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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27116

Bron
NTR

Verkorte titel
Investigating CSI

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Central Sensitization Inventory

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Care as Usual for patients, not applicable for healty volunteers

Contactpersonen

Publiek

Universitair Medisch Centrum Groningen
I. Schuttert

0651402937

Wetenschappelijk

Universitair Medisch Centrum Groningen
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Healthy volunteers
- Self-reported healthy and pain-free

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2017
Aantal proefpersonen:	1650
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-01-2021

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9241
Ander register	METc Univeristy Medical Center Groningen : METc 2020/284 and METc 2021/361, non-WMO confirmation

Resultaten

Samenvatting resultaten
N/A