■ KNEE

Willingness to participate in placebo-controlled surgical trials of the knee

A DISCRETE CHOICE EXPERIMENT OF PATIENTS AND SURGEONS

L. Wall,
S. Bunzli,
E. Nelson,
L. J. Hawke,
M. Genie,
M. Hinwood,
D. Lang,
M. M. Dowsey,
P. Clarke,
P. F. Choong,
Z. J. Balogh,
L. S. Lohmander,
F. Paolucci

From The University of Newcastle, Newcastle, Australia

Aims

Surgeon and patient reluctance to participate are potential significant barriers to conducting placebo-controlled trials of orthopaedic surgery. Understanding the preferences of orthopaedic surgeons and patients regarding the design of randomized placebo-controlled trials (RCT-Ps) of knee procedures can help to identify what RCT-P features will lead to the greatest participation. This information could inform future trial designs and feasibility assessments.

Methods

This study used two discrete choice experiments (DCEs) to determine which features of RCT-Ps of knee procedures influence surgeon and patient participation. A mixed-methods approach informed the DCE development. The DCEs were analyzed with a baseline category multinomial logit model.

Results

The proportion of respondents (surgeons n = 103; patients n = 140) who would not participate in any of the DCE choice sets (surgeons = 31%; patients = 40%), and the proportion who would participate in all (surgeons = 18%; patients = 30%), indicated strong views regarding the conduct of RCT-Ps. There were three main findings: for both surgeons and patients, studies which involved an arthroscopic procedure were more likely to result in participation than those with a total knee arthroplasty; as the age (for patients) and years of experience (for surgeons) increased, the overall likelihood of participation decreased; and, for surgeons, offering authorship and input into the RCT-P design was preferred for less experienced surgeons, while only completing the procedure was preferred by more experienced surgeons.

Conclusion

Patients and surgeons have strong views regarding participation in RCT-Ps. However, understanding their preferences can inform future trial designs and feasibility assessments with regard to recruitment rates.

Cite this article: *Bone Joint J* 2024;106-B(12):1408–1415.

Introduction

Randomized placebo-controlled trials (RCT-Ps) are the gold standard in medical research methodology when evaluating procedures with subjective outcomes such as pain and quality of life.[1,2] Many orthopaedic procedures are primarily aimed at improving such outcomes and are thus, in principle, suitable for evaluation with a surgical placebo in a randomized control trial (RCT). The ASPIRE guidelines for RCT-Ps in orthopaedic surgery indicate that they are most appropriate when there is "potentially low efficacy … where a significant placebo response is expected" and where the risk-benefit considerations of a RCT-P have been considered.[3] One such risk-benefit consideration is the cost to the healthcare system for high-volume, high-cost procedures that have limited evaluation with gold-standard methodology. Orthopaedic surgery, in particular knee surgery, incorporates high-volume, high-cost procedures such as joint arthroplasty and arthroscopy, which have variable patient outcomes and satisfaction.[2,4] Further, these procedures have shown evidence of potentially low efficacy, arguable clinical benefits, and greater

Correspondence should be sent to Z. J. Balogh; email: zsolt.balogh@health.nsw.gov.au

doi:10.1302/0301-620X.106B12.BJJ-2023-1266.R2 $2.00

Bone Joint J 2024;106-B(12):1408–1415.

Table I. Attributes and levels for the discrete choice experiment (DCE) for each cohort. As seen in the example choice set in Supplementary Tables i and ii, each choice set involved two options, with each option having one of the levels shown below for each attribute. The selection of the levels per option was determined through the DCE design, the details of which can be found in the Methods and Supplementary Material.

Attribute	Levels	Cohort
The procedure being tested	Knee arthroplasty surgery	Patients, surgeons
	Knee arthroscopy	
Who approaches the patients and describes the study	You, the surgeon	Surgeons
	A research nurse	
The terminology used to describe the placebo	Placebo	Patients
	Sham	
The arms of the study*	A two-arm study: arm 1) the standard surgery; arm 2) a low-fidelity placebo	Patients, surgeons
	A three-arm study: arm 1) the standard surgery; arm 2) a low-fidelity placebo; arm 3) a high-fidelity placebo	
	A three-arm study: arm 1) the standard surgery; arm 2) a low-fidelity placebo; arm 3) non-surgical treatment as usual	
The anaesthetic used in the study	Regional/spinal anaesthesia	Patients, surgeons
	General anaesthesia	
The conditions under which patients can cross over†	After 3 months, before results are known	Patients, surgeons
	After 6 months, before results are known	
	After 12 months, before results are known	
	After 12 months, when results are known, if the procedure is found to be effective	
Role in the trial	In addition to performing the surgeries, you would be invited to have input into the trial design and to join the authorship team	Surgeons
	You would only perform the surgeries, you would not have input into the trial design and would not be invited to join the authorship team	
Number of additional appointments	You would not have any extra study appointments in addition to your usual follow-up appointments	Patients
	You would have a couple of extra study appointments in addition to your usual follow-up appointments	

*This wording was used for surgeons. Patients were provided with a lay-person description.
†Patients only had levels 2 and 4.

risks of adverse events through RCTs involving non-surgical and placebo controls.[5,6] These findings create risk-benefit considerations for the patient and surgeon: are they willing to undertake an invasive procedure with a risk of adverse events when its efficacy is uncertain?

Although several RCT-Ps have been performed in orthopaedic surgery,[7,8] significant challenges in their implementation emerged.[6,9] A recent systematic review found that no orthopaedic RCT-Ps were completed within target timeframes.[10] Trials that fail to meet recruitment and timeframe parameters risk being underpowered, potentially jeopardizing the trustworthiness of trial outcomes,[10] and introducing another issue into an area that is already ethically contested.[3] Furthermore, patients who participate in these trials perceive that the increase in knowledge gained (through their altruism) outweighs the risks involved in undergoing a surgical procedure involving anaesthetic.[11] If the increase in knowledge is jeopardized by low participation, then the patient risk-benefit ratio has been changed.

It is critical that potential RCT-Ps are assessed in terms of their feasibility and under-recruitment risk, so that research funding and surgical time are spent appropriately, and the risks of patient participation are balanced with the likelihood of RCT-P completion. Feasibility assessment is also one of the key recommendations from the ASPIRE guidelines.[3] One of the ways in which such an assessment can occur is through an evaluation of surgeon and participant reluctance to participate, as these factors have emerged as barriers to conducting placebo-controlled trials of orthopaedic surgery.[11] Recent findings indicate that surgeons and patients may be more willing to participate in a surgical RCT-P if their preferences are incorporated into the RCT-P design.[10,12] Therefore, understanding which features of trial designs are preferred by patients and surgeons, and which features are most likely to influence participation, can help to determine the risks of trial under-recruitment and feasibility. However, no study has yet quantitatively examined patient and surgeon preferences and willingness to participate in a RCT-P of an orthopaedic surgical procedure. Discrete choice experiments (DCEs) are useful tools to understand how preferences for different features impact decisions to use, purchase, or participate in products, services, or activities.[13] This study used two DCEs to determine how different aspects of RCT-Ps could influence patient and surgeon participation decisions in RCT-Ps of knee surgery.

Methods

Two online, anonymous surveys were developed in Qualtrics (USA) separately for orthopaedic surgeons and patients. The different nature of participation between surgeons and patients, and the non-overlapping nature of some identified attributes and levels, justified using two separate DCEs, one for surgeons and one for patients. Each survey involved a short, mostly

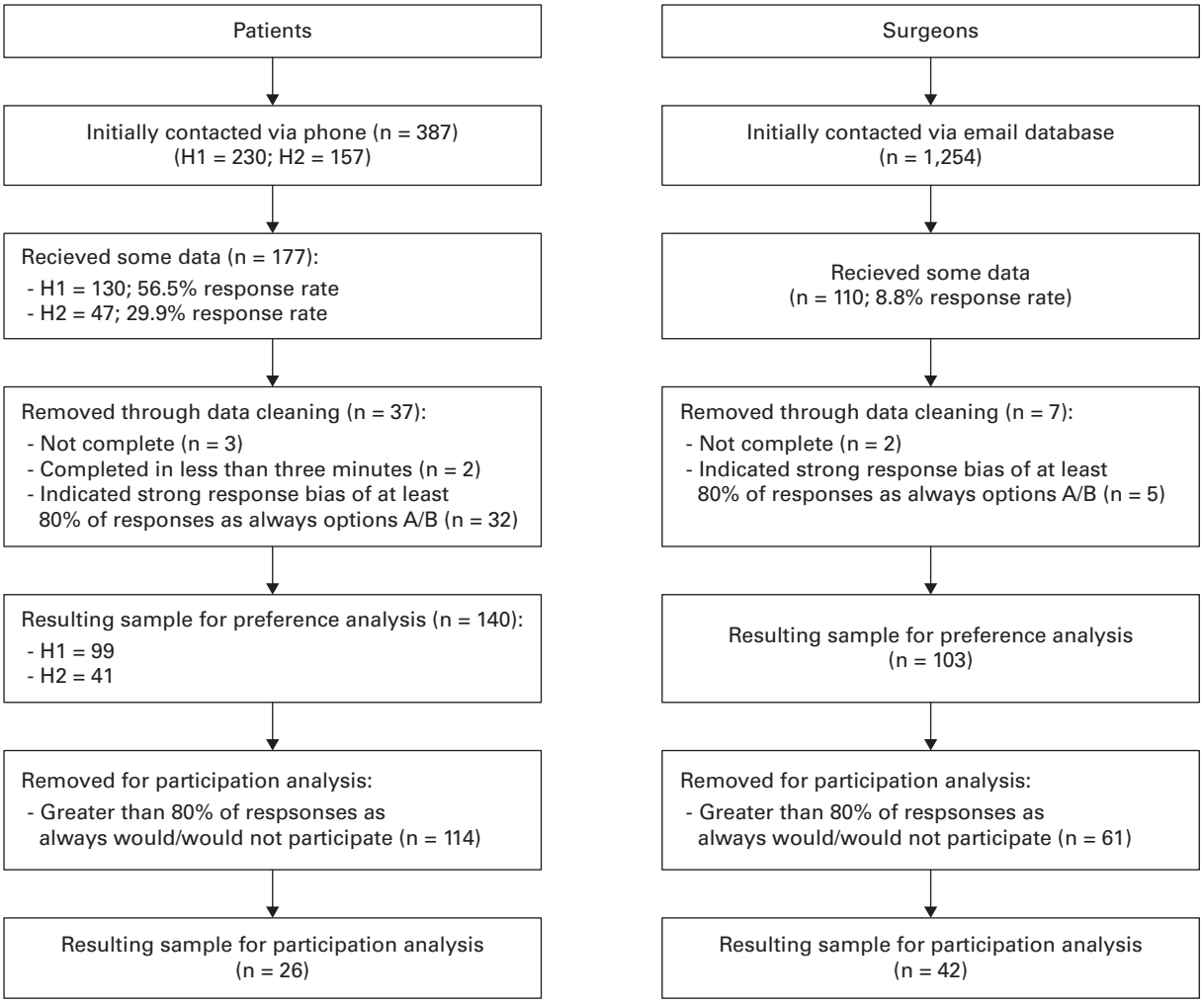

Fig. 1

Recruitment rates, data cleaning processes and resulting sample sizes for the patient and surgeon groups. H1, St Vincent's Hospital, Melbourne, Australia; H2, John Hunter Hospital, Newcastle, Australia.

demographic questionnaire at the start, followed by the DCE instrument (a series of choices, described below) with instructions, and a final free-response comment box.

Discrete choice experiment. For each choice, surgeons and patients were presented with two different, hypothetical study designs of RCT-Ps of knee surgery and asked to imagine they were being offered the opportunity to participate. For each pair of study designs, respondents first indicated which design they preferred, and then whether they would participate in such a study if offered it in real life. For the purposes of this research, we adhered to the terminology used by Bunzli et al,[10] where a surgical placebo is a procedure which involved anaesthesia and skin incision with or without the injection of anaesthesia into the subcutaneous tissue. This type of procedure is referred to as a 'low-fidelity' placebo. A 'high-fidelity' placebo is a procedure where only essential therapeutic steps were missing (e.g. insertion of needle to rest on the lamina in vertebroplasty).

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) checklist for conjoint analysis applications in health informed the development of both DCEs.[14] A mixed-methods approach to initial attribute and level selection was used, followed by a survey development and refinement stage and a pilot DCE for patients (n = 52) and surgeons (n = 99). The views of patient and surgeon representatives were included throughout this process. A final surgeon DCE and patient DCE, each comprising six attributes (as seen in Table I), were produced. More details regarding this and other DCE design and sample size decisions can be seen in Supplementary Material 1.

All DCE designs were constructed in Ngene and evaluated for efficiency.[15] The final surgeon DCE used an S-efficient design with inputs from the pilot DCE analysis. The final patient DCE used an orthogonal optimal in differences (OOD) design.

The final DCE instruments comprised two blocks of ten choice sets for surgeons and six choice sets for patients, with each choice set containing two full, unlabelled profiles. Supplementary Material 2 provides an example choice set in Tables i (surgeon) and ii (patient). Each respondent was randomly

Table II. Surgeon participation discrete choice experiment results (n = 42). The model included all attribute main effects with the inclusion of the design, years of practising, and the interaction between years of practising and surgeon involvement in the trial. Parameter estimates represent the effect of each attribute level on preferences; *z* scores note the effect size. Estimates are the influence of each level compared to the non-listed baseline levels of: arthroscopic procedure, nurse, general anaesthetic, two-arm study, invited to be an author and investigator, and 12-month crossover if effective. Log likelihood = -262.35; Akaike information criterion = 548.71; number of observations = 420.

Variable	Estimate (SE)	*z* value	p-value
Procedure (total knee arthroplasty)	-1.26 (0.28)	-4.49	< 0.001
Who approaches the patient (surgeon)	0.08 (0.25)	-0.33	0.744
Anaesthetic (regional)	0.20 (0.22)	0.90	0.369
Study arms			
Three-arm study with inspection	-0.03 (0.31)	-0.11	0.914
Three-arm study with no surgery	0.14 (0.27)	0.54	0.590
Involvement in the trial (perform surgeries only)	-1.33 (0.36)	-3.69	< 0.001
Crossover			
12 mths before results are known	-0.16 (0.34)	-0.46	0.643
6 mths before results are known	-0.48 (0.36)	-1.34	0.179
3 mths before results are known	-0.11 (0.35)	-0.33	0.742
Years practising*	-0.05 (0.01)	-3.09	0.002
Perform surgeries only (x years practising)*	0.05 (0.02)	2.51	0.012

*Years of practising was entered into the model as a continuous variable, therefore a positive coefficient for the interaction with performing surgeries, indicates that more years of practising leads to a greater preference for trial designs where the surgeon performs the surgeries only. A negative coefficient for years practising indicates a greater likelihood of participation with fewer years practising.
SE, standard error.

Table III. Surgeon preference discrete choice experiment results (n = 103). The model included all attribute main effects. Parameter estimates represent the effect of each attribute level on preferences; *z* scores note the effect size. Estimates are the influence of each level compared to the non-listed baseline levels of: arthroscopic procedure, nurse, general anaesthetic, two-arm study, invited to be an author and investigator, and 12-month crossover if effective. Log likelihood = -1,342.96; Akaike information criterion (AIC) = 2,705.92; number of observations = 2,060.

Variable	Estimate (SE)	z value	p-value
Procedure (total knee arthroplasty)	-0.43 (0.12)	-3.68	< 0.001
Who approaches the patient (surgeon)	0.17 (0.10)	1.64	0.100
Anaesthetic (regional)	-0.20 (0.10)	-2.04	0.041
Study arms			
Three-arm study with inspection	-0.07 (0.13)	-0.57	0.569
Three-arm study with no surgery	0.06 (0.12)	0.46	0.642
Involvement in the trial (perform surgeries only)	-0.87 (0.09)	-9.46	< 0.001
Crossover			
12 mths before results are known	0.64 (0.15)	4.39	< 0.001
6 mths before results are known	0.34 (0.14)	2.48	0.013
3 mths before results are known	0.01 (0.14)	0.07	0.946

SE, standard error.

allocated to one of the two blocks of choice-sets. Two preference elicitation questions were asked for each choice-set presented. The first was a forced choice: "Which study design do you prefer?". The second was an opt-in: "Would you participate in the study you preferred?". Both required a response before progressing to the next choice-set. Surgeon participation was defined as "would involve your patients (who consent) being randomized to the study and you performing the placebo/surgery on your patients based on their randomization."

Sample, recruitment, and ethics. Orthopaedic surgeons were recruited through the Australian Medical Publishing Company (AMPCo), an Australia-wide database, while patients were recruited from elective orthopaedic surgical waiting lists at two large public hospitals in New South Wales and Victoria, Australia.[4] All patients who are consented by an orthopaedic surgeon to undergo an elective orthopaedic procedure are entered onto a waiting list. This is where patients' progression to surgery is managed by the hospital's standard waiting list procedures, which follow the principle of patients being treated in turn with a predetermined priority which, in the Australian public system for uncomplicated lower limb osteoarthritis, is usually surgery recommended within 365 days. These waiting lists include patient details such as their name and phone number. These two details were passed on to the study recruitment team, who called these patients and informed them of the study. The phone script is found in the Supplementary Material.

A survey link was sent to all orthopaedic surgeons on the database (n = 1,254); patients were contacted by phone (n = 387) and emailed a survey link after verbal consent (n = 177).

The final sample sizes, after data cleaning, were 103 surgeons and 140 patients. Consistent with the preferences of surgeon representatives, surgeons were not reimbursed for their participation, however patients received a AUD $25 gift voucher. Ethical approval was provided by St Vincent's Hospital, Melbourne Human Research Ethics Committee (LRR 072/19) and site approval was obtained for both hospitals. At the beginning of both surveys was an information sheet which contained the text "your completion of the questionnaire implies your voluntary consent to participate in the survey", thus proceeding to the survey provided informed consent.

Statistical analysis. Statistical analysis was conducted separately for each group of respondents (surgeon and patient) and each question (preference and participation). Data cleaning processes and results are seen in Figure 1. Sociodemographic variables were analyzed with independent-samples *t*-tests, analysis of variance (ANOVA), and chi-squared tests. All DCE data were analyzed with a baseline category multinomial logit model.[16] All plausible interactions between attributes and demographic variables were explored through model comparison; the results reported are those consistent with the best-fitting model according to the Akaike Information Criterion (AIC)[17] or, when similar, parsimony. All logit models were estimated utilizing maximum likelihood techniques with the statistical software R using the ordinal and mclogit packages.[18,19]

Results

Surgeons. In the pre-DCE portion of the survey, 63% of surgeons indicated that they were willing to be involved in a surgical RCT-P. However, across all the DCE choices, the proportion of responses selected as "I would participate" was only 46%. While 31% of surgeons selected "I would not participate" for

Table IV. Patient participation discrete choice experiment results (n = 26). The model included all attribute main effects with the inclusion of age. Parameter estimates represent the effect of each attribute level on preferences; z scores note the effect size. Estimates are the influence of each level compared to the non-listed baseline levels of: sham, arthroscopic procedure, general anaesthetic, two-arm study, no extra appointments, and 12-month crossover if effective. Log likelihood = -96.96; Akaike information criterion = 211.92; number of observations = 155.

Variable	Estimate (SE)	z value	p-value
Terminology (placebo)	-0.30 (0.37)	-0.82	0.411
Procedure (total knee arthroplasty)	-0.79 (0.35)	-2.25	0.025
Anaesthetic (regional)	-0.03 (0.38)	-0.07	0.946
Study arms			
3-arm study with inspection	0.76 (0.42)	1.83	0.068
3-arm study with no surgery	-0.44 (0.45)	-0.99	0.324
Appointments (couple of extra	-0.11 (0.37)	-0.31	0.759
Crossover (six mths before results are known)	0.16 (0.38)	0.42	0.678
Age*	-0.03 (0.01)	-2.27	0.023

*Age was entered into the model as a continuous variable, therefore a negative coefficient for age indicates a greater likelihood of participation with fewer years of age.
SE, standard error.

Table V. Patient preference discrete choice experiment results (n = 140). The model included all attribute main effects. Parameter estimates represent the effect of each attribute level on preferences; z scores note the effect size. Estimates are the influence of each level compared to the non-listed baseline levels of: sham, general anaesthetic, two-arm study, no extra appointments, and 12-month crossover if effective. The procedure attribute could not be estimated for the preference question, as it did not vary across alternatives. Log likelihood = -1,075.03 Akaike information criterion = 2164.06; number of observations = 1,676.

Variable	Estimate (SE)	z value	p-value
Terminology (placebo)	0.11 (0.10)	1.04	0.297
Anaesthetic (regional)	-1.15 (0.10)	-11.13	< 0.001
Study arms			
3-arm study with inspection	-0.22 (0.13)	-1.73	0.083
3-arm study with no surgery	-0.48 (0.13)	-3.78	< 0.001
Appointments (couple of extra	0.13 (0.10)	1.25	0.211
Crossover (six mths before results are known)	0.57 (0.10)	5.48	< 0.001

every choice, 18% selected "I would participate" for every choice. The clinical characteristics of the surgeons (n = 103) and their views towards RCT-Ps are summarized in Supplementary Table iii. Years practising was the only demographic variable included in the DCE model.

As seen in Table II, surgeons were less likely to participate in studies that included a total knee arthroplasty (TKA), and studies where surgeons' involvement was limited to performing the surgeries. The more years a surgeon had practised, the less likely they were to participate, however surgeons with more years of experience were more likely to participate if their involvement was limited to only performing the surgeries.

As seen in Table III, when deciding which study is preferred, studies with a regional anaesthetic were less preferred than those with a general anaesthetic, and studies with crossover options at 12 and six (but not three) months, not contingent on study results, were preferred to studies with crossover offered after 12 months, if the study results find the intervention procedure effective. There was no difference in preference or participation between studies with a surgeon approaching the patients compared to a nurse, or an additional 'high-fidelity' or 'non-surgical' third arm compared to the base two-arm 'low-fidelity' (incision- and anaesthetic-only) placebo versus intervention.

Patients. Across patients, there was a general preference not to participate in a surgical RCT-P, with only 45% of DCE responses selected as willing to participate. While 40% of patients indicated they would not participate for every choice, 30% selected they would participate for every choice. As seen in Table IV, as the age of participants increased, the likelihood of participating decreased, and, consistent with surgeon preferences, studies that involved an arthroscopic procedure were more likely to be participated in than those with a TKA.

As seen in Table V, studies that involved a third 'no-surgery' arm were less preferred compared to a two-arm-only study. Consistent with surgeons, studies that included the option to cross over at six months, before results were known, were preferred over studies that only offered crossover at 12 months, if the results found the intervention effective, and studies with a general anaesthetic were preferred to those with a regional anaesthetic. The terminology used to describe the placebo (sham vs placebo), or the number of extra appointments (none vs a couple), had no effect on preferences or participation.

Discussion

Almost half the surgeons and most of the patients selected 'no' or 'yes' to the opt-in participation question for all DCE choice-sets. This suggests that these individuals have fixed views regarding participation in RCT-Ps and would/would not participate regardless of the specific RCT-P features. For context, the target sample for knee arthroscopy RCT-Ps is around 150 (mean age approximately 50 years);[10] from our results (mean age 59 years), we can loosely infer that of 300 approached patients, 90 would participate and 120 would not participate regardless, while the participation of 90 would depend on the study. It is this latter group, who in our study indicated they would participate in some hypothetical studies but not others, that can best inform future trial designs and recruitment estimates. Estimates from a DCE on willingness to participate in placebo-controlled trials can inform formalized economic models, such as those which estimate the costs of trials based on consent rates.[20] The DCE estimates provide insights into the preferences and trade-offs that potential participants consider in their decision to consent, allowing for more accurate predictions of consent rates and costs based on specific trial designs.

There was generally alignment in the preferences between patients and surgeons, suggesting that RCT-P designs with greater chance of recruitment for patients will benefit recruitment of surgeons as well. For both groups, the type of procedure influenced the willingness to participate in RCT-Ps. This may be because arthroscopic procedures are less invasive, so are likely to be perceived as less risky, and the effectiveness of arthroscopic surgery is uncertain.[21,22] In contrast, TKAs, despite being more invasive, are widely considered to be effective procedures for people with advanced joint disease who no

longer respond to non-surgical care.[23–25] Furthermore, while there are RCTs of knee arthroplasty,[5] there have yet to be any RCT-Ps investigating the effectiveness of any joint arthroplasty procedure.[10,26] As the core question of the trial, we cannot modify the procedure under investigation, however this information can inform the recruitment feasibility of such trials.

Years of age (patients) and experience (surgeons) were another common influence across both groups, with more years leading to less participation. This is relevant for feasibility assessments of studies investigating procedures that have age-related participation criteria. In our sample, there was a significant trend of greater pain and poorer function with older age, which may contribute to older adults' reluctance to participate. The results of experience by involvement interaction for surgeons suggests that tailoring surgeon involvement in surgical RCT-Ps could be easily implemented to boost surgeon participation. Less experienced surgeons may be more interested in active research opportunities to progress their research careers.[27] More experienced surgeons, however, have potentially reached their desired career stage, with a full caseload; thus, less time commitment is more of an incentive than authorship.

For both patients and surgeons, there was a preference for general anaesthetic over regional, and for designs with a definite crossover over contingent, however these preferences did not influence participation, which was the core question of this study. As such, the exploration of these preferences, and the potential reasons for their lack of effect on participation, is noted in Supplementary Material 1.

This DCE only considered two types of procedures, both for knee surgery. The orthopaedic surgeons and patients, however, covered a range of specialities and waitlisted procedures. As such, some surgeons' and patients' results may not be reflective of their views for RCT-Ps in their own speciality area or condition, as highlighted by comments such as, "As a foot and ankle surgeon, I don't think the knee surgery scenarios would be relevant to my practice." A broader example may have been more useful, however if each respondent imagined their own speciality procedure, they would bring to the decision other distinct factors that might influence interpretation of results.

All scenarios in the DCE were of RCT-Ps, as the aim was to determine preferences between different designs of this trial type. However, many features were not specific to placebo trials, or trials generally, e.g. the procedure. These preferences could therefore reflect a general preference (e.g. patients would prefer to undergo an arthroscopy over a TKA), not relevant to RCTs or RCT-Ps. While clear instructions to participants regarding the context mitigated this uncertainty in interpretation, including scenarios that were RCTs with no placebo component, such as a purely pharmacological or non-surgical control, would have helped to determine which preferences were specific to the placebo aspect of the RCT. This would have strengthened the generalizability of the results, as these other options are part of recommended care,[28] and it is likely that future RCTs and RCT-Ps would include these as a study arm. This broader range of study arm levels was beyond the scope of this DCE, and study aim, but should be an avenue for future research.

The sample sizes for the preference question were consistent with those estimated for adequate power. Unfortunately, it was necessary to remove many participants who held 'non-modifiable views' (yes or no to all questions). As such, the interpretation of effects in the participation question was limited by a lack of statistical power. There was also a likely sample bias. Previous research has shown that RCT-Ps can elicit strong patient and surgeon views, often against placebo surgery.[10] Those with strong views on placebo surgery are potentially more likely to respond to recruitment and to dedicate time to the survey. Finally, the inclusion of a repeated or dominant alternative is an important validity check for DCEs; however, to balance other important design and validity considerations (noted in Supplementary Material 1), these were not included in our DCE.

Patients and surgeons have strong views regarding participation in RCT-Ps which can influence study recruitment. However, not all barriers are weighted equally when it comes to participation decisions, with the procedure under investigation, the age of the patients, and the level of involvement offered to surgeons as key barriers. These findings highlight the importance of considering trial designs and target procedures carefully, given that these significantly impact response rates and the likelihood of meeting recruitment targets. In areas where recruitment is known to be challenging, conducting formal recruitment feasibility assessments is crucial to ensure that only trials with sufficient patient and surgeon acceptance are funded and undertaken, maintaining a balance between rigorous scientific practice and ethical considerations.

Take home message

- There is major patient and surgeon resistance against placebo-controlled orthopaedic surgical trials, especially by potential older participants, more experienced surgeons, and in the context of more invasive operations.
- Most of these factors are non-modifiable by trials aiming for results generalizable to wide range of patients.
- While arthroscopic surgical placebo-controlled trials with younger surgeons' participation in study design and authorship may be possible, alternative designs need to be developed to gain a high level of evidence for arthroplasty surgery, as neither surgical nor patient participation is likely.

Social media

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Supplementary material

The supplementary material provides more information on: the discrete choice experiment development process, with example choice sets for both patients and surgeons; the statistical analysis, with tables of the sociodemographic and clinical characteristics of the patients and surgeons; and additional discussion points, exploring the non-significant results.

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Author information:

L. Wall, PhD (Psychology), Lecturer in Psychology, Affilliate, Post-Doctoral Research Fellow, Research Associate, School of Psychological Sciences, University of Newcastle, Newcastle, Australia; Hunter Medical Research Institute, Newcastle, Australia; Newcastle Business School, University of Newcastle, Newcastle, Australia.

S. Bunzli, BPhty (Hons) Grad Cert (Research methodology), PhD, Senior Research Fellow, School of Health Sciences and Social Work, Griffith University, Brisbane, Australia; Physiotherapy Department, Royal Brisbane and Women's Hospital, Brisbane, Australia.

E. Nelson, PhD, Clinical Research Associate
L. J. Hawke, PhD, MClinRehabNeuroPhysio, BPhysio,, Research Assistant
M. M. Dowsey, BHealthSci, MEpi, PhD, Professorial Fellow
P. F. Choong, MBBS, MD FRACS, FAOrthA, FAAHMS, MAICD, Sir Hugh Devine Professor of Surgery Head of Department of Surgery, Associate Dean Innovation & Enterprise
Department of Surgery, St Vincent's Hospital, The University of Melbourne, Melbourne, Australia.

M. Genie, PhD (Economics), MaRS Fellow, Lecturer in Health Economics, Honorary Research Fellow, Newcastle Business School, The University of Newcastle, Newcastle, Australia; Health Economics Research Unit, University of Aberdeen, Aberdeen, UK; Department of Population Health Sciences, Duke University, Durham, North Carolina, USA.

M. Hinwood, PhD (Psychology), MClinEpid, Senior Statistician, Data Sciences, Conjoint Lecturer
D. Lang, BMaths/Economics, GDipHealthEcon, Research Academic, Affiliate
Hunter Medical Research Institute, Newcastle, Australia; School of Medicine and Public Health, The University of Newcastle, Newcastle, Australia.

P. Clarke, PhD, MEconomics, Professor in Health Economics, Health Economics Research Centre, University of Oxford, Oxford, Oxford, UK; School of Population and Global Health, University of Melbourne, Melbourne, Australia.

Z. J. Balogh, MD, PhD, FRACS (Ortho), FACS, FIOTA, Director of Trauma Services and Senior Specialist Orthopaedic Trauma Surgeon, Professor of Surgery and Traumatology, Discipline Head of Surgery, Director, Injury and Trauma Research Program, Department of Traumatology, John Hunter Hospital and University of Newcastle, Newcastle, Australia.

L. S. Lohmander, MD, PhD, Professor Emeritus (Orthopaedics), Department of Clinical Sciences Lund, Orthopaedics, Lund University, Lund, Sweden.

F. Paolucci, PhD (Economics), Professor of Health Economics & Policy, Newcastle Business School, The University of Newcastle, Newcastle, Australia; School of Economics & Management, University of Bologna, Bologna, Italy.

Author contributions:

L. Wall: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing.
S. Bunzli: Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Writing – review & editing.
E. Nelson: Conceptualization, Data curation, Investigation, Methodology, Project administration, Writing – review & editing.
L. J. Hawke: Investigation, Writing – original draft, Writing – review & editing.
M. Genie: Formal analysis, Validation, Writing – review & editing.
M. Hinwood: Conceptualization, Investigation, Methodology, Writing – review & editing.
D. Lang: Conceptualization, Investigation, Methodology, Writing – review & editing.
M. M. Dowsey: Conceptualization, Funding acquisition, Investigation, Writing – review & editing.
P. Clarke: Conceptualization, Funding acquisition, Writing – review & editing.

P. F. Choong: Conceptualization, Funding acquisition, Investigation, Project administration, Resources, Writing – review & editing.
Z. J. Balogh: Investigation, Project administration, Resources, Writing – review & editing.
L. S. Lohmander: Investigation, Writing – review & editing.
F. Paolucci: Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Writing – review & editing.

Funding statement:
The authors disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: his study is part of a project supported by a National Health and Medical Research Council Project Grant (APP1163613); Professor M. Dowsey holds a University of Melbourne Dame Kate Campbell Fellowship; Professor P. Choong holds a National Health and Medical Research Council Practitioner Fellowship (APP1154203).

ICMJE COI statement:
S. Bunzli reports a project grant from National Health & Medical Research Council (#1163613), related to this study. M. Dowsey reports a project grant from National Health & Medical Research Council, related to this study, as well as grants from National Health & Medical Research Council, Medical Research Future Fund, HCF Foundation, and Eli Lilly, unrelated to this study. P. F. Choong reports grants from the Medical Research Future Fund and the National Health & Medical Research Council, royalties or licenses from Johnson & Johnson, and consulting fees from Stryker and Medacta, all of which are unrelated to this study. L. S. Lohmander reports consulting fees from Arthro Therapeutics, unrelated to this study. F. Paolucci reports a grant from the National Health & Medical Research Council (APP1163613), related to this study.

Data sharing:
Further methodological details and examples of materials are provided in the electronic supplementary material. The datasets generated and/or analysed during the current study are not publicly available due to the ethics approved consent forms and protocols not indicating the data would be stored or disseminated in a publicly available manner but are available from the corresponding author on reasonable request.

Acknowledgements:
We wish to acknowledge Josefa Henriquez for her support in implementing the DCE in Qualtrics. Artificial intelligence has not been used in any part of this research or manuscript preparation.

Ethical review statement:
Ethics approval was provided by St Vincent's Hospital, Melbourne Human Research Ethics Committee (LRR 072/19) and site approval was obtained for both hospitals. This approval was registered with The University of Newcastle Human Research Ethics committee (H-2019-0222). The study was performed in in line with the principles of the Declaration of Helsinki. All participants provided informed electronic consent for participation and publication prior to completing the online DCE.

Open access funding:
The open access fee was funded by the University of Newcastle, Newcastle, Australia.

This article was primary edited by M. Hossain.