Sensor-Based Intervention to Enhance Movement Control of the Spine in Low Back Pain

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Primary Objective: To evaluate if a sensor-based movement control intervention enhances movement control of the trunk in low back pain patients to a greater extent than a standard core stability intervention over the course of a multidisciplinary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON50809

Source
ToetsingOnline

Brief title
SensI MoveS

Condition

- Joint disorders

Synonym
Chronic low back pain, Long lasting pain in the lower back

Research involving
Human

Sponsors and support

Primary sponsor: Militair Revalidatie Centrum 'Aardenburg'
Source(s) of monetary or material Support: Stichting Ziektekostenverzekering Krijgsmacht

Intervention

Keyword: Intervention, Low Back Pain, Movement Control, Sensors

Outcome measures

Primary outcome

Trunk movement control

Average tracking error of three trunk-controlled tracking tasks on a laptop (one flexion-extension, one lateral flexion, one rotation) at the beginning and end of the intervention, reported in as average tracking error (degrees).

Secondary outcome

Trunk movement control

Results from clinical movement control tests of the low back.

Cycle-to-cycle variability of trunk rotations (degrees) during gait at low (2 km/h), comfortable (subject specific) and high (6 km/h) gait speed.

Cycle-to-cycle variability of trunk flexion during a repetitive bending task while standing.

Cycle-to-cycle variability of trunk rotation during a repetitive standing rotation task.

Therapy adherence

Number of individual therapy sessions present and reported reason for missing a session (not scheduled / therapist absent / patient absent).

Dutch version of the Exercise Adherence Rating Scale for the prescribed homework exercises.

Disability

Two questionnaires will be used.

(1) The Dutch version of the Oswestry Disability Index 2.1a.

(2) The Dutch version of the Roland Morris Disability Questionnaire.

*

Pain intensity

A numeric rating scale (0-10) for current, week-average, and

week-maximum pain intensity of the low back.

Fear Avoidance Beliefs

The Dutch version of the Fear Avoidance Beliefs Questionnaire.

Health related quality of life.

The scales *physical functioning*, *mental health*, *general health*

and *pain* from the Dutch version of the RAND-36.

Study description

Background summary

According to current evidence, the best treatment for low back pain is exercise, preferably in combination with education. There is no evidence that certain exercises work better than others. For this reason, guidelines such as the Dutch Physiotherapy guideline recommend that the personal preferences of the therapist and patient be taken into account.
In a considerable part of the intervention studies with a focus on physical exercises, "core stability" exercises are offered. During these programs, patients learn to selectively contract the deep trunk muscles (m.transversus abdominis and mm. Multifidi) and fixate their spine during postures and movements that gradually increase in complexity. Although these exercises are more effective than no intervention, they are not superior to other physical exercise interventions consisting of, among others, strength exercises, stretching exercises and / or aerobic exercises.
Physical rehabilitation interventions usually aim at reducing functional

limitations, such as strength, flexibility, endurance or coordination. The question is to what extent core-stability exercises eliminate limitations in function. Patients with low back pain generally fixate their spine during every-day movements. This behavior could be stimulated with core-stability exercises. Patients with low back pain, on the other hand, do experience problems performing controlled movements of the back. Designing exercises to improve the movement control of the back is a challenge. Movement control over less centrally located joints, such as the elbow or knee, can be trained using simple tasks, such as bringing a spoon to the mouth or kicking a ball against a pillon. The success of the execution (not spilling the soup or knocking over the pillon) can be used as an indication of good control over the movement of the joint. Giving meaningful feedback on back movements is much more complicated. Sensors that measure the back movements can offer a solution. There are several solutions available on the market, but no intervention studies incorporating these technologies have yet to be performed.

Study objective

Primary Objective:
To evaluate if a sensor-based movement control intervention enhances movement control of the trunk in low back pain patients to a greater extent than a standard core stability intervention over the course of a multidisciplinary rehabilitation programme.

Secondary Objective:
To evaluate if differences exist between the offered interventions in therapy adherence and the effect on disability, pain intensity, physical fear avoidance beliefs and health related quality of life.

Study design

Randomized Controlled Trial

Intervention

Both interventions will be offered over a course of eight weeks (week 2 - 9 of the study), each week consisting of:
- Two supervised therapy sessions of 20-30 minutes
- Provided by experienced therapists (physiotherapist, occupational therapists
(in Dutch: *ergotherapeuten*) and sport therapists) that will be trained to provide the
intended interventions.
- The first six sessions will be individual, i.e., with one patient for each session.
- The final ten sessions will be in groups, i.e., with a maximum of

three patients per
session.
- Seven non-supervised homework exercises of 5-10 minutes
One video-instruction for each week that will be performed each day of that week.
These instructions will be available *unlisted* on YouTube, i.e., these videos can be
viewed anonymously on any device (e.g., laptop, smartphone or tablet), but only by
individuals that have a link to the video. Separate exercises will be provided for each
intervention.

The supervised therapy sessions and homework exercises of the standard core-stability intervention will consist of exercises in which participants will be instructed to contract their m. transversus abdominis during a variety of postures and body movements while keeping their spine *stable*, i.e., trying to make as little spinal movements as possible. The exercises will be offered with increasing intensity, difficulty and complexity.

For the supervised therapy sessions of the sensor-based movement control intervention Valedo® Motion will be used. During each session, patients will play a number of games that are controlled with spinal movements in a variety of postures. Spinal movement is tracked using three inertial sensors that are placed on the pelvis, the spine at the 12th thoracic vertebrae and the sternum. The exercises will be offered with increasing intensity, difficulty and complexity.

Study burden and risks

In general, exercise therapy results in small, but significant improvements in function of low back pain, regardless of the exact type of exercises. Hence, only relatively small advantages of being in a specific intervention groups are to be expected.
The tests at the beginning and end of the intervention could result in a transient increase in low back pain.
Training with sensors could result in spinal tissue overload as a result of lack of focus on bodily sensations. Moreover, Valedo has not been used previously at the Military Rehabilitation Center. As a result of this inexperience, it could happen that the offered exercises for this group are more often too intensive than for the core-stability group, which could result in an increase of low back pain. However, the Military Rehabilitation Center has more than 10 years of experience with providing a similar type of therapy in low back pain patients. Moreover, the complexity, duration and intensity of the exercises will be increased gradually, which would minimize the chance of overloading the spinal structures.

Contacts

Public
Militair Revalidatie Centrum 'Aardenburg'

Korte Molenweg 3
Doorn 3941PW
NL
Scientific
Militair Revalidatie Centrum 'Aardenburg'

Korte Molenweg 3
Doorn 3941PW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Between 20 and 60 years of age
- Experienced low back pain on a daily basis over the last 3 months, with or without accompanying leg pain above the knee.

Exclusion criteria

- Any condition (other than chronic low-back pain) that might interfere with motor control of the trunk.
- A recent surgical intervention on the spinal column, proven serious pathology of the
spine* and related structures (canal and/or foramen stenosis, spondylolysis,

spondylolisthesis, osteoid osteoma), infections, recent fractures or psychiatric disorders.
- Signs of neurological compression, e.g., loss of sensory or motor functions in the legs and/or pelvis and/or radiating pain in the lower leg and/or foot.
- The use of drugs that influence the reaction time (In the Netherlands, drugs with a yellow sticker on the box that reads (translated): "This medication may influence your reactions. Use with caution when driving a car or operating dangerous machinery.").
- A Body Mass Index of 30 (kg/m2) or more as this could hamper the planned movement control intervention as a result of movement artefacts.
- Implanted electronic devices of any kind, including cardiac pace-makers or similar assistive devices, electronic infusion pumps, and implanted stimulators.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	14-05-2021
Application type:	First submission

Review commission: METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL76811.028.21

Study results

Date completed: 11-07-2023

Actual enrolment: 67