Active Vibration Induced Treatment by Abdominal Excitation

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1. HALF-MIS is a safe and well tolerated intervention. 2. HALF-MIS decreases pain significantly compared to a placebo treatment in elderly patients suffering from chronic musculoskeletal pain. 3. Central sensitization mediates the effect of HALF-MIS...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25538

Bron
NTR

Verkorte titel
ActiVitae

Aandoening

chronic musculoskeletal pain disorders

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: ZONMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Numeric pain Ratomg Scale, Quality of Life (EuroQol - 5D 3L)

Toelichting onderzoek

Achtergrond van het onderzoek

HALF-MIS (High Amplitude Low Frequency Music Impulse Stimulation)', is an innovative treatment modality aimed at stimulation of the Pacinian bodies with the use of infrasound to stimulate vagal activity. Previously, substantial effects were demonstrated on reduction of depression. It is, however, expected to be effective when used in pain management.

Doel van het onderzoek

1. HALF-MIS is a safe and well tolerated intervention. 2. HALF-MIS decreases pain significantly compared to a placebo treatment in elderly patients suffering from chronic musculoskeletal pain. 3. Central sensitization mediates the effect of HALF-MIS.

Onderzoeksopzet

Visit 1. screening
Visit 2. HALFMIS, NRS, EQ 5D-L3, PDI,QST,CSI,HADS,
Visit 3-8. HALFMIS, NRS
Visit 9. HALFMIS, NRS, EQ 5D-L3, PDI,QST,CSI,HADS
Visit 10. 6 weeks after visit 9. NRS, EQ 5D-L3, PDI,QST,CSI,HADS, UTAUT, ARTS

Visit 2-9 in 3 weekly treatments over course of 3 weeks, 8 treatments in total

Onderzoeksproduct en/of interventie

Each patient will have a schedule consisting of 3 weekly treatments over the course of 3 weeks. Each session will last 20 minutes and 27 seconds according to the length of the music. In all of the eight visits, patients in the treatment group will undergo the HALF-MIS treatment. For this treatment the patient have to sit in a chair and get a belt around the waist with a built-in vibro-tactile unit which delivers vibro-stimulation. For the music patients get a headphone. An iOS app is used to administer the stimuli, synchronize the audio and log the patients' treatments. Patients in the placebo group will follow the same procedure, but without the vibro-stimulation.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. The symptoms of pain have been present for 3 months or more
2. The symptoms of pain are present every day with a minimum level of NRS=4 (Moderate and severe pain)
3. The symptoms of pain are resulting from a condition diagnosed as a musculoskeletal disease listed in the ICD-10 of the WHO M00-M99.9 (But NOT M50.0, M50.1, M51.0 and M51.1 that are Prolapsus Disci Intervertebralis with myelopathy/radiculopathies – as the pain syndrome in these cases are expected to be predominantly neurogenic)
4. Adequate communication and understanding of the language
5. Age ≥ 65 years
6. Available during the intervention.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. The medical examination showing signs of significant active, untreated comorbidities. Excluded are patients with Delirium and/or psychotic symptoms or moderate or severe depression. The distinction between light depression and moderate and severe depression is done according to the ICD-10: Light depression is F32.0 – moderate and severe depression are F32.1 and F32.2.
2. Patients with decreased signs of autonomic responses, metal implants such as ICD, organ transplantations and surgery on central nervous system in history.
3. The medical examination showing signs of the pain syndrome being exclusively or predominantly neurogenic with the condition diagnosed as a neurological disease listed in the WHO G00-G99.8.
4. The belt doesn’t fit properly.
5. Pain related to malignancies.
6. Enrolled in any other clinical study within the duration of the current study.
7. Enrolled in other music therapy.

8. Incapable of giving consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-04-2019
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49209
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7606
CCMO	NL69608.042.19
OMON	NL-OMON49209

Resultaten