

# A simple low cost Doctor DELivered PHysical activity Intervention

<b>Submission date</b> 14/06/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/04/2014	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In recent years there have been significant reductions in walking and cycling for transport that has not been replaced by increases in recreational activity, so the population has become more inactive and rates of obesity have increased. Increasing physical activity in the population is most likely to be achieved by reversing the trend of reductions in walking. Walking can easily be undertaken at sufficient intensity for health gain and can be integrated more easily into daily life than more formal exercise. To be beneficial to health, physical activity should be performed at a moderate intensity which for most people is equivalent to walking at a brisk or fast pace (approximately 5.6 to 6.4 km/hour). Although 77% of adults walk for at least 30 minutes once a month, only 32% do so at a self reported brisk/fast pace. It is likely that advice to increase the frequency and intensity (pace) of walking will be more acceptable than advice to take up new, less common activities. Studies have shown that advising people to walk a fixed distance at a brisk pace, leads to moderate intensity walking speeds and improvements in established cardiovascular disease risk factors and fitness. A simple message such as walk a mile at a brisk pace can lead to self-selected walking paces that are of sufficient intensity to produce benefits, but still low enough to be safe. Although volunteers can follow simple walking messages in controlled settings, it is uncertain whether people would adopt and adhere to messages if they were delivered opportunistically (while they are waiting for routine appointments with a GP) by a GP, to inactive people who were not seeking advice. Simple walking messages requiring little or no explanation can be delivered quickly and are therefore suitable for time pressured settings such as general practice. General practitioners (GPs) understand the importance of physical activity and are enthusiastic about giving advice but frequently cite lack of time as the main barrier to doing so. If it was shown that a simple screening system and easy to deliver physical activity message was a cost-effective way to reduce inactivity, then it is likely that adoption by GPs could be achieved. A recent review of pedometer interventions shows that pedometer users significantly increase their physical activity, especially if set a target number of steps per day. Therefore, we propose to examine the feasibility of conducting a trial comparing usual care, usual care plus simple advice, and usual care plus simple advice and use of a pedometer, to reduce the number of inactive patients.

### Who can participate?

Any male or female aged 40-74 years who can walk for 5 minutes continuously without undue fatigue or discomfort and who is registered with one of the participating practices.

### What does the study involve?

Twenty four general practices (8 each in Devon, Bristol and Coventry) will be recruited. Half of the practices will recruit patients opportunistically (while they are waiting for routine appointments with a GP) and half will recruit patients by written invitation if they are registered at the practice and in the age group 40-74 years.

All consenting participants will be randomly allocated to one of three treatment groups.

Two methods of allocation will be tested: i) randomisation at the level of the practice (all patients from the same practice will be randomised to the same arm of one of the three arms of the study) and ii) randomisation of individual patients within practices (patients within the same practice will be randomised to one of the three study arms).

Participants allocated to the control arm (Arm A) will be given: (i) written information on physical activity and its benefits; (ii) a pedometer (which will be sealed so that participants cannot view the readings during the intervention) and written information on how to use it.

(Arm B), participants will receive the same items and information as for Arm A but will also be advised by their GP to walk at least a mile per day (1520 minutes) at a brisk to fast pace, each day of the week.

(Arm C), participants will receive the same items, written physical activity information and verbal advice as in Arm B. However, for arm C, the pedometer will be unsealed (allowing them to view the readings showing the number of steps taken) and participants will be given written information about how to use it. All patients will complete a questionnaire at baseline and 12 weeks post randomisation.

### Where is the study run from?

The study is coordinated from the University of Exeter but also involves Bristol and Warwick University.

### When is the study starting and how long is it expected to run for?

The study will run from June 2010 to September 2011

### Who is funding the study?

The National Prevention Research Initiative managed by the Medical Research Council

### Who is the main contact?

Associate Professor Melvyn Hillsdon

### Study website

<http://theddelphistudy.org.uk/>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Melvyn Hillsdon

### Contact details

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

10/H0203/18

## **Study information**

**Scientific Title**

The feasibility of a simple, low cost, general practitioner delivered intervention to promote physical activity

**Acronym**

DDELPHI

**Study objectives**

Is a randomised controlled trial of a simple, lowcost, general practitioner delivered intervention to promote physical activity feasible?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

REC reference number 10/H0203/18 approval given by the South West 1 Research Ethics Committee on 20th April 2010

**Study design**

Randomised controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

## **Study type(s)**

Quality of life

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Physical inactivity

## **Interventions**

Two interventions delivered at the level of general practice were compared to usual care. All patients invited to take part in the study were informed that their GP was participating in a study assessing the effect of physical activity information on physical activity behaviour.

Arm A (Usual care control). Following written informed consent, patients were given the written physical activity information and instructions on how to wear a sealed pedometer. Written information included the benefits of physical activity and how to use the pedometer. Patients were also given an envelope containing a baseline questionnaire, pre-paid return envelope, a summary of the study and patient information.

Arm B (Brief GP advice). In addition to receiving the written physical activity information in Arm A, patients were advised by their GP to walk at least a mile per day (15-20 minutes) at a brisk to fast pace, each day of the week. Patients in Arm B also received the study envelope described above including sealed pedometer.

Arm C (Brief GP advice + pedometer). Following the GP walking advice, patients were given an unsealed pedometer and written information about how to use it. They were specifically guided to work towards 10,000 steps per day (approximately equivalent to 150 minutes per week). The written information provided details of how to work towards 10,000 steps and set intermediary goals based on published guidelines. All patients were sent a repeat of the baseline questionnaire at 3 months, along with a pre-paid envelope for return. Patients were also requested to wear their pedometers for 7 consecutive days and then return them in a provided pre-paid envelope so that the data could be extracted. After data extraction, pedometers were returned to patients for them to keep as an incentive for participation.

All patients will complete a questionnaire at baseline and 12 weeks post randomisation.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

1. An estimate of the intervention effect size and where appropriate an ICC.
2. The average number of steps per day recorded by a pedometer, measured for 7-days at baseline and 12-weeks post randomization.

## **Secondary outcome measures**

1. Estimates of practice and patient recruitment rates and estimates of loss to follow up
2. Estimates of costs of the delivery of the intervention and the data collection methods
3. Assessment of GP and patient acceptability to undertake a trial
4. Estimates of the reduction in physical inactivity
5. Physical activity commitment measured on a 3-item self rating scale with responses ranging from 010 (15) measured at baseline and 12 weeks
5. Health-related quality of life using the EQ-5D measured at baseline and 12 weeks.

**Overall study start date**

01/06/2010

**Completion date**

30/09/2011

## Eligibility

**Key inclusion criteria**

Aged 40-74 and able to walk unassisted, continuously for 5 minutes, without undue fatigue or discomfort.

Eligibility for randomisation further includes categorization as physically inactive based on the General Practice Physical Activity Questionnaire (GPPAQ). The age range represents the maximum age for validity of the GPPAQ and the age range for the government's vascular checks programme that is linked in with the Physical Activity Care Pathway.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

144

**Key exclusion criteria**

1. Registered disabled or unable to walk for continuously for 5 minutes, unassisted, without undue fatigue or discomfort.
2. Already participating in a study at the practice.

**Date of first enrolment**

01/06/2010

**Date of final enrolment**

30/09/2011

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Sport and Health Science**

Exeter

United Kingdom

EX1 2LU

## **Sponsor information**

**Organisation**

University of Exeter (UK)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.exeter.ac.uk/>

**ROR**

<https://ror.org/03yghzc09>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Medical Research Council (UK) - National Prevention Research Initiative G0802118/1

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	21/04/2014		Yes	No