The effect of a prototype feedback and passive spinal support device on spinal loading during load handling tasks in healthy subjects and low back pain patients.

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

Summary

ID

NL-OMON47119

Source
ToetsingOnline

Brief title
The effect of feedback and spinal support on spinal loading.

Condition

- Joint disorders

Synonym
low back pain

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: European Commitee

Intervention

Keyword: assistive device, low back pain, reintegration, spinal loading

Outcome measures

Primary outcome

In part I and II, our main goal is to investigate if our assistive device is

effective in reducing mechanical back loads, defined in terms of:

* Peak and cumulative L5S1 compression force

* Lumbar angular accelerations (uncontrolled spine motion)

* Lumbar angles (spine flexion and asymmetrical spine motion)

* Co-contraction

In part III our main goal is to analyze the feasibility and satisfaction to use

the assistive device in the working environment, defined in terms of:

* System Usability Scale (SUS) score of each participant

* Patient*s Global Impression of Change (PGIC) score

* Clinicians Global Impression of Change (CGIC) score

* Individual classification code based on the ICF- framework

Secondary outcome

In parts I and II, our secondary goals are to investigate the effect of our

assistive device on the work performance in terms of:

* Effort

- Heart rate

- Perceived effort

* Productivity

- Time to complete the task cycle

* Discomfort

- Local Perceived Discomfort Scale

and to investigate the effect on performance of daily activities in terms of:

* Self-Paced Walk Test (SPWT)

- Walking speed

* Stair Climb Test (SCT)

- Time

* Six-Minute Walk Test (6MWT)

- Distance

* Chair Stand Test (CST)

- Time

* Timed Up and Go (TUG)

- Time

In part III, our secondary goal is to analyze the effect on fear of movement in

terms of:

* Score of Tampa Scale Kinesiophobia (TSK)

Study description

Background summary

Low-back pain (LBP) is often termed a pandemic of the modern world and represents a large socioeconomic burden. Epidemiological studies have shown that physically demanding jobs correlate with prevalence of LBP and exaggeration of symptoms. One way to target this problem is to develop technologies that either augment or substitute human physical abilities and prevent negative effects on the human body. Most of the assistive devices that have been developed so far mainly focus on augmenting the motion of the arms. Recently these devices have been extended to the trunk. Several studies have found that wearing assistive devices that passively support the users* trunk movements reduces spinal loading during lifting, bending and static holding tasks. However, the actual effect on spine loading has not yet been assessed. Moreover, most devices have not been tested beyond the laboratory, and there are still some concerns regarding discomfort, practicality and usability. In addition, the potential of integrated real-time feedback on spine motion and spine loading has not been explored and systems have not yet been tested for effectiveness in low back pain patients.

Study objective

The objective of this project is to design and test a novel assistive device to ultimately prevent low-back pain in able-bodied workers and to support workers with low-back pain who are re-integrating in the vocational setting. In this project, two different assistive devices will be evaluated: 1) a feedback system based on force sensors and an inertial motion capture system providing feedback about physical risk factors measured in real-time 2) a passive exoskeleton that is able to support the weight of the trunk and prevent awkward trunk postures. In doing so, the effects of the system on spinal loading are evaluated in terms of L5S1 spinal compression forces, lumbar angles and accelerations, and co-contraction. Furthermore the effects of wearing the device on work performance (effort, productivity and comfort) and daily activity performance (5 common daily tasks) will be investigated. Finally, feasibility of using the system, and satisfaction in using the system will be analysed in the working environment of the subjects.
*

Study design

This cross-sectional study will be divided into three parts. Part I will test

the effectiveness in terms of in limiting spinal movement and load of the lumbar spine of the device in healthy people only. These experiments will be performed in a mock-up laboratory setting at the Vrije Universiteit Amsterdam over a period of 18 months.
It is expected, that part I will show that the device never increases but only reduces spine motion and spine loading without substantial negative side effects. If this holds true, the device is safe to be tested with people who suffer from recurrent low back pain. Then, a second assessment of the device will be conducted at the Vrije Universiteit Amsterdam, including employees who suffer from recurrent low back pain (Part II).
In part III, feasibility and satisfaction of using the device will be assessed. These tests will be performed in the working environment of the subjects, hence on site (various work locations).

Parts I and II: Laboratory testing
The effectiveness of spinal load reduction, the work performance and the daily activity performance when wearing the assistive device will be tested in a mock-up laboratory setting.

Measurements will be taken in two sessions. In the first session, a classification of the subjects will be conducted. Participants will fill in the Work Productivity and Activity Impairment Questionnaire, The Owestry Disability Index and the RAND-36 Questionnaire. Furthermore, a first familiarisation of wearing the assistive device will be given and a pain rating during the familiarisation will be filled in by the subjects to adjust the device and by that ensuring good comfort in the following session.

In the second session subjects will perform a task cycle with a number of sequenced load handling tasks. In order to arrive at a variety of tasks and to guarantee intrinsically safe load handling, we will base our task selection on the revised NIOSH lifting equation which was developed to determine a recommended weight limit for a specific task. A number of 30 different tasks will be used to simulate lifting and lowering tasks and 10 different tasks will be used to simulate pulling, pushing and carrying tasks. Subjects will perform the task cycle without and with wearing the SPEXOR device. To assess effectiveness of the assistive device spinal movement and load will be determined using measured forces in the shoes and by measuring body kinematics with Xsens sensors, i.e. matchbox-size inertial sensor units, attached with rubber bands to body segments. Forces will be measured by force platforms and body kinematics and kinetics by using an optical motion capture system (Optotrak). Additionally, EMG activity of the main trunk muscles (Erector Spinae, Multifidus, Rectus Abdominus and External Obliques) will be recorded, placing electrodes on the respective muscles based on SENIAM recommendations.

In order to assess work performance, heart rate will be recorded over the whole task cycle and the subject will be asked for rating of perceived exertion, using the Borg Rating of Perceived Exertion (RPE) and perceived local

discomfort, using the Local Perceived Discomfort Scale (LPD). Furthermore, the time to complete the whole task cycle will be measured to assess a change in productivity due to the device.
Daily activity performance will be analysed by including 5 common daily tasks.

1) Self-Paced Walk Test : time needed to cover a specified distance (sec)
2) Stair Climb Test: time needed to complete the test (sec)
3) Six-Minute Walk Test: travelled distance (m)
4) Sit-To-Stand Test: total number of complete Sit-Stand-Sit cycles in one minute.
5) Timed Up and Go: time needed to complete the test, consisting of stand up, walk 5 meters, turn, return to chair, and sit down (sec)

Participants will perform these tasks with and without the assistive device to monitor whether the device limits performance on these activities.

Part III: Field testing
Feasibility and user satisfaction will be tested at the work site of the included participants in two sessions. In the first session each participant will wear the device for a full day while performing normal working activities. Usability will be assessed with the System Usability Scale (SUS) and the Users* Impression Questionnaire (see Addendum 1) that will be filled in by the subjects after the working day.
User satisfaction will be assessed in the second session using the PGIC questionnaire (Patients* Global Impression Of Change) and semi-structured interviews based on the ICF (International Classification of Functioning) framework. Satisfaction of rehabilitation professionals will be assessed using the CGIC questionnaire (Clinicians* Global Impression of Change).

Intervention

see study design

Study burden and risks

Since the SPEXOR exoskeleton will either passively assist or monitor movement and give feedback in case of unfavourable loading or motion, both systems only intend to reduce loading on the spine and therefore will not result in overloading of the spine. In addition all tasks are within the accepted NIOSH safety limits. When testing, all tasks will be adapted so that individual limits are not exceeded with or without the device. During measurements, participants will be instructed that they can, at any time, ask for further load or motion reductions, or skip parts of the tasks. Hence, the risk associated with participation is negligible to low. Testing will take only one day. Both, healthy worker and worker with recurrent low back pain may benefit

from the results of this study in the way that an effective assistive device can be used to prevent healthy worker from low back pain and to reintegrate people with recurrnet low back pain in their vocational setting.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy Worker
- No previous history of LBP in the last 12 months
- Owestry Disability Index <20 indicating minimal disability
- Working in an occupational field that requires manual material handling ;Patients
- Lumbar or lumbosacral pain without proximal radicular pain (limited distally to the knees)
- Presence of recurrent low back pain
- Owestry Disability Index >20 and <50 to make sure that patients have sufficiently severe

CLBP but are still able to perform hand loading tasks
- Working or have been working in an occupational field that requires manual material handling

Exclusion criteria

Healthy worker
* - Motor deficits and sensorimotor deficits (lower limb immobility, posture, gait, upper limbs)
* - Specific radiographic abnormalities (severe disc space narrowing, spondylolysis, spondylolisthesis, scoliosis, etc.).
* - Previous back surgery
* - Thoracic or cervical pain
* - Pain in the hip region
* - Neurological disorders
* - LBP in the last 2 years that did require them to seek medical attention or to change their activities;Workers with recurrent low back pain
* - Motor deficits and sensorimotor deficits (lower limb immobility, posture, gait, upper limbs)
* - Specific radiographic abnormalities (severe disc space narrowing, spondylolysis, spondylolisthesis, scoliosis, etc.).
* - Previous back surgery
* - Thoracic or cervical pain
* - Pain in the hip region
* - Neurological disorders

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2016
Enrollment:	40

Type:	Actual

Medical products/devices used

Generic name:	SPEXOR
Registration:	No

Ethics review

Approved WMO Date:	14-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL57404.029.16