participants might have tried harder with PA when monitored, but this would also have affected controls and would have been reduced by using a 7-day data collection protocol[6]. Also, the intervention groups increased their MVPA in ≥10 minute bouts, implying that participants made changes as advised. Whilst the Actigraph accelerometer provides valid estimates of time spent in different intensity levels, including MVPA[27], any waist-mounted activity monitor may underestimate upper body movement such as weight training and carrying heavy loads[28], it also underestimates cycling and did not measure swimming. However, crucially, accelerometers are most sensitive to ambulatory activities such as walking, which was the main intervention component of both trials. A further potential limitation is that minimal interventions were offered to both trial control groups after 12-month follow-up. However, this contamination would tend to weaken intervention effects, so the existence of differences in PA levels at 3 and 4 years is an important positive finding and helps us to understand the additional support required for a successful postal intervention.

This paper provides novel, important evidence on sustained effects of pedometer-based walking interventions on objectively measured PA levels. A recent systematic review of the effectiveness of behavioural interventions in increasing PA at 12 to 36 months[8] identified two studies which provided objectively measured outcomes beyond 12 months[9, 10]. We identified two more recent studies using a similar search strategy[29, 30]. In reviewing these studies several issues emerge. First, interventions differed dramatically in duration, intensity and resources needed; particularly important when considering cost effectiveness. Second, studies reported follow-up length post-baseline, not post-intervention; maintenance of effects is defined by the latter. None of the four studies provided outcomes more than 12 months post-intervention: one was 6 months post-intervention[10]; two were ongoing at the point of assessment[29, 30] and the final one was 12 months post-intervention[9]. Our two studies thus provide the first clear evidence of efficacy for pedometer-based interventions at 33 months and 45 months post-intervention, providing the type of evidence from PA interventions recently called for[8, 11, 13]. The simplicity of our postal intervention makes it likely to be more cost-effective than more intensive interventions and for the PACE-UP trial cost-effectiveness analyses at 12-month follow-up demonstrated this[14, 31].

Our findings support guidance to promote pedometers alongside support for goal setting, self-monitoring and feedback[32]. However, it is important to consider which factors in pedometer-based interventions are important for success. Both PACE-UP and PACE-Lift included a pedometer, step-count diary and patient handbook, including BCTs and practice nurse PA consultations[16, 19]. Despite PACE-Lift providing a more intensive nurse intervention than PACE-UP, both trials delivered similar effects on PA outcomes at 12-months[14, 15] and at 3 or 4 years. Additionally, nurse and postal interventions in PACE-UP achieved similar outcomes at 12 months[14] and 3 years. These findings confirm that shorter, simpler interventions can be equally effective[8, 33]. Systematic reviews suggest that individual tailoring, personalised activity goals and using a step-count diary are important[6, 8], all interventions from both trials provided these elements. That the minimal postal interventions given to both trial control groups at 12-months were not effective at increasing PA levels, suggests that the additional support given to the original PACE-UP trial postal arm (follow-up telephone call after a week and encouragement to return completed PA diary after 3 months) was important for this group’s success. The original postal group also had step-count targets set based on baseline blinded pedometer use and received the intervention when they had just been recruited to the trial, so may have been more motivated. These factors may also have been important to the trial postal intervention’s success. PA guidelines stress the importance of increasing time in MVPA[1, 4] rather than just steps. Both of our interventions addressed this, PACE-Lift by nurse feedback on PA intensity from accelerometers[19] and PACE-UP by the “3000 steps in 30 minutes”[34] advice given to nurse-support and postal arms[16]. Both trials were effective at increasing MVPA in bouts for all intervention groups at all outcome assessments, 3 and 12 months[14, 15] and now at 3 years (PACE-UP) and 4 years (PACE-Lift).

We took the effect estimates from the simplest intervention (PACE-UP postal) to estimate long-term health benefits. Based on a systematic review which quantified the strength of association between walking and coronary heart disease[35], 28 minutes per week increase in MVPA in bouts seen in the postal group at 3 years should reduce coronary heart disease risk by approximately 4% (95% CI 3%-5%) (see S5 Text)). A cohort study which related pedometer steps to mortality[36] allowed us to estimate that a sustained increase of 627 steps/day in the postal group at 3 years should lead to a decrease in all-cause mortality of approximately 4% (95% CI 1%-5%) (see S5 text).

Whilst environmental and policy interventions are urgently required to address the global inactivity challenge[37], individual PA behaviour change interventions are also important. The sustained effects seen on objective PA outcomes at 3 years for the lower cost postal intervention suggest that this would be an effective and cost-effective[31] intervention to roll-out. Minimal support is also required, to check materials have arrived and to encourage return of completed PA diaries, but need not be face-to-face, or delivered by a health care professional. We are currently conducting implementation work (PACE-UP Next Steps) exploring reach, retention and ease of adoption in primary care recruiting via postal and face-to-face routes.

The use of wearables to monitor personal PA levels has dramatically increased, through smartphones, wrist or body-worn devices and mobile apps, offering opportunities for increasing PA. The “3000-steps-in-30-minutes” captures intensity and could become an important new public health goal[34], with new, easy ways to measure steps. Small short-term studies in adults and older adults demonstrate that mobile PA apps can increase PA self-monitoring[38, 39] and engagement in regular PA[38, 39] and that body-worn fitness trackers can increase time spent in MVPA[39]. PACE-UP Next Steps is currently testing online resources and a mobile app to support the PACE-UP postal intervention. However, despite new PA monitoring opportunities, it is important not to ignore robust, trial-based evidence on effective and cost-effective pedometer plus paper-based interventions.

**Conclusion:**

We previously reported increased PA at 12 months following 12-week pedometer-based walking interventions for adults and older adults recruited through primary care, delivered either by post with minimal support, or through nurse-supported PA consultations. This current paper demonstrates that these findings are still present in participants followed up at 3-4 years. The long-term success of these interventions suggest that they could help to address the public health physical inactivity challenge.

**Word count 3050**

**Supporting Information**

S1 Text. PACE-UP protocol including 3-year follow-up. (DOCX)

S2 Text. PACE-Lift trial protocol including 4-year follow-up. (DOCX)

S3 Text. CONSORT checklist for PACE-UP 3-year follow-up. (DOCX)

S4 Text. CONSORT checklist for PACE-Lift 4-year follow-up. (DOCX)

S5 Text. Details on cardiovascular and overall mortality risk reduction. (DOCX)

S1 Table. PACE-UP and PACE-Lift trial baseline findings

S2 Table. PACE-UP study summary means and standard deviations for accelerometry data at baseline, 3 months, 12 months and 3 years. (DOCX)

S3 Table. PACE-Lift study summary means and standard deviations for accelerometry data at baseline, 3 months, 12 months and 4 years. (DOCX)

S4 Table. PACE-UP and PACE-Lift studies: effects of limiting analyses to those with at least 4 days of follow-up data at 3 years (PACE-UP) and 4 years (PACE-Lift)

S5Table. PACE-UP and PACE-Lift studies patient reported outcome measures at 3 months, 12 months, 3 years (PACE-UP) and 4 years (PACE-Lift). (DOCX)

S1 Figure. PACE-UP age sub-group analyses for changes in average daily step-counts at 3 years. (TIF)

S2 Figure. PACE-UP and PACE-Lift trials long-term follow-up missing not at random analyses. (TIF)

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