The effect of communication on pain

No registrations found.

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

Summary

ID

NL-OMON28669

Source
Nationaal Trial Register

Brief title
NA

Health condition

tonsillectomy, removal of tonsils (in Dutch: tonsillectomie, verwijderen van keelamandelen)

Sponsors and support

Primary sponsor: NIVEL / Recipient SPINOZA award, Prof dr JM Bensing
Source(s) of monetary or material Support: Supported by the Spinoza Prize from the Dutch Research Council (NWO) awarded to Prof dr JM Bensing

Intervention

Outcome measures

Primary outcome

Pain intensity: Patients¡¯ pain will be assessed on the basis of Numeric Rating Scale (NRS).

Secondary outcome

Pain related: e.g. Pain expectations, overal benefit of analgesia, analgesic dosage, analgesic request, general pain

evaluation, general experiences/expectations/attitudes medications, general reporting of pain, perceived expectation.
Psychosocial: e.g. perceived empathy, state anxiety, mood, satisfaction, general evaluations regarding hospitalization,
attitudes towards medication.

Data from medical record: e.g. medical background data.
Adherence to communication manipulation protocol (via taped interactions).

Study description

Background summary

Background of the study:

Placebo effects are true biopsychological effects that arise from the overall clinical context. Placebo effects can be
attributed to several mechanisms, such as expectancy manipulation and empathy provision by means of the
practitioners¡¯ communication. The latter mechanism has received little attention in the literature so far. Moreover, the
distinct effects of both mechanisms are unclear from current clinical studies. In previous experimental studies we have
started to disentangle both mechanisms in highly controlled settings, but there is a need to test and potentially validate
these mechanisms in the clinical setting of doctor-patient communication research.

Objective of the study:

The aim of this study is to determine the separate and combined effects of expectancy manipulation and empathy
manipulation during pre- and post-operative tonsillectomy analgesia care on clinical adult patients¡¯ outcomes (main
outcome measures is pain perception).

More specifically, the goals of this research project are in subsequent order:

1. To examine whether adult patients following tonsillectomy in the enhanced outcome expectancy condition will
experience less pain (and other outcomes), compared to patients in the standard condition.

2. To examine whether adult patients following tonsillectomy in the enhanced empathy communication condition will
experience less pain (and other outcomes) compared to patients in the standard empathy communication condition.

3. To examine the interaction effects of the different levels of outcome expectancy and empathy on adult patients¡¯
experiences of pain and other outcomes.

Study design:

A four-arm (2x2 design) single-blind randomized controlled trial will be conducted at nursing wards. Nurses who
provide pre- and post-operative (analgesic) care to adult patients undergoing tonsillectomy will systematically
manipulate their communication. Patients will be randomly assigned to one of the 4 arms, which vary in the induction of
expectations (standard vs enhanced), and (the level of) nurses¡¯ communication of empathy/affect (standard vs
enhanced).

Study population:

Patients who are scheduled for tonsillectomy in daycare, ¡Ý18 years of age, speaking and understanding of the Dutch
language, having mental capacity.

Intervention (if applicable):

Patients are randomly assigned to 1 of the 4 groups:

1) enhanced empathy + enhanced expectations

2) enhanced exmpathy + standard expectations

3) standard empathy + enhanced expectations

4) standard empathy + standard expectations.

In each group the communication of the nurses will be in line with group assignment.

The standard medical care will be the same for all patients.

Primary study parameters/outcome of the study:

Pain intensity: Patients¡¯ pain will be assessed on the basis of Numeric Rating Scale (NRS).

Secundary study parameters/outcome of the study (if applicable):

Pain related: e.g. Pain expectations, overal benefit of analgesia, analgesic dosage, analgesic request, general pain
evaluation, general experiences/expectations/attitudes medications, general reporting of pain, perceived expectation.
Psychosocial: e.g. perceived empathy, state anxiety, mood, satisfaction, general evaluations regarding hospitalization,
attitudes towards medication.

Data from medical record: e.g. medical background data.
Adherence to communication manipulation protocol (via taped interactions).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

Patients will complete until day 3 extra questionnaires, which will take in total approximately 50 minutes (prehospitalization
(approx 20 min); post-operation (approx 5min), day 2 post-hospitalization (approx 5 min), day 3 study end (approx 20 min). Participants receive usual care with regard to surgery, analgesic therapy and postoperative
treatment. The communication manipulation will be provided on top of the standard care. Although practitioners¡¯
communication is deliberately manipulated, we will ensure the communication manipulation will not be harmful for
patients nor will it affect the psychological integrity of patients.

Study objective

More specifically, the goals of this research project are in subsequent order:

1. To examine whether adult patients following tonsillectomy in the enhanced outcome expectancy condition will
experience less pain (and other outcomes), compared to patients in the standard condition.

2. To examine whether adult patients following tonsillectomy in the enhanced empathy communication condition will
experience less pain (and other outcomes) compared to patients in the standard empathy communication condition.

3. To examine the interaction effects of the different levels of outcome expectancy and

empathy on adult patients¡¯
experiences of pain and other outcomes.

Study design

Data is collected at several timepoints (not all outcomes are collected at all timepoints):

- Pre-hospitalization

- During hospitalization (pre-peri- and post-operation)

- Post-hospitalization: day 2

- Post hospitalization: day 3

Intervention

Patients are randomly assigned to 1 of the 4 groups:

1) enhanced empathy + enhanced expectations

2) enhanced exmpathy + standard expectations

3) standard empathy + enhanced expectations

4) standard empathy + standard expectations.

In each group the communication of the nurses will be in line with group assignment.

The standard medical care will be the same for all patients.

Contacts

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Eligibility criteria

Inclusion criteria

- Scheduled for tonsillectomy in daycare

- ¡Ý18 years of age

- Speaking and understanding of the Dutch language

- Having mental capacity

Exclusion criteria

At study start (during inclusion process):

- Not scheduled for tonsillectomy in daycare

- <18 years of age

- Not speaking and understanding of the Dutch language

- Lacking mental capacity (cognitive decline, dementia).
During study:
- Patients who experience a post-operative bleeding will be excluded.
- The health professionals involved and investigators can decide to withdraw a subject from the study for urgent
medical reasons (e.g. if patients are not discharged on the day of operation due to complications).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-08-2016
Enrollment:	128
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-08-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45805
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5839
NTR-old	NTR5994
CCMO	NL55225.041.16
OMON	NL-OMON45805

Study results