Pavlovian and other learning mechanisms: what works best to facilitate placebo analgesia?

Gepubliceerd: 02-12-2019 Laatst bijgewerkt: 18-08-2022

The combination of all three different learning techniques will elicit a stronger placebo analgesic effect than individual application for experimentally-induced thermal pain.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25261

Bron
NTR

Verkorte titel
COMBI

Aandoening

Placebo analgesia

Ondersteuning

Primaire sponsor: Leiden University
Overige ondersteuning: Dutch Arthritis Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Placebo analgesia:

The measurement for placebo analgesia will be the mean difference scores for pain intensity measured between the placebo and control trials for the initial three trial pairs (control - placebo) in the testing phase. The pain scores will be measured on an 11-point Numeric Rating Scale ranging from 0 to 10. The difference scores will be analyzed between groups as planned comparisons.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:
Placebo analgesia can be established by means of different learning techniques, with most evidence existing for classical (Pavlovian) conditioning, observational learning, and verbal suggestions. However, not all studies show consistent results, often multiple techniques are used simultaneously (e.g., conditioning combined with verbal suggestions), which makes it impossible to determine each specific effects, and no studies have directly compared the effects of all three techniques separately and in combination. In addition, individual characteristics (e.g., personality traits, genetics) might play a role in determining the degree of placebo analgesia and the mechanisms through which these learning techniques have their effects. Although many studies have examined specific predictor or mediator variables, because of the same reasons as mentioned for the learning techniques, the current evidence is inconsistent. Within the current study, we aim to examine each learning mechanism both in itself and in combination with the others to shed more light on how to best induce placebo analgesia. Next to this, we will study the role of individual characteristics in placebo analgesia.

Design
In this 8-arm between-subjects randomized controlled trial, healthy participants will learn through different (combinations of) learning techniques that a sham medical device, when turned on, relieves them from experimentally-induced thermal pain (placebo analgesia); a natural history group is also included that will receive sham learning techniques and a similar amount of thermal pain stimuli to ensure comparability. The 8 arms are: 1. Natural history, 2. Verbal suggestions, 3. Observational learning, 4. Conditioning, 5. Verbal suggestions & Observational learning, 6. Verbal suggestions & Conditioning, 7. Observational learning & Conditioning, 8. Verbal suggestions & Observational learning & Conditioning. Questionnaires and saliva swabs will be administered to assess individual characteristics that might impact placebo analgesia.

Doel van het onderzoek

The combination of all three different learning techniques will elicit a stronger placebo analgesic effect than individual application for experimentally-induced thermal pain.

Onderzoeksopzet

Participants will visit the laboratory once with a total duration of 165 minutes. Initially, participants are asked to fill in questionnaires to assess individual characteristics. Afterwards, a calibration phase is started to determine individual pain thresholds, followed by 72 low or moderate thermal pain stimuli; 36 learning stimuli and 36 test stimuli. Participants in the conditioning groups will receive low thermal pain stimuli when the sham device is turned on during the learning phase and moderate thermal pain stimuli when the sham device in turned off. Participants in the verbal suggestion groups receive a positive suggestion about the sham device. Lastly, participants in the observational learning groups watch a video that depicts a confederate reporting lower pain when the sham device is turned on. The three different learning techniques are also combined, and a natural history group is included, yielding a total of 8 groups. In groups that contain a single learning procedure, we will implement sham learning techniques to level out the amount of time invested in someone.

In the testing phase, all participants receive moderate pain stimuli and the difference between the pain reported in response to the stimuli given when the sham device is turned on (placebo trials) and turned off (control trials) is the total amount of placebo analgesia.

After the testing phase, participants are asked to donate their saliva for DNA analysis.

Onderzoeksproduct en/of interventie

Individual application or any combination of the placebo-related learning techniques verbal suggestion, observational learning and conditioning.

Contactpersonen

Publiek

Leiden University
Hans van Lennep

0615885322

Wetenschappelijk

Leiden University
Hans van Lennep

0615885322

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. healthy participants, aged 18-35 years, female or male, Dutch or English speaking.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Presence of pain at the moment of testing (this includes chronic pain disorders, but also acute pain, meaning a NRS score of 1 or higher).
2. Use of prescription analgesics 24 hours prior to the day of testing (e.g., opioids, 5-HT receptor agonists.)
3. Use of over the counter analgesics within 12 hours before testing.
4. Presence of any severe physical or mental disabilities (e.g. cardiovascular disease, kidney disease, depression, autism).
5. Use of long-term medication for a physical or mental disability that might interfere with pain perception (e.g., anti-epileptics, antidepressants, opioids, cannabinoid oil).
6. Use of >2 alcoholic units within 12 hours before testing.
7. Use of any hard drugs (e.g. amphetamines) within 48 hours prior to testing.
8. Use of any soft drugs (e.g., marijuana) within 12 hours prior to testing.
9. Experience with previous research regarding placebo related learning techniques (verbal suggestion, conditioning, and social learning)
10. Pregnancy or currently breastfeeding
11. Injuries on the hands, wrists, or arms that will be used for testing and are at the location of the thermode or TENS electrode, at the time of participation.
12. Presence of a pace-maker or implantable cardioverter- defibrillator (ICD)
13. Minimal difference in pain score ranges (low-mid) after calibration of the heat pain, which makes application of different pain stimuli impossible.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-12-2019
Aantal proefpersonen:	320
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Coded research data will be made publically available in an online data repository after publication of the research findings.

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8207
Ander register	Psychology Research Ethics Committee of Leiden University : CEP19-0912/461

Resultaten

Samenvatting resultaten
N/A