ISRCTN17592092 https://doi.org/10.1186/ISRCTN17592092

Supervised Walking In comparison to Fitness Training for back pain

Submission date	Recruitment status
08/09/2008	No longer recruiting
Registration date	**Overall study status**
08/01/2009	Completed
Last Edited	**Condition category**
21/08/2019	Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
2007-1

Study information

Scientific Title
A single-blinded randomised controlled trial exploring the effectiveness of a walking programme and a supervised general exercise programme versus usual physiotherapy for chronic low back pain

Acronym
SWIFT Trial

Study objectives
In people referred for physiotherapy for chronic low back pain (LBP) there is no difference in clinical outcome and costs between those receiving a walking programme, a supervised general exercise programme and usual physiotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committees:
1. Connolly Hospital Blanchardstown, Dublin: 21st September 2007
2. Beaumont Hospital, Dublin: 9th October 2007 (ref: 07/63)
3. Mater Hospital, Dublin: 21st November 2007 (ref: 1/378/1135)
4. Adelaide and Meath Hospital, Dublin: 14th September 2007 (ref: 2007/09/09)

Study design
Single-blind multicentre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic low back pain

Interventions
1. Walking programme (WP):
Within two weeks of randomisation participants will commence participation in the WP at each participating 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 below), 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 pedometer to wear for seven days to record habitual daily activity levels. The subject will then re-attend and using the information recorded from the pedometer, 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 Yamax Digiwalker 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 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.

2. Supervised exercise class (SEC):
Within two weeks 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 recently published UK BEAM trial. 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 the relevant participating 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 treatment 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.

3. Usual physiotherapy (UP - control group):
Within two weeks of randomisation, participants randomised to the UP group will commence individual physiotherapy at the discretion of the treating physiotherapist in the participating 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 by the researchers. 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 during the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Oswestry Disability Index, measured at 3, 6 and 12 months by postal follow-up.

Key secondary outcome(s))
1. Pain using a Numerical Rating Scale
2. Health-related quality of life measured by the EuroQol questionnaire
3. Psychosocial beliefs using the Fear Avoidance Beliefs Questionnaire and the Back Beliefs Questionnaire
4. Number of days reported sick leave over the past year for those in paid employment only
5. Physical activity levels using the International Physical Activity Questionnaire (IPAQ), an exercise diary and the activPalTM accelerometer

6. Patient satisfaction will be assessed using Likert scales assessing satisfaction with outcome and satisfaction with care
7. Self efficacy questionnaire

The outcomes will be measured at 3, 6 and 12 months by postal follow-up.

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Patients with chronic (greater than or equal to three months) or recurrent (greater than or equal to three episodes in previous 12 months) LBP of mechanical origin with/without radiation to the lower limb
2. Males/females between 18 - 65 years
3. No spinal surgery within the previous 12 months
4. Patients deemed suitable by their General Practitioner (GP)/hospital consultant to carry out an exercise programme
5. Patients willing to attend for an 8-week treatment programme of exercise classes
6. Access to a telephone (for follow-up support)
7. Fluency in English (verbal and written)
8. Low levels of physical activity measured by the International Physical Activity Questionnaire (IPAQ) (less than 600 MET-minutes/week)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
246

Key exclusion criteria
1. Currently or having received treatment for chronic low back pain (CLBP) within previous three months
2. Red flags indicating serious spinal pathology, e.g. cancer, cauda equina lesion
3. Radicular pain indicative of nerve root compression
4. Patients diagnosed with severe spinal stenosis, spondylolisthesis, fibromyalgia
5. History of systemic/inflammatory disease, e.g. rheumatoid arthritis

6. Patients with any confounding conditions such as a neurological disorder or currently receiving treatment for cancer
7. Patients with acute (less than six weeks) or subacute LBP (6 - 12 weeks), provided that they have experienced less than three LBP episodes during previous 12 months
8. Unstable angina/uncontrolled cardiac dysrhythmias/severe aortic stenosis/acute systemic infection accompanied by fever
9. Medico-legal issues

Date of first enrolment
01/10/2008

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Ireland

Study participating centre
UCD Health Sciences Centre
Dublin
Ireland
D14

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) (ref: 2007-79)

Alternative Name(s)

HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

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	01/01/2015	21/08/2019	Yes	No
Protocol article	protocol	02/07/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes