ISRCTN28051878 https://doi.org/10.1186/ISRCTN28051878

# Changing illness perceptions of patients with intermittent claudication

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

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Quality of life

## 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(s)
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).

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Other

### Sex
All

### 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
United Kingdom

Scotland

### Study participating centre
**Psychology Department**
Stirling
United Kingdom
FK9 4LA

## Sponsor information

### Organisation
University of Stirling (UK)

### ROR
https://ror.org/045wgfr59

## Funder(s)

### Funder type
University/education

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

# Results and Publications

## 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 | 01/01/2012 | | Yes | No |
| Results article | results | 01/05/2013 | | Yes | No |
| Protocol article | protocol | 07/10/2010 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |