Touch; reducing pain in Parkinson patients study 1

Published: 30-04-2020
Last updated: 17-01-2025

To determine whether CT optimal touch reduces pain experience in PD patients.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49609

Source
ToetsingOnline

Brief title
Touch; reducing pain in Parkinson patients study 1

Condition

- Other condition
- Structural brain disorders

Synonym
Chronic pain in Parkinson patients

Health condition

Chronische pijn bij Parkinson

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: het Parkinsonfonds

Intervention

Keyword: Affective touch, Pain, Parkinson

Outcome measures

Primary outcome

The most important parameters are the changes in pain perception between the two types of stimulation measured with the questionnaires. We will do this by comparing the scores on the Faces Pain Scale and CAS Pain Scale for the non-stimulation condition, AT condition and the non-AT condition.

Secondary outcome

Secondary outcomes are the pleasantness of the two types of stimulation measured with the questionnaires. Previous studies show that AT is rated significantly more pleasant than non-AT. Therefore to replicate this effect, we will measure pleasantness as well. This will be done by comparing the scores on the PANAS and VAS pleasantness for the AT condition and the non-AT condition.

In addition, we will look for differences over time for the different timepoints (morning, afternoon and evening) and assess the stimulation duration (0,5,10,15 minutes), to see how long stimulation is necessary and what the preferences of the participants are. We will do this by comparing the scores on the pain and pleasantness questionnaires (Faces Pain Scale, CAS Pain Scale and VAS pleasantness) for the different timepoints in the AT and non-AT condition.

Study description

Background summary

Pain is a common problem in Parkinson's disease (PD), with 30-95% of the patients experiencing pain. Due to changes in central pain processing PD complicates the pain management process. Pain studies reveal that patients with PD experience the sensory-discriminative aspects (pain threshold) as well as the affective/motivational aspects of pain (pain tolerance) more severely than people without PD. This is caused by overactivation of regions involved in pain processing. Currently, 50% of patients with PD do not receive any pain treatment, while patients who are treated with medication do not always report a sufficient decrease in discomfort. Therefore, the development of a more adequate treatment is important.

Recent research suggests that there may be a non-pharmacological alternative to alleviate pain. A particular type of low threshold mechanosensory C-fibers (C-tactile or CT afferents), appears to have a modulatory role on pain. The CT afferent responds to gentle types of touch and provides a pleasant perception, hence this type of touch is also called *affective touch*. CT afferents can be activated by slow stroking, between 1-10 cm/s (optimal activation at 3 cm/s), with a soft brush or with the hand. Interestingly, a recent study revealed that PD patients, similar to healthy participants, report higher pleasantness ratings for CT-optimal stroking velocities compared to higher or lower stroking velocities. We therefore hypothesize that CT optimal touch is perceived and processed in the same way in PD patients as in healthy controls.

The mechanisms underlying the positive effects of affective touch on pain might be as follows. The CT afferent system activates several brain areas associated with the motivational and subjective evaluation of touch. These areas are also highly activated and important in the subjective appreciation of pain (pain tolerance). Recent studies confirm that activation of the CT afferents results in pain relief in healthy controls. There are two ways through which the CT afferents can modulate pain processing. First, pain modulation occurs in the dorsal horn (spinal cord) through an inhibitory connection that is related to CT afferent input. This system prevents the pain stimulus of reaching the (sub)cortical brain regions involved in pain processing. Second, a fMRI study shows that the CT afferent system can modulate pain also at supraspinal levels. When the CT afferent system is activated, it causes deactivation of regions which play a major role in pain processing, inhibiting these regions modulates the motivational aspects of pain. As indicated, in PD the pain tolerance is decreased which is mostly caused by over-activation of the medial pain system. We therefore hypothesize that CT optimal touch (affective touch) will also reduce pain experience in PD patients.

Taken together the purpose of this project is to determine whether CT optimal touch reduces pain experience in PD patients.

Study objective

To determine whether CT optimal touch reduces pain experience in PD patients.

Study design

Current research will include two studies to answer our research question. The first study will be addressed within this document. For the second study another METC application will be submitted.

In this first study we will examine whether CT optimal touch, also called affective touch (AT), as an intervention may reduce pain in PD. AT can be activated by slow stroking, between 1-10 cm/s (optimal activation at 3 cm/s), on the hairy part of the skin, with a soft brush or with the hand. During the intervention study the partner or caregiver of the participant will apply the two types of touch by using the hand.
Prior to the intervention, participants will be seen by the experimenter. During this appointment the experimenter will provide information and will assess possible short term effects of AT and the participant will fill in three questionnaires. To measure the severity and intensity of the experienced chronic pain the participant will fill in; a 11-point Likert pain scale for itch intensity and the severity and frequency of pain will be measured by the Kings Parkinson*s Disease Pain Scale (KPDPS). The KPDPS will be filled in together with the experimenter. In addition, the quality of the relationship in terms of perceived support of the participant and caregiver will be assessed through the Quality of Relationships Inventory (QRI) short form. The QRI will be used because the caregiver will apply the touch during the intervention, the quality of the relationship could influence the way they apply touch or how the participants perceives touch.. These questionnaires will be used as a baseline measurement prior to the intervention. As mentioned, during the appointment the experimenter will also assess the short-term effects of AT. At first to assess possible changes in pain experience the modified Colour Analogue Scale (CAS) for pain (affective component) and the Faces Pain Scale will be administered. Hereafter, AT will be administered for 5 minutes by the experimenter, this will be done by stroking the forearm of the participant with a soft brush on a slow speed of around 3 cm/s. This is followed by a second administration of the pain ratings. In addition, to look for any after-effects pain ratings will also be administered after 10 minutes. This will also been done for non-affective touch (non-AT). Non-AT will also be administered by stroking the forearm of the participant at a faster but still quit natural speed of around 18 cm/s, this could be compared to rubbing. The order will be randomized between patients.

Proof of concept intervention study
To assess whether application of AT in a home setting, as would be used in the potential treatment (second study), reduces pain, first pain experience will be measured three times a day (morning, afternoon and evening) for one

week to control for normally present pain fluctuation. One week later, half of the participants (selected randomly) will receive AT stimulation daily for one week followed by one week of non-AT stimulation. The other half of the participants will first receive one week of non-AT stimulation, which is followed by one week of AT stimulation. Stimulation will take place twice a day (morning and evening) for 15 minutes, and is administered by the caregiver of the patient. AT will be administered by stroking the forearm (possible effects of AT on pain are independent of pain location) of the participant at a slow but natural speed of around 3 cm/s. Non-AT will also be administered by stroking the forearm of the participant at a faster but still quit natural speed of around 18 cm/s. Both types of stroking are easy to apply and do not involve trained therapists. Caregivers will receive instructions, so they can apply (non)AT during the study. Recent studies also show that CT optimal touch is quite natural to provide by close relatives.
Pain ratings will be administered before, during (every 5 minutes) and after the stimulation.
In addition, to look for any after stimulation effects during the day pain ratings will also be administered in the afternoon. Participants will also keep a diary during this 3-week intervention study in which the frequency of tactile stimulation and the experienced pain is recorded.
In addition to the effect of AT on pain, the relationship between pleasantness ratings and stroking velocities will be further explored, to confirm that increased pleasantness ratings are also found in this population for AT. Pleasantness ratings will be measured during the intervention by a visual analogue scale (VAS) for pleasantness. In addition, on the first and last day of the stimulation the Positive Affect and Negative Affect Scale (PANAS) will be administered.

Intervention

Within this study we make use of a within-subject design. So patients will receive affective touch and non-affective touch (placebo).

Study burden and risks

The burden consist of undergoing one week pain measurements, one week of affective touch stimulation and one week non-affective touch stimulation. The time investment is based on stimulating twice a day for 15 min., the total duration of the study is three weeks. All research procedures are well-validated and with careful screening of subjects for exclusion criteria, participating in this research has a very minimal to no risk. Participants are adults with Parkinson's disease, mentally able to participate and to inform consent.

Contacts

Public
Universiteit Utrecht

Heidelberglaan 1
Utrecht 3584 CS
NL
Scientific
Universiteit Utrecht

Heidelberglaan 1
Utrecht 3584 CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Age >=18
-Diagnosed with PD, confirmed by ParkinsonNEXT and if necessary; i.e. inclusion criteria are unclear or the experimenter still has some questions, the experiment will check with the patient*s general practitioner.
-Pain associated with PD (musculoskeletal, dystonic, akathisia) and pain worsened by PD (i.e. (osteo)arthritis or other age related pain conditions)
-Pain must be present for at least 3 months, with clear impact on physical/psychological functioning, which must be assessed as at least moderate in intensity (>=4 points on an 11-point Likert pain scale).
-Written informed consent (to assess whether participants are able to give informed consent the MoCa will be used prior to intervention).

Exclusion criteria

-Incapability of giving informed consent
-Incapability of interpreting questionnaires
The following criteria will be checked for and confirmed by ParkinsonNEXT and if necessary; i.e. inclusion criteria are unclear or the experimenter still has some questions, the experiment will check with the patient*s general practitioner:
-Suffering from conditions that affect the ability to feel or process touch
-Pain conditions that can also influence the perception and processing of touch; i.e. Neuropathic pain;
-A history of cerebral traumata or psychiatric disorders unrelated to PD (e.g., schizophrenic episodes)
-Currently suffering from a mood disorder (e.g. depression or anxiety disorder)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-09-2020
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO

Date:	30-04-2020
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL71563.041.20

Study results

Date completed: 19-12-2022

Results posted: 02-08-2024

First publication
01-08-2024