

# A randomised controlled trial of a brief walking intervention

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<b>Registration date</b> 24/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2014	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof David French

**Contact details**  
Applied Research Centre in Health and Lifestyle Interventions  
Whitefriars Building  
Faculty of Health and Life Sciences  
Priory Street  
Coventry  
United Kingdom  
CV1 5FB  
david.french@coventry.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
8297; MRC: 85368

# Study information

## Scientific Title

An explanatory randomised controlled trial to evaluate the efficacy of a brief walking intervention delivered in primary care in promoting walking behaviour

## Study objectives

Research objective:

The aim of the present research is to conduct a definitive, fully powered explanatory trial to evaluate the efficacy of a brief intervention to increase walking, to be routinely delivered in primary care by practice nurses (PNs)/Healthcare Assistants (HCAs) to patients for whom increasing physical activity is a particular priority. The intervention already has demonstrated efficacy with a volunteer population, and has since been through an iterative process of refinement in primary care, to maximise acceptability to both providers and recipients. This explanatory trial forms the fourth and final phase of a larger project for which we have secured funding.

The overall aim of the present research therefore, is to conduct a fully powered, definitive explanatory trial to:

1. Assess the efficacy of the intervention in changing objective walking behaviour
2. Identify key intervention mechanisms by conducting a mediation analysis
3. Estimate the cost of the intervention and the difference in the cost of the resources used by patients in each arm of the trial, by conducting a full economic evaluation

This explanatory trial will be a two-arm cluster randomised controlled trial, with clustering by GP practice. Allocation to experimental condition will be according to practice, stratified by practice size and Index of deprivation. Practice will be stratified by median practice size and index of deprivation for each of the three Primary Care Trusts (PCTs).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Birmingham, East, North and Solihull Research Ethics Committee approved on the 14th December 2009 (ref: 09/H1206/116). Amendments approved on the 4th March 2010.

## Study design

Multicentre randomised interventional treatment trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

GP practice

## Study type(s)

Treatment

## **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**

Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Health Services Research

## **Interventions**

Information provision and pedometer:

Patients who choose to take part in the study will give informed consent. The PN/HCA will then give the patients a set of questionnaires to complete, and an information pack of materials promoting walking produced by the British Heart Foundation and Walking the Way to Health. The PN/HCA will answer any questions the patient may have about walking more, and continue to provide usual care for that patient with regard to walking.

Motivation and volition to walk:

This proposal builds on published and ongoing research conducted by Professor French and colleagues that has identified the principal psychological determinants of walking in a "well" adult volunteer sample. Following extended developmental work, a 15-minute intervention consisting of strategies to increase self-efficacy (confidence in ability to perform the behaviour), and enact "good intentions" was developed.

Follow-up length: 6 months

Study entry: multiple randomisations

## **Intervention Type**

Other

## **Phase**

Phase III

## **Primary outcome measure**

Pedometer, measured at 1 week, 6 weeks and 6 months post-intervention

## **Secondary outcome measures**

1. EQ-5D, measured at 6 months
2. Information on resource use, measured at 6 months
3. Theory of planned behaviour process measure, measured immediately post-intervention, 6 weeks and 6 months

## **Overall study start date**

14/12/2009

## **Completion date**

31/05/2011

## **Eligibility**

### **Key inclusion criteria**

The anticipated recipients of the intervention are patients in primary care who:

1. Are aged between 16 and 65 years old, either sex
2. Have chronic conditions where physical activity has been shown to have a positive effect on health status, e.g., hypertension, type 2 diabetes (prediabetes, impaired glucose tolerance, insulin resistance), low back pain, fibromyalgia, coronary heart disease (CHD), cerebrovascular disease (CVD), hypercholesterolemia, osteoporosis and osteoarthritis, overweight or obese, or would otherwise benefit from increased walking
3. Are not currently being investigated/treated by secondary care specialists for the condition(s) or are awaiting investigation/treatment by secondary care specialists for the condition(s)
4. Are "sedentary" in terms of not meeting the 30 mins/day at least 5 times/ week guidelines
5. Are able to speak English (and therefore could potentially benefit from the PN/HT intervention session)
6. Do not have learning difficulties which would preclude active engagement with the intervention session
7. Do not have mental health problems, i.e., anxiety, depression which would preclude active engagement with the intervention session, or where the patient is being investigated/treated by secondary care specialists for the problem
8. Wish to participate
9. Are referred by their GP, practice nurse or health care assistant

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

Planned sample size: 400; UK sample size: 400 Each PN/HCA will deliver the intervention to 20 eligible patients, referred by their GP/PN/HCA, giving a total of 400 patient recipients.

### **Key exclusion criteria**

1. Children aged less than 16 years
2. Adults aged over 65 years
3. Individuals unable to speak English (and therefore would not benefit from the intervention sessions)
4. People who are being investigated/treated by secondary care specialists
5. People with learning difficulties or mental illness which would preclude active engagement with the intervention session

### **Date of first enrolment**

14/12/2009

### **Date of final enrolment**

31/05/2011

## **Locations**

### **Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Applied Research Centre in Health and Lifestyle Interventions**

Coventry

United Kingdom

CV1 5FB

## **Sponsor information**

**Organisation**

Coventry University (UK)

**Sponsor details**

Applied Research Centre in Health and Lifestyle Interventions

Whitefriars Building

Faculty of Health and Life Sciences

Priory Street

Coventry

England

United Kingdom

CV1 5FB

**Sponsor type**

University/education

**Website**

<http://wwwm.coventry.ac.uk/Pages/index.aspx>

**ROR**

<https://ror.org/01tgmhj36>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Medical Research Council (MRC) (UK) (ref: 85368)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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	05/02/2014		Yes	No