Investigating the Central Sensitisation Inventory (CSI). Re-establishing clinically significant values to identify central sensitization.

No registrations found.

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

Summary

ID

NL-OMON27116

Source
Nationaal Trial Register

Brief title
Investigating CSI

Health condition

chronic pain, central sensitization, pain rehabilitation, pelvic pain, back pain.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Central Sensitization Inventory

Secondary outcome

None

Study description

Background summary

Central sensitization (CS) is a state of hyper responsiveness of the central nervous system. According to Woolf, CS is “operationally defined as an amplification of neural signaling within the central nervous system that elicits pain hypersensitivity.” In clinical practice, CS manifests as pain hypersensitivity, particularly dynamic tactile allodynia, secondary punctate or pressure hyperalgesia, longer aftersensations, and enhanced temporal summation. CS seems to be (part of) the explanation for pain in several clinically well-known chronic disorders such as fibromyalgia, chronic pelvic pain, chronic low back pain, osteoarthritis, temporomandibular disorders, chronic whiplash, and chronic patellar tendinopathy.
The Central Sensitisation Inventory (CSI) has been used to identify patients with signs possibly related to central sensitisation. In Dutch the CSI is validated for a group of chronic pain patients (n=368). But no analysis has been done on age, sex and type of pain in relation with the CSI. Therefor we want to analyse these factors in relation with the CSI in a larger group of chronic pain patients (at least n = 1500). The original CSI has an established cut-off value of 40 out of 100. This cut-off value is based on 121 patients with chronic pain and 129 non-patient sample (undergraduate students not currently in treatment for chronic pain). We want to re-establish a cut-off value for the CSI based on a larger group of chronic pain patients (at least n=1500) and healthy, pain-free volunteers. The healthy, pain-free volunteers will not have pain, pain medication, pain treatment, antidepressants, anti-epileptics and no CSS reported in the CSI part B.

The primary aim of this study is to re-establish the cut-off value for the CSI score based on the presence of CSS. Our secondary aim is to identify sex, age, weight, height, BMI, number of reported CS syndromes, quality of life, pain catastrophizing, pain disability, pain severity, pain location, and pain disorders as possible predictors for the CSI score. Our third aim is to establish possible alternative cut-off values dependent on sex or one or more of the other factors found in our secondary analysis as predictors.

Study objective

The hypothesis is that there might be a different cut-off value when using a larger sample.

Sex, age, weight, height, BMI, number of reported CS syndromes, quality of life, pain catastrophizing, pain disability, pain severity, pain location, and pain disorders can predict the CSI score.

Study design

For patients:
Intake
Follow-up (if available in medical record, at time points 3, 6 and 12 months)

For healthy volunteers:
One moment of collecting questionnaires

Intervention

Care as Usual for patients, not applicable for healty volunteers

Contacts

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Eligibility criteria

Inclusion criteria

Patients:
- Patients who visited the UMCG pain center between November 1, 2017 and October 1, 2021

Healthy volunteers
- Self-reported healthy and pain-free

Exclusion criteria

Age younger than 18 years

Healthy volunteers:
- using pain medication

- undergoing treatment for pain
- reporting a CSS diagnosis in the CSI part B
- reporting the use of antidepressants at moment of completing questionnaire
- reporting the use of anti-epileptics at the moment of completing questionnaire

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2017
Enrollment:	1650
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-01-2021
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	NL9241
Other	METc Univeristy Medical Center Groningen : METc 2020/284 and METc 2021/361, non-WMO confirmation

Study results

Summary results
N/A