Central Sensitisation and Functioning in patients with Chronic Low Back Pain

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

Summary

ID

NL-OMON45648

Source
ToetsingOnline

Brief title
Sensitisation and Functioning in patients with CLBP

Condition

- Muscle disorders

Synonym
multifactorial back pain, Nonspecific back pain

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiegeneeskunde
Source(s) of monetary or material Support: Ontwikkelgelden pijnrevalidatie

Intervention

Keyword: Central Sensitisation, Chronic Low Back Pain, Functioning, Fysical Functioning

Outcome measures

Primary outcome

Main study parameters each study will be the measures of sensitisation and

functioning:

* Sensitisation: QST, HRV, CSI

* Functioning: Lifting capacity, aerobic capacity, accelerometry, RAND PF, PDI,

WAI.

Secondary outcome

N/a.

Study description

Background summary

Functioning is often limited in patients with chronic low back pain (CLBP), which has a negative effect on participation. Limited functioning is one of the main reasons to refer patients for pain rehabilitation. Until now, there is limited evidence to explain the limited functioning, despite of hundreds of studies that have investigated biological, psychological en social variables. One of the few variables that is consistently related to functioning, although to a moderate extend, is pain intensity . In the past decennia there is growing evidence for sensitisation in (a relevant subsample of) patients with chronic pain. Theoretically, sensitisation can be plausible linked to pain intensity and to functioning. Some evidence is found for the relation between sensitisation and intensity of pain, but not with functioning.
Sensitisation and functioning can be operationalized and measured in different ways:
Sensitisation can be measured with a standardized protocol called Quantitative Sensory Testing* (QST) . This examination must be performed by a trained professional and takes 30-60 minutes. Another way to measure sensitisation is by means of a questionnaire called *Central Sensitisation Inventory * (CSI; 25 questions, 5 minutes), and the measurement of *heart rate variability* (HRV; 5

minutes). The relationship between these measures is unknown yet. Functioning can be measured by means of capacity testing (aerobic capacity, lifting capacity), performance testing (accelerometry), or a questionnaire (RAND Physical Functioning [PF], Pain Disability Index [PDI], Work Ability Index [WAI]). The relationship between sensitisation and functioning is unknown. It is also unknown if a decrease in sensitisation is related to improved functioning.

Study objective

The overarching aim of this project is to study the relation between sensitisation and functioning in patients with CLBP.

The project consists of 3 studies, each with a different main objective.
1. To analyse the association between instruments measuring sensitisation in patients with CLBP.
2. To analyse the association between sensitisation and functioning in patients with CLBP.
3. To analyse whether a decrease in sensitisation is related to improved functioning in patients with CLBP.

Study design

Study 1 and 2: Cross sectional. Measurements during admission phase of rehabilitation.
Study 3: prospective. Measurements during discharge phase of rehabilitation.

Study burden and risks

Burden and risk:
Patients will scheduled for a separate 1 hour appointment to complete all additional assessments (at baseline and at discharge; additional to care as usual). If possible, this will be adjacent to a care as usual appointment.

Exrta tests * burden and risks:
* QST: 30 minutes. No risks.
* HRV: 5-10 minutes. No risks.
* Accelerometry: 1 week continuous wearing of an accelerometer to measure daily movements. A small device will be worn on the trouser belt. No risks.

Benefit:
Patients will be informed about the results of the assessments. No direct benefits on their health status.
Patients will receive compensation for extra travel costs (¤0.19/km) and a gift check of ¤10 when both assessments are completed.

Contacts

Public
Selecteer

Dilgtweg 5
Haren 9750 RA
NL
Scientific
Selecteer

Dilgtweg 5
Haren 9750 RA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult (18-65 years old) patients with chronic (>3 months) low back pain admitted to pain rehabilitation at UMCG Centre for Rehabilitation (CvR).
All subjects will have signed an informed consent form before they are included in this study.

Exclusion criteria

Radicular radiation to the leg

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):	22-09-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-08-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL60247.042.16