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Physiotherapy for sleep disturbance in chronic low back pain trial

Submission date	Recruitment status	[_] Prospectively registered
10/08/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/01/2014	Musculoskeletal Diseases	

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
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
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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?
Results article	results	01/11/2013		Yes	No
Protocol article	protocol	16/04/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes