Do open label placebos induce placebo analgesia in a pain conditioning paradigm?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23347

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Pain

Sponsors and support

Primary sponsor: Leiden university
Source(s) of monetary or material Support: Leiden University

Intervention

Outcome measures

Primary outcome

Placebo effects (VAS scores between first yellow and first purple cues) compared between the open label placebo group and the control group. Mean VAS scores of all three yellow versus purple cues will also be compared.

Secondary outcome

Placebo effects (VAS scores between first yellow and first purple cues) compared between the open label placebo group and the deceptive placebo group. Mean VAS scores of all three yellow versus purple cues will also be compared.
For exploratory purposes we will also investigate the role of demographics, anxiety and optimism as predictors for the magnitude of placebo effects with linear regression analyses.

Study description

Background summary

Converging evidence has demonstrated that placebo effects can have a positive influence on pain experience and can be induced by expectations and conditioning. To facilitate applicability of placebo effects in clinical practice, several experimental and clinical studies have demonstrated that it is possible to induce placebo effects even when patients are informed about this (open label placebos), thereby overcoming ethical constraints and facilitate shared decision making. In the current study, a Transcutaneous Electrical Nerve Stimulation (TENS) will be used as a placebo device. Placebo effects will be induced by combining verbal suggestions (about the activation of the TENS device) and conditioning (colored cues paired with low (yellow) and moderate (purple) pain intensities). The main aim of this study is to gain more insight in open label placebo effects. The primary objective is to assess whether open label placebos induce significant placebo effects compared to a control group (no treatment) and the secondary objective assesses whether open label placebo analgesic effects differ from deceptive placebo effects.

Study objective

The primary aim of the current study is to assess analgesic effects of open label placebos compared to a control group (no treatment). We hypothesize that pain scores rated on a visual analogue scale (VAS) will be significantly lower in the open label placebo group compared to the control group, thereby demonstrating the placebo analgesic effect of open label placebos.
The secondary aim of this study is to compare placebo analgesic effects of the open label placebo group and deceptive placebo group. We hypothesize that there will be no significant difference between VAS pain scores from the open label placebo group and deceptive placebo group.

For exploratory purposes we will also investigate the role of demographics, anxiety and optimism as predictors for the magnitude of placebo effects in a linear regression analysis, as these factors have been associated with placebo effects in previous research findings.

Study design

The study consists of an online screening questionnaire, a calibration phase, a conditioning phase, a testing phase and self-report questionnaires on one test day.

Intervention

Healthy participants will undergo a thermal heat pain procedures in which a series of short heat stimuli are administered. During the calibration phase, individual pain thresholds are assessed for low, moderate and high pain. In the conditioning phase, a sham TENS device of which it is suggested that it affects nerve conductivity will be used as a placebo device and colored cues will be paired with low (yellow) and moderate (purple) pain intensities, combined with verbal suggestions about the activation of the TENS device. Participants in the control group undergo a sham conditioning procedure in which only half of the cues correctly correspond to pain intensities to negate conditioning effects but control for the visual input in the other groups. During the testing phase, all participants receive a moderate intensity of heat stimuli and placebo effects are evoked by presenting the color cues and “TENS ON” or “TENS OFF”.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy male and female volunteers from age 16 – 35 years. Participants have a good understanding in speaking and understanding English.

Exclusion criteria

Refusal to give written informed consent, severe morbidity (e.g. multiple sclerosis, heart and

lung disease), suffering or have suffered from pain lasting for ≥ 6 months, serious neurological or psychiatric conditions, regular use of recreational drugs, current use of analgesic medication, substance abuse, injuries on arms or hands, colour-blindness, pregnancy or lactation and previous participation in similar previous heat pain experiments (‘Aan de slag met pijn’ and ‘Generalization Study’). Exclusion criteria will be stated on the online research platform (SONA) where participants can apply for the experiment and will be assessed by asking the participants before the start of the screening phase whether they experience any of the abovementioned symptoms.
Participants that report high pain thresholds during the screening phase (see: Calibration) will also be excluded from the study. Participants will be asked to withhold from alcohol consumption 24 hours prior to the experiment, and caffeine and nicotine 3 hours prior the experiment. Recreational drug use is not permitted one week before participation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-10-2019
Enrollment:	96
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Coded research data will be made publicly available in an online data repository after publication of the research findings

Ethics review

Positive opinion

Date:	10-12-2019
Application type:	First submission

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
NTR-new	NL8220
Other	Commissie Ethiek Psychologie – Universiteit Leiden : CEP19-1010/497

Study results

Summary results

N/A