

# Physiotherapy for sleep disturbance in chronic low back pain trial

<b>Submission date</b> 10/08/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/01/2014	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Deirdre Hurley

**Contact details**  
UCD School of Physiotherapy and Performance Science  
Health Sciences Centre  
University College Dublin  
Belfield  
Dublin  
Ireland  
4  
+353 (0)1 716 6515  
deirdre.hurleyosing@ucd.ie

## Additional identifiers

**Protocol serial number**  
2007-16

## Study information

**Scientific Title**

The effectiveness of three forms of physiotherapy for sleep disturbance in chronic low back pain: a pilot single-blinded randomised controlled trial

## **Acronym**

SLEEP

## **Study objectives**

There will be a difference in the effects of a supervised exercise class, usual physiotherapy and a walking programme on sleep disturbance in chronic low back pain.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Beaumont Hospital Ethics (Medical Research) Committee approved in October 2008

## **Study design**

Single-blinded feasibility randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Chronic low back pain

## **Interventions**

### **1. Supervised exercise class (SEC):**

Within one week of randomisation, participants will commence the SEC. This class will follow a group-based format based on the 'Back to Fitness' programme used in the UK BEAM trial and endorsed by the recent NICE guidelines for persistent low back pain. Each participant will attend the Physiotherapy Department for an initial individual assessment prior to the class, where there will be discussion and agreement between the Therapist and the patient on short and long-term goals; recording of the patient's exercise capabilities and perceived barriers to recovery and the individual's treatment expectations. Participants will then attend the Physiotherapy Department of Beaumont Hospital once a week for 8 weeks for a one-hour supervised group exercise class led by a Chartered Physiotherapist. The Physiotherapist will advise patients according to their individual goals and exercise capabilities, and help identify which exercise(s) they could continue independently of the group sessions, i.e. foster the development of self-management strategies. Subjects will also be required to rate their perceived exertion during the class on the Borg scale. Patients will be encouraged to accept responsibility for determining and carrying out their weekly programme of activity. Adherence with the SEC will be recorded as the number of sessions attended.

### **2. Walking programme (WP):**

Within one week of randomisation participants will commence participation in the WP at Beaumont Hospital through an appointment with a Chartered Physiotherapist. The focus will be on increasing physical activity through a graded walking programme. As with the SEC (see

above), each participant will attend the Physiotherapy Department for an individual initial assessment, where there will be discussion and agreement between the therapist and the patient on short and long-term goals; recording of the patient's exercise capabilities and perceived barriers to recovery and the individual's treatment expectations. Each subject will be given a Yamax Digiwalker Pedometer to record habitual daily activity levels and instructed in its use. A starting point for the eight week progressive walking programme will be established; the minimum being a 10-minute walk (approx 1200 steps) on at least four days per week to be decided with, where possible, one day's rest between walks. The aim of the programme is to progress to the ACSM guidelines of 30 minutes moderate intensity walking on five days per week by week five and then to maintain this level for the remainder of the programme. All participants will use their pedometer as a motivational feedback tool, providing immediate information on activity levels. Adherence with the walking programme will be assessed by the frequency, distance, number of steps taken and duration of walks recorded in a training diary.

The subjects will then be contacted once per week by the Chartered Physiotherapist who performed the initial assessment by telephone to progress their walking frequency and duration and provide encouragement, and will reattend the Physiotherapy Department at the end of the intervention for reassessment and discharge from physiotherapy.

