

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s)**

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/m<sup>2</sup>], 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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

Northern Ireland

**Study participating centre**

**Room 01F118**

Newtownabbey

United Kingdom

BT37 0QB

## **Sponsor information**

**Organisation**

University of Ulster (UK)

**ROR**

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

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Physiotherapy Research Foundation (UK)

## **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?
<a href="#">Results article</a>	results	15/07/2010		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes