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Influence of health system and patient characteristics on expectations and outcome in total hip arthroplasty patients in the Dutch-German border region: protocol for a mixed-methods prospective observational comparative study (hip across)

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ABSTRACT

Introduction Total hip arthroplasty (THA) is the treatment of choice for end-stage osteoarthritis of the hip. Management of THA differs between countries, and it is hypothesised that this can influence patients' expectations and self-efficacy. Using Chen's intervening mechanism evaluation approach, this study aims to explore how structure of care influences expectations and self-efficacy of patients undergoing THA, and how expectations and self-efficacy in turn influence outcome in terms of perceived physical function and satisfaction.

Methods and analysis A mixed-methods study will be conducted in two German and two Dutch hospitals near the Dutch-German border. In the quantitative part, patients will complete questionnaires at three timepoints: preoperatively and at 3 and 6 months postoperatively. Data analysis will include multiple regression analysis and structural equation modelling. In the qualitative part, interviews will be held with patients (preoperatively and 3 months postoperatively) and healthcare providers. Analysis will be performed using structured qualitative content analysis.

Ethics and dissemination The study is approved by the Institutional Review Boards of both Carl von Ossietzky University Oldenburg (2021–167) and University Medical Center Groningen (METc 2021/562 and METc 2021/601). The results will be disseminated in the international scientific community via publications and conference presentations.

Trial registration number The study is registered in the German Clinical Trials Registry (DRKS: DRKS00026744).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A cross-border comparison of usual care is made, enabling study of the influence of structure of care on treatment outcome.
⇒ The data collection and analysis are based on a theoretical approach.
⇒ Most of the questionnaires used have been validated in both Dutch and German.
⇒ Although we tried to minimise language-based differences in data collection by extensive pretesting, differences between Dutch and German participants due to language or culture cannot be entirely ruled out.

INTRODUCTION

Total hip arthroplasty (THA) is a highly effective treatment for end-stage hip osteoarthritis (OA).[1] The purpose of THA and its subsequent rehabilitation is to reduce pain and improve functioning, aiming to enable patients to continue performing their activities of daily living (ADL) and thus live independently[2]—a highly valued component of quality of life (QoL).[3]

There is no international standard for THA management,[4–6] so countries structure treatment in different ways. Germany and the Netherlands, neighbouring countries, are interesting examples. In Germany, the most THAs per capita in Europe are performed, with 315 THAs per 100 000 inhabitants, compared with 222 THAs per 100 000 inhabitants in the Netherlands in 2019.[7] In Germany, patients generally stay in the hospital for about 10 days, followed by 3 weeks as inpatients or outpatients at a specialised rehabilitation centre, with all costs covered by the patient's health insurance.[8–10] In the Netherlands, patients generally undergo fast-track surgery and are discharged within 3 days of surgery with no rehabilitation covered by

basic health insurance. However, most patients have an additional insurance package for a set number of physiotherapy sessions.[11–13] Previous research compared the clinical and cost effectiveness of THA rehabilitation in the northern German-Dutch border region. Wijnen *et al* showed that German patients had better functional outcomes and satisfaction than Dutch patients at 12 weeks and 6 months postoperatively.[14] A similar study showed no significant differences.[8]

How healthcare is structured might influence patients' expectations and self-efficacy,[15] which have previously been linked to better clinical outcomes.[16 17] To our knowledge, only Lingard *et al*[18] have compared the association between expectations and outcomes for arthroplasty across countries, including total knee arthroplasty (TKA) patients from the USA, United Kingdom and Australia. They found that Australian patients expected better functioning after surgery, but no differences were found between the countries for postoperative outcomes.

The current study aims to analyse to what degree the healthcare systems and patient characteristics influence expectations and self-efficacy of people undergoing THA. Moreover, it will be analysed how patients' expectations and self-efficacy eventually influence THA outcomes in terms of perceived physical function and satisfaction. To that end, a comparison will be made between the German and Dutch systems.

THEORETICAL FRAMEWORK

The theoretical framework is based on two different theories. To structure the theoretical framework, Chen's programme evaluation theory was used.[19 20] Based on this theory, a framework was created with four domains: treatment domain, outcome domain, determinant domain and implementation environment. To structure the content of the framework within the determinant domain, expectations and self-efficacy are conceptualised using the integrative model of Laferton *et al*.[21] The theoretical framework will be used to gain insight into how management of care may influence patients' expectations and self-efficacy and how in turn expectations and self-efficacy influence patients' perceived physical function and satisfaction and to evaluate whether causal effects work as expected and contribute to the success or failure of a treatment. The model will be tested using Chen's intervening mechanism evaluation approach to assess the success of the action and conceptual theory.[19] Figure 1 depicts the model.

Treatment domain

The treatment domain constitutes the basic, essential element that produces the intended changes in a programme or intervention.[19] For this study, the treatment domain can be seen as the THA procedure, including preoperative preparation, surgery and postoperative rehabilitation, with the goal to lower symptoms and improve health related QoL of patients suffering from OA. There are differences in the organisation surrounding this procedure between Germany and the Netherlands.

In Germany, less than half (9.9%) of the patients receiving THA for OA receive physiotherapy preoperatively.[22] Following surgery, most patients stay in the hospital for approximately 10 days receiving daily physiotherapy. After discharge, most patients are referred to specialised inpatient or outpatient rehabilitation centres to follow a 3-week rehabilitation programme.[8] During rehabilitation, patients undergo a multidisciplinary approach including (but not limited to) core and lower-quarter muscle

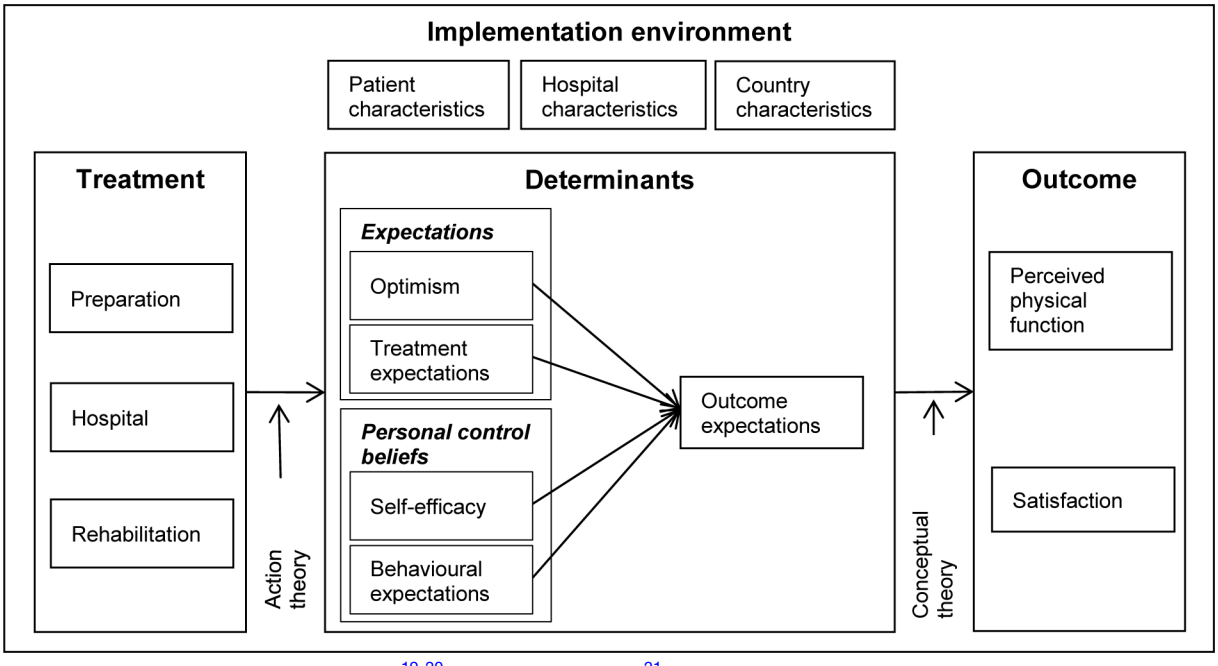

Figure 1 Combined change model of Chen[19 20] and Laferton *et al*.[21]

strengthening for purposes of joint protection, measures to improve joint function, coping strategies to better deal with everyday life with disabilities and nutritional counselling.[9 10] Following rehabilitation centre discharge, physiotherapy can be prescribed without restrictions on number of sessions for the first 6 postoperative months if deemed necessary by the treating physician and is fully covered by the patient's health insurance.

In the Netherlands, most THA or TKA patients with OA (73%) receive physiotherapy before surgery.[13] In contrast to Germany, most patients in the Netherlands undergo fast-track surgery and are discharged from the hospital within 3 days. During hospitalisation, physiotherapy is provided. Most patients are directly discharged to their home environment, with only 10% receiving inpatient rehabilitation.[11] No standard rehabilitation programme is provided at discharge, but patients are advised to follow physiotherapy. However, postoperative physiotherapy is not covered by the Dutch basic health insurance. Patients who need or want postoperative physiotherapy need a supplementary insurance package or have to pay the physiotherapy by themselves.[22] Following surgery, patients have routine follow-ups after 6–12 weeks, 1 year and 5 years postoperatively.[23]

Outcome domain

The outcome domain reflects the treatment goals.[19] From the patients' perspective, perceived physical function and satisfaction with the outcome of THA are essential aspects to consider, primarily as it is known that objectively measured physical function shows only moderate correlations with perceived physical function.[24–27] Therefore, perceived physical function and satisfaction are the primary outcomes of interest.

Determinant domain

The determinant domain reflects the leverage mechanism by which treatment affects outcomes.[19] In this study, expectations and self-efficacy reflect the determinant mechanism. The concept of expectations in healthcare includes several constructs, which Laferton *et al*[21] conceptualised into an integrative model: outcome expectations are formed by optimism, treatment expectations and personal control beliefs. Optimism reflects general expectations, unspecific to a particular context. Treatment expectations reflect the expected benefit of the treatment. Personal control beliefs are formed by self-efficacy and expectations of benefit of certain behaviour. Self-efficacy is a person's particular set of beliefs that they can successfully execute certain behaviour required to produce a desired outcome[28]—for example, a person's belief that they are able to do whatever it takes to recover from THA. Expectations of benefit of certain behaviour are about positive or negative outcomes when performing the behaviour, for example, whether someone believes that performing a prescribed exercise will positively influence post-THA outcome. To have higher behavioural specific expectations, a person must believe they can perform the necessary behaviour and that this behaviour will result in positive outcomes.[21]

Implementation environment

The implementation environment domain is about the environment in which a treatment is implemented.[19] Within the implementation environment, a distinction can be made between environmental factors on a microlevel (eg, patients and providers), mesolevel (eg, healthcare organisations) and macrolevel (eg, culture, society and healthcare system).

On the microlevel, for patient characteristics, the fact that 40% more people per 100 000 capita undergo THA in Germany compared with the Netherlands[7] might indicate differences in patient characteristics as a result of different selection criteria between the two countries. As a result, patients with less severe symptoms may be more likely to undergo THA in Germany. Those patients could have better preoperative function, while studies show that better preoperative function positively influences postoperative outcomes.[29]

Regarding the mesolevel, a hip replacement is a highly standardised procedure.[30] It should be noted that there might be practice variation within this procedure (eg, robot-assisted or computer-assisted procedures and different anaesthesia procedures), but it is hypothesised that these will not have a major impact in the context of this study. This study's focus will be on influences of preoperative expectations (microlevel) and system characteristics (macrolevel) on postoperative outcome.

On the macrolevel, the main difference is health insurance. In Germany, the entire THA procedure is paid by the patient's health insurance and pension insurance. Approximately 11% of the German population is privately insured and may be receiving additional services depending on their individual package.[31] In the Netherlands, the THA and hospital stay are paid by the health insurer. However, in principle, THA rehabilitation is not covered. Only for patients with a special indication being unable to rehabilitate at home is postoperative rehabilitation available at specialised centres. For the vast majority of THA patients, postoperative physiotherapy is not covered by Dutch basic health insurance. Patients must thus pay for physiotherapy out of their own pocket or will need an additional insurance package in order to be reimbursed.[12] In a cross-sectional survey among OA patients undergoing hip or knee arthroplasty in the Netherlands, almost all patients (98%) indicated having at least one additional insurance package.[13] The number of physiotherapy sessions covered by the additional packages differs considerably though.[22]

Several other differences exist between the two healthcare systems.[32 33] One that specifically might influence expectations between Dutch and German patients is that the latter patients can choose the surgeon themselves—who they consider the 'best' surgeon—possibly resulting in high expectations. In principle, Dutch patients can also choose their own surgeon, yet this may be restricted

to only those surgeons and hospitals who have a contract with the specific health insurer. Patients who go to an out-of-network surgeon may have to pay for all or part of the treatment, including surgery. In practice, Dutch patients go to the nearest hospital that has a contract with their specific health insurer. Also, cultural differences between the countries might influence expectations. For example, Germany has a more paternalistic patient-physician relationship culture, whereas shared decision-making is more common in the Netherlands.[34]

Action theory

Action theory explains how treatment affects the determinants, which in this study means how the provided treatment influences patients' expectations and self-efficacy.[19] Multiple factors might lead to different treatment and behavioural expectations, and thus outcome expectations, between German and Dutch patients. To our knowledge, research on this topic is sparse.

For treatment expectations, the foremost reason the provided treatments might result in different expectations for German than for Dutch patients is simply because of what the treatment looks like. With German patients receiving more extensive treatment, their expectations of the treatment and its results might be higher than those of their Dutch counterparts. Research into coronary artery disease patients shows that treatment expectations can be influenced by how extensive the treatment is. Expectations of patients undergoing surgery were much higher than those of patients receiving medication only, even though both treatments show similar outcomes.[35]

For behavioural expectations, differences might exist in both self-efficacy and the expectations of benefit of certain behaviour. For self-efficacy, we hypothesise that the difference in treatment could have two possible effects. First, one could assume there is no difference in self-efficacy between German and Dutch patients. However, patients might judge a treatment differently in terms of how difficult it is to perform, which might lead to a different judgement of one's ability to perform the required behaviour. With German patients receiving more support during their rehabilitation, it might be that their programme is perceived as easier to perform. Besides, self-efficacy may increase when doing rehabilitation at a dedicated centre observing other patients reach their goals.[28] This would result in German patients reporting higher levels of self-efficacy. On the other hand, maybe German patients believe that everything is arranged for them and they will be fine when following the extensive programme. By contrast, Dutch patients might recognise they will have to work hard for their rehabilitation and will not go into surgery unless they believe that they can perform the behaviour deemed necessary to recover from surgery. If that is the case, Dutch patients might have higher self-efficacy. For expectations of benefit of certain behaviour, similar reasoning can be used, with Dutch patients increasingly recognising that they must do more by themselves to achieve the best outcomes, whereas German patients might believe that the extensive rehabilitation will give them the best results and thus might assign less value to its influence over their behaviour.

Conceptual theory

Conceptual theory describes how determinants affect the outcome variables[19]—how patient expectations and self-efficacy influence outcome. The working mechanism of expectations is similar to (or part of) the placebo effect.[15 21 36] Higher treatment expectations are therefore thought to influence outcomes positively. In addition, higher self-efficacy and, to a lesser extent, higher treatment expectations lead to higher adherence.[37–39] This might be particularly important for Dutch patients rehabilitating at home.

Expectations are evidenced to influence pain and physical function following surgery, with higher expectations resulting in better outcomes.[36 40] Also for THA, high expectations are related to better outcomes.[16 17] Unrealistic or unfulfilled expectations have been linked to inferior satisfaction after THA.[41] For self-efficacy, one systematic review found weak evidence for an association between preoperative self-efficacy and improved functional outcomes, and strong evidence for an association between postoperative self-efficacy and improved functional outcomes.[42] Two other systematic reviews found unclear associations between preoperative expectations or self-efficacy and post-THA outcomes.[43 44]

METHODS

Study design

A prospective observational comparative study will be performed. A natural German and Dutch cohort of patients undergoing primary THA will be compared using a quantitative and qualitative approach. The quantitative approach will consist of a survey. The qualitative part will use semistructured interviews with THA patients and healthcare professionals (physicians, physical therapists and nurses), as well as a mixed focus group interview with healthcare professionals from both sides of the border.

Research setting

Four hospitals in the northern Dutch-German cross-border region participate in the study. In each country, one university hospital and one general hospital will be involved in the data collection: in Germany, University Hospital for Orthopaedics and Trauma Surgery Pius-Hospital, Medical Campus University of Oldenburg and the Department of Orthopaedics and Trauma surgery of Klinikum Leer, and in the Netherlands, the orthopaedic departments of University Medical Center Groningen (UMCG) and Ommelander Ziekenhuis Groningen in Scheemda. Inclusion for all parts of the study starts in late June 2022 and will be terminated when the planned sample size is reached.

Subjects

Sample

For the quantitative portion, the sample size calculation is based on the patient acceptable symptom state (PASS). Escobar *et al* showed that 70% of patients achieve an acceptable PASS at 3 months following primary THA, meaning they were satisfied.[45] A difference of 20% between the German and Dutch samples in the proportion of satisfied patients is considered clinically significant, as described in the OMERACT-OARSI criteria.[46] Consequently, based on the results of Escobar *et al*[45] a sample size of 60 patients in each country group is required to detect a 20% difference, with a power of 80% and a significance level of 0.05. Considering a drop-out rate of 10%, a final enrolment of 132 patients (66 Dutch and 66 German) is needed.

For the qualitative portion, purposeful sampling will be used to arrive at a heterogeneously composed group of patients and healthcare professionals to capture several perspectives.[47] We strive to include 20 patients and 20 professionals, 10 of each on each side of the border.

Inclusion criteria

For both the quantitative and qualitative part, patients must fulfil the following inclusion criteria: age >18 years and an indication for primary THA due to OA. Patients will not be eligible for study enrolment if they cannot understand, read and write German or Dutch (depending on the country), received any previous joint replacement or have cognitive limitations.

To be eligible for participation in the interviews, healthcare professionals must fulfil the following inclusion criteria: age >18 years and working as a physician, physical therapist or nurse and involvement in THA patient management. Healthcare professionals will not be eligible if they cannot understand, read and write German or Dutch (depending on the country). Additionally, for the focus group interviews, participating healthcare providers will be excluded if they cannot speak and understand English.

Recruitment

For the quantitative study, the following recruitment procedure will be used. Eligible participants will be identified from a waiting list. Information letters, informed consents, questionnaires (as applicable) and return envelopes will be send out by postal mail. Non-respondents are sent a reminder 2 weeks later. Patients unwilling to participate are asked to return the forms empty. For the qualitative study, the same procedure will be used. Participants consenting to participate in the interviews will be called to make an appointment. It is possible for participants to participate both in the qualitative and quantitative study.

Healthcare professionals of the participating orthopaedic centres will be approached by a representative of the study at each specific institution to participate. After providing information, oral consent is obtained, and an appointment for the interview is scheduled. Written informed consent will be obtained before the interview starts.

Table 1 Overview of the questionnaires used at each timepoint

Construct	Measure	T0	T1	T2
Subject and disease characteristics	Demographics	X		
	Lifestyle	X		X
	Comorbidities	X		
	Hip history	X		
Physical function and pain	Hip disability and Osteoarthritis Outcome Score-Physical Function Short Form	X	X	X
	Numeric Rating Scale-pain	X	X	X
General health perception	Short Form-12	X	X	X
Generalised expectations	Life Orientation Test-Revised	X	X	X
Behavioural expectations	Self-Efficacy scale for Rehabilitation	X	X	X
	Behaviour outcome expectancy Likert scale	X	X	X
Treatment expectations	Credibility Expectancy Questionnaire	X	X	X
	Trust in healthcare system	X		
Outcome expectations	Hospital for Special Surgery Expectancy scale	X		
Satisfaction	Likert scale satisfaction with current symptoms	X	X	X

Measurement procedures

For the quantitative part, data will be collected using paper-based questionnaires delivered at three timepoints: preoperatively (T0) and at 3 months (T1) and 6 months (T2) postoperatively. At 6 months, patients are essentially considered as rehabilitated.[48] Table 1 summarises which questionnaires will be used at which timepoint.

The preoperative questionnaire starts off by asking about subject and disease characteristics. This includes demographics (eg, age and gender), lifestyle (eg, smoking and physical activity), comorbidities and hip joint medical history, including duration of symptoms and previous treatment. Information on body mass index and length of hospital stay will be obtained from patient records.

Physical function and pain will be addressed using the Hip disability and OA Outcome Score-Physical Function Short Form (HOOS-PS) and two Numeric Rating Scales (NRSs). The HOOS-PS measures hip function during ADL and recreational/sport activities using five questions, with five standardised response options from 0 (no problems) to 4 (extreme problems in function). It is translated into German and Dutch and cross-culturally validated.[49 50] Hip pain will be asked about using two NRS, about pain at rest and pain during activity.

Preoperative health related QoL will be measured using the Short Form-12 (SF-12), which calculates a physical component summary and a mental component

summary. The Dutch and German versions are valid and reliable.[51 52]

Several aspects of expectations will be measured. Generalised expectations will be measured with the Life Orientation Test-Revised, a tool to measure optimism using 10 questions of which four are filler items. Each question is answered on a 5-point Likert scale ranging from 0 (totally disagree) to 4 (totally agree).[53] The questionnaire is translated into German and Dutch and validated in both languages.[54 55] Personal control beliefs will be measured using the Self-Efficacy scale for Rehabilitation (SER) and a single-item NRS about behaviour outcome expectancy. The SER aims to assess patients' self-efficacy on their ability to perform the exercises required during rehabilitation. It consists of 12 questions of increasing difficulty regarding the exercises that must be performed or the inconvenience experienced. Patients answer on an 11-point Likert scale ranging from 0 (I cannot do it) to 10 (certain I can do it). The English and Dutch translations are considered reliable and valid.[56 57] For the German version, we will analyse the psychometric properties in our sample. The single-item behaviour outcome expectancy question asks patients to indicate on a Likert scale ranging from 0 (I do not believe this at all) to 10 (I completely believe this) how much they believe their behaviour influences the outcome of their THA. Treatment-related expectations will be measured using the Credibility Expectancy Questionnaire (CEQ), a single-item NRS about general trust in the healthcare system, and an open-ended question on usage of other health services. The CEQ, developed by Borvorec and Costello,[58] is a scale measuring treatment expectancy and rational credibility consisting of two parts: part 1 with four questions about what patients think and part 2 with two questions about how patients feel. Scoring is done on two rating scales, one from 1 (not at all) to 9 (very much) and one from 0% (not at all) to 100% (very much). The original questionnaire shows high-internal consistency and good test-retest reliability, and factor structure was confirmed in the Dutch translation.[59 60] For the German version, we will analyse the psychometric properties in our sample. Outcome expectations will be measured using the Hospital for Special Surgery Expectancy scale, consisting of 18 questions to determine patient expectations before surgery. Expectations relate to symptoms, physical activity, work and psychological well-being. A five-point scale is used on which patients can express how much improvement they expect for each item, ranging from 'complete improvement or back to normal' to 'this expectation does not apply to me/I do not have this expectation'. The scale has been validated in both Dutch and German.[61–63]

Satisfaction with current symptoms will be measured using the PASS.[64 65] A Likert scale with the question 'if you were to spend the rest of your life with the hip symptoms you have now, how would you feel?' will be used, as done by previous authors.[14] Four response options are given: very satisfied, somewhat satisfied, somewhat dissatisfied and very dissatisfied.

In the qualitative part, semistructured interviews will be conducted, recorded and held in the respective interviewee's language by a researcher fluent in that language to ensure proper understanding. The Dutch researcher, who understands German, will also join the German interviews to ensure a comparable methodology. The focus group interviews, in which German and Dutch healthcare professionals participate, will be held in English and led by two researchers, one fluent in Dutch, one fluent in German and both fluent in English to provide proper understanding and translation when necessary.

Patients will be interviewed twice, using a longitudinal qualitative design.[66 67] The first interview will be held preoperatively, asking about the process prior to surgery, the information received about the surgery and following rehabilitation, and patients' expectations regarding the surgery and subsequent time at the hospital, rehabilitation and outcomes. The second interview, 3 months after surgery, will be about their experiences with the surgery, time at the hospital and rehabilitation. Patients will be asked about what keeps them motivated during their rehabilitation, what the outcomes are so far and what they expect the outcomes to be 1 year postoperatively.

Healthcare professionals will be interviewed once about their knowledge of and involvement in the THA procedure: which related information they provide their patients, what they believe patients expect from the procedure, how they believe those expectations may influence the outcomes and what they consider the strengths and weaknesses of each healthcare system's approach. In the focus groups, healthcare professionals from both countries will be invited together to facilitate a discussion about these strengths and weaknesses.

Data analysis

The qualitative and quantitative results will be interpreted in context of each other using a joint display. Therefore, the qualitative data will be used to improve the interpretation of and support the quantitative data. Besides, the qualitative data will be used to identify relevant aspects not covered by the current questionnaires.

Statistical analysis will be performed using SPSS (IBM, Armonk, New York, USA). Level of significance will be set at α=0.05. Sample characteristics will be described using mean, SD, frequencies and percentages, or median and IQR. To investigate the assumptions from the theoretical background, the survey data will be analysed using multiple regression analysis and structural equation modelling, using demographics, country, preoperative outcomes and preoperative expectations and SE as predictors. Besides, an analysis stratified by country will be performed.

The interviews will be audio recorded, transcribed verbatim and pseudonymised according to established transcription standards.[68] Analysis of the interviews will be performed using a structured qualitative content

analysis. This is a multistage process in which first, a priori main categories derived from the interview guidelines are developed. During the coding process, subcategories are inductively formed. Computer-aided coding into categories will be performed using the program MAXQDA (VERBI, Berlin, Germany). The entire coding process will be performed independently by two individuals.

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Ethical considerations and dissemination

This study will be conducted in agreement with the latest World Medical Association Declaration of Helsinki and is approved by the Institutional Review Boards of both the Carl von Ossietzky University Oldenburg (2021–167) and UMCG (METc 2021/562 and METc 2021/601). The study was registered in a trial register prior to subject recruitment (DRKS: DRKS00026744). All procedures used are in line with the data protection regulations of the involved institutions. Both the interviews and the questionnaires will be pretested before the start of the study. Participation in the study is voluntary and requires signed informed consent. All measures will be taken to protect subjects' human rights. During recruitment, participants will be informed about their right to withdraw from the study at any time without consequences for their medical care and without the need to provide reasons for withdrawal. The results of this study will be disseminated in the international scientific community via publications and presentations at conferences.

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