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A randomised controlled trial of a brief walking intervention

Submission date	Recruitment status	[_] Prospectively registered
24/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2014	Other	

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?
Results article	results	05/02/2014		Yes	No