

Changing illness perceptions of patients with intermittent claudication

Submission date 01/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/05/2013	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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
Scotland
United Kingdom
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
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