Central Sensitization and Physical Functioning in patients with Chronic Low Back Pain

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24502

Source
Nationaal Trial Register

Health condition

Musculoskeletal disorders
Chronic low back pain
Central sensitization
Physical functioning

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Central Sensitization measurements:

- Bedside Examination (BSE): DFNS protocol.

- Quantitative Sensory Test (QST): NASQ protocol.

- Heart-Rate Variability (HRV): 5 min Heartmath protocol.

- Central Sensitization Inventory (CSI): questionnaire in Dutch.

Physical Functioning measurements:

- Lift test: FCE WorkWell protocol.

- Cardiopulmonary Exercise Test (CPET): .

- Accelerometer: 7 days.

Questionnaires:

- Work Ability (WAS).

- Pain Disaability (PDI).

- Physical Functioning (Rand36-PF).

Secondary outcome

Pain characteristics: Intensity - VAS; Response to exercise - PRQ.

Patients Characteristics: Age, Sex, BMI (Height, Weight), Nationality, Educational level, Employment Status, Pain location, Psychological traits (Catastrophizing - PCS, Injustice - IEQ, and Symptoms - BSI).

Test characteristics: patient and assessor perceived exertion during capacity tests - Borg CR-10 and RPE.

Study description

Background summary

Physical functioning is individuals' capacity to perform everyday tasks which are essential for an independent living and/or quality of life. A limited functioning, often manifested in patients with CLBP, has a negative effect on participation. Limited functioning and participation 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 and 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 sensitization in (a relevant subsample of) patients with chronic pain. Central Sensitization is produced by nociceptor inputs that trigger a prolonged, but reversible, increase in the excitability and synaptic efficacy of neurons in central nociceptive pathways ("pain pathways"). This increase in neural signalling may lower the threshold to activate noxious stimulus and, as a result, previously innocuous inputs are now sufficient to be felt as damaging. Thus, Central Sensitization is manifested as pain hypersensitivity, particularly dynamic tactile allodynia, secondary punctate or pressure hyperalgesia, aftersensations, and enhanced temporal summation. Theoretically, sensitization can be plausible linked to pain intensity and to physical functioning. Some evidence is found for the relation between sensitization and intensity of pain, but:

- The relationship between the measures for Central Sensitization is unknown.

- The relationship between the Central Sensitization and Physical Functioning measures is unknown.

- Whether a decrease in Central Sensitization levels is related to improved Physical Functioning is unknown.

Study objective

Theoretically, central sensitization can be plausible linked to pain intensity and to physical functioning. Some evidence is found for the relation between sensitisation and intensity of pain, but not with physical functioning.

Study design

T0=Intake measurements

T1=Discharge measurement

Intervention

The study is designed as close as possible to 'care as usual' for the patients.

Patients follow regular procedures according to Pain Rehabilitation team of the Center for Rehabilitation of the UMCG.

For the purposes of the study, additionally they perform sensitization and physical functioning tests during intake and discharge assessments, and fill out questionnaires during treatment.

Contacts

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Eligibility criteria

Inclusion criteria

- Mentally competent adults between 18 and 65 years of age.

- Referred to Pain rehabilitation with chronic low back pain (without radiation below the knee) as primary diagnosis.

- Admitted to Pain rehabilitation according to the Pain rehabilitation guidelines.

- Voluntarily signed written informed consent.

Exclusion criteria

- Unwillingness to participate in the study.

- No or not sufficient understanding of Dutch language, and/or incapacity to follow instructions.

- Manifest neuralgia; Pregnancy; Psychiatric disorders or other relevant co-morbidities.

- Specific contraindications of the tests according to the center for rehabilitation guidelines.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2017
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-04-2018
Application type:	First submission

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
NTR-new	NL6980
NTR-old	NTR7167
Other	UMCG Ethical Committee : METc 2016/702

Study results