### **3. Usual physiotherapy (UP - control group):**

Within one week of randomisation, participants randomised to the UP group will commence individual physiotherapy at the discretion of the treating Physiotherapist in Beaumont Hospital. All physiotherapy treatments will be recorded for the study period in previously designed treatment record forms. On the basis of a previous RCT by the research team in the Republic of Ireland Public Physiotherapy Health Service the anticipated mean (SD) number of treatments is 5.8 (3) over a mean (SD) of 7.7 weeks (5.8) weeks. A multimodal approach of education/advice, manipulative therapy and exercise therapy will be permitted on the basis of the results of previous surveys of physiotherapy practice in the UK and Ireland. As part of this it is expected that subjects will be provided with an individualised exercise programme at the discretion of the treating Therapist but will not be permitted to attend group exercise classes or undertake a supervised walking programme during the trial. Adherence will be assessed by the number of visits prior to discharge from physiotherapy.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

1. Self-reported sleep quality using the Pittsburgh Sleep Quality Index, Insomnia Severity Index, and the Pittsburgh Sleep Diary
2. Objective sleep quality using the Actiwatch (Model AW4, CamNTEch, Cambridge, UK) on all patients and the Sleep Minder (BiancaMed Ltd, Dublin, Ireland) on a sample of the patients recruited on two separate occasions each lasting seven nights:
  - 2.1. At baseline, and
  - 2.2. Three months after initial randomisation
3. Functional disability due to LBP measured by the Oswestry Disability Index (ODI)
4. Pain using Numerical Rating Scales for current and average pain for both back and leg pain
5. Health-related quality of life measured by the 36-item Short-Form, Version 2 questionnaire
6. Psycho-social beliefs using the Fear Avoidance Beliefs Questionnaire and the Anxiety and

Depression using the Hospital Anxiety and Depression Scale

7. Employment status and number of days reported sick leave over the past year for those in paid employment only

8. Self-report physical activity levels using the International Physical Activity Questionnaire (IPAQ)

9. Exercise self efficacy questionnaire

10. Patient satisfaction will be assessed using Likert scales assessing satisfaction with outcome and satisfaction with care at 3 months only

All outcomes are measured at baseline, 3 and 6 months, apart from objective sleep measures of actiwatch and sleep minder (baseline and 3 months) and patient satisfaction (3 months).

### **Key secondary outcome(s)**

No secondary outcome measures

### **Completion date**

28/02/2010

## **Eligibility**

### **Key inclusion criteria**

1. Males/females aged between 18 - 70 years

2. Patients with chronic (greater than or equal to 3 months) or recurrent (greater than or equal to three episodes in the previous 12 months) low back pain (LBP) of mechanical origin with /without radiation to the lower limb

3. No spinal surgery within the previous 12 months

4. Patients deemed suitable by their GP/hospital consultant to carry out an exercise programme

5. Patients willing to attend for an 8-week treatment programme of exercise classes

6. Fluency in English (verbal and written)

7. Access to a telephone (for follow-up support)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Clinically diagnosed primary sleep disorder, e.g., sleep apnoea, insomnia

2. Currently on sleeping medication

3. Currently or having received treatment for CLBP within previous 3 months

4. Patients with minimum disability on the Oswestry Disability Index (less than 10)
5. Red flags indicating serious spinal pathology, e.g., cancer, cauda equina lesion
6. Radicular pain indicative of nerve root compression
7. Patients diagnosed with severe spinal stenosis, spondylolisthesis, fibromyalgia
8. History of systemic/inflammatory disease, e.g., rheumatoid arthritis
9. Patients with any confounding conditions such as a neurological disorder or currently receiving treatment for cancer
10. Patients with acute (less than 6 weeks) or subacute LBP (6 - 12 weeks), provided that they have experienced less than three LBP episodes during previous 12 months
11. Unstable angina/uncontrolled cardiac dysrhythmias/severe aortic stenosis/acute systemic infection accompanied by fever
12. Medico-legal issues
13. Pregnancy

**Date of first enrolment**

23/10/2008

**Date of final enrolment**

28/02/2010

## **Locations**

**Countries of recruitment**

Ireland

**Study participating centre**

UCD School of Physiotherapy and Performance Science

Dublin

Ireland

4

## **Sponsor information**

**Organisation**

Health Research Board (HRB) (Ireland)

**ROR**

<https://ror.org/003hb2249>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Health Research Board (HRB) (Ireland) - Partnership Award (ref: 2007-16)

## 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	01/11/2013		Yes	No
<a href="#">Protocol article</a>	protocol	16/04/2010		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes