Technology for physiotherapist to identify subgroups in patients with non-specific low back pain.

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Using technology for improving diagnostics of non-specific lower back pain by physiotherapists.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45616

Source
ToetsingOnline

Brief title
Technology for patients with non-specific low back pain.

Condition

- Muscle disorders

Synonym
back complaints, low backpain

Research involving
Human

Sponsors and support

Primary sponsor: Saxion, University of Applied Sciences
Source(s) of monetary or material Support: NWO

Intervention

Keyword: - low back pain, - lumbar artrophy, - multifidus, - technology

Outcome measures

Primary outcome

The primary study parameter are the amount of EMG, with parameters relative rEMG, amplitude (mV), frequency amount(Fmed) in Hz. Range of motion of the trunk by using 3D kinematics and cross-sections and fatty degeneration of the multifidus by using ultrasound.

Secondary outcome

Questionnaires and personal characteristics.

Study description

Background summary

Non-specific lower back pain is a pain syndrome, however the exactly cause is not known. Probably there are several factors that contribute to this pain syndrom. The last several years, people are interest to divide non-specific lower back pain patients in different subgroups. Because these different subgroups need probably different specific treatments. In physiotherapy treatment the most attention focused on disbalans between back and belly muscles. This project will focus on validation of technology to improve the diagnosis of non-specific lower back pain by physiotherapists. Ultrasound, surface electromyography and 3D accelerometry will be validated to improve distinguishing of subgroups of non-specific lower back pain patients by physiotherapists.

Study objective

Using technology for improving diagnostics of non-specific lower back pain by physiotherapists.

Study design

cross sectional study design

Study burden and risks

The burden of the subjects is very limited. Subjects will be measured once at one of the participating physiotherapy centers. Time expense will be maximally 1.5 hour. All the technology measurements are used as care as usual at physiotherapist centers, and there will not be measured invasive. There will be no risks associated with participation.
The advanced of participating in this study for the subjects is, they will contribute to create more knowledge about to diagnostic non-specific lower back pain patients in the physiotherapy. The subjects will get traveling expenses and a cheque of 15 euros for participation in this study.

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

Patients
* Between 18 and 65 years old
* Acute (<6 weeks), subacute (6-12 weeks), chronic non-specific lower back pain (> 12 weeks)
* Score > 30% points at the Oswestry Disability Index (ODI)
* Signed the informed consent form;Healthy subjects
* Between 18 and 65 years old
* Signed the informed consent form

Exclusion criteria

Patients
* Presence of red flags* and lumbarsacral radicular syndrom
* Previous backsurgery
* Pregnancy or < 6 months after childbirth
* Actual psychiatric diagnosis
* Insufficient knowledge of the Dutch language
* Body mass index > 30;Healthy subjects
* non-specific lower back pain
* Presence of red flags* and lumbarsacral radicular syndrom
* Pregnancy or < 6 months after childbirth
* Previous backsurgery
* Actual psychiatric diagnosis
* Insufficient knowledge of the Dutch language
* Body mass index > 30;*Red flags are:
Cancer
Unexplained weight loss
Immunosuppression
Prolonged use of steroids
Intravenous drug use
Urinary tract infection
Pain that is increased or unrelieved by rest
Fever
Significant trauma related to age (e.g., fall from a height or motor vehicle accident in a young patient, minor fall or heavy lifting in a potentially osteoporotic or older patient or a person with possible osteoporosis)
Bladder or bowel incontinence
Urinary retention (with overflow incontinence)
Physical examination
Saddle anesthesia
Loss of anal sphincter tone
Major motor weakness in lower extremities

Fever
Vertebral tenderness
Limited spinal range of motion
Neurologic findings persisting beyond one month

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2017
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL60064.044.16
Other	NTR-nummer nog niet beschikbaar