**Effect of a primary care walking intervention with and without nurse support on physical activity levels in 45-75 year olds: the PACE-UP (*P*edometer *A*nd *C*onsultation *E*valuation) cluster randomised clinical trial**

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Short Title: PACE-UP walking intervention trial

**Abstract:**

**Background:** Pedometers can increase walking and moderate-to-vigorous physical activity (MVPA) levels, but their effectiveness with or without support has not been rigorously evaluated. We assessed the effectiveness of a pedometer-based walking intervention in predominantly inactive adults, delivered by post or through primary care nurse-supported physical activity (PA) consultations.

**Methods and Findings:** Parallel three-arm cluster randomised trial, randomised by household, with 12-month follow-up, in seven London, UK, primary care practices. 11,015 randomly selected patients aged 45-75 years, without PA contraindications, were invited. 548 self-reporting achieving PA guidelines were excluded. 1023 people from 922 households were randomised between 2012-2013 to: usual care (n=338); postal pedometer intervention (n=339); nurse-supported pedometer intervention (n=346). 956 participants (93%) provided outcome data (usual care n=323, postal n=312, nurse-supported n=321). Both intervention groups received pedometers, 12-week walking programmes, and PA diaries. The nurse group was offered three PA consultations. Primary and main secondary outcomes were changes from baseline to 12-months in average daily step-counts and time in MVPA (in ≥10 minute bouts), respectively, measured objectively by accelerometry. Only statisticians were masked to group. Analysis was by intention-to-treat. Average baseline daily step-count was 7479 (s.d. 2671) and average time in MVPA bouts was 94 (s.d.102) minutes/week. At 12 months mean steps/day (s.d) were: control 7246 (2671); postal 8010 (2922); nurse 8131 (3228). PA increased in both intervention groups compared with the control group, additional steps/day were postal 642 (95% CI 329 to 955), nurse-support 677 (95% CI 365 to 989); additional MVPA in bouts (minutes/week) were postal 33 (95% CI 17 to 49), nurse-support 35 (95% CI 19 to 51). There were no significant differences between the two interventions at 12 months. The 10% (1023/10467) recruitment rate was a study limitation.

**Conclusions:** A primary care pedometer-based walking intervention in predominantly inactive 45-75 year olds increased step-counts by about one-tenth and time in MVPA in bouts by about one-third. Nurse and postal delivery achieved similar 12-month PA outcomes. A primary care pedometer intervention delivered by post, or with minimal support, could help address the public health physical inactivity challenge.

**Trial registration:** isrctn.org identifier:ISRCTN98538934.

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**Author summary**

**Why was this study done?**

Brisk walking for at least 30 minutes daily on five or more days weekly is a good way to achieve moderate-to-vigorous physical activity (MVPA) guidelines for health, yet many adults and older adults do not achieve these levels.

Pedometers measure steps taken (step-count) and can increase walking and physical activity levels.

Pedometer trials have usually measured short term outcomes, combined pedometer effects with other support provided and reported only step-counts, not time spent in MVPA.

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

1023 inactive 45-75 year olds from seven family (general) practices in London, UK were randomly allocated to either a usual physical activity (control) group or to one of two intervention groups.

The postal group were posted out a pedometer, diary and instructions for a 12-week walking programme to add in 3000 steps or a 30-minute walk on 5 or more days weekly, the nurse group received these materials through practice nurse physical activity consultations.

Both intervention groups significantly increased their walking from baseline to 12 months (step-counts by about 10% and time in MVPA by about a third) compared to controls, with similar effect sizes for nurse and postal groups.

**What do these findings mean?**

The findings suggest that a primary care pedometer intervention, delivered by post, or with minimal support, could provide an effective way to increase physical activity levels in adults and older adults.

**Abbreviations**

BCTs behavior change techniques

CPM count per minute

MET metabolic equivalent

MVPA moderate-to-vigorous physical activity

PA physical activity

**Introduction:**

Physical activity helps adults remain healthy and improves physical function, quality of life and emotional wellbeing[[1](#_ENREF_1)]. Physical inactivity is the fourth leading risk factor for global mortality[[2](#_ENREF_2)]; leading to high health service costs[[1](#_ENREF_1), [3](#_ENREF_3)].

Current physical activity (PA) guidelines in adults and older adults advise at least 150 minutes of moderate-to-vigorous PA (MVPA) or 75 minutes of vigorous intensity PA weekly, or a combination of both, in at least 10 minute bouts[[1](#_ENREF_1), [4](#_ENREF_4), [5](#_ENREF_5)]. One way to achieve this is by 30 minutes of MVPA on at least 5 days weekly[[1](#_ENREF_1)]. While setting such goals is helpful, a graded dose-response relationship exists for PA and health, so for inactive people any PA increase is valuable[[6](#_ENREF_6)]. Emphasising that the MVPA can occur in 10 rather than 30 minute bouts enables older subjects and those with disabilities to increase their MVPA gradually. Walking is the most common adult PA; a pace of 5km/hour qualifies as moderate intensity[[7](#_ENREF_7)]. Walking is safe, as both frequency and intensity can be increased gradually[[7](#_ENREF_7)]. Despite individual variation, moderate intensity walking approximates 100 steps/minute[[8](#_ENREF_8)], or 3000 steps in 30 minutes. Adding “3000 steps-in-30 minutes” onto habitual activity can increase step-counts[[9](#_ENREF_9)] and reduce fasting glucose[[9](#_ENREF_9)] in people with impaired glucose tolerance, but evidence for a change in MVPA in bouts is lacking. Reducing sedentary time may also be beneficial[[1](#_ENREF_1)].

Physical activity programmes using personalised PA goals and behavioural strategies[[10-12](#_ENREF_10)] can achieve PA increases. Cochrane reviews called for PA interventions to include objective PA measurement[[13](#_ENREF_13), [14](#_ENREF_14)], adverse events[[13](#_ENREF_13)] and comparisons of face-to-face with remote interventions[[14](#_ENREF_14)]. Comparative evidence on individuals, couples or households is also needed[[15](#_ENREF_15)]. Systematic reviews of pedometer-based walking interventions showed increases of 2000-2500 steps/day[[10](#_ENREF_10), [16](#_ENREF_16), [17](#_ENREF_17)]. However, studies were mainly small, volunteer-based and short-term; independent pedometer effects were unclear; and outcomes focused on step-counts, not MVPA[[10](#_ENREF_10), [16](#_ENREF_16), [17](#_ENREF_17)]. Primary care provides an ideal context for PA interventions; allowing population-based sampling, practice nurse involvement and continuity of care. Brief PA advice in primary care is advocated[[18](#_ENREF_18)]. However, to date primary care has had little success in playing its part in the challenge of increasing population PA levels. Some small primary care pedometer-based walking interventions in older adults have increased PA levels at 3[[19](#_ENREF_19)] 6[[20](#_ENREF_20)] and 12 months[[21](#_ENREF_21)], but the effects of exercise referral schemes have been disappointing[[22](#_ENREF_22)]. We therefore conducted a trial of a pedometer-based walking intervention in 45-75 year old predominantly inactive primary care patients, with novel separate evaluation of pedometer and nurse-support effects on objective PA outcomes, including MVPA in bouts. The research questions were: i) does a 3 month postal pedometer-based walking intervention increase PA in inactive 45-75 year olds at 12 month follow-up; and ii) do practice nurse PA consultations provide additional benefit? We also present effects on patient reported outcomes, anthropometric measures, and adverse events. Cost-effectiveness analyses will be published separately.

**Methods:**

**Study design and participants**

The trial protocol is published[[23](#_ENREF_23)] (S1 Text). A three-arm parallel cluster trial, randomised by household (allowing individuals and couples to participate) compared a 3-month pedometer-based walking intervention, by post or with nurse support, with usual care. We recruited from an ethnically and socio-economically diverse population in South London, United Kingdom between September 2012 and October 2013, follow-up was completed by October 2014. Six general (family) practices were selected, a seventh was later added, to ensure recruitment to target in the available time period. Eligible patients were 45-75 years old, without contra-indications to increasing MVPA. Care-home residents and those with unsuitable conditions were excluded[[23](#_ENREF_23)]. All eligible subjects were classified by household. Households were selected at random using STATA’s random number generator. All subjects in single person households were included. In multi-person households an index person was selected at random and a second person randomly selected from amongst those aged within 15 years of the index person. Random samples of 400 eligible households were selected per practice[[23](#_ENREF_23)], individual invitations were posted. Those reporting achieving ≥150 minutes of MVPA weekly on a validated self-report PA question[[24](#_ENREF_24)] were excluded. The London Research Ethics Committee (Hampstead) provided approval (12L/LO/0219). Trial registration: ISRCTN 98538934.

**Randomisation and masking**

Random allocation, by household, avoiding couple contamination, was in a 1:1:1 ratio using the Kings College Clinical Trials Unit internet service, ensuring allocation concealment. Block randomisation was used within practice, with random-sized blocks for balanced groups and an even nurse workload. Participants, nurses and researchers were unmasked to intervention allocation. Main outcome analyses were conducted by statisticians masked to study group.

**Procedures**

Trial procedures, including individual informed written consent, baseline and 3 and 12 month follow-up assessments and complex intervention components are fully described elsewhere[[23](#_ENREF_23)] (S1 Text) and summarised in S1 Fig. Of note, if participants were unable to be contacted at 3 months, contact was still attempted again at the main 12-month outcome. Assessment of outcomes were conducted identically for all three groups; an accelerometer (GT3X+, Actigraph LLC) was used for baseline, 3 and 12 month masked PA assessment of step-counts and time in different PA intensities. A simple pedometer, the SW-200 Yamax Digi-Walker was used by both nurse and postal groups to record their own step-counts, as part of the intervention. The interventions incorporated behavior change techniques (BCTs) and included individualised step-count and PA goals and the “3000-in-30” PA intensity message. Key intervention components were: pedometers (SW-200 Yamax Digi-Walker); patient handbook; physical activity diary (including individual 12-week walking plan); and three individually-tailored practice nurse PA (10-20 minute) consultations (nurse-support group only) were offered at approximately weeks 1, 5 and 9. The handbook and diary are available on the PACE-UP website [www.paceup.sgul.ac.uk/materials](http://www.paceup.sgul.ac.uk/materials) and both explain that adding 3000 steps/day (approximating a 30 minute walk) on 5 or more days weekly to an individual’s baseline step-count, progressing over 12 weeks, would help achieve PA guidelines. BCTs, including goals and planning, self-monitoring and feedback and encouraging social support, were included in the handbook, diary and nurse consultations[[23](#_ENREF_23)]. Participants in both postal and nurse intervention groups were encouraged to continue using the pedometer to monitor their walking and step-count beyond the 3 month intervention period, if they found this helpful. Control group participants were not provided with any feedback on their PA levels or materials promoting PA during the trial. They had follow-up assessments as per the intervention groups and were informed at the start of the trial that after 12 month follow-up they would be offered feedback on their PA levels over the trial, a pedometer and trial handbook and diary, either by post or as part of a single nurse consultation (according to their preference).

**Outcomes**

The primary outcome is change in average daily step-count, assessed by accelerometry over 7 days, between baseline and 12 months. Secondary PA outcomes (all accelerometry) are: changes in step-counts between baseline and 3 months; changes in time spent weekly in MVPA in ≥10 minute bouts and time spent sedentary between baseline and 3 and 12 months.

Ancillary outcomes reported are:

1. changes in anthropometry (body mass index, waist circumference, body fat)[[23](#_ENREF_23)] at 12 months;
2. changes in patient reported outcomes (exercise self-efficacy, anxiety, depression, health related quality of life, pain (see protocol for full references[[23](#_ENREF_23)] (S1 Text)) at 3 and 12 months;
3. adverse outcomes - falls, injuries, fractures, cardiovascular disease events and deaths, assessed from trial monitoring procedures, questionnaires at 3 and 12 months and primary care records.

The following additional outcomes specified in the trial registry and trial protocol (S1 Text) will be published separately: economic (cost-effectiveness, including health service use outcomes and including a Markov model to simulate long-term cost effectiveness); self-report PA variables[[23](#_ENREF_23)]; and a process evaluation*.* Qualitative evaluations from non-participants,[[25](#_ENREF_25)] participants[[26](#_ENREF_26)] and practice nurses[[27](#_ENREF_27)] are already published. An additional paper comparing trial participants and non-participants is also in progress.

**Statistical analysis**

A sample of 993 (331 per group) was required to detect a 1000 steps/day difference (assuming a standard deviation of 2700) at 12 months, when comparing any two groups, with 90% power, at p=0.01. Household clustering was allowed for, assuming an intra-cluster correlation of 0.5 and an average household size of 1.6 and we assumed 15% attrition[[23](#_ENREF_23)]. Analysis and reporting followed CONSORT guidelines (S2 Text).

Actigraph data were reduced using Actilife software (v 6.6.0), ignoring runs of ≥60 minutes of zero counts[[23](#_ENREF_23)]. Vertical counts were used as these are the basis of the validated step-count and MVPA algorithms. The analysis summary variables used were: step-counts; accelerometer wear-time; time spent in MVPA (≥1,952 Counts Per Minute (CPM), equivalent to ≥3 Metabolic Equivalents (METs)[[28](#_ENREF_28)]; time spent in ≥10 minute MVPA bouts; and time spent sedentary (≤100 CPM, equivalent to ≤1.5 METs)[[29](#_ENREF_29)].

Changes from protocol planned analyses[[23](#_ENREF_23)] (S1 Text) were approved by the Trial Steering Committee, prior to analyses. We report MVPA in ≥10 minute bouts, as this relates more closely to PA guidelines[[1](#_ENREF_1), [4](#_ENREF_4)]. Only 20% of participants were non-white; ethnic group was therefore excluded from sub-group analyses, due to low power.

To lessen attrition bias, our primary analysis included all participants with ≥1 day of 540 minutes wear-time at 12 months. All analyses were carried out using Stata, version 12.0 [StataCorp]. Regression analyses used the *xtmixed* procedure. For accelerometry this was in two stages. Stage 1 estimated average daily step-count at 12 months and at baseline derived by using the same two-level model (level 1 was day within individual, level 2 was individual) in which daily step-counts were regressed on day-order-of-wear and day-of-week. Random effects were assumed to be independent. In stage 2, we regressed estimated average daily step-count at 12 months on estimated average daily baseline step-count, month of baseline accelerometry, age, gender, general practice and treatment group. This effectively measured change in step-count over the 12 months, minimising bias and maintaining power. In this analysis, level 1 was individual and level 2 household. The pwcompare (pairwise comparison) post estimation command was used to generate estimates and confidence limits for the difference in change between the Nurse and Control groups and the Postal and Control groups. The same command was used to provide a direct comparison of the Nurse and Postal groups; while the difference is effectively the difference of the previous 2 estimates, it is important to put confidence limits on this comparison. Secondary outcome measures, MVPA in ≥10 minute bouts and sedentary time, were analysed using identical approaches, as were 3 month outcomes. Checks confirmed that distributions of residuals from the regression models were normally distributed (S2 Fig). Change in anthropometric measures and patient reported outcomes were estimated using identical models to stage 2 above. Sensitivity analyses were carried out for our primary outcome. We assessed: (i) the effect of restricting analyses to those with ≥600 minutes of daily wear-time (both with ≥1 day of accelerometry at 12 months and ≥5 days of accelerometry data at 12 months; (ii) whether participants lost to follow-up, or who failed to record a single adequate day at 12 months, might have introduced bias, using the Stata procedure *mi impute*; (iii) the possible impact of outcomes not being missing at random; iv) the effect of adjusting for wear-time. We also conducted further analyses examining total time in MVPA, as opposed to time in MVPA in ≥10 minute bouts.

**Patient involvement**

Pilot work with older primary care patients from three general practices was carried out ahead of seeking trial funding, with focus groups at each practice discussing ideas for a pedometer-based physical activity intervention. Patients were enthusiastic about the study and felt that the postal approach to recruitment and the interventions offered would be acceptable. They had input into aspects of the study design, for example they encouraged us to offer the usual care arm a pedometer at the end of the follow-up period and they encouraged us to recruit couples, as well as individuals, and to allow couples to attend nurse appointments together. A patient advisor was a Trial Steering Committee member and was involved in discussions about recruitment and study conduct, as well as advising about patient materials, dissemination of results to participants and safety reporting mechanisms. All participants were provided with timely feedback of their individual trial results after completion of 12 month follow-up, including their physical activity and body size measures over the trial duration. Summaries of results for the whole trial were disseminated to all trial participants as A4 feedback sheets after completion of baseline assessments and after analysis of the main results. A trial website has been created and details circulated to participants [www.pace-up.sgul.ac.uk](http://www.pace-up.sgul.ac.uk). This also provides a summary of the trial results and details about further trial follow-up. All publications relating to the trial are provided on the website. The burden of the intervention was assessed by all participants in the nurse group with a questionnaire as part of the process evaluation, and by samples of both intervention groups as part of the qualitative evaluation[[26](#_ENREF_26)].

**Results:**

**Participants**

Of 11,015 invited, 6,399 did not respond, 548 were excluded due to self-reported PA guideline achievement, 127 were recruited but did not attend baseline assessment or provided inadequate baseline accelerometry data, 1023/10,467 (10%) were randomised (Fig 1). 32/1023 (3%) of participants withdrew and 8/1023 (1%) were uncontactable at 12 months. In total, 956/1023 (93%) participants provided at least 1 day of 540 minutes wear-time accelerometer data and were included in 12 month primary analyses. Baseline findings (Table 1) showed recruitment was balanced across age-groups; over a third were male. Characteristics were similar between groups. The nurse-support group had a slightly higher baseline adjusted average daily step-count (7653s.d. 2826) and minutes spent weekly in MVPA in bouts of ≥10 minutes (105 s.d. 116) compared with the postal (steps 7402 s.d.2476, MVPA in bouts 92 s.d.90) and control groups (steps 7379 s.d. 2696, MVPA in bouts 84 s.d. 97). Overall 218/1023 (21%) achieved PA guidelines of ≥150 minutes of MVPA in bouts. Accelerometer wear-time was similar between groups at baseline, 3 and 12 month follow-ups (Tables 1 & 2). Over 90% of all groups provided ≥5 days of ≥540 minutes wear-time at 12 months (S1 Table).

# **Fig 1. PACE-UP CONSORT diagram**

**Table 1. Baseline characteristics of 1023 randomised subjects.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Control (n=338)** | **Postal (n=339)** | **Nurse (n=346)** |
|  |  **n**  | **(%)** |  **n**  | **(%)** |  **n**  | **(%)** |
| **Age at randomisation** |  |  |  |  |  |  |
| 45-54 years | 101 | (30%) | 118 | (35%) | 121 | (35%) |
| 55-64 years | 138 | (41%) | 125 | (37%) | 124 | (36%) |
| 65-75 years | 99 | (29%) | 96 | (28%) | 101 | (29%) |
| **Gender: Male** | 115 | (34%) | 124 | (37%) | 128 | (37%) |
| **Marital Status:** Married | 213 | (64%) | 215 | (65%) | 230 | (68%) |
| **Randomised as a couple \*** | 66 | (20%) | 68 | (20%) | 73 | (21%) |
| **Employment status** |  |  |  |  |  |  |
| In full or part-time employment | 190 | (57%) | 193 | (59%) | 190 | (56%) |
| Retired | 102 | (31%) | 96 | (29%) | 101 | (30%) |
| Other | 39 | (12%) | 39 | (12%) | 50 | (15%) |
| **National Statistics Socio-economic Classification (NS-SEC) (current or previous job)** |  |  |  |  |  |  |
| Higher managerial, administrative, professional | 199 | (62%) | 191 | (60%) | 184 | (56%) |
| Intermediate occupations | 70 | (22%) | 85 | (27%) | 95 | (29%) |
| Routine & manual occupations | 51 | (16%) | 44 | (14%) | 52 | (16%) |
| **Ethnicity** |  |  |  |  |  |  |
| White | 253 | (78%) | 270 | (83%) | 267 | (80%) |
| Black / African / Caribbean / Black British | 30 | (9%) | 31 | (10%) | 40 | (12%) |
| Asian / Asian British | 26 | (8%) | 20 | (6%) | 22 | (7%) |
| Other | 15 | (5%) | 4 | (1%) | 6 | (2%) |
| **Current smoker** | 27 | (8%) | 29 | (9%) | 26 | (8%) |
| **General Health†:** Very Good or Good | 265 | (80%) | 277 | (84%) | 277 | (82%) |
| **Chronic diseases†** |  |  |  |  |  |  |
| None | 129 | (39%) | 135 | (41%) | 117 | (35%) |
| 1-2 | 183 | (55%) | 171 | (51%) | 188 | (55%) |
| ≥ 3 | 21 | (6%) | 27 | (8%) | 34  | (10%) |
| **Presence of self-reported pain†** | 220 | (66%) | 236 | (71%) | 234 | (70%) |
| **Limiting long-standing illness†** | 76 | (23%) | 73 | (22%) | 74 | (22%) |
| **Townsend disability score†** |  |  |  |  |  |  |
| None (0) | 190 | (57%) | 196 | (59%) | 210 | (62%) |
| Slight or some disability (1-6) | 127 | (38%) | 130 | (39%) | 124 | (36%) |
| Appreciable or severe disability (7-18) | 15 | (5%) | 8 | (2%) | 7 | (2%) |
| **HADS depression score†:** borderline or high | 36 | (11%) | 33 | (10%) | 42 | (12%) |
| **HADS anxiety score†:** borderline or high | 65 | (19%) | 64 | (19%) | 71 | (21%) |
| **Low self-efficacy score†** | 102 | (31%) | 96 | (29%) | 117 | (35%) |
| **Month of baseline measure** |  |  |  |  |  |  |
| March – May | 80 | (24%) | 75 | (22%) | 76 | (22%) |
| June – August | 105 | (31%) | 106 | (31%) | 110 | (32%) |
| September – November | 88 | (26%) | 82 | (24%) | 92 | (27%) |
| December – February | 65 | (19%) | 76 | (22%) | 68 | (20%) |
| **Physical characteristics** |  |  |  |  |  |  |
| Overweight/obese: BMI ≥25kg/m2 | 227 | (67%) | 221 | (65%) | 233 | (67%) |
|  | **Mean** | **(s.d.)** | **Mean** | **(s.d.)** | **Mean** | **(s.d.)** |
| Fat mass (kg) | 26  | (10) | 27  | (11) | 26  | (11) |
| Waist circumference (cm) | 93  | (14) | 94  | (14) | 93  | (13) |
| **Accelerometry data** | **Mean** | **(s.d.)** | **Mean** | **(s.d.)** | **Mean** | **(s.d.)** |
| Adjusted baseline step count per day | 7379 | (2696) | 7402 | (2476) | 7653 | (2826) |
| Total weekly minutes of moderate or vigorous physical activity (MVPA) in ≥10 minute bouts | 84 | (97) | 92 | (90) | 105 | (116) |
| Average daily sedentary time (minutes) | 613 | (68) | 614 | (71) | 619 | (78) |
| Average daily wear time (minutes) | 789 | (73) | 787 | (78) | 797 | (84) |

**Footnotes**

**\*** 2 and 1 participants in the postal and nurse groups respectively were randomised and took part in the trial as a couple, although their partner was excluded before randomisation due to lack of wear time.

**†** Full references for General Health, Chronic disease score, self-reported pain, HADS depression and anxiety scores, Townsend Disability Score, Self-Efficacy Score, are given in the trial protocol 23

# **Table 2. Primary and secondary accelerometry outcome data**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Postal vs Control** |  | **Nurse vs Control** |  | **Nurse vs Postal** |
|  | **Effect** | **95% CI** | ***p*-value** |  | **Effect** | **95% CI** | ***p*-value** |  | **Effect** | **95% CI** | ***p*-value** |
| **Daily step count** |  |  |  |  |  |  |  |  |  |  |  |
| **3 months** | 692 | (363, 1020) | <0.001 |  | 1172 | (844, 1501) | <0.001 |  | 481 | (153, 809) | 0.004 |
| **12 months** | 642 | (329, 955) | <0.001 |  | 677 | (365, 989) | <0.001 |  | 36 | (-277, 349) | 0.82 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Total weekly minutes of MVPA in ≥10 minute bouts** |  |  |  |  |  |  |  |  |  |
| **3 months** | 43 | (26, 60) | <0.001 |  | 61 | (44, 78) | <0.001 |  | 18 | (1, 35) | 0.04 |
| **12 months** | 33 | (17, 49) | <0.001 |  | 35 | (19, 51) | <0.001 |  | 2 | (-14, 17) | 0.83 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Daily sedentary time (minutes)** |  |  |  |  |  |  |  |  |  |  |  |
| **3 months** | -2 | (-12, 7) | 0.59 |  | -7 | (-16, 3) | 0.16 |  | -4 | (-13, 5) | 0.38 |
| **12 months** | 1 | (-8, 10) | 0.83 |  | -0.2 | (-9, 9) | 0.96 |  | -1 | (-10, 8) | 0.79 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Daily wear time (minutes)** |  |  |  |  |  |  |  |  |  |  |  |
| **3 months** | 2 | (-8, 12) | 0.69 |  | 4 | (-6, 14) | 0.40 |  | 2 | (-8, 12) | 0.65 |
| **12 months** | 9 | (-1, 19) | 0.08 |  | 9 | (-0.8, 19) | 0.07 |  | 0.3 | (-10, 10) | 0.96 |
|  |  |  |  |  |  |  |  |  |  |  |  |

**Footnotes**

Results shown for “Postal vs Control” are the additional effect seen in the Postal group relative to the Control group and similarly for “Nurse vs Control” and “Nurse vs Postal”.

Accelerometry data were available in the control, postal and nurse groups respectively for 318, 317 and 319 participants at 3 months and for 323, 312 and 321 at 12 months.

All models include practice, gender, age at randomisation and month of baseline accelerometry as fixed effects and household as a random effect in a multi-level model.

The *xtmixed* command in Stata v12 was used followed by the post-estimation command *pwcompare* to generate the pairwise estimates of effects and their confidence intervals.

Among intervention participants, 256/346 (74%) of the nurse-support group attended all three sessions and 268/339 (79%) of the postal and 281/346 (81%) of the nurse-support group sent back PA diaries completed with their pedometer step-counts after the intervention.

**Effect of the intervention on physical activity at 3 and 12 months (Table 2)**

*3 month (interim) outcomes*

There were significant differences for change in step-counts from baseline to 3 months between intervention groups and the control group: additional step-counts (steps/day) postal 692 (95% CI 363, 1020) (p<0.001), nurse support 1172 (95% CI 844, 1501) (p<0.001); the difference between the intervention groups was statistically significant 481 (95% CI 153, 809) (p=0.004). Findings for MVPA showed a similar pattern: additional MVPA in bouts (minutes/week) postal 43 (95% CI 26, 60) (p<0.001), nurse-support 61 (95% CI 44, 78) (p<0.001), difference between intervention groups 18 (95% CI 1, 35) (p=0.04). Sedentary time was similar between groups. Summary data for 3-month PA outcomes are shown in S2 Table.

*12 month (main) outcomes*

Both intervention groups increased their step-counts at 12 months compared with controls: additional step-counts (steps/day) postal 642 (95% CI 329, 955) (p<0.001), nurse-support 677 (95% CI 365, 989) (p<0.001), with no statistically significant difference between intervention groups, 36 (-277, 349). Time spent in MVPA in bouts showed a similar pattern, both intervention groups increased at 12 months compared with controls: additional MVPA in bouts (minutes/week) postal 33 (95% CI 17, 49) (p<0.001, nurse-support 35 (95% CI 19, 51) (p<0.001) with no statistically significant difference between intervention groups, 2 (-14, 17). Sedentary time was similar between groups. Summary data for 12-month PA outcomes are shown in S2 Table.

**Effect of the intervention on other health-related outcomes (Table 3)**

Fat mass was slightly reduced at 12 months in both intervention groups, but these differences did not differ significantly from the control group. There was no change in body mass index or waist circumference. The interventions had no significant effects on anxiety, depression, health related quality of life or pain scores at 3 or 12 months. Exercise self-efficacy score significantly increased in both intervention groups at 3 months compared with controls and there was a greater effect in the nurse group compared with postal. By 12 months, there was a difference in self-efficacy score between only the nurse and control groups, the postal group was intermediate between, but not significantly different from, the other groups. Summary data for health-related outcomes are shown in S2 Table.

# **Table 3. Ancillary outcomes**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Postal vs Control** |  | **Nurse vs Control** |  | **Nurse vs Postal** |
|  | **Effect** | **95% CI** | ***p*-value** |  | **Effect** | **95% CI** | **p-value** |  | **Effect** | **95% CI** | ***p*-value** |
| **Body Mass Index (kg/m2)** |  |  |  |  |  |  |  |  |  |  |  |
| **12 months** | -0.1 | (-0.3, 0.1) | 0.24 |  | -0.03 | (-0.2, 0.1) | 0.71 |  | 0.07 | (-0.1, 0.3) | 0.42 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Fat Mass (kg)** |  |  |  |  |  |  |  |  |  |  |  |
| **12 months** | -0.4 | (-0.8, 0.07) | 0.10 |  | -0.2 | (-0.7, 0.2) | 0.30 |  | 0.1 | (-0.3, 0.6) | 0.54 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Waist circumference (cm)** |  |  |  |  |  |  |  |  |  |  |  |
| **12 months** | -0.04 | (-0.8, 0.7) | 0.92 |  | 0.08 | (-0.6, 0.8) | 0.23 |  | 0.1 | (-0.6, 0.8) | 0.74 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **HADS Anxiety Score** |  |  |  |  |  |  |  |  |  |  |  |
| **3 months** | -0.3 | (-0.7, 0.1) | 0.13 |  | -0.3 | (-0.7, 0.1) | 0.16 |  | 0.01 | (-0.4, 0.4) | 0.94 |
| **12 months** | -0.2 | (-0.6, 0.2) | 0.28 |  | -0.2 | (-0.6, 0.2) | 0.28 |  | 0.0006 | (-0.4, 0.4) | 1.00 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **HADS Depression Score** |  |  |  |  |  |  |  |  |  |  |  |
| **3 months** | -0.2 | (-0.6, 0.1) | 0.12 |  | -0.2 | (-0.5, 0.1) | 0.19 |  | 0.04 | (-0.3, 0.3) | 0.82 |
| **12 months** | -0.1 | (-0.5, 0.2) | 0.44 |  | -0.02 | (-0.4, 0.3) | 0.91 |  | 0.1 | (-0.2, 0.5) | 0.51 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **EQ5D** |  |  |  |  |  |  |  |  |  |  |  |
| **3 months** | -0.005 | (-0.02, 0.01) | 0.60 |  | -0.01 | (-0.03, 0.01) | 0.26 |  | -0.006 | (-0.03, 0.01) | 0.54 |
| **12 months** | -0.01 | (-0.03, 0.01) | 0.30 |  | -0.01 | (-0.03, 0.01) | 0.23 |  | -0.002 | (-0.02, 0.02) | 0.87 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Exercise self-efficacy** |  |  |  |  |  |  |  |  |  |  |  |
| **3 months** | 1.1 | (0.2, 2.0) | 0.01 |  | 2.3 | (1.4, 3.2) | <0.001 |  | 1.2 | (0.3, 2.1) | 0.01 |
| **12 months** | 0.6 | (-0.3, 1.6) | 0.20 |  | 1.2 | (0.3, 2.2) | 0.01 |  | 0.6 | (-0.4, 1.5) | 0.22 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Self-report pain** |  |  |  |  |  |  |  |  |  |  |  |
| **3 months** | 0.05 | (-0.06, 0.17) | 0.37 |  | 0.05 | (-0.07, 0.16) | 0.42 |  | -0.004 | (-0.12, 0.11) | 0.94 |
| **12 months** | 0.05 | (-0.06, 0.17) | 0.35 |  | 0.02 | (-0.10, 0.13) | 0.76 |  | -0.04 | (-0.15, 0.08) | 0.53 |
|  |  |  |  |  |  |  |  |  |  |  |  |

**Footnotes**

Results shown for “Postal vs Control” are the additional effect seen in the Postal group relative to the Control group and similarly for “Nurse vs Control” and “Nurse vs Postal”.

At baseline, data were available for all participants for BMI and waist circumference, and for 335, 337 and 346 participants in the control, postal and nurse groups respectively for fat mass.

At 12 months, data were available in the control, postal and nurse groups respectively for 323, 314 and 321 participants for BMI and waist circumference, and for 319, 308 and 320 for fat mass.

Questionnaire data were available for varying numbers of participants at baseline, 3 months and 12 months.

All models include practice, gender, age at randomisation and month of baseline accelerometry as fixed effects and household as a random effect in a multi-level model.

**Sub-group analyses (Figs 2a & 2b)**

There was no evidence of effect modification on change in step-count at 12 months for either of the intervention groups versus control for any of the following: age; gender; taking part as a couple; body mass index, disability; pain; socio-economic group; exercise self-efficacy.

**Effect of the intervention on adverse events and serious adverse events (Table 4)**

Total adverse events did not differ between groups at 3 or 12 months, whether self-reported on the questionnaire (falls, fractures, sprains and injuries) or from primary care records (any adverse event). There was also no between group difference in trial serious adverse events reported for safety monitoring. Self-reported falls were lower in the nurse group at 12 months (p=0.02). Falls reported in primary care records over 12 months are fewer, but also in the same direction, although differences are non-significant (p=0.13). Primary care recorded cardiovascular events over 0-12 months were lower in the intervention groups than in controls (p=0.04).

**Figure 2. Treatment effect for primary outcome by sub-group at 12 months**

1. Postal and Control groups b) Nurse and Control groups

**Table 4. Adverse events.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **0-3 months** |  | **0-12 months** |
|  | **N** | **Control** | **(%)** | **Postal** | **(%)** | **Nurse** | **(%)** | ***p*-value†** |  | **N** | **Control** | **(%)** | **Postal** | **(%)** | **Nurse** | **(%)** | ***p*-value†** |
| **Adverse events reported on the questionnaire** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Fall, fracture, sprain or injury | 931 | 59/313 | (19) | 70/310 | (23) | 65/308 | (21) | 0.51 |  | 946 | 113/318 | (36) | 99/310 | (32) | 96/318 | (30) | 0.34 |
| Fall |  | 25 | (8) | 24 | (8) | 24 | (8) | 0.99 |  |  | 71 | (22) | 57 | (18) | 43 | (14) | 0.02 |
| Fracture |  | 3 | (1) | 3 | (1) | 7 | (2) | 0.28 |  |  | 15 | (5) | 10 | (3) | 11 | (3) | 0.57 |
| Sprain or injury |  | 49 | (16) | 54 | (17) | 47 | (15) | 0.74 |  |  | 66 | (21) | 68 | (22) | 63 | (20) | 0.81 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Deterioration in health problems already present, since start of study | 911 | 33/311 | (11) | 30/303 | (10) | 39/297 | (13) | 0.42 |  | 924 | 68/313 | (22) | 67/300 | (22) | 65/311 | (21) | 0.91 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Adverse events from Primary Care records‡** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Any adverse event | 1005 | 29/334 | (8.7) | 23/331 | (7.0) | 20/340 | (5.9) | 0.36 |  | 1005 | 85/334 | (25.5) | 75/331 | (22.7) | 77/340 | (22.7) | 0.62 |
| Cardiovascular§ |  | 2 | (0.6) | 0 |  | 1 | (0.3) | 0.55 |  |  | 8 | (2.4) | 1 | (0.3) | 2 | (0.6) | 0.04 |
| Fracture |  | 4 | (1.2) | 2 | (0.6) | 2 | (0.6) | 0.68 |  |  | 11 | (3.3) | 4 | (1.2) | 4 | (1.2) | 0.11 |
| Sprain / injury  |  | 2 | (0.6) | 1 | (0.3) | 2 | (0.6) | 1.00 |  |  | 8 | (2.4) | 4 | (1.2) | 5 | (1.5) | 0.51 |
| Fall |  | 0 |  | 0 |  | 0 |  |  |  |  | 8 | (2.4) | 4 | (1.2) | 2 | (0.6) | 0.13 |
| Pain (back or lower limb) |  | 23 | (6.9) | 20 | (6.0) | 16 | (4.7) | 0.48 |  |  | 65 | (19.5) | 65 | (19.6) | 70 | (20.6) | 0.93 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Serious adverse event spontaneously reported\*** | 1023 | 3/338 | (0.9) | 1/339 | (0.3) | 3/346 | (0.9) | 0.65 |  | 1023 | 10/338 | (3.0) | 5/339 | (1.5) | 11/346 | (3.2) | 0.30 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Footnotes**

1. Chi-squared tests or Fisher exact tests were carried out to assess statistical significance for overall differences between the three groups.
2. 1005 participants gave permission at randomisation for their primary care records to be accessed and downloaded.
3. Cardiovascular events recorded in primary care records included a new episode of any of the following: myocardial infarction, coronary artery bypass graft, angioplasty, ischaemic heart disease, angina, transient ischaemic attack, stroke.

\* Information on spontaneously reported serious adverse events were collected for the entire cohort, n=1023. Serious adverse events were recorded for safety purposes contemporaneously in the trial and included the following: deaths, hospital admission and new onset disability. All the serious adverse events reported during the 0-12 month trial follow-up were emergency hospital admissions.

**Sensitivity analyses and imputations (S3 Table)**

Restricting analyses to those with ≥600 minutes daily wear-time (and either ≥1 or ≥5 days of accelerometry data at 12 months) and imputations with both missing at random and missing not at random assumptions and analyses adjusting for accelerometer wear-time gave broadly similar effect size estimates for both interventions compared with control and to each other, and made no difference to interpretation.

Analyses of total MVPA as the outcome produced almost identical effect size estimates as found with MVPA in ≥10 minute bouts: at 12 months postal versus control was 36 (17, 55) minutes per week and nurse versus control was 32 (13, 50) minutes per week. In other words, all of the increase in MVPA was in ≥10 minute bouts.

**Discussion:**

*Principal Findings*

The interventions increased objectively assessed PA (step-counts by about 650-700 steps per day and MVPA in bouts by about 33-35 minutes per week) among predominantly inactive 45-75 year olds at 12 months. Whilst nurse delivery had a greater effect than postal delivery at 3 months, by 12 months this difference was not sustained. Exercise self-efficacy was significantly increased by both interventions compared to control at 3 months and in the nurse group at 12 months. The interventions had no effect on sedentary time, anthropometry, or other outcomes and did not increase adverse events. Both interventions were well accepted; three quarters of the nurse group attended all three sessions and ~80% of both groups returned completed step-count diaries. The trial was novel in clearly separating out the effects of pedometer provision and nurse support in a general population sample of adults and older adults and demonstrating the effects on both step-counts and MVPA in bouts, thus making the outcome assessment relevant to current national and international PA guidelines.

*Study Strengths and Limitations*

Study strengths include: a large, population-based, primary care sample; household randomisation, allowing comparison of individual and couple effects; three arms, allowing separation of nurse support and pedometer/handbook effects; practice nurses, rather than researchers or exercise specialists delivering the intervention; good uptake of nurse appointments and return of completed step-count diaries; an objective PA outcome, relevant to PA guidelines; adverse event measurement from primary care records; a 93% follow-up rate; and embedded economic and qualitative evaluations (not presented here). There were some study limitations. The 10% (1023/10467) recruitment rate raises issues of generalizability which are dealt with in the later section on Implications for Policy, Practice and Future Research. At baseline 218/1023 (21%) achieved PA guidelines based on accelerometry. They were not excluded, because if rolled out in primary care, self-report would define participation. Our nurse intervention group had slightly higher baseline PA levels; however, results were not biased, as analyses were based on individual change, controlling for baseline PA level. It was impossible to mask participants and nurses to group and, pragmatically, research assistants recruited and followed up the same participants, so were unmasked to group at outcome assessment. However, all the primary and secondary PA outcomes were assessed objectively. Participants might have tried harder with their PA when monitored; but this would also have affected controls and would be reduced by using a 7-day protocol[[16](#_ENREF_16)]. Also, our intervention groups increased MVPA in bouts of ≥10 minutes, implying that participants made changes suggested by the programme. Despite recruiting to target and having excellent follow-up, our confidence intervals for the difference between intervention groups cannot rule out a small 12 month difference.

*Main Results in Context of Other Literature*

To our knowledge, this is the largest population-based trial of a pedometer-based walking intervention with 12 month follow-up and is consistent with our findings in 60-75 year olds in the smaller PACE-Lift trial[[21](#_ENREF_21)]. Whilst the PACE-Lift intervention also included pedometer feedback, step-count diary and practice nurse PA consultations based around BCTs, it comprised four, longer consultations which also included accelerometer feedback on PA intensity. PACE-Lift only had a single intervention arm and was therefore unable to separate out PA monitor effects from those of the nurse support. Despite a less intense intervention, PACE-UP has delivered similar levels of effect at both 3 and 12 months and additionally has shown what can be achieved via a postal route. Compared with systematic reviews[[10](#_ENREF_10), [16](#_ENREF_16), [17](#_ENREF_17)], our absolute step-count increase was modest. However, most trials with 12 month data have been based on small numbers and either volunteers[[30](#_ENREF_30)], high risk groups[[9](#_ENREF_9)], or self-report PA data[[31](#_ENREF_31)], likely leading to larger effects. PA guidelines focus on time in MVPA, not step-counts; the reviews presented no data on this important outcome[[10](#_ENREF_10), [16](#_ENREF_16), [17](#_ENREF_17)]. PACE-UP results confirm PACE-Lift findings[[21](#_ENREF_21)], with significant 12 month increases in MVPA in bouts. Based on the “3000 in 30” formula, 35 extra minutes of MVPA/week in bouts, corresponds to 500 extra steps/day. Thus, three-quarters of the extra steps achieved contributed to MVPA in bouts. We believe our trial is the first to show that the “3000-in-30” message[[8](#_ENREF_8)] can lead to an approximately one third increase in weekly MVPA in bouts at 12 months, achieved across both intervention groups. It is also reassuring that our interventions did not increase sedentary time, given its potential harm, as compensation can sometimes occur.

Most pedometer-based interventions have not separated pedometer and support effects[[14](#_ENREF_14), [16](#_ENREF_16), [21](#_ENREF_21)]. The Healthy Steps trial showed pedometers achieved an additional effect compared with a primary care PA prescription, but PA outcomes were self-reported[[31](#_ENREF_31)]. PACE-UP demonstrates that whilst the nurse intervention group had a significantly greater effect on both step-counts and time in MVPA at 3 months, by 12 months both nurse and postal interventions still had a significant effect, but with no evidence of difference between them. This stronger effect during the period of contact with the nurse, which was not sustainable longer-term, has also been shown in other interventions with health professionals[[32](#_ENREF_32)]. Both nurse and postal groups received a pedometer, diary and handbook as part of the PACE-UP package, it is not possible to know how much the individual components contributed. A systematic review suggested that step-count diaries were common to successful pedometer interventions[[16](#_ENREF_16)] and approximately 80% of both of our intervention groups returned completed step-count diaries. Also, our qualitative findings suggest that participants from both groups valued the handbook and diary, as well as the pedometer[[26](#_ENREF_26)].

We found no effect of the interventions on body mass index or fat mass, consistent with other studies[[21](#_ENREF_21), [30](#_ENREF_30)]. Our interventions did not affect anxiety or depression scores, consistent with other primary care pedometer-based interventions, suggesting either no effect, or insensitivity of these measures to change, particularly when levels are in the normal range for most people[[19](#_ENREF_19), [21](#_ENREF_21)]. However, whilst a few participants mentioned negative effects from overdoing walking, most intervention participants talked about feeling fitter, sleeping better, improved mood, having more energy, less pain and keeping more active into older age[[26](#_ENREF_26)]. There is a lack of data comparing individual, couple or household participation in walking studies[[15](#_ENREF_15), [21](#_ENREF_21)]. Household sampling allowed us to investigate this, but only 20% participated as couples, reducing the power of our sub-group analyses, which showed no effect.

Self-efficacy differences between both intervention groups and controls at 3 months and between the nurse group and controls at 12 months are consistent with the positive relationship between changing self-efficacy and PA behaviour[[33](#_ENREF_33)]. The BCTs most associated with self-efficacy and successful outcomes are: goal and action planning; prompting self-monitoring and feedback; planning of social support/change[[33](#_ENREF_33)]. All were specifically recommended in recent guidance[[11](#_ENREF_11)] and were included in our study in written materials for both intervention groups and as a focus of nurse PA consultations[[23](#_ENREF_23)]. Our qualitative interviews found that more BCT comments were made by the nurse than postal group, apart from around self-monitoring[[26](#_ENREF_26)]. Increased self-efficacy is important for long-term PA adherence[[34](#_ENREF_34)].

Walking is a safe intervention, indicated in many chronic diseases[[1](#_ENREF_1), [7](#_ENREF_7)], although empirical data is limited[[13](#_ENREF_13)] and a large trial on 40-74 year old women, encouraging a single 30 minute brisk walk 5 days weekly, reported increased falls and injuries[[24](#_ENREF_24)]. Our findings showing no increase in adverse events builds on similar evidence from PACE-Lift[[21](#_ENREF_21)], using both self-report and primary care data, and highlights the potential importance of building up MVPA gradually, particularly in those who are inactive or have co-morbidities[[1](#_ENREF_1), [6](#_ENREF_6)]. The suggestion of a protective effect of the interventions on falls and cardiovascular events is plausible, but not definitive, as it is based on small numbers of events.

*Implications for Policy, Practice and Future Research*

Individual PA behaviour change approaches, such as PACE-UP, are important in tackling the public health challenge of physical inactivity, but for maximum benefit need to occur alongside environmental and policy approaches[[12](#_ENREF_12)]. Our results support current guidance for pedometers, which suggests that they are used as part of a package which includes support to set realistic goals, monitoring and feedback[[35](#_ENREF_35)]. Only 10% of eligible individuals were randomised, similar to other primary care PA trials[[19](#_ENREF_19), [36](#_ENREF_36)], but lower than the 30% in our recent older adult trial[[21](#_ENREF_21)]. However, 10% of a population sample is still a very useful percentage to be participating in a public health intervention and this trial shows the potential of primary care to contribute to physical activity public health goals. It is important to consider whether the subjects randomised are representative of the target population from which they were drawn, particularly given the uptake rate of 10%. From table 1, we can see that of those randomised, there were more women than men and the proportion of subjects of Asian origin and from deprived areas was low and fewer than expected from the areas sampled. While approximately 4/5 of those randomised reported their health as good or very good, about 2/3 were overweight or obese, half reported 1-2 chronic diseases, nearly 2/5 reported slight/some disability and over 1/5 reported a limiting longstanding illness. Older subjects were well represented. Thus while it is unlikely that those randomised are entirely typical of the practice populations (it would be surprising if they were), there was substantial representation from groups who are particularly likely to benefit from the intervention; specifically older subjects, women, and the overweight. Moreover 1/3 of those randomised rated their self-efficacy for exercise as low. Nevertheless, some groups, for example Asians, will be under-represented and we are carrying out further work comparing participants and non-participants to identify these. Tailoring future interventions to be more acceptable to such groups will be important.If the intervention were to be rolled out in routine primary care, take-up could be higher, with no requirement for informed consent, randomisation and rigorous evaluation. Handing out the intervention materials (pedometer, handbook and diary) in primary care consultations where advice to increase low PA levels is already being offered is also likely to increase the intervention’s reach (e.g. in relevant chronic disease consultations or as part of preventive health checks, such as the United Kingdom National Health Service Health Checks, which cover a similar age-group and aim to reduce cardiovascular risk[[37](#_ENREF_37)]). The intervention could also be a valuable addition to diabetes prevention strategies, such as the National Health Service Diabetes Prevention Programme[[38](#_ENREF_38)], where primary care is being used to identify patients at high risk of developing diabetes, the majority of whom are inactive. The “3000 steps-in-30 minutes” neatly captures intensity and could become a commendable new public health goal, with many people now having the ability to measure steps easily with their mobile phones.

Our interventions led to an extra 33-35 minutes weekly of MVPA in bouts (an increase of about a third from baseline) and an extra 642-692 steps per day, in a predominantly inactive cohort. Based on a systematic review which has quantified the strength of association between PA (particularly walking) and developing coronary heart disease[[39](#_ENREF_39)], the increase of 33 minutes per week in the postal group in our study at 12 months, if sustained, would be expected to reduce coronary heart disease risk by 4.5% (95% C.I. 3%, 6%) (see S3 Text for details). Similarly, a cohort study relating pedometer measured steps to mortality[[40](#_ENREF_40)]. allowed us to estimate that a sustained increase of 642 steps/day would be expected to decrease all-cause mortality by 4% (95% C.I. 1%, 7%).

Whilst the nurse intervention produced greater effects at 3 months, by 12 months both interventions performed similarly. However, maintenance is important to consider, as long-term health effects require sustained PA increases and little is known about the effectiveness of PA interventions beyond 12 months[[13](#_ENREF_13), [16](#_ENREF_16)]. We designed both PACE-UP interventions to have lasting effects[[23](#_ENREF_23)], including techniques shown to help maintain behaviour change, e.g. encouraging feedback and self-monitoring; relapse prevention strategies and “if-then” plans in case of relapse; building social support; and incorporating new behaviours into daily routines[[11](#_ENREF_11)]. Some strategies may have been more effective in the nurse group; the sustained self-efficacy difference between nurse and control groups at 12 months supports this possibility. It is therefore important to test the long-term effectiveness of both interventions, and we are currently following up the PACE-UP cohort at 3 years.

*Conclusion:*

The PACE-UP pedometer-based walking intervention increased step-counts by approximately a tenth and time in MVPA in bouts by a third, in predominantly inactive 45-75 year old primary care patients. Nurse delivery over three consultations had no greater effect on 12-month PA outcomes than postal delivery. A primary care pedometer intervention, delivered by post, or with minimal contact, would provide an effective approach to addressing the public health physical inactivity challenge.

**Supporting Information**

S1 Text PACE-UP trial protocol (PDF)

S2 Text PACE-UP CONSORT checklist (DOCX)

S3 Text Details on cardiovascular and overall mortality risk reduction (DOCX)

S1 Fig. Trial procedures and complex intervention components (PDF)

S2 Fig. Residuals from 12 month models for steps and weekly MVPA in ≥10 minute bouts

S1 Table. Number of days with ≥540 minutes accelerometer wear-time by treatment group at baseline, 3 months and 12 months

S2 Table. Summary data for main outcome and ancillary outcome variables

S3 Table. Sensitivity and imputation analyses for the primary outcome (step-count at 12 months)

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**References:**

1. Department of Health. Start Active, Stay Active: A report on physical activity for health from the four home countries' Chief Medical Officers. 2011.

2. Lee IM, Shiroma EJ, Lobelo F, Puska P, Blair SN, Katzmarzyk PT. Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy. Lancet. 2012;380(9838):219-29.

3. Carlson SA, Fulton JE, Pratt M, Yang Z, Adams EK. Inadequate physical activity and health care expenditures in the United States. Prog Cardiovasc Dis. 2015;57(4):315-23.

4. World Health Organisation. Global Recommendations on Physical Activity for Health. 2010 2010.

5. U.S. Department of Health & Human Services 2008 physical activity guidelines for Americans. Washington D.C. United States.

6. Sparling PB, Howard BJ, Dunstan DW, Owen N. Recommendations for physical activity in older adults. BMJ. 2015;350:h100.

7. Morris JN, Hardman AE. Walking to health. Sports Med. 1997;23(5):306-32.

8. Marshall SJ, Levy SS, Tudor-Locke CE, Kolkhorst FW, Wooten KM, Ji M, et al. Translating physical activity recommendations into a pedometer-based step goal: 3000 steps in 30 minutes. Am J Prev Med. 2009;36(5):410-415.

9. Yates T, Davies M, Gorely T, Bull F, Khunti K. Effectiveness of a pragmatic education program designed to promote walking activity in individuals with impaired glucose tolerance: a randomized controlled trial. Diabetes Care. 2009;32(8):1404-10.

10. Hobbs N, Godfrey A, Lara J, Errington L, Meyer TD, Rochester L, et al. Are behavioral interventions effective in increasing physical activity at 12 to 36 months in adults aged 55 to 70 years? A systematic review and meta-analysis. BMC Med. 2013;11:75.

11. National Institute for Health and Care Excellence. Behaviour change: individual approaches. 2014.

12. Heath GW, Parra DC, Sarmiento OL, Andersen LB, Owen N, Goenka S, et al. Evidence-based intervention in physical activity: lessons from around the world. Lancet. 2012;380(9838):272-81.

13. Richards J, Hillsdon M, Thorogood M, Foster C. Face-to-face interventions for promoting physical activity. Cochrane Database Syst Rev. 2013;9:CD010392.

14. Richards J, Thorogood M, Hillsdon M, Foster C. Face-to-face versus remote and web 2.0 interventions for promoting physical activity. Cochrane Database Syst Rev. 2013;9:CD010393.

15. Ogilvie D, Foster CE, Rothnie H, Cavill N, Hamilton V, Fitzsimons CF, et al. Interventions to promote walking: systematic review. BMJ. 2007;334(7605):1204.

16. Bravata DM, Smith-Spangler C, Sundaram V, Gienger AL, Lin N, Lewis R, et al. Using pedometers to increase physical activity and improve health: a systematic review. JAMA. 2007;298(19):2296-304.

17. Kang M, Marshall SJ, Barreira TV, Lee JO. Effect of pedometer-based physical activity interventions: a meta-analysis. Res Q Exerc Sport. 2009;80(3):648-55.

18. National Institute for Health and Clinical Excellence Public Health Intervention Guidance Physical Activity: brief advice for adults in primary care: component 2 economic analysis. Economic modelling of brief advice on physical activity for adults in primary care. London: 2012

19. McMurdo ME, Sugden J, Argo I, Boyle P, Johnston DW, Sniehotta FF, et al. Do pedometers increase physical activity in sedentary older women? A randomized controlled trial. J Am Geriatr Soc. 2010;58(11):2099-106.

20. Mutrie N, Doolin O, Fitzsimons CF, Grant PM, Granat M, Grealy M, et al. Increasing older adults' walking through primary care: results of a pilot randomized controlled trial. Fam Pract. 2012. doi: cms038 [pii];10.1093/fampra/cms038 [doi].

21. Harris T, Kerry SM, Victor CR, Ekelund U, Woodcock A, Iliffe S, et al. A primary care nurse-delivered walking intervention in older adults: PACE (pedometer accelerometer consultation evaluation)-Lift cluster randomised controlled trial. PLoS Med. 2015;12(2):e1001783.

22. Pavey TG, Taylor AH, Fox KR, Hillsdon M, Anokye N, Campbell JL, et al. Effect of exercise referral schemes in primary care on physical activity and improving health outcomes: systematic review and meta-analysis. BMJ. 2011;343:d6462.

23. Harris T, Kerry SM, Victor CR, Shah SM, Iliffe S, Ussher M, et al. PACE-UP (Pedometer and consultation evaluation - UP) - a pedometer-based walking intervention with and without practice nurse support in primary care patients aged 45-75 years: study protocol for a randomised controlled trial. Trials. 2013;14:418.

24. Lawton BA, Rose SB, Elley CR, Dowell AC, Fenton A, Moyes SA. Exercise on prescription for women aged 40-74 recruited through primary care: two year randomised controlled trial. BMJ. 2008;337:a2509.

25. Normansell R, Holmes R, Victor C, Cook DG, Kerry S, Iliffe S, et al. Exploring non-participation in primary care physical activity interventions: PACE-UP trial interview findings. Trials. 2016;17(1):178.

26. Normansell R, Smith J, Victor C, Cook DG, Kerry S, Iliffe S, et al. Numbers are not the whole story: a qualitative exploration of barriers and facilitators to increased physical activity in a primary care based walking intervention. BMC Public Health. 2014;14.

27. Beighton C, Victor C, Normansell R, Cook D, Kerry S, Iliffe S, et al. "It's not just about walking.....it's the practice nurse that makes it work": a qualitative exploration of the views of practice nurses delivering complex physical activity interventions in primary care. BMC Public Health. 2015;15(1):1236.

28. Freedson PS, Melanson E, Sirard J. Calibration of the Computer Science and Applications, Inc. accelerometer. Med Sci Sports Exerc. 1998;30(5):777-81.

29. Matthews CE, Chen KY, Freedson PS, Buchowski MS, Beech BM, Pate RR, et al. Amount of time spent in sedentary behaviors in the United States, 2003-2004. Am J Epidemiol. 2008;167(7):875-81.

30. Fitzsimons CF, Baker G, Gray SR, Nimmo MA, Mutrie N. Does physical activity counselling enhance the effects of a pedometer-based intervention over the long-term: 12-month findings from the Walking for Wellbeing in the west study. BMC Public Health. 2012;12:206.

31. Leung W, Ashton T, Kolt GS, Schofield GM, Garrett N, Kerse N, et al. Cost-effectiveness of pedometer-based versus time-based Green Prescriptions: the Healthy Steps Study. Aust J Prim Health. 2012;18(3):204-11.

32. Marcus BH, Lewis BA, Hogan J, King TK, Albrecht AE, Bock B, et al. The efficacy of moderate-intensity exercise as an aid for smoking cessation in women: a randomized controlled trial. Nicotine Tob Res. 2005;7(6):871-80.

33. Ashford S, Edmunds J, French DP. What is the best way to change self-efficacy to promote lifestyle and recreational physical activity? A systematic review with meta-analysis. Br J Health Psychol. 2010;15(Pt 2):265-88.

34. Cox KL, Flicker L, Almeida OP, Xiao J, Greenop KR, Hendriks J, et al. The FABS trial: a randomised control trial of the effects of a 6-month physical activity intervention on adherence and long-term physical activity and self-efficacy in older adults with memory complaints. Prev Med. 2013;57(6):824-30.

35. National Institute for Health and Clinical E. Walking and cycling. Local measures to promote walking and cycling as forms of travel or recreation. 2012.

36. Tully MA, Cupples ME, Chan WS, McGlade K, Young IS. Brisk walking, fitness, and cardiovascular risk: a randomized controlled trial in primary care. Prev Med. 2005;41(2):622-8.

37. Health Checks Programme NHS: Putting prevention first: NHS Health Checks: Vascular Risk Assessment and management best Practice Guidelines. London: 2009.

38. NHS England Preventing Type 2 Diabetes in England. Healthier You: NHS Diabetes Prevention programme (NHS DPP) 2015. Available from: <https://www.england.nhs.uk/ourwork/qual-clin-lead/action-for-diabetes/diabetes-prevention>

39. Zheng H, Orsini N, Amin J, Wolk A, Nguyen VT, Ehrlich F. Quantifying the dose-response of walking in reducing coronary heart disease risk: meta-analysis. Eur J Epidemiol. 2009;24(4):181-92.

40. Dwyer T, Pezic A, Sun C, Cochrane J, Venn A, Srikanth V, et al. Objectively Measured Daily Steps and Subsequent Long Term All-Cause Mortality: The Tasped Prospective Cohort Study. PLoS One. 2015;10(11):e0141274.