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Examining the effects of enhanced provider–patient communication on postoperative tonsillectomy pain: protocol of a randomised controlled trial performed by nurses in daily clinical care

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ABSTRACT

Introduction Placebo effects (true biopsychological effects not attributable to the active ingredients of medical technical interventions) can be attributed to several mechanisms, such as expectancy manipulation and empathy manipulation elicited by a provider's communication. So far, effects have primarily been shown in laboratory settings. The aim of this study is to determine the separate and combined effects of expectancy manipulation and empathy manipulation during preoperative and postoperative tonsillectomy analgesia care on clinical adult patients' outcomes.

Methods and analysis Using a two-by-two randomised controlled trial, 128 adult tonsillectomy patients will be randomly assigned to one out of four conditions differing in the level of expectancy manipulation (standard vs enhanced) and empathy manipulation (standard vs enhanced). Day care ward nurses are trained to deliver the intervention, while patients are treated via the standard analgesia protocol and hospital routines. The primary outcome, perceived pain, is measured via hospital routine by a Numeric Rating Scale, and additional prehospitalisation, perihospitalisation and posthospitalisation questionnaires are completed (until day 3, ie, 2 days after the operation). The manipulation is checked using audio recordings of nurse–patient interactions.

Ethics and dissemination Although communication is manipulated, the manipulations do not cross norms or values of acceptable behaviour. Standard medical care is provided. The ethical committee of the UMC Utrecht and the local OLVG hospital committee approved the study. Results will be published via (inter)national peer-reviewed journals and a lay publication.

Trial registration number NTR5994; Pre-results.

Strengths and limitations of this study

- This study is a randomised controlled trial on the (placebo) effects of communication on top of standard medical care, building the evidence base of communication.
- This study is conducted in clinical care opposed to a laboratory setting; strenghtening the results' generalizability.
- The success of the intervention will depend on the ability of nurses to carry out the different communication styles successfully.

INTRODUCTION

In clinical care, patients' outcomes are influenced not only by the active ingredients of drugs or other medical technical interventions but also by the context in which care is delivered. Such biopsychosocial effects on patients' outcomes that are not attributable to the active ingredients of treatments or interventions are called 'non-specific' or 'placebo effects'.[1 2] They are real and robust, occurring on top of natural history and regression to the mean,[3] and can be observed alongside 'sham treatments' as well as 'real treatments'.[4]

Several mechanisms underlie the generation of placebo effects on patient outcomes such as pain.[5] A well-understood mechanism is the manipulation of expectations. According to a recent systematic review of our research group, manipulating patients' expectations seems capable of influencing clinical patients' pain perceptions.[6] For example, the verbal suggestion that a drug is an active pain killer is more effective than receiving the same dosage medication without such a suggestion.[7] Manipulating expectations also contribute to the recent described positive effects of open-label

placebos (inert treatments being described as such).[8] A less well understood mechanism is the communication of empathy in healthcare professional–patient encounters. Only few scholars have pointed out the potential role of the professional–patient relationship in explaining placebo effects.[9–11] In our systematic review, we found that empathy had a less strong effect on pain compared with expectations,[6] but studies used different empathy operationalisation and empathy was often manipulated together with other elements of the clinical encounter, making it difficult to draw strong conclusions from empathy.[6]

When looking at these mechanisms, it seems reasonable that healthcare professionals' communication can influence them, and can thus produce placebo effects. Until recently, however, the entities of communication and placebo effects have hardly been integrated.[11] Communication is traditionally associated with 'art, not science' and placebos with 'evidence-based medicine' in which their effects are typically ruled out by the study design of randomised controlled trials (RCTs).

The tide is changing. A landmark study led by Kaptchuk *et al*[10] found that placebo acupuncture delivered with high outcome expectations and an empathic approach led to statistically and clinically significant improvements in the functioning of patients with irritable bowel syndrome compared with placebo acupuncture delivered without expectations and empathy. The distinct and combined effects of both mechanism and the effects alongside an active treatment remain, however, unknown from this study.

Our research group has started to unravel the potential separate and combined effects of both expectancy manipulation and empathy manipulation in highly controlled settings. Using scripted video vignettes and role-play studies, we found that expectancy mainly influences cognitive outcomes (eg, expected treatment effect) and empathy mainly influences affective outcomes (eg, anxiety). The largest positive effects were found when the two elements were combined and a physician raised high expectations, meanwhile communicating in a warm, empathic manner.[12 13] However, whether these distinct and combined effects also translate to the clinical setting, alongside an active intervention, remains, as yet, an unanswered question. Answering this question is important, as it will provide insight into how specific communication elements can influence specific health outcomes.

Study objective

This study, therefore, aims to disentangle the role of communication in eliciting placebo effects in the clinical setting within the context of standard medical care. More specifically, the objective is to determine the separate and combined effects of expectancy manipulation (standard vs enhanced) and empathy manipulation (standard vs enhanced) during preoperative and postoperative tonsillectomy analgesia care on clinical adult patients' outcomes (main outcome measure is pain perception). This will be studied using a two-by-two RCT design. By following this approach, the evidence base on the effects of expressed outcome expectancy and conveyed empathy will be built in clinical care.

Accompanying the study objective, the goals of this study 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 with 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 with 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).

METHODS AND ANALYSIS

Design and setting

A four-arm (two-by-two design) single-blind RCT will be conducted at the day care nursing wards on two locations of a Dutch general hospital (OLVG Amsterdam), in which adult tonsillectomy patients are preoperatively and postoperatively monitored and treated by nurses. Patients will be randomly assigned to one out of four arms, which vary in the induction of expectations (standard vs enhanced), and (the level of) nurses' communication of empathy (standard vs enhanced). Depending on the patient's allocation, nurses will express a standard or enhanced outcome expectation of patients' pain, and provide care in a standard or enhanced empathic manner. See figure 1 for the study design. All patients will be treated according to the usual analgesic treatment protocol and daily routine care of the hospital. Recruitment started in August 2016 and will presumably continue until early 2018.

Patients

This study focuses on adult tonsillectomy patients. This population was carefully selected as it is a homogeneous population. These patients are young adults, generally aged 18–35 years, without complex comorbidity (American Society of Anesthesiologists classification 1) and lack a history of chronic pain. Moreover, tonsillectomy is generally accepted as a strong confound nociceptive trigger resulting into high levels of postoperative pain

		Expectancy	
		enhanced	standard
Empathy	enhanced	Group 1	Group 2
	standard	Group 3	Group 4

Figure 1 Study design.

that only lasts for a relatively short period of time (1–2 weeks).

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet the following criteria:

- scheduled for tonsillectomy in day care,
- ≥18 years of age,
- speaking and understanding of the Dutch language,
- having mental capacity.

Exclusion criteria

A potential patient who meets the following criteria will be excluded from participation in this study.

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 the course of the study:

- patients who experience a postoperative bleeding will be excluded.
- The healthcare professionals involved and research team can decide to withdraw a patient from the study for urgent medical reasons (eg, if patients are not discharged on the day of operation due to complications).

If a patient drops out, data until exclusion will be included in the analyses unless the patient objects to this (this will be asked on exclusion).

Sample size

The sample size calculation is based on the primary outcome, that is, pain. This calculation is based on a previous similar study,[7] in which an open versus hidden administration of analgesic showed a difference of 1.2 and a total variance of 2.18. Based on a power of 0.80 and alpha of 0.05, and including an interaction effect (with a within variance of 1.92), this results in a needed sample size of 32 patients per arm and 4×32=128 patients in total.

Recruitment

The recruitment of patients occurs in several steps.

1. Patients are approached for the study while discussing the operation with their consulting ear nose and throat specialist (ie, ENT doctor). All eligible and interested patients are provided with a Patient Information Folder (PIF) and informed consent form. The PIF omits specific study aims but mentions that communication will be manipulated. It is stressed that participation is free of choice and will not affect usual medical care;
2. During the preoperative examination, which is mostly conducted within a few days of the ENT consultation, the anaesthesiology clinician asks whether the patient is informed about the study. If not, they will provide them the PIF and consent form. They will ask whether the patient is interested in participation and whether the research team can call the patient to provide them with more information. This response is noted in the electronic record and transferred to the researchers via an (automated) email;
3. The research team will call the patient, explain the study in more detail and ask the patient to return the completed informed consent form.

Patients who are already planned for surgery when the study opens (the normal time between ENT consultation and the operation is 6–8 weeks) will be called by involved healthcare practitioners (from the ENT/Anaesthesiology department). They are informed about the study via telephone. In case they are interested, their name and telephone number are transferred to the researchers. The researchers will call the patient, and send them an information letter and consent form which participants can complete and return in case they are willing to participate.

Randomisation

On providing informed consent, patients are randomised using a random number generator (1:1:1:1 allocation rate). Assignments will be provided via sequentially numbered, opaque, sealed envelopes. A secretary not otherwise involved in the study will open the assignment envelopes.

After patients are randomised, the research team will inform the healthcare professionals about their inclusion. They will insert this information in the medical records of the hospital system (EPIC). Moreover, they will inform the day care administrators and key contact persons about the patients that are scheduled in the upcoming week or days and which condition they are randomised to. On the day of admission, the researchers will ensure that all appropriate systems (eg, the ward lists and the hard copy patient records) are adequately signposted with the patients' condition. We will use colour codes for this to avoid unblinding patients. Only one patient per room is included at any time point.

Intervention

The intervention consists of a (protocolled) communication manipulation on top of standard analgesic treatment. Nurses at the day care ward will incorporate an (protocolled) expectancy manipulation (standard vs enhanced) related to the effects of the pain medication and empathy manipulation (standard vs enhanced) into their communication. The communication intervention will be provided at all nurse–patient communication moments during patients' stay at the day care ward (preoperation and postoperation, day 1, the day care wards are open between 07:00–18:00 and 6.45–19:00, respectively), and during the nurses' telephone consultation with patients the day post discharge (day 2). In practice, this means that all communication patients receive from day care ward nurses during this time frame will be according to patients' assigned condition. This includes interactions during intake, pain assessments, medication allocation and transferal to the operation theatre and

from the postanaesthesia care unit (PACU), discharge and all other interactions due to patients' questions or medical need.

All nurses will receive training to ensure their ability to perform the different communication manipulations. We will make use of a professional trainer and comprehensive training protocol including scripts (ie, written examples), video examples and role play. Moreover, posters are placed in the communal spaces for nurses with information about the study, for example, examples of the manipulations and study procedures. Pocket cards with examples of the manipulations are provided. To ensure the communication differs between the four conditions and to minimise carry-over effects (eg, nurses' stressing enhanced expectations display automatically an enhanced empathy style), the four conditions are trained separately and the posters and pockets cards focus on the four different conditions. The importance of the manipulations being successful in order to draw conclusions from the found results is stressed during the training day.

Expectancy manipulation

In the standard condition, nurses do not aim to create the expectation that the pain medication will work very well. They might use sentences such as 'The medications attempt to reduce your pain ever so slightly', or 'This is your pain medication'.

In the enhanced condition, nurses aim to create the expectation that the pain medication will work very well. They might use sentences such as: 'The medications I am giving you now will lead to a strong decrease of your pain', or 'This pain medication is known for working very well'.

Empathy manipulation

In the standard condition, nurses aim to create a neutral atmosphere which is standard. They will be trained to (among other behaviour) keep standing when communicating with patients, react with standard empathy to patients' cues and concerns, not explore concerns in detail, to not express extra interest in the patient as a person, to not pay extra attention to not interrupting patients and to not make extra eye contact.

In the enhanced condition, nurses aim to create an atmosphere, which is extra warm and extra friendly. They will be trained to (among other behaviour) introduce themselves properly, sit while communicating with patients, react extra empathically to patients' cues and concerns (verbal and nonverbal) and take their concerns seriously, to show extra interest in the patient as a person, to not interrupt the patient and to make adequate eye contact.

It should be noted that the communication manipulation does not cross important norms or values of acceptable behaviour and that the psychological integrity of patients will not be harmed. An observational study among clinical postsurgical patients showed that nurse–patient interactions are often subject to interruptions related to other tasks, for example, searching for equipment, answering telephone calls or being interrupted by other professionals.[14] The interruptions and nurses' attempts to address competing demands impact on the time and attention spent with patients. It can, therefore, be assumed that variations in communication are inherently due to clinical encounters. This was also confirmed by field observations conducted by the research team before study start. The aforementioned developed scripts/examples which are used in the training have been commented on by nurses and researchers in a pilot study to ensure they are realistic and do not trespass ethical boundaries and have been finalised in collaboration with involved clinicians.

Standardising of communication

The communication patients receive from other clinicians involved during their hospitalisation (eg, from the surgical team working in the operation theatre and the clinical team working in the PACU) will be standardised as much as possible. Also, the communication during the preoperative ENT and Anaesthesiology visit will be standardised as much as possible. Involved healthcare professionals will be informed of the study aims and the importance to keep their communication neutral (if possible) (ie, to not provide extra empathy or raise extra expectations about pain) for included patients. This is feasible, as the ENT and anaesthesiology team are involved in the study, and it is uncommon for patients to ask about pain medication during their time at the PACU.

Blinding

Patients will be blinded to the specific study aims and treatment allocation.

The involved healthcare personnel cannot be blinded. All healthcare personnel involved will receive clear and specific instructions about informing and including patients to preserve experimental control. Besides, all interactions within the study between nurses and patients will be audio recorded to evaluate the fidelity of the communication manipulation.

Study procedure

After receiving informed consent, the research team will send a baseline questionnaire to the patient. Completion of this questionnaire will be done at home and will take no more than 20 min. Postoperatively (at day care, day 1) a short (5 min) questionnaire is administered. As part of routine care, preoperatively and postoperatively, patients rate their level of pain. At day 2 (the day after discharge), patients will complete another questionnaire about their pain and medication use. At day 3, a last questionnaire will be completed which will take 20 min. Patients are given the choice between paper and pencil and online completion of questionnaires. This time frame of follow-up is chosen as we expect the effect of the intervention (delivered within a few hours by day care ward nurses solely) to wane within a few days.

Moreover, the interactions between involved nurses and included patients will be recorded. Nurses will be provided with a portable audio-recording device with microphone. During every visit, the nurses will mention patient's identification number by means of reference, to protect patients' privacy. At day 4 (3 days after discharge), patients will receive a debriefing letter by postal mail which will inform them about the study aims and their assigned condition. If they wish to receive more information, they can contact the research team.

Withdrawal of individual patients

Patients can leave the study at any time for any reason if they wish to do so without any consequences. The healthcare professionals involved and research team can decide to withdraw a patient from the study for urgent medical reasons (eg, a bleeding after operation). If a patient drops out, the research team is informed of this. Patients will continue to receive standard medical care and communication.

Informed consent nurses

Nurses involved in the study will be asked to participate as participants using an information sheet and a consent form. They will be asked to complete the consent form and a questionnaire about their background characteristics. We will offer them, at study end, participation in a (accredited) communication training to thank them for their participation in this project.

Outcomes

Main study outcome

Pain perception/intensity

As part of routine care, during hospitalisation and post-hospitalisation patients' pain will be assessed on the basis of a Numeric Rating Scale (NRS) (0–10), ranging from 'no pain' to 'worst imaginable pain'.[15 16] Pain is rated preoperatively at day care ward, at the PACU and post-operatively at day care ward. On study day 2, 1 day after discharge, day care ward nurses will contact the patients by telephone and again assess their pain. On top of this standard routine, pain is assessed at home on day 2 and day 3 (study end).

Secondary study outcome

In the patient questionnaires, the following secondary outcomes will be assessed:

Pain expectations

Patients' pain expectations are measured using two items (both measured using a self-created Visual Analogue Scale (VAS): (1) patients' pain expectations for the few days following the operation (VAS ranging from no pain to 'the most intense pain imaginable', ranging from 0 to 10, adapted from Petersen *et al*[17]), and (2) patients' expectations of improvement in pain following receiving pain medication (VAS ranging from '0% improvement' (no improvement) to '100% improvement' (most improvement imaginable), adapted from the Credibility and Expectancy Questionnaire.[18] These questions will be assessed postoperatively (during hospitalisation).

Overall benefit of analgesia

The Overall Benefit of Analgesia Score (OBAS) will be assessed.[19] The OBAS is a multidimensional seven-item instrument in which patients indicate (on a 0–4 scale, ranging from 'not at all' to 'very much') the level of current pain and distress arising from several symptoms such as itch. The OBAS is measured posthospitalisation (at home) at days 2 and 3 (study end).

Analgesic dosage

The total dosage of administered analgesics will be assessed during hospital stay and noted in the medical record. The total dosage of administered analgesic at home post operation will be assessed at days 2 and 3 (study end) by asking patients to indicate which pain medication they use/have used.

Analgesic request by a patient

Analgesic request will be assessed during hospital stay and noted in the medical record.

Perceived empathy

Perceived empathy will be determined using the Consultation and Relational Empathy Measure (CARE)[20] in which the term 'doctor' is replaced with 'nurse' and 'consultation' is replaced with 'contact' (10 items, 1–5 scale ranging from 'poor' to 'excellent' (and 'not relevant'), eg, 'How was the nurse at showing care and compassion'). Perceived empathy is measured at day 3 (study end).

Perceived expectation

We will measure the extent to which participants thought nurses had induced the expectation that medication would be effective to decrease their pain. This will be assessed using a one-item self-created VAS scale ('no effect at all' to 'a lot of effect', ranging from 0 to 10). Perceived expectation will be measured at day 3 (study end).

State anxiety

Patients' level of anxiety will be measured by the Dutch 10-item State measure of the State-Trait Anxiety Inventory (STAI-state)[21](1–4 scale ranging 'not at all' to 'very much'). Patients' anxiety is assessed prehospitalisation, and at day 3 (study end).

Mood

Mood will be measured using the Positive and Negative Affect Schedule (PANAS)[22] (20-items, 1–5 scale ranging from 'not at all' to 'very much', eg, 'I am exited' or 'I am upset'). Mood is measured prehospitalisation, and at day 3 (study end).

Satisfaction

Participants' satisfaction with the provided care by the nurses during day care will be assessed using a one-item self-created VAS scale ('not at all' to 'very much', 0–10 range). Satisfaction will be measured at day 3 (study end).

General pain evaluation

Whether the pain following the operation has been better or worse than expected will be measured using a one-item self-created VAS scale (ranging from 'much worse than expected' to 'much better than expected', 0–10 range). Pain evaluation is measured at day 3 (study end).

General evaluations regarding hospitalisation

Patients' evaluations of their hospitalisation are measured using two items: (1) how likely it is that the patient would recommend this hospital to other tonsillectomy patients (using an adapted item from the Consumer Quality Index (CQ Index)[23] (0–10 scale 'would definitely not recommend' to 'would definitely recommend') and (2) their overall rating of the quality of care provided by the hospital during hospitalisation, using an adapted item from the CQ Index[23] (0–10 scale, 'very poor care' to 'extremely good care'). This is measured at day 3 (study end).

Other outcomes

The following background characteristics of patients are measured prehospitalisation:

Sociodemographics

For example, date of birth, gender, marital status, education, ethnicity, societal position and date of operation.

Functional health status

Measured using the Dartmouth COOP [from the Dartmouth Primary Care Cooperative Information Project known as the "CO-OP Project"] functional health assessment charts/World Organisation of National Colleges, Academies, and Academic Associations of General Practices/Family Physicians (COOP-WONCA); seven-item scale assessing several health status elements, for example, physical fitness, on a 1–5 scale ranging from 'not limited at all' to 'severely limited'.[24 25]

General experiences/expectations/attitudes medications

We will measure the extent to which patients generally (1) benefit from, (2) have positive expectations towards the effect of and (3) have objections against taking medicines. This will be done using self-created VAS scales (ranging from 'not at all' to 'very much', 0–10 range).

General reporting of pain

We will measure whether patients generally are inclined to report their pain using a self-created VAS scale (ranging from 'never' to 'always', 0–10 range).

Attitudes towards operation

The extent to which participants (1) are dreading, and (2) are afraid of the operation will be measured using two self-created VAS scales (ranging from 'not at all' to 'very much', 0–10 range).

In addition, we will measure:

Data medical record

We will ask patients' permissions to access the medical record. We will routinely use medical background data (diagnosis, weight and prescribed medication) and analgesic information (as aforementioned). If needed, additional data will be screened for (eg, in cases of outlier data the medical record might provide useful information).

Background measures for nurses

The following nurses' characteristics will be measured at study start.

Sociodemographics

For example, date of birth, gender and type of nurse (ie, nurse in training, regular nurse, specialised nurse).

Empathy personality trait

We will measure nurses' empathic abilities using the Interactive Reactivity Index (IRI).[26] The IRI consists of 28 items (eg, 'I often feel sorry for people who are less fortunate than me') which are scored on a 1–5 scale (ranging from 'describes me not at all' to 'describes me very well').

An overview of the measured outcomes at different time points is provided in table 1.

Adherence to the communication manipulation protocol

To verify the fidelity of the communication manipulation, the interaction between nurses and patients will be audio recorded. The adherence will be verified by listening back to a random sample (10% of the sample) of audio-recorded visits and to determine the adherence to the protocol (as is comparably done by Kaptchuk *et al*[10]). Two research assistants who are not otherwise involved in the study will independently evaluate the audio recordings on adherence to the protocol.

Data analysis plan

All data will be analysed using STATA 13.0 with two-sided significance testing at $p<0.05$. All available data from patients will be included in the analysis and missing data might be imputed. An intention to treat analysis will be performed, thereby also examining selective attrition.

Primary outcomes

Descriptive statistics will be calculated for patients' reported pain intensity (main outcome measure) for the different time points during and post hospitalisation. Since our design consists of a two (expectancy: enhanced vs standard) by two (empathy: enhanced vs standard) design, all outcomes will be analysed using either analyses of variance (ANOVA) (if focused on a specific time point) or multilevel repeated-measures regression analyses (if focused on different time points which means that several ratings are included for one person). Both communication elements (ie, expectancy and empathy) are dummy coded. Main effects and interaction effects of expectancy and empathy will be explored. New insights gathered during the analysing process might be examined (if feasible).

Table 1 Overview measured outcomes at different time points

Domain	Measure	Collected	Prehospitalisation	Postoperation (at day care, day 1)	During hospitalisation (preoperative–perioperative–postoperative, day 1)	Posthospitalisation (at home, day 2)	Posthospitalisation/ study end (at home, day 3)
Pain perception/intensity	Standard hospital NRS	Patient			x	x	x
Pain expectations	Adapted VAS scale	Patient		x			
Overall benefit of analgesia	OBAS	Patient				x	x
Analgesic dosage		Medical record/ patient			x	x	x
Analgesic request		Medical record			x		
Perceived empathy	CARE	Patient					x
Perceived expectation	Self-created VAS	Patient					x
Anxiety	State-anxiety (STAI-State)	Patient	X				x
Mood	PANAS	Patient	X				x
Satisfaction	Self-created VAS scale	Patient					x
General pain evaluation	Self-created VAS Scale	Patient					x
General evaluation about hospitalisation	Adapted CQ Index items	Patient					x
Socio demographics		Patient	X				
Functional health status	COOP-WONCA	Patient	X				
General experiences/expectations/ attitudes	Self-created VAS scales	Patient	X				
General reporting of pain	Self-created VAS scale	Patient	X				
Attitudes towards operation	Self-created VAS scale	Patient	X				
Data medical record	For example, diagnosis, weight and prescribed medication	Medical record	X		X		
Nurse—sociodemographics		Nurse	At study start				
Nurse—empathy	IRI	Nurse	At study start				

CARE, Consultation and Relational Empathy Measure; CQ Index, Consumer Quality Index; COOP-WONCA, Dartmouth COOP [from the Dartmouth Primary Care Cooperative Information Project known as the "CO-OP Project"] functional health assessment charts/World Organisation of National Colleges, Academies, and Academic Associations of General Practices/Family Physicians; IRI, Interactive Reactivity Index; NRS, Numeric Rating Scale; OBAS, Overall Benefit of Analgesia Score; PANAS, Positive and Negative Affect Schedule; STAI-State, State measure of the State-Trait Anxiety Inventory; VAS, Visual Analogue Scale.

Secondary outcomes

Descriptive statistics will be calculated for secondary outcome measures. The effect of our manipulated variables will be analysed using analyses of variance.

Other outcomes

Frequencies and means will be calculated for the demographics. The four groups will be checked on equality by using chi-squared tests or ANOVA. If groups differ on specific variables, these variables might be used as control variables in the multilevel analysis.

Adherence to communication protocol

Data of the audio recordings are observed by trained coders on adherence to the protocol to verify fidelity. First, 10% of the audio recordings are independently checked on adherence to the protocol. For this purpose, the aforementioned main (verbal) features of the manipulations (see 'Intervention section') are described and rated for their occurrence when listening to the audio recordings. Using this, it is determined to which of the four conditions the audio recording belongs to. Second, inter-rater reliability between the coders of the outcomes will be assessed by calculating Cohen's kappa. Values ranging between 0.21 and 0.41 are considered fair, values between 0.41 and 0.60 are considered moderate and values greater than 0.61 are considered good (ie, substantial/almost perfect). We consider values as reliable if Cohen's kappa is greater than 0.41.[27 28] Moreover, the number of nurse–patient interactions and duration of interactions is measured for each audio recording.

ETHICS AND DISSEMINATION

Risks and burden for participants

All participating patients receive usual care with regard to surgery, analgesia and preoperative and postoperative treatment. There are no risks associated with this clinical study. The communication manipulation will be provided on top of standard care and is designed in such a way that there will be no harmful effects for patients. Although practitioners' communication is deliberately manipulated and associated with both positive and less positive effects, the communication manipulation does not cross important norms or values of acceptable behaviour nor will it affect the psychological integrity of patients. Variations in nurse–patient interactions occur naturally within clinical settings, justifying our approach. Moreover, although patients are informed about the study by their treating clinicians, informed consent will be gathered by the research team. The clinical and research team will stress that participation is voluntary and will not affect standard clinical care. Patients are always free to withdraw their participation in the study. Finally, it can be a burden for patients to complete a few additional questionnaires. We attempt to decrease the burden by using short questionnaires and limiting follow-up to 3 days. Results, ultimately, will provide more insight into the effect of communication on patient outcomes.

Adverse and serious adverse events

All adverse events reported spontaneously by the patient or observed by the clinical or research team will be recorded. All serious adverse events (SAEs) will be reported to the ethical committee who has approved the study and the online database. This will be done within 15 days (7 days for the first reporting if an SAE resulted in death or was life threatening). Due to the content of the intervention, we do not expect SAE's to happen. The research team, supported by the clinical team, will regularly check the medical records for the occurrence of any adverse events and serious adverse events.

