A pedometer-based walking intervention in 45- to 75-year-olds, with and without practice nurse support: the PACE-UP three-arm cluster RCT

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Scientific summary

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Scientific summary

Background

Physical activity (PA) helps adults and older adults to remain healthy, and improves physical function and emotional well-being. Inactivity is an important risk factor for mortality and leads to high health service costs. One way to achieve current national and international PA guidelines for health is by doing at least 30 minutes of moderate to vigorous physical activity (MVPA) in at least 10-minute bouts on ≥ 5 days weekly. However, a graded dose–response relationship exists for PA and health; therefore, for inactive people, any PA increase is valuable, as is decreasing sedentary time. Walking is the most common adult PA, and moderate-intensity walking approximates 100 steps per minute, so using a pedometer to add '3000 steps in 30 minutes' onto habitual activity helps to achieve PA guidelines. Systematic reviews of pedometer-based walking interventions show significant step count increases. However, studies were mainly small, recruited volunteers and had short-term follow-up. In addition, previous pedometer studies have not rigorously evaluated their effectiveness with or without face-to-face support, and have used step counts, not MVPA, as the outcome. Programmes using personalised PA goals and behavioural strategies can achieve PA increases. Cochrane reviews have called for PA interventions to include objective PA measurement, adverse events reporting, comparisons of face-to-face interventions with remote interventions, longer follow-up and cost-effectiveness evaluations. 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; however, more primary care PA trials are required.

Objectives

The research questions were:

1. Does a 3-month postal pedometer-based walking intervention increase PA (step count and time in MVPA in bouts) in inactive 45- to 75-year old primary care patients at 12-month follow-up?
2. Do dedicated practice nurse PA consultations provide additional benefit?

We also present cost-effectiveness analyses and effects on patient-reported outcomes, anthropometric measures and adverse events. A qualitative evaluation explored participant and practice nurse views. Longer-term follow-up was conducted at 3 years.

Methods

Design

A three-arm parallel-group, cluster randomised trial, comparing a 3-month pedometer-based walking intervention, by post or with nurse-support, with usual care. Randomisation was by household, allowing individuals and couples to participate, in a 1 : 1 : 1 ratio.

Participants and setting

Recruitment was from seven ethnically and socially diverse, south London-based general practice populations, between September 2012 and October 2013. The 12-month follow-up was completed in October 2014. Eligible patients were aged 45–75 years, without contraindications to increasing MVPA. Exclusions included care home residents and those with unsuitable medical conditions. Random samples of 400 eligible households per practice were selected; this process was repeated until enough individuals were recruited. Individual invitations were posted. Those participants who reported achieving ≥ 150 minutes of MVPA

weekly on a validated self-report PA questionnaire were excluded. Anonymised demographic data were available through general practice records for all those invited, enabling investigation of trial recruitment inequalities. Non-participants were invited to complete a questionnaire.

Procedures and intervention

Individual informed consent was obtained and baseline assessment undertaken prior to randomisation. Identical outcome assessments were conducted for all three groups. An accelerometer (GT3X+; ActiGraph LLC, Pensacola, FL, USA) was used for baseline, and 3- and 12-month masked PA assessment of step counts and time in different PA intensities. The interventions incorporated behaviour change techniques (BCTs) and included individualised step count and PA goals and the '3000 in 30' PA intensity message. The key intervention components were pedometers (SW-200 Yamax Digi-Walker; Yamasa Tokei Keiki Co. Ltd, Tokyo, Japan) to record individual step counts, a patient handbook, a PA diary (including an individual 12-week walking plan) and three individually tailored practice nurse PA (10- to 20-minute) consultations (nurse-support group only). The patient handbook and diary explained that adding 3000 steps per day (or a 30-minute walk) on ≥ 5 days weekly to their baseline, progressing over 12 weeks, would help to achieve PA guidelines. BCTs, including goals and planning, self-monitoring, feedback and encouraging social support, were included in the handbook, diary and nurse consultations. Control group participants were offered a pedometer, a handbook and a diary after the 12-month follow-up.

Outcomes

All primary and secondary PA outcomes were assessed by 7-day accelerometry measurements. The primary outcome was change in average daily step count between baseline and 12 months. The secondary PA outcomes were changes in step counts between baseline and 3 months; changes in time spent weekly in MVPA in ≥ 10-minute bouts; and time spent being sedentary between baseline and 3 and 12 months. The other secondary outcome was cost-effectiveness.

Ancillary outcomes were:

- changes in anthropometry (body mass index, waist circumference, body fat) at 12 months
- changes in patient-reported outcomes – exercise self-efficacy, anxiety, depression [as measured via the Hospital Anxiety and Depression Scale (HADS)], health-related quality of life [as measured via the EuroQol-5 Dimensions, five-level version (EQ-5D-5L)], pain and self-reported PA variables [as measured via the International Physical Activity Questionnaire (IPAQ), short form and the General Practice Physical Activity Questionnaire (GPPAQ)] at 3 and 12 months
- adverse outcomes – falls, injuries, fractures, cardiovascular events and deaths – assessed from trial monitoring procedures, 3- and 12-month questionnaires and primary care records.

Sample size

A sample of 993 (331 per group) was needed to detect the 1000 steps per day difference at 12 months, comparing any two groups, with 90% power, at a *p*-value of 0.01, allowing for household clustering and 15% attrition.

Statistical analyses

Accelerometry regression analyses were in two stages. Stage 1 estimated the average daily step count at 12 months and at baseline, derived by using the same two-level model (level 1, day within individual; level 2, individual) in which daily step counts were regressed on day order of wearing the accelerometer (from day 1 to day 7) and day of week, as fixed effects. At stage 2, the estimated 12-month average daily step count was regressed on the estimated baseline average daily step count, month of baseline accelerometry, age, sex, general practice and treatment group, effectively measuring the change in step count over 12 months. In this analysis, level 1 was individual and level 2 was household. MVPA in ≥ 10-minute bouts, sedentary time, wear time and 3-month outcomes were analysed using identical approaches. The change in anthropometric and patient-reported outcomes was estimated using stage 2 models.

Economic evaluation

Cost-effectiveness was estimated, from the NHS viewpoint, to generate the incremental cost per change in step count, minutes of MVPA in ≥ 10-minute bouts and quality-adjusted life-years (QALYs). The probability of the interventions being cost-effective given different willingness-to-pay values for QALYs and incremental net benefit (difference between monetised benefit and costs of the intervention vs. the comparator) was calculated. A Markov model used the results to simulate lifetime cost-effectiveness. Deterministic and probabilistic sensitivity analyses were undertaken for short- and long-term analyses.

Process evaluation

Data were collected contemporaneously with trial data collection, and associations between process measures and trial outcome measures were sought.

Qualitative evaluation

Telephone interviews were conducted with nurse and postal participants, targeting some participants who had increased their PA and some who had not, to investigate their views of the intervention and the barriers to, and facilitators of, increasing PA levels. A practice nurse focus group session was conducted to understand practice nurses' experience of delivering the intervention.

Three-year follow-up

Participant follow-up was conducted 3 years from baseline, including postal 7-day accelerometry, questionnaire and qualitative telephone interviews. The latter were carried out with randomly selected nurse and postal participants, to examine the factors affecting PA levels and maintenance of any increase in PA; and with control participants, to see the effect of the 12-month minimal intervention on PA levels.

Results

Of the 11,015 people invited, 6399 did not respond, 548 self-reported PA guideline achievements and were excluded and 10% (1023/10,467) were randomised. Participation rates were lower in men, younger subjects, those living in deprived postcode areas and Asian patients. Black people were equally likely to participate as white people. Baseline findings for all those randomised were as follows: average steps per day, 7479 steps [standard deviation (SD) 2671 steps]; and average minutes per week in MVPA of ≥ 10-minute bouts, 94 minutes (SD 102 minutes). Overall, 21% of participants (218/1023) achieved the PA guidelines of ≥ 150 minutes of MVPA in bouts. A total of 93% of participants (956/1023) were included in the 12-month primary analyses.

At the interim 3-month outcome, both intervention groups had increased their steps per day from baseline compared with the control group. Additional steps per day were 692 steps [95% confidence interval (CI) 363 to 1020 steps; $p < 0.001$] for the postal group, and 1172 steps (95% CI 844 to 1501 steps; $p < 0.001$) for the nurse-support group. The difference between intervention groups was statistically significant: 481 steps (95% CI 153 to 809 steps; $p = 0.004$). MVPA findings showed a similar pattern: additional MVPA in bouts (minutes per week) was 43 minutes (95% CI 26 to 60 minutes; $p < 0.001$) for the postal group, and 61 minutes (95% CI 44 to 78 minutes; $p < 0.001$) for the nurse-support group; the difference between intervention groups was 18 minutes (95% CI 1 to 35 minutes; $p = 0.04$). Sedentary time and accelerometer wear time were similar between groups.

For the primary outcome, both intervention groups increased their step counts from baseline to 12 months compared with control participants; additional steps per day were 642 steps (95% CI 329 to 955 steps; $p < 0.001$) for the postal group, and 677 steps (95% CI 365 to 989 steps; $p < 0.001$) for the nurse-support group, with no statistically significant difference between intervention groups (36 steps, 95% CI –277 to 349 steps). Time spent in MVPA in bouts showed a similar pattern: both intervention groups increased at 12 months compared with control participants. Additional MVPA in bouts (minutes per week) was 33 minutes (95% CI 17 to 49 minutes; $p < 0.001$,) for the postal group, and 35 minutes (95% CI 19 to

51 minutes; $p < 0.001$) for the nurse-support group, with no statistically significant difference between intervention groups (2 minutes, 95% CI –14 to 17 minutes). Sedentary time and accelerometer wear time were similar between groups.

The interventions had no significant effects on anthropometric measures, anxiety, depression, health-related quality of life or pain scores. The 12-month exercise self-efficacy score was significantly higher in the nurse-support group compared with control participants. None of the following acted as an effect modifier for the intervention effect: age, sex, taking part as a couple, body mass index, disability, pain, socioeconomic group and exercise self-efficacy. Total adverse events (self-reported or from primary care records) and serious adverse events (from trial safety monitoring) were similar between groups.

Economic evaluation

The incremental cost per step was £0.19 and £3.61 per minute in a ≥ 10-minute MVPA bout for the nurse-support group, whereas the postal group took more steps and cost less than control participants. The postal group had a 50% chance of being cost-effective at a £20,000 per QALY threshold within 1 year, and had both lower costs (–£11M, 95% CI –£12 to –£10) and higher QALYs (759 QALYs gained, 95% CI 400 to 1247 QALYs) than the nurse-support and control groups in the long term, with an incremental net benefit of £26M per 100,000 population. Sensitivity analyses largely supported findings, except in the trial analysis, in which four alternative assumptions were made: (1) extending the perspective to participants, (2) excluding health service use, (3) using self-reported adverse events and (4) using 3-month outcome data, when control dominated postal. Long-term cost-effectiveness results were very robust.

Process evaluation

A total of 256 out of 346 participants (74%) in the nurse-support group attended all three sessions, and 268 out of 339 participants (79%) in the postal group and 281 out of 346 participants (81%) in the nurse-support group returned completed step count diaries. Positive associations were seen between increases in step count and time in MVPA in bouts and between both the number of nurse sessions attended and completed step count diary return.

