Active Vibration Induced Treatment by Abdominal Excitation

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25538

Source
NTR

Brief title
ActiVitae

Health condition

chronic musculoskeletal pain disorders

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Pain disability index (PDI), Quantitative Sensory Testing (QST), Central sensitization index

(CSI), Depression and Anxiety (HADS), Safety (UTAUT) and treatment satisfaction (ARTS)

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2019
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-03-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49209
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results