The effect of communication on pain

Gepubliceerd: 22-08-2016 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28669

Bron
Nationaal Trial Register

Verkorte titel
NA

Aandoening

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

Ondersteuning

Primaire sponsor: NIVEL / Recipient SPINOZA award, Prof dr JM Bensing
Overige ondersteuning: Supported by the Spinoza Prize from
the Dutch Research Council (NWO) awarded to Prof dr JM Bensing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

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2. To examine whether adult patients following tonsillectomy in the enhanced empathy communication condition will
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3. To examine the interaction effects of the different levels of outcome expectancy and empathy on adult patients¡¯
experiences of pain and other outcomes.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Postbus 1568
Liesbeth Vliet, van
Otterstraat 118-124
Utrecht 3500 BN
The Netherlands
+31 (0)30 2729632

Wetenschappelijk

Postbus 1568
Liesbeth Vliet, van
Otterstraat 118-124
Utrecht 3500 BN
The Netherlands
+31 (0)30 2729632

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Scheduled for tonsillectomy in daycare

- ¡Ý18 years of age

- Speaking and understanding of the Dutch language

- Having mental capacity

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	22-08-2016
Aantal proefpersonen:	128
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-08-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45805
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten