

BMJ Open Patient, physiotherapist and surgeon endorsement of the core domain set for total hip and total knee replacement in Germany: a study protocol for an OMERACT initiative

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ABSTRACT

Introduction There is a lack of harmonising measures for clinical trials on total joint replacement (TJR) that would allow for results from TJR studies to be compared or pooled. The Outcome Measures in Rheumatology (OMERACT) TJR core domain set is already endorsed among patients and physicians in the USA and Australia. Physiotherapists use different types of measurements compared to orthopaedic surgeons while both make substantial contributions to research in the field of TJR. To achieve consensus on core measurements sets, patients, physiotherapists and orthopaedic surgeons need to achieve consensus on the core domains for TJR trials.

Methods and analysis For this multistage study, first, the OMERACT TJR core domain set survey will be translated to German and validated according to WHO guidelines. Next, the TJR core domain set will be considered for endorsement in different German stakeholder groups including patients, physiotherapists and orthopaedic surgeons.

Ethics and dissemination Ethical approval for this protocol was given by the ethics committee of the Brandenburg University of Technology Cottbus—Senftenberg (BTU—CS, EK 2019—2). This article is based on the protocol version 2.5 from 6 May 2020. Anonymous data will be presented only. We will publish the results in peer-reviewed publications and at international conferences.

Trial registration number German Clinical Trials Registry (DRKS00016015).

INTRODUCTION

Osteoarthritis (OA) is a significant cause for disability.¹ Total joint replacement (TJR) is a frequently used and evidently effective treatment for end stage OA, when other treatments have failed.^{2–4} The knee and hip are the most commonly replaced joints. In 2016, over 135 000 total hip replacements (THAs) and 105 000 total knee replacements (TKAs) were performed in Germany.⁵ The

Strengths and limitations of this study

- This is the first study that cross-culturally validates the Outcome Measures in Rheumatology total joint replacement core domain set, thus establishing a German version for further clinical and research use.
- A German translation will provide broader insights outside English speaking countries.
- The iterative international process for core domain set development will help to produce generalisable data for stakeholder priorities.
- Germany only partly represents the cultural diversity of Europe.

American Joint Replacement registry reports more than 300 000 THAs and more than half a million of TKAs for the same period in the USA.⁶ About 50 000 THAs and 60 000 TKAs were implanted that year in Australia.⁷ The Outcome Measures in Rheumatology (OMERACT) TJR working group, an international group of methodologists, patient partners, physiotherapists, orthopaedic surgeons and rheumatologists was established in 2008.⁸ This group performed systematic reviews, identifying a lack of comparability between TJR randomised trials.⁹ When combining the results of systematic reviews on this topic^{9–11} and the result of surveys and Delphi panels in different stakeholder groups (patients, surgeons, physical therapists and rheumatologists), the group derived a preliminary core domain set for clinical TJR trials for knee and hip OA at OMERACT 2014.¹² This core domain set was developed using an iterative process over several years to ensure that important stakeholder priorities regarding core domains were not missed.^{13–17} While it is possible that new domains may be identified

**Table 1** Modified Standard Protocol Items: Recommendations for Interventional Trials figure of study schedule and design

Timepoint	Study period					
	Step 1: validated questionnaire translation				Step 2: endorsement patients, physiotherapists and orthopaedic surgeons for outcome measures in TJR	
	T1	T2	T3	T4	T1	T2
Validated questionnaire translation						
Forward translation	X					
Panel discussion		X				
Backward translation			X			
Panel discussion with regard to differences to initial version				X		
Endorsement of core measurement domains in stakeholder groups						
Patients					X	
Physiotherapists					X	
Orthopaedic surgeons					X	
Evaluation of consensus across stakeholder groups						
Likert scale ratings of proposed core domains in stakeholder groups						X

TJR, total joint replacement.

during this study, they will have to achieve a threshold high enough to merit inclusion in the core domain set based on frequency (arbitrarily at 30% of the sample) and validation in another independent sample, preferably in another language.

OMERACT uses an onion model to signify the importance of areas that should be reported in clinical trials, where outcome domains placed in the inner circle are termed 'core' and are considered the most important ones to report. Consensus was reached on the inner critical circle, including pain, function, patient satisfaction, revision, adverse effects and death as the core domain set. Cost and participation are in the middle circle, and the range of motion is in the outer circle or research agenda. The next step now is to develop a core measurement set for TJR trials but a weakness in broad international acceptance of the core domains is the limited validation of the findings in Europe. Moreover, both orthopaedic surgeons and physiotherapist substantially contribute to research in the field of TJR. However, physiotherapists use different types of measurement instruments compared with orthopaedic surgeons.¹⁸ To harmonise TJR clinical trial outcomes, it is important that all stakeholders agree on the core domain areas and on the instruments used to measure these areas. However, no information about such agreement is yet available in Germany. Therefore, it is necessary to assess whether physiotherapists, patients and orthopaedic surgeons in Germany agree on the TJR core domain set.

Methods and analysis

The aim of the study is to achieve further consensus on the OMERACT TJR core domain set including three important stakeholder groups: patients, physiotherapists

and orthopaedic surgeons in Germany. A multistage study is necessary to achieve this goal. In accordance to the OMERACT handbook, partners from at least three continents must be chosen in a first step. Studies previously have included patients from the USA and Australia. At the OMERACT meeting 2018 in Terrigal (Australia), the TJR group met and agreed to do another survey and validation in Germany, as an initial approach of representing European populations. The validated and successfully used OMERACT TJR core domain set survey will be used for an endorsement in these stakeholder groups.

Before the core domain survey can be used for data collection in a German speaking population, the original English version must first be translated to German and subsequently be validated in accordance to recognised

Table 2 Baseline characteristics of the three endorsement groups

	Orthopaedic surgeons (N)	Physiotherapists (N)	Patients (N)
Female, n (%)			
Age, years, mean (SD)			
Age category, n (%)			
<44			
45–54			
55–64			
65–74			
≥75			

Data are presented as mean (SD) or n (%) unless otherwise stated.

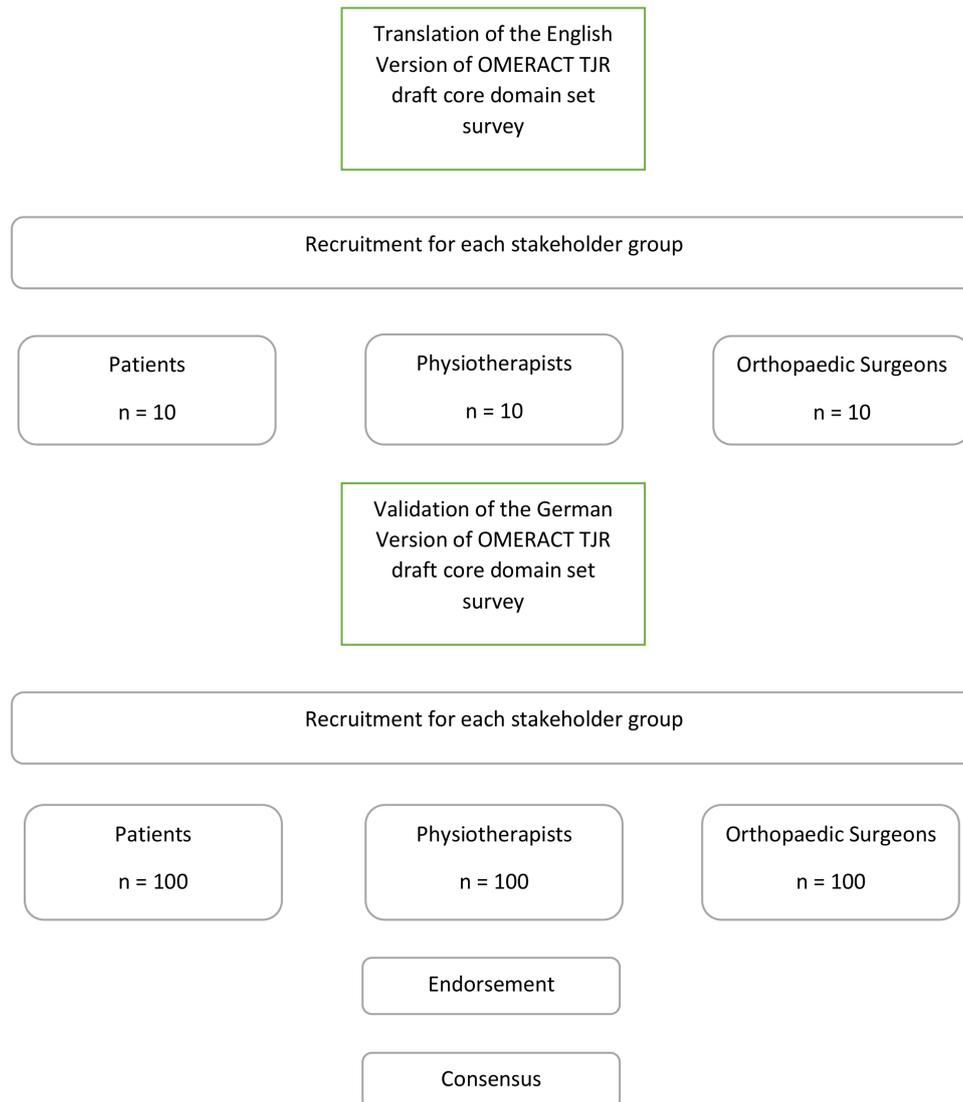


Figure 1 Flow chart. OMERACT, Outcome Measures in Rheumatology; TJR, total joint replacement.

standards. The planned steps of the study are visualised in [table 1](#).

Step 1: validation of the German version of the OMERACT TJR draft core domain set survey

In accordance to the WHO recommendation for the process of translation and adaptation of instruments,¹⁹ a German version of the original English core domain set survey will be established as described below. First two native German-speaking individuals, one medical professional and one lay person, will translate the original English version into German. Subsequently, a bilingual expert panel of the author's team will discuss the translated German versions and provide suggestions for improvement. Following this, two native English-speaking persons, one medical professional and one lay person, unaware of the original English version, will do a back-translation. Any differences between the original English version and the forward-backward translated version will be discussed in the expert panel and the German wording will be adjusted if necessary. As soon as the

bilingual expert panel regards the new German version acceptable, it will be pretested in five representatives from each stakeholder group (ie, patients, orthopaedic surgeons, physiotherapists). While filling out the survey, they will be systematically debriefed to state with their own words, what they think each question is asking for. Furthermore, they will be asked to explain how they chose their answer. This will be repeated for each survey item. Respondents will be asked to give feedback about each word they did not understand or found unacceptable. When wording discrepancies are identified, the respondents will be asked during in-depth personal interviews which of the alternatives fit best to their usual language. A written report of the pretesting will be provided by the TJR working group and the authors being involved in this protocol. This process will result in the final German version of the OMERACT TJR core domain set survey 1.0 (OMERACT TJR CDS-G1.0). As recommended by the WHO, the initial forward version, a summary of recommendations from the expert panel, the back translation,

**Table 3** Stakeholder ratings of different core domains

Core domains to be reported in every TJR clinical trial	Orthopaedic surgeons (N)	Physiotherapists (N)	Patients (N)	P value
Joint pain				
Function or functional ability (ability to function in society, work; work productivity, employability; disability; work disability)				
Patient satisfaction (satisfaction with the outcome, satisfaction with the procedure)				
Revision surgery (including reoperation)				
Adverse events (total and specific)				
Death				
<i>Additional domains for consideration for reporting in TJR clinical trials</i>				
Patient participation				
Cost				

Data are presented as median (IQR) unless otherwise stated.
TJR, total joint replacement.

a summary of difficulties occurring during pretesting, the proposed clarifications and the final version will be documented and published.

Step 2: a three-armed endorsement in patients, physiotherapists and orthopaedic surgeons for outcome measures in TJR within rheumatology (OMERACT)

The research group (1) prospectively registered the study in the German Clinical Trials Register prior to starting the validation of a German OMERACT TJR core domain set survey, (2) developed the study protocol and (3) proposed for ethical approval. In a next step leading societies for patients, physiotherapists and orthopaedic surgeons specialised in TJR, as well as health centres with a focus on TJR will be informed about the upcoming endorsement.

Study population and participant selection

The study population will comprise (a) group A: patients with elective THA or TKA, (b) group B: physiotherapists with experience of treating patients with TJR and (c) group C: orthopaedic surgeons with a focus on TJR. Patients will be recruited by contacting patients from the registry of hospitals with a focus on TJR, so called 'Endoprothetikzentren der Maximalversorgung' (EPZmax). Physiotherapists will be recruited in two stages. First, the physiotherapy departments of EPZmax will be contacted and second, if not enough suitable participants take part, the leading physiotherapy societies 'Physio Deutschland', 'IFK - Bundesverband selbständiger Physiotherapeuten' and 'Deutsche Gesellschaft für Physiotherapiewissenschaft' will be contacted for additional participants using a snowball sampling approach. Orthopaedic surgeons will be recruited the same way, first contacting the EPZmax and second, the leading German society for orthopaedic surgery 'Arbeitsgemeinschaft Endoprothetik' (AE)

and the 'Deutsche Gesellschaft für Orthopädie und Unfallchirurgie'.

Inclusion criteria

To be involved in the patient group A, participants must have undergone TKA or THA due to end stage OA, refractory to non-surgical treatments, within the last 2 years. In order to have a share in the physiotherapist group B, participants must be physiotherapist with at least 3 years of working experience in either the management of patients with TJR or research involving patients with TJR. In the orthopaedic surgeons group C, participants will be included if they state at least 3 years of experience in THA or TKA surgery or research including patients with THA or TKA.

Exclusion criteria

Participants of group A, B and C will be excluded, if they:

1. Fail to fill out at least 80% of the survey.
2. Are not identifiable as members of one of the three groups.

Participants of group A will be excluded, if they:

1. Were provided a THA or TKA due to an accident or non-OA cause.
2. Currently have major complications after THA or TKA surgery.

Participants of group B and C will be excluded, if they:

1. Are unfamiliar with the management or research in patients with TJR.
2. Have less than 3 years of work experience.

Recruitment of participants

Every potential group A participant will be selected randomly from the hospital registries until the estimated number of patients agreeing to participate is reached. For the group B sample, we will contact all German EPZmax

Table 4 Stakeholder consensus of different core domains on three different subclassifications of patients with TJR

Core domains to be reported in every TJR clinical trial	Patients with THA (N)	Patients with TKA (N)	P value
Joint pain			
Function or functional ability (ability to function in society, work; work productivity, employability; disability; work disability)			
Patient satisfaction (satisfaction with the outcome, satisfaction with the procedure)			
Revision surgery (including reoperation)			
Adverse events (total and specific)			
Death			
<i>Additional domains for consideration for reporting in TJR clinical trials</i>			
Patient participation			
Cost			
Core domains to be reported in every TJR clinical trial	Females (N)	Males (N)	P value
Joint pain			
Function or functional ability (ability to function in society, work; work productivity, employability; disability; work disability)			
Patient satisfaction (satisfaction with the outcome, satisfaction with the procedure)			
Revision surgery (including reoperation)			
Adverse events (total and specific)			
Death			
<i>Additional domains for consideration for reporting in TJR clinical trials</i>			
Patient participation			
Cost			
Core domains to be reported in every TJR clinical trial	Patients <55 years (N)	Patients ≥55 years (N)	P value
Joint pain			
Function or functional ability (ability to function in society, work; work productivity, employability; disability; work disability)			
Patient satisfaction (satisfaction with the outcome, satisfaction with the procedure)			
Revision surgery (including reoperation)			
Adverse events (total and specific)			
Death			
<i>Additional domains for consideration for reporting in TJR clinical trials</i>			
Patient participation			
Cost			

Data are presented as median (IQR) unless otherwise stated.
TJR, total joint replacement.

in a random way for participating and will distribute the link at the annual congress of the 'Deutsche Gesellschaft für Physiotherapiewissenschaft'. In case the needed number of group B participants is not reached with this procedure, the leading physiotherapy societies will be contacted for distributing surveys with a shared link to physiotherapists fitting the inclusion criteria. To include group C participants, the orthopaedic surgeons society AE will be contacted for distributing the surveys to their members at their annual congress or per email. Because of the few expected participants fitting the inclusion criteria for surgeons, random selection is not feasible for group C.

Outcomes

The survey will ask for individual characteristics of the three stakeholder groups, whether the surgeon or physiotherapist is a clinician, researcher or both, and to rate the importance of the items in the core domains set of the OMERACT TJR CDS-G1.0. Participants have to rate every single core domain on a Likert scale (1–9), which was developed by the Grading of Recommendations Assessment, Development and Evaluation working group and used by the OMERACT group for several studies on developing of treatment guidelines and on ranking of core domains.^{15 17} A rating of 1–3 will indicate a domain of limited or no importance. A domain rated 4–6 means

it is important, but still not critical and 7–9 means it is a critically important domain. The overall aim is to determine whether consensus exists within and between the stakeholder groups within the three selected countries.

Sample size

There is a lack of agreement on how to estimate sample sizes for Delphi studies and endorsements, many published Delphi studies use panels consisting of 10–100 panellists.²⁰ There is no reliable data available about the total number of physiotherapists working with patients with TJR or doing research in this field in Germany. About 20 000 physiotherapists work in German hospitals, but only a few of them have contact to patients with TJR. Surgery is being done in 1160 hospitals for TKA and 1229 hospitals for THA.^{21 22} The estimated sample size for this study will be 100 per stakeholder group. We will be enrolling approximately 50 patients with THA and 50 patients with TKA. We anticipate this will provide similar numbers of men and women. We anticipate a slightly greater proportion of people older than 65 years (60%–65%) in our sample, and therefore our subgroup with younger people will be a bit smaller. We believe that even with sample, we will have enough for subgroup analyses.

Study process

The expert panel will be formed as described. The validation process of the German version will start after publishing this protocol and is estimated to take 6 months. Once the German version of the survey is validated, a phase of 3 months will be used for data collection. Participants will be provided with a link from LimeSurvey, a copy of the survey via email, or receive a paper version of the survey. An accompanying cover letter will ask the participants to complete the survey and send it back once filled in.

On receipt of responses from the different stakeholders, the working group will organise all data in Excel sheets separately for each stakeholder group. The study itself is planned to be finished within 1 year after protocol publication. Following this, data will be statistically analysed and interpreted. In case the data provide reasons for modifications of the core domain set, this will be discussed within the working group, and changes will be implemented, as needed. As to be seen in the flow chart (figure 1), the collected data will be used to achieve further endorsement and consensus among the leaders of orthopaedic international societies and the OMERACT.

Data analysis

Data analysis will be performed using the statistical software R (V.3.5.1 or newer). The three stakeholder groups will be described according to gender, age category and working background. Descriptive statistics will comprise numbers with corresponding percentages. Statistics will be generated separately for each of the three stakeholder groups, including median (IQR, a measure of variance) ratings for each of the domains within each group as well

as median (IQR) ratings for the following patients with TJR subgroups: men versus women, <55 years versus ≥55 years and THA versus TKA. Ratings for each domain will be compared between patients versus surgeons versus physiotherapists, as well as between the different subgroups of patients, using a Kruskal-Wallis test when comparing three groups and a Mann-Whitney test when comparing two groups. A p value <0.05 will be considered significant. Data will be presented in tables 2–4. Templates for the tables are attached to this protocol.

Patient and public involvement

OMERACT has its own patient research partner network to ensure patient's voices in core outcome set development. Patients were involved in the development of this OMERACT TJR core domain set from the very beginning and they will be stakeholders in the translation process and in the endorsement described in this protocol.

DISCUSSION

The inclusion of different stakeholder groups in this survey offers unique opportunities and challenges. We may reach consensus about the TJR core domain set that is concordant with the consensus achieved in the USA and Australia.

We anticipate several study limitations. The sample size may not be large for all subgroup analyses, since we balanced feasibility with desired size of the study sample. We anticipate enough people in the subgroups. It is possible that new suggestions may be noted for inclusion in the core domain set, despite a rigorous process we previously followed with multistakeholder input and multiple rounds of validation and the use of independent samples. We have prespecified the thresholds for inclusion of new domains in the core domain set during cross-cultural validation. We recognise the validation in a German population does not represent the cultural diversity of the whole European population, and we consider this an initial step, anticipating that researchers in other countries will also test these in their populations.

Our study has several strengths as well. With cross-cultural validation of this core domain set, we will ensure its generalisability across language and culture. Since we are following the same rigorous methodology as we previously followed, results can be directly replicated and compared with the previous studies, and variations noted.

We expect to get insights into the intergroup and intragroup homogeneity or heterogeneity among physiotherapists, surgeons and patients. It can be hypothesised that healthcare stakeholders such as physiotherapists or surgeons may rate different domains more important than patient stakeholders. For sustainable and generalisable research, consensus about core domains between different stakeholders, are of utmost importance. Deepening knowledge about consensus in those groups, respecting multicultural diversity, will help to harmonise clinical trials on TJR. When finally, research on the same

topic reports the same outcomes, first the comparability and then the level of evidence for healthcare interventions will increase.

Trial status

When this manuscript was submitted, recruitment had not yet begun.

Ethics and dissemination

This study involves human participants. All authors declare that international ethical standards are consistently adhered. Ethical approval has been obtained by the Brandenburg Technical University Research Ethics Committee (BTU—CS, EK 2019—2). The current protocol version number is 2.5 from the 6 May 2020. The consent for participation will be asked for in LimeSurvey, before starting to answer the survey. This manuscript does not contain any individual person's data apart from the authors'. All authors agreed on publishing their contact details. We will publish the results in peer-reviewed publications and at international conferences.

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Contributors RP wrote the manuscript. He will, together with HH, coordinate the project in Germany and will recruit, together with CK, physiotherapists for the validation of the German survey and for the endorsement. JAS, SG and PC will coordinate the project worldwide and make the major methodical decisions. JAS, SG, SM, GHS, PC, SMN and CK reviewed the content of each manuscript draft critically and made substantial contributions to the writing and content. RS is writing the registration in the German trials registry and will lead contributions to the method section. SMN and JAS are responsible for data analyses of the whole project and especially for this manuscript. SG and GHS reviewed the language and writing style. SG makes substantial contributions to the consensus process. HH will recruit patients and orthopaedic surgeons for the validation of the German survey and for the endorsement and will coordinate the inclusion and data collection of those stakeholders. He is responsible for acquisition of necessary funding. All aforementioned authors are part of the expert team for discussion regarding the back translated English version of the survey to identify problems within the translation and validation process. Furthermore, all aforementioned authors will review the final version of the manuscript critically.

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Medisys, Fidia, UBM LLC, Medscape, WebMD, Clinical Care options, Clearview healthcare partners, Putnam associates, Spherix, the National Institutes of Health and the American College of Rheumatology. JAS owns stock options in Amarin pharmaceuticals and Viking therapeutics. JAS is a member of the executive of OMERACT, an organisation that develops outcome measures in rheumatology and receives arms-length funding from 36 companies. JAS serves on the FDA Arthritis Advisory Committee. JAS is a member of the Veterans Affairs Rheumatology Field Advisory Committee. JAS is the editor and the Director of the UAB Cochrane Musculoskeletal Group Satellite Center on Network Meta-analysis. JAS previously served as a member of the following committees: member, the American College of Rheumatology's (ACR) Annual Meeting Planning Committee (AMPC) and Quality of Care Committees, the Chair of the ACR Meet-the-Professor, Workshop and Study Group Subcommittee and the cochair of the ACR Criteria and Response Criteria subcommittee. PC received institutional support from Medacta. PC also received consultancies from Johnson & Johnson and Stryker. PC received royalties from Johnson and Johnson as part of an instrument design team. PC is part of a Federal Government (Australian) funded industry led consortium (Innovative Manufacturing Cooperative Research Centre) investigating advanced manufacturing in prosthetic design and manufacture. PC is a recipient of National Health and Medical Research Council grants, as well as Australian Research Council grants.

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