Statistical analysis plan:

Impact of an in-consult patient decision aid on decisional quality, involvement, and health outcome for patients with severe hip or knee osteoarthritis – a study protocol for a multicentre, cluster randomised controlled trial (PATI-study)

Date: 01.02.2024

Revision date: 04.12.2024

ClinicalTrials.gov: NCT05972525

Section 1: Administrative information

1.1	Title and trial registration number	Impact of an in-consult patient decision aid on decisional quality, involvement, and health outcome for patients with severe hip or knee osteoarthritis – a study protocol for a multicentre, cluster randomised controlled trial (PATI-study) ClinicalTrials.gov: NCT05972525
1.2	Names, affiliations and roles of SAP contributers	Trine Ahlmann Pedersen[1,2], Martin Lindberg-Larsen[3,4], Charlotte Myhre Jensen[3,4], Signe