Expectancies and pain modulation

No registrations found.

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

Summary

ID

NL-OMON19877

Source
NTR

Brief title
Which factors influence pain modulation?

Health condition

Pain, expectations;

Pijn, verwachtingen

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The primary study outcome is the difference in pressure pain thresholds (which will be determined by averaging 3 pressure pain threshold determinations following validated protocols) in combination with the cold pressor test compared to the determination without the cold pressor test. These difference scores will be compared between the three groups: a analgesia group in which participants receive positive verbal suggestions, a hyperalgesia

group in which participants receive negative verbal suggestions and a control group in which participants receive no verbal suggestions.

Secondary outcome

Secondary analyses will be conducted to examine sex differences in the role of expectations on CPM, the relationship between CPM and cognitive inhibition, and the effects of expectancy manipulation on other outcome parameters (e.g., pain ratings, psychophysiological assessments of heart rate and skin conductance levels and subjective stress). Pain and subjective stress levels will be assessed using 0-10 cm visual analog scales. In addition, the possible influence of psychological parameters on outcomes will be explored.

Study description

Background summary

In the present study, the effects of negative and positive outcome expectations, induced by verbal suggestions, on conditioned pain modulation are studied. In a randomized controlled trial, participants will be allocated to one of three study groups: 1) an analgesia group where positive verbal suggestions are given; 2) a hyperalgesia group where negative verbal suggestions are given; or 3) a control group where no verbal suggestions are given. Participants will take part in one experimental test session. It is expected that the analgesia group will show an increased CPM effect compared to the control group and that the hyperalgesia group will show a decreased CPM effect compared to the control group following the verbal suggestions. Secondary outcomes include sex differences in the effects of expectations on CPM, the association between CPM and cognitive inhibition, and the effects of expectancy manipulation on other outcome parameters (e.g., pain ratings, psychophysiological assessments of heart rate and skin conductance levels and subjective stress).

Study objective

The primary objective of the study is to investigate the role of expectations on conditioned pain modulation (CPM). Based on previous research it is expected that negative outcome expectations, induced by the verbal suggestion that a second painful stimulus will increase pain of the first painful stimulus, will decrease CPM efficacy and that positive outcome expectancies, induced by the verbal suggestion that a second painful stimulus will decrease pain of the first painful stimulus, will increase CPM efficacy compared to a control condition where no expectancies will be given. CPM will be assessed by the difference in pressure pain thresholds when assessed with and without a second painful stimulus, the cold pressor test.

As secondary objectives, sex differences in the role of expectations on CPM are assessed, the relationship between CPM and cognitive inhibition is examined and the effects of expectancy manipulation on other outcome parameters are assessed (e.g., pain ratings,

psychophysiological assessments of heart rate and skin conductance levels and subjective stress). Finally, the role of psychological parameters are explored.

Study design

The study consists of one session lasting approximately 1 hour.

Intervention

Positive outcome expectations will be induced by verbal suggestions. Participants will be told that they will experience either less or more pain or receive no instruction (the nature of the instructions varies depending on group allocation) during a second determination of pressure pain thresholds compared to a baseline assessment of pressure pain thresholds, as a result of the simultaneous immersion of the hand in cold water (cold pressor test).

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy male and female participants

2. Between 18 and 35 years old

3. Good understanding of written and spoken Dutch

Exclusion criteria

1. Refusal to provide written informed consent

2. Severe somatic or psychological morbidity (e.g. cardiovascular diseases, chronic pain or DSM-V psychiatric disorders) that would adversely affect participant’s safety or that might interfere with the study protocol

3. Substance abuse

4. Problems with hearing or vision

5. Recent injury to body parts to be tested (hands, arms)

6. Current pain complaints

7. Recent use of medication

8. Raynaud syndrome

9. Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2017
Enrollment:	114

Type: Anticipated

Ethics review

Positive opinion
Date: 01-11-2017

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	NL6614
NTR-old	NTR6798
Other	Ethics committee FSW : CEP17-1002/319

Study results

Summary results
N/A