ISRCTN80064281 https://doi.org/10.1186/ISRCTN80064281

Movement control exercise for low back pain

Submission date
13/07/2010

Recruitment status
No longer recruiting

Registration date
26/08/2010

Overall study status
Completed

Last Edited
17/01/2012

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] 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

Contact name
Mrs Jeannette Saner

Contact details
School of Health Professions
Zurich University of Applied Sciences
Technikumstrasse 71
P.O. Box
Winterthur
Switzerland
CH-8401
jeannette.saner@zhaw.ch

Additional identifiers

Study information

Scientific Title
Movement control exercise for low back pain: a randomised controlled trial

Study objectives
The aim of this study is to investigate the effect of two different exercise treatments on a selected subgroup of subacute/chronic nonspecific low back pain (LBP) patients. It has the following research questions:
Question 1: Are movement control exercises more effective than general exercises in patients

with chronic non-specific LBP and movement control impairment?
Question 2: Is the improvement of movement control of the lumbar spine, assessed with standardised clinical tests, associated with the functional improvement and pain reduction?
Question 3: Is outcome associated with physical or psychosocial factors assessed before treatment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Swiss Ethics of Cantons Zurich, Aargau and Basel approved on the 25th May 2010 (ref: KEK-ZH-Nr. 2010-0034/5)

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-specific low back pain

Interventions
Current interventions as of 20/12/2011
4 private practices more are involved in the recruitment and treatment phase, in total 7 private practices. In addition patients are also recruited by email announcement and subsequently treated by physiotherapy staff of the university.

Intervention group:
Specific individual exercise and treatment based on subjective and physical findings. The patients in the movement control group will participate in a training/treatment program aiming at improving movement control of the lumbar spine.

Control group:
All patients will carry out strengthening exercises of abdominal, back, gluteal and thigh muscles under surveillance of a physiotherapist:. Weights and resistance will be individually adapted according to the needs of the patient.

The program will last 12 weeks in maximum. The patients will have one to two individual treatment sessions of half an hour weekly, between 9 - 18 treatment sessions in total. In both groups no more than 10 minutes of other therapies like massage or mobilisation are allowed. Each therapy is applied by a specially trained physiotherapist. Each therapist will treat at least 4 patients in the trial.

Time-points of assessment are at baseline, after treatment phase, 6 and 12 months follow-up after inclusion. Data will be collected through video assessment (movement control tests),

physical measures (range of motion, endurance and two point discrimination) pre and post treatment and questionnaires given or in a later phase sent out to the patients. All patients receive 3 individualised home-exercises and are encouraged to use them for the next year.

Previous interventions

Patients will be recruited in five physiotherapy departments of clinics and three private practices after referral to physiotherapy by their physicians.
Intervention group:
Specific individual exercise and treatment based on subjective and physical findings. The patients in the movement control group will participate in a training/treatment program aiming at improving movement control of the lumbar spine.
Control group:
All patients will carry out strengthening exercises of abdominal, back, gluteal and thigh muscles under surveillance of a physiotherapist:. Weights and resistance will be individually adapted according to the needs of the patient.
The program will last 12 weeks in maximum. The patients will have one to two individual treatment sessions of half an hour weekly, between 9 - 18 treatment sessions in total. In both groups no more than 10 minutes of other therapies like massage or mobilisation are allowed. Each therapy is applied by a specially trained physiotherapist. Each therapist will treat at least 4 patients in the trial.
Time-points of assessment are at baseline, after treatment phase, 6 and 12 months follow-up after inclusion. Data will be collected through video assessment (movement control tests), physical measures (range of motion, endurance and two point discrimination) pre and post treatment and questionnaires given or in a later phase sent out to the patients. All patients receive 3 individualised home-exercises and are encouraged to use them for the next year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change in patients' major complaints, is assessed with the Patient Specific Functional Scale, PSFS, at baseline, after treatment phase, with 6 and 12 months follow-up after inclusion.

Key secondary outcome(s)
1. Low back pain specific disability will be assessed with the Roland and Morris disability questionnaire at baseline, after treatment phase, and 6 and 12 months following inclusion
2. Graded chronic pain scale assesses the grade of chronicity at baseline, after treatment phase, with 6 and 12 months follow-up after inclusion
3. Endurance of lumbar and abdominal muscles is assessed with static isometric tests pre- and post-treatment
4. Two-point-discrimination assesses local perception in the lumbar spine pre- and post-treatment
5. Usage of medication, health care as well as sick leave because of LBP at baseline, after treatment phase, and 6 and 12 months following inclusion

Co-variates:
We will record the following potential predictors for positive or negative outcomes:

6. Age (years), Height (m), Weight (kg), body mass index (BMI)
7. Disease characteristics: duration of the complaints, pain intensity, pain location
8. Movement control of the lumbar spine is assessed with the movement control test battery consisting of 6 tests
9. Medication: type, dose and duration in the last month
10. Fear avoidance beliefs questionnaire
11. The belief of patient of what would help him/her the most

Cointerventions:
13. Activity level in general hours per week
14. Impression of home exercises done: yes, no, sometimes

Adherence to the exercise program is assessed using a diary that is kept by the physical therapists. Adherence to a home exercise program is assessed post treatment by a questionnaire.

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/12/2011
1. Age 18 to 75 years, male and female
2. Non-acute non-specific LBP (greater than 6 weeks duration of symptoms) but not longer than 6 months of sick leave due to LBP
3. Two or more positive tests for impaired movement control
4. At least 5 points on Roland Morris Disability questionnaire
5. Back pain that is provoked or worsened by distinct movements, activities or postures as described as the typical clinical behaviour
6. Written informed consent

Previous inclusion criteria
1. Age 18 to 65 years, male and female
2. Non-acute non-specific LBP (greater than 6 weeks duration of symptoms) but not longer than 6 months of sick leave due to LBP
3. Two or more positive tests for impaired movement control
4. At least 5 points on Roland Morris Disability questionnaire
5. Back pain that is provoked or worsened by distinct movements, activities or postures as described as the typical clinical behaviour
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Specific LBP (Fractures, carcinoma, anomalies, nerve root affection with neurological signs e.g. sensibility or reflex loss, muscle weakness)
2. Less than 6 weeks post-surgery; all post spinal fusion surgery
3. Psychosocial risk factors controlled with Örebrö Musculoskeletal Pain Questionnaire (ÖMOQ)
4. Peripheral or central neurological disease
5. Contraindications for exercise, e.g. major cardiovascular problems or postural hypotension
6. Inability to understand the purpose of the study
7. Psychological or psychiatric problems
8. Chronic abuse of toxic substances such as drugs or alcohol
9. Use of neuroleptics, sedatives, anti-epileptics and anti-depressives

Date of first enrolment
21/06/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Switzerland

Study participating centre
School of Health Professions
Winterthur
Switzerland
CH-8401

Sponsor information

Organisation
Institut of Physiotherapy (Switzerland)

ROR
https://ror.org/05pmsvm27

Funder(s)

Funder type
Research organisation

Funder Name
Swiss National Science Foundation (Fonds National Suisse de la Recherche Scientifique [SNSF]) (Switzerland) (ref: SNF 13DPD6_127240/1 of 2. Sept)

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/09/2011		Yes	No