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Changing illness perceptions of patients with intermittent claudication

Submission date 01/04/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/10/2009	**Overall study status** Completed	
Last Edited 28/05/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Changing illness perceptions of patients with intermittent claudication: a pilot randomised controlled trial to increase walking

Study objectives
Principal research question:
Will a brief psychological intervention to modify illness perceptions increase walking behaviour for patients with intermittent claudication?

Secondary research questions:
1. Will a brief psychological intervention increase intention to walk?
2. Will a brief psychological intervention increase walking self-efficacy?
3. Will a brief psychological intervention change illness perceptions?

As of 03/11/2009 this record was updated to include an extended anticipated end date; the initial anticipated end date at the time of registration was 01/10/2009.

As of 13/01/2010 this record was updated to include a further extended anticipated end date; the previous anticipated end date at the time of registration was 30/11/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fife and Forth Valley NHS Research Ethics Committee approved on the 12th February 2008 (ref: 08/S0501/6).

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Intermittent claudication

Interventions
Session 1: one hour in the participant's own home:
1. Modify illness beliefs regarding interpretation of symptoms and chronicity of disease by

providing information about disease, and behaviour health link
2. Modify understanding of consequences of disease and future health risk perception by providing information on consequences of disease
3. Operationalise above points 1 and 2 using motivational interviewing

Session 2: one hour in the participant's own home:
4. Improve personal control/self efficacy by prompting specific goal setting for walking; prompt barrier identification to formulate a coping plan

Three follow up phone calls (monthly):
5. Prompt review of behavioural goals through monthly phone calls
6. Provide social support through the inclusion in the intervention of a key partner

Control:
Control group receives usual care and phone calls to minimise social support effects.

Total duration of treatment is 2 hours. Follow-up for both arms is at 4 months, however an amendment to ethical approval has been submitted to carry out long-term follow-ups at 1 year and 2 years after recruitment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Increase in walking behaviour as measured by pedometer (mean daily steps measured over 1 week at each time point) at baseline, 4 months, and 1 year and 2 years (subject to the approval of the amendment).

Secondary outcome measures
All outcomes will be measured at baseline, 4 months, and 1 year and 2 years (subject to the approval of the amendment):
1. Self-report physical activity, measured with the International Physical Activity Questionnaire (IPAQ)
2. Quality of life, measured with the Intermittent Claudication Questionnaire (ICQ)
3. Psychological outcomes, measured with a range of psychological questionnaires adapted for use in this study
4. Clinical outcome, measured by type of treatment received or scheduled by each time point e.g. angioplasty, bypass graft, conservative treatment

Overall study start date
07/04/2008

Completion date
01/02/2012

Eligibility

Key inclusion criteria

1. Newly diagnosed patients with intermittent claudication
2. English speaking
3. Aged over 55 years, either sex

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Severe cardiac disease
2. Patients unable to perform simple exercise test at slow speed
3. Severe debility, e.g., arthritis
4. History of orthopaedic surgery
5. Ankle Brachial Blood Pressure Index (ABPI) at diagnosis of less than 0.35

Date of first enrolment
07/04/2008

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Psychology Department
Stirling
United Kingdom
FK9 4LA

Sponsor information

Organisation

University of Stirling (UK)

Sponsor details
Head of Psychology Department
Psychology Department
Stirling
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FK9 4LA

Sponsor type
University/education

Website
http://www.stir.ac.uk/

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
University/education

Funder Name
University of Stirling (UK) - Internally funded PhD

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?
Protocol article	protocol	07/10/2010		Yes	No
Results article	results	01/01/2012		Yes	No

Results article	results	01/05/2013	Yes	No