

The Step Back Up trial: the feasibility of a pedometer driven walking programme for chronic low back pain

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| Submission date 02/03/2009 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 17/06/2009 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 09/02/2011 | Condition category Musculoskeletal Diseases | <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

A pedometer driven walking programme for chronic low back pain: a single centre, randomised, feasibility trial

Study objectives

Study aim:

To test the feasibility of using a pedometer-driven, individually tailored, walking programme as an adjunct to a single education session for patients with chronic low back pain.

Specific objectives of the study are:

1. To assess recruitment rate and adherence to a walking group or education only group
2. To compare changes in outcome between groups
3. To determine the incidence of musculo-skeletal and other related injuries between groups
4. To carry out a qualitative exploration of participants' experience of the interventions

Ethics approval required

Old ethics approval format

Ethics approval(s)

Office for Research Ethics Committees Northern Ireland (ORECNI); application to be submitted on the 26th May 2009.

Study design

Single centre randomised feasibility trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Chronic low back pain

Interventions

Walking Group:

Graded, individually tailored, pedometer (Yamax Digiwalker SW-200, Yamax, Japan) driven walking programme given by a physiotherapist. This will be based on baseline assessment of PA using an accelerometer (PAL Technologies, Glasgow, UK). The physiotherapist will recommend an additional 25% of any shortfall in activity (25% of recommended 10,000-baseline), per week, for three weeks.

Education Only Group:

Single session with a physiotherapist including a physical examination and standardised advice using the Back Book.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Oswestry Disability Questionnaire (ODQ). All outcome measures will be assessed at baseline, at eight weeks (on completion of trial) and at six months. All follow up outcomes shall be assessed by a researcher blinded to group allocation.

Secondary outcome measures

1. Objective measurement of PA level (assessed by accelerometry)
2. International Physical Activity Questionnaire [IPAQ] - short form
3. Fear-Avoidance Beliefs Questionnaire (FABQ)
4. General Perceived Self-Efficacy Scale (GPSES)
5. Health outcomes (changes in body mass index [BMI kg/m²], waist:hip ratio and resting blood pressures)
6. Stage of change questionnaire
7. Patient Preference
8. Participant Satisfaction Questionnaire

All outcome measures will be assessed at baseline, at eight weeks (on completion of trial) and at six months. All follow up outcomes shall be assessed by a researcher blinded to group allocation.

Overall study start date

01/09/2009

Completion date

01/09/2010

Eligibility**Key inclusion criteria**

Adults (aged 18 - 65 years, either sex) with a diagnosis of chronic low back pain (defined as pain and discomfort localised below the costal margin and above the inferior gluteal folds, with or without referred leg pain, persisting for more than 12 weeks)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

n = 50

Key exclusion criteria

1. Any potential participant with a high level of physical activity (assessed by the International Physical Activity Questionnaire [IPAQ]) at initial screening
2. Any potential participant taking more than an average of 8,500 steps per day (recorded by an accelerometer) over 7 days prior to randomisation

Date of first enrolment

01/09/2009

Date of final enrolment

01/09/2010

Locations

Countries of recruitment

Northern Ireland

United Kingdom

Study participating centre

Room 01F118

Newtownabbey

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Sponsor information

Organisation

University of Ulster (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.ulster.ac.uk/>

ROR

<https://ror.org/01yp9g959>

Funder(s)

Funder type

Research organisation

Funder Name

Physiotherapy Research Foundation (UK)

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 | 15/07/2010 | | Yes | No |