ISRCTN48684087 https://doi.org/10.1186/ISRCTN48684087

Efficacy of movement control exercises versus general exercises on recurrent sub-acute non-specific low back pain in a sub-group of patients with movement control dysfunction

Submission date
04/12/2011

Recruitment status
No longer recruiting

Registration date
18/01/2012

Overall study status
Completed

Last Edited
24/03/2016

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Practice guidelines recommend various types of exercise for chronic back pain but there have been only a few head-to-head comparisons of these treatments. General exercise seem to be an effective treatment for chronic low back pain (LBP) but very little is known about the treatment of a sub-acute LBP within sub-groups. Clinical tests have been developed to identify a subgroup of patients with chronic non-specific LBP who have movement control dysfunction (MD). The aim of this study is to compare the effects of general exercise and specific movement control exercise (SMCE) on disability and function in patients with MD within recurrent sub-acute LBP.

Who can participate?
Patients aged between 16 and 65 years seeking treatment for sub-acute non-specific LBP from one physical therapy clinic in Kotka, Finland.

What does the study involve?
Participants will be randomly allocated to take part in either a movement control exercise program or a general exercise program. A physical therapist carries out an initial assessment of each participant allocated to the each exercise group to determine how physically active the participant is, how troublesome the back problem is, and the ability of the participant to perform the exercises. These are measured by the treating physiotherapist by asking the participant. Participants are then taught the exercises and advised regarding the intensity at which they should exercise. The exercises are performed under supervision of a physical therapist. The intensity of the exercises is progressed over the five treatments with participants being encouraged to improve their own performance. Each session lasts 45 minutes and includes a short session (10-15 minutes) of manual therapy.

What are the possible benefits and risks of participating?
The possible benefit to the participants is to learn a healthy way to cope with their low back problem. The possible risk to the participants is musculoskeletal pain after the exercises.

Where is the study run from?
University of Eastern Finland (Finland)

When is the study starting and how long is it expected to run for?
October 2010 to November 2012

Who is funding the study?
Kela The Social Insurance Institution of Finland and Finnish Cultural Foundation (Finland)

Who is the main contact?
Vesa Lehtola
vesa.lehtola@omt.org

Contact information

Type(s)
Scientific

Contact name
Mr Vesa Lehtola

Contact details
Allintie 8
Kotka
Finland
48220
+35 (0)844 556 0865
vesa.lehtola@omt.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of movement control exercises versus general exercises on recurrent sub-acute non-specific low back pain in a sub-group of patients with movement control dysfunction: protocol of a randomized controlled trial

Study objectives
Do patients within a sub-group of movement control dysfunction profit more through a specific individually tailored exercise program than through general exercise?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Carea (Kymenlaakso Hospital District) Finland, 17/05/2010

Study design
Randomised single-blind placebo-controlled cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
GP practice

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
Movement Control Dysfunction within recurrent sub-acute LBP

Interventions
There will be approximately 35 participants in each group (movement control exercises versus general exercises). A physical therapist carries out an initial assessment of each participant allocated to each exercise group to determine how physically active the participant is, how troublesome the back problem is, and the ability of the participant to perform the exercises. These are measured by the treating physiotherapist by asking the participant. Participants are then taught the exercises and advised regarding the intensity at which they should exercise. The exercises are performed under supervision of a physical therapist. The intensity of the exercises is progressed over the five treatments with participants being encouraged to improve their own performance. Each session lasts 45 minutes and includes a short session (10-15 minutes) of manual therapy.

Intervention Type
Behavioural

Primary outcome measure
Roland-Morris Disability Questionnaire measured at baseline, after the 3 months intervention and finally 12 months after the start.

Secondary outcome measures
1. Patient-Specific Functional and Pain Scale (PSFS)
2. Oswestry Disability Index

3. Movement control tests described by Luomajoki et al.
4. The amount of absence from work with a questionnaire
5. The need for other treatment modalities with a questionnaire
6. The need for pain medication with a questionnaire
7. Patient satisfaction with global assessment with a questionnaire
Measured at baseline, after the 3 months intervention and finally 12 months after the start.

Overall study start date
01/10/2010

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. The aim of the 'rest' inclusion regimen is to sub-classify those patients who have movement dysfunction (MD). The inclusion criteria involves three questionnaires and physical examination. Within the results of the questionnaires the participant should score:
1.1. Roland-Morris Disability Questionnaire to be > 5 points
1.2. DEPS < 12 points, Tampa Scale for Kinesiophobia < 38 points
1.3. Motor Control Abilities Questionnaire < 80 points
The Motor Control Abilities Questionnaire (MCAQ) is a self-report tool that was developed to screen people for their ability to learn specific motor control stability exercise and specific movement control exercise. Reliability and validity have been established. A cut-off point of 80 has a specificity of 0.98 and a sensitivity of 0.88. The MCAQ should be used to exclude those subjects who are unable to learn the exercises and thus not benefit from the treatment.
2. Within the physical examination the participant should have > 2/6 positive movement control dysfunction test described by Luomajoki et al and not to have Straight Leg Raise (SLR) under 50 degrees positive or any positive sacroiliac-joint pain provocation tests to be eligible to participate in the study. Clinical assessment should indicate that the subject is suitable for active exercise, which is asked within a questionnaire.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Neurological signs (leg weakness)
2. Specific spinal pathology (e.g. malignancy, or inflammatory joint or bone disease)
3. Have undergone back surgery
4. The aim of the measurement of DEPS, TSK and MCAQ is to rule out those patients with LBP of

non-mechanical origin, e.g. depression, fear-avoidance and a poor ability to learn exercises
5. The aim of physical examination of SLR and sacroiliac-joint provocation tests is to rule out those patients with mechanical movement impairment

Date of first enrolment
01/10/2010

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Finland

Study participating centre
Allintie 8
Kotka
Finland
48220

Sponsor information

Organisation
Kela The Social Insurance Institution of Finland (Finland)

Sponsor details
Kela, PL 20
Helsinki
Finland
00232
-
tutkimus@kela.fi

Sponsor type
Government

Website
http://www.kela.fi

ROR
https://ror.org/057yw0190

Funder(s)

Funder type
Government

Funder Name
Kela

Alternative Name(s)
Social Insurance Institution of Finland, Kansaneläkelaitos

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Finland

Funder Name
Finnish Cultural Foundation (Finland)

Alternative Name(s)
Finnish Cultural Foundation, SKR

Funding Body Type
Private sector organisation

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

Location
Finland

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?
Protocol article	protocol	11/04/2012		Yes	No
Results article	results	22/03/2016		Yes	No