Confidentiality

Patients' data will be anonymised using an identification number. This code will be safeguarded by an independent contact person at NIVEL and this information will be kept on a protected drive using a protected file independently of the research data. The researchers involved in this study will have access to the research data. The audio recordings will not be destroyed after the research, but will be added to the NIVEL audio/video database. At present, NIVEL has a database of around 18 000 (digitised) video-recorded and audio-recorded healthcare visits and a well-equipped infrastructure with computerised observation units.

Ethics and dissemination

At the minimum, the results of this study will be published in international peer-reviewed scientific journals. A lay summary of the results will be published as well and sent to participants if they are interested.

DISCUSSION

This innovative study aims to manipulate communication to determine how expectations and empathy can lead to placebo effects and help minimise patients' postoperative pain (among other outcomes). The results can help to shed more light on how communication can be used alongside medical care to enhance patients' outcomes for the better.

That being said, manipulating communication in clinical care poses methodological, ethical and logistical challenges. The success of the study will depend on the success of the delivery of the manipulations. To ensure communication differs between the various groups, and to avoid contamination, all nurses have been trained and the research team is available (onsite and offsite) for questions, practice and feedback. On most intervention days, a member of the research team is present at the day care ward. This is much appreciated by nurses, and ensures that the appropriate manipulation is often practiced before a patient is admitted. Throughout an intervention day,

the signposting of all systems (ward lists/hard copy patient records) and the appropriate pocket cards with examples also serve as a constant reminder of the group allocation. The success of the manipulation is checked using the audio recordings of nursing interactions and will assist in interpreting our results. While varying communication, the ethical boundaries of not providing any suboptimal communication are and will be clearly adhered to and are stressed in contacts with involved healthcare professionals. Finally, patients come in contact with many clinicians before and during hospitalisation. Informing all clinicians and ensuring all but the day care ward nurses will standardise their communication is crucial to ensure causal effects of the manipulated communication can be determined. Therefore, both the research and clinical team involved have ensured many contact moments with clinicians to personally inform them about the study and appropriate information material has been circulated at study start.

Of course, this study is beforehand not without limitations. Most importantly, due to the clinical nature of the study, it is impossible to standardise communication elements beyond expectancy and empathy. We did, however, instruct nurses to vary only the manipulated communication and keep the remaining care and communication standard. We, therefore, believe these elements to not differ widely, but if evenly, between conditions. Moreover, time differences and differences in the number of nurse–patient interactions between the conditions could potentially occur. We did, however, tried to ensure that the manipulations differed as minimally as possible in time (eg, enhanced empathy consists of little time-consuming behaviours such as sitting opposed to standing) and all interventions need to be delivered within nurses' standard work time. Moreover, we instructed nurses to display the manipulations during all their standard interactions, and did not instruct them to have extra interactions in the enhanced conditions. We, therefore, believe to have minimised the risk for time differences and interaction differences to occur between conditions. For the 10% checked audio recordings, consultation time and the number of nurse–patient interactions are measured, which might help us in interpreting the findings. We acknowledge it remains a limitation of this complex clinical study that due to focus and power constraints we will not completely measure or control for all variables beyond, and time/interaction differences between, the manipulations. A last limitation is that nonverbal behaviour (eg, eye contact) cannot be taken into account when determining adherence to the protocol using the audiotapes.

Despite these challenges and limitations, we believe that this study is of utmost importance to bring the field of communication and pain research forward. Without conducting controlled studies into the effect of communication, communication will always remain a soft-sided add-on. In order to overcome this, we would recommend future studies to also include biological and clinical outcomes. Most importantly, we hope that this study and detailed protocol will provide an impetus for further work in this important area turning communication from 'art to science'.

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