ISRCTN66262199 https://doi.org/10.1186/ISRCTN66262199

Short-term effect on pain and function of neurophysiological education and sensorimotor retraining compared to usual physiotherapy in patients with chronic or recurrent non-specific low back pain (NSLBP)

Submission date
29/12/2013

Recruitment status
No longer recruiting

Registration date
08/01/2014

Overall study status
Completed

Last Edited
15/02/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
The effect of treatment in patients with long-term low back pain is usually minimal and it is not clear which treatment is better. In this study, we will find out about the short-term effect of a multimodal program applied in patients suffering from long-term or recurrent low back pain to decrease pain and disability.

Who can participate?
People suffering from low back pain for at least three months can participate in this study.

What does the study involve?
Patients are randomly allocated to receive either a multimodal treatment or the usual physiotherapy. Treatment duration is eight to twelve weeks and includes individual physiotherapy once or twice a week and 10 to 30 minutes of home training five times a week.

What are the possible benefits and risks of participating?
Participation in this study poses no additional risk compared with usual treatment.

Where is the study run from?
Medbase Centre for Health Care at Saint Gallen, Switzerland.

When is study starting and how long is it expected to run for?
Participant enrolment started in November 2012 and ended in May 2013.

Who is funding the study?
The study is funded by the Zurich University of Applied Sciences, Switzerland.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Short-term effect on pain and function of neurophysiological education and sensorimotor retraining compared to usual physiotherapy in patients with chronic or recurrent non-specific low back pain (NSLBP): a randomized controlled trial

Study objectives
This study was designed to investigate the short-term effect of a multimodal program applied on a specific subgroup of chronic NSLBP patients to decrease pain and disability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Canton of St.Gallen, 31/10/2012, EKSG 12/140/1B

Study design
Single-center randomised controlled 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 non-specific low back pain

Interventions
Patients will be randomly allocated to either a multimodal treatment (interventional group, n=14) or usual physiotherapy (control group, n=14). Treatment period will be 8 to 12 weeks with a frequency of once to twice a week with a maximum of 16 sessions. Subjects in both groups will have to execute a home training five times per week lasting 10 to 30 minutes. Assignments for home training will be displayed and protocolled on a web-based personalized home-training interface, for subjects to administer self-consistent.

The treatment aims at reducing pain and disability, potentially addressing abnormal cortical processing in chronic low back pain (cLBP).

Multimodal treatment includes:
1. Education about the neurophysiology of pain according to the book Explain Pain from D. Butler
2. Sensory retraining using two point discrimination and graphaesthesia training
3. Motor retraining using movement control exercises, videos of small, respectively full range lumbar movement to watch and either simultaneously perform or to visualize to do so and laterality recognition training (patients will be shown photographs of a human trunk rotated or side-bended to right or left on the computer and will have to determine the perspective of the picture as quickly as possible using the computer program Recognise®).
The home training for this group will contain all three aspects mentioned above.

Control group:
Basic patient education about adequate behaviour when having LBP including short period of protection, return to normal movement, work and leisure activities as soon as possible. Sessions will contain treatment addressing signs and symptoms. Two thirds (i.e., 20 minutes) of each session will consist of active treatment, like exercises for muscle strengthening, neuro-meningeal mobilisation and muscle stretching. A maximum of ten minutes of passive applications per session will be allowed (such as massage, manual therapy, electro therapy, mud packs). The home training for this group will contain classical exercises for strengthening, stretching and neuro-meningeal mobilisation.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Mean pain intensity of LBP on average during the last 7 days measured on a numeric rating scale (NRS) from zero to ten.

Secondary outcome measures
1. General disability, measured with the Roland and Morris Disability Questionnaire (RMDQ)
2. Patient specific disability, measured with the Patient Specific Functional Scale (PSFS)
3. Cognitive aspects concerning pain and function, measured with the Fear Avoidance Beliefs Questionnaire (FABQ) and the Pain Catastrophizing Scale (PCS)
4. Sensory acuity of the lower back, parameterized by measuring two-point discrimination across focal point of LBP
5. Motor control impairment (MCI), measured with the six tests developed by Luomajoki et al.
6. Sick leave recording the number of days absent from work during last seven days
7. Mean analgesic intake during the last seven days
8. A benchmark of 80 percent completion is a priori set for minimum adherence to the home training protocols

All outcomes were taken at baseline and three months later.

Overall study start date
01/11/2012

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Men and women 18 to 60 years of age
2. A history of low back pain (LBP) of at least three months
3. Moderate disability, i.e. five points or more on the Roland and Morris Disability Questionnaire (RMDQ)
4. Medium or high risk for poor outcome, evaluated with the Keele Start Back Tool (KSBT)
5. Ability to speak and read German
6. Having someone available for assistance to execute home training
7. Having home access to the internet
8. Participants have to consent to an expenditure of time of 30 minutes five times per week over eight weeks to execute a home program and one to two 30-minute physiotherapy sessions per week

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
28

Key exclusion criteria
1. Nerve root pain
2. Diagnosed specific spinal pathology (such as malignancy, fracture, infection or inflammatory joint or bone disease)
3. Pregnancy or less than 6 months postpartum
4. Coexisting major medical disease causing a relative or absolute contraindication to general exercise
5. Undergone spinal surgery within the preceding two years
6. Intra-articular or perineural steroid injection on the lumbar spine during the previous five months

Date of first enrolment
01/11/2012

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
Switzerland

Study participating centre
Haldenstrasse 15
St.Gallen
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9000

Sponsor information

Organisation
Zurich University of Applied Sciences (Switzerland)

Sponsor details
ZHAW Institute of Physiotherapy; ZHAW School of Health Professions
Technikumstrasse 71

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CH-8401

Sponsor type
University/education

Website
http://www.gesundheit.zhaw.ch

ROR
https://ror.org/05pmsvm27

Funder(s)

Funder type
University/education

Funder Name
Zurich University of Applied Sciences (Switzerland)

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	10/04/2015		Yes	No