Qualitative evaluation

Forty-three trial participants were interviewed. The intervention was acceptable and primary care was an appropriate setting. Almost all participants felt that they had benefited, irrespective of their step count change. Important facilitators included a desire for a healthy lifestyle, improved physical health, enjoying walking, having a flexible routine, appropriate external monitoring and self-monitoring and social support. Important barriers included health problems, an inflexible routine, the weather, work and other commitments. Although the postal group participants were mainly confident to increase their PA without individually tailored nurse support, two important caveats were health problems and overcoming barriers. Practice nurses enjoyed delivering the Pedometer And Consultation Evaluation-UP (PACE-UP) intervention, and believed that taking part, especially in the BCT training, enhanced the quality and delivery of support provided within routine consultations.

Three-year follow-up

Of the 1023 trial participants, 681 (67%) provided adequate accelerometry outcome data. The nurse-support and postal intervention groups both showed persistent effects on the 3-year follow-up PA measures, with no difference between them; for the nurse-support group and the postal group versus the control group, additional steps per day were 648 steps (95% CI 272 to 1024 steps), and additional MVPA in ≥ 10-minute bouts (minutes per week) were 26 minutes (95% CI 8 to 44 minutes). Qualitative interview findings at 3 years on factors affecting PA maintenance with intervention group participants complemented earlier qualitative findings. The pedometer was reported as 'kick-starting' regular activity and helping to maintain activity. Factors that facilitated PA level maintenance were striving to maintain good health, self-motivation, social support and good weather. Lack of time was the most frequently cited barrier; other barriers were often the reverse of facilitators, such as poor health or bad weather. Findings from the control group

participants, who were sent the pedometer and materials at 12 months, suggested that many had not used them. The persistent 3-year intervention effects, despite control participants receiving intervention materials at 12 months, suggest that other postal group factors were important (e.g. telephone contact after sending out materials and returning completed PA diaries). The postal group seemed to require this additional minimal support (not provided face to face, or by a health professional) in order to be effective.

Conclusions

The PACE-UP pedometer-based walking intervention increased step counts by about one-tenth, and time in MVPA in bouts by about one-third, at 1 year, in predominantly inactive 45- to 75-year-old primary care patients. Nurse and postal delivery had similar effects on 12-month PA outcomes. The intervention was safe and acceptable to patients and nurses. The postal group had a 50% chance of being cost-effective at a £20,000 per QALY threshold within 1 year, and was significantly more cost-effective than nurse support and the control group in the long term, thus providing a cost-effective way of delivering long-term quality-of-life benefits. Both intervention groups had persistent positive effects on objective PA levels at 3 years, suggesting long-term benefit.

Implications for health care

- A primary care pedometer-based walking intervention, delivered by post with minimal support, could provide an effective and cost-effective approach to addressing the public health physical inactivity challenge.
- The 3000 steps in 30 minutes neatly captures intensity and could become a useful new public health goal, particularly as many people can measure steps easily with their mobile phones.
- The PACE-UP 12-week pedometer-based walking intervention could be considered for inclusion into the NHS Health Check programme, aimed at a similar age group (of 40- to 74-year-olds) and/or the NHS Diabetes Prevention Programme.

Recommendations for research

- The PACE-UP trial generalisability is limited by the 10% overall recruitment rate and lower recruitment in Asian and socioeconomically deprived patients. Further research into different recruitment methods is needed, as is research assessing the recruitment achievable if this programme were to be offered outside a trial setting over a more prolonged time period.
- Although overall postal outcomes were as effective as, and more cost-effective than, nurse outcomes, further research is required to understand who would benefit most from the individual tailoring offered by a nurse-supported intervention.
- There has been a recent dramatic increase in the use of wearables to monitor personal PA levels, including smartphones, wrist-worn devices, online monitoring and mobile apps. Further research into how the PACE-UP 12-week PA programme could be integrated into the use of these devices (with or without a pedometer) is needed.

Trial registration

This trial is registered as ISRCTN98538934.

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