

# A primary care pedometer-based walking intervention with and without practice nurse support: PACE-UP cluster-randomised controlled trial

Tess Harris, Sally M Kerry, Elizabeth Limb, Christina R Victor, Steve Iliffe, Sunil M Shah, Michael Ussher, Peter Whincup, Ulf Ekelund, Julia Fox-Rushby, Judith Ibison, Stephen DeWilde, Lee David, Cheryl Furness, Emma Howard, Rebecca Dale, Jaime Smith, Derek G Cook

## Abstract

**Background** WHO guidelines recommend walking to increase moderate-to-vigorous physical activity. Pedometer-based interventions have focused on step-counts, not moderate-to-vigorous physical activity, and have not distinguished between pedometer and support effects. We assessed whether a postal pedometer-based walking intervention could increase step-counts and moderate-to-vigorous physical activity in inactive adults and whether physical activity consultations delivered by a practice nurse could add benefit.

**Methods** 11 015 men and women aged 45–75 years, randomly selected from seven family practices in London, UK, with no physical activity contraindications, were invited by post to participate in a parallel three-arm cluster-randomised trial. Randomisation was by household, stratified by practice, using random-sized blocks. 6399 were non-responders; 548 respondents who self-reported achievement of physical activity guidelines were excluded. 1023 people (922 households) were randomised after consent to usual care (338), postal pedometer intervention (339), or nurse-supported pedometer intervention (346). Intervention groups received pedometers, 12 week walking programmes, and physical activity diaries. The nurse group was offered three physical activity consultations. Assessors were unmasked to group for pragmatic reasons. The primary and main secondary outcomes were, respectively, changes from baseline to 12 months in average daily step-counts and time in moderate-to-vigorous physical activity in bouts ( $\geq 10$  min), measured over 7 days objectively by accelerometry. Analysis accounted for clustering, was by intention to treat, and was masked to group for main outcomes. Ethics approval was granted by the London Research Ethics Committee (Hampstead). This trial is registered with Current Controlled Trials, ISRCTN98538934.

**Findings** Recruitment rate was 10% (1023/10 467). 955 participants (93%) provided 12 month outcome data. Baseline mean number of step-counts and time in moderate-to-vigorous physical activity in bouts for those randomised were 7479 steps per day (SD 2671) and 94 min/week (102), respectively. Both intervention groups significantly increased number of step-counts and time in moderate-to-vigorous physical activity in bouts compared with controls, with no significant differences between interventions: postal intervention 641 additional steps per day (95% CI 328–954), nurse-support 682 (371–994); postal intervention 33 min/week of additional bouts of moderate-to-vigorous physical activity (17–49), nurse-support 35 (19–51).

**Interpretation** A primary care pedometer-based walking intervention in inactive 45–75-year-olds increased step-counts by about a tenth and increased time in moderate-to-vigorous physical activity in bouts by a third. There was no evidence that nurse delivery had a greater effect on 12 month physical activity outcomes than simpler, resource-efficient postal delivery. A primary care postal pedometer intervention could help address the challenge of public health physical inactivity.

**Funding** National Institute for Health Research Health (NIHR) Technology Assessment (HTA) Programme (project number HTA 10/32/02). This project will be published in full in *Health Technology Assessment*. The funding body was not involved in the study design, collection, analysis, and interpretation of data, writing of the abstract, or the decision to submit for publication.

### Contributors

TH, DGC, SMK, CRV, SMS, SI, PW, MU, UE, and JF-R conceived and designed the PACE-UP trial. CF was the trial manager. EH, RD, and JS collected the trial data. EL, DGC, SMK, and TH analysed the data. LD, MU, TH, and CF contributed to participant handbooks and diaries and nurse training. JI and SD helped with recruitment of general practices and practice nurses and downloading of the general practice data. TH is the guarantor for the study and the abstract. TH prepared the abstract with substantial input from DGC, SMK, and EL. All authors reviewed and approved the final copy of the abstract for publication.

### Declaration of interests

LD declares that she is Director of 10 Minute CBT. Her services as part of 10 Minute CBT were used for preparation of patient materials (handbook and diary) and for preparation and conduct of nurse training sessions. All other authors declare no competing interests.

### Acknowledgments

The views and opinions expressed in this abstract are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, National Health Service, or Department of Health.

Published Online

November 13, 2015

Population Health Research

Institute, St George's,

University of London,

London, UK (T Harris MD,

E Limb MSc, S M Shah MBBS,

Prof M Ussher PhD,

Prof P Whincup MD,

J Ibison MBBS, S DeWilde MD,

C Furness MSc, E Howard MSc,

R Dale MSc, J Smith MSc,

Prof D G Cook PhD); Pragmatic

Clinical Trials Unit, Queen Mary

University of London, London,

UK (S M Kerry MSc);

Gerontology and Health

Services Research Unit, Brunel

University, London, UK

(Prof C R Victor PhD);

Department of Population

Health Sciences, University

College London, London, UK

(Prof S Iliffe MBBS); Department

of Sports Medicine, Norwegian

School of Sports Sciences, Oslo,

Norway (Prof U Ekelund PhD);

Health Economics Research

Group, Brunel University,

London, UK

(Prof J Fox-Rushby PhD);

and 10 Minute CBT, Devonshire

Business Centre, Letchworth,

UK (L David MBBS)

Correspondence to:

Dr Tess Harris, Population Health

Research Institute, St George's,

University of London,

London SW17 0RE, UK

tharris@sgul.ac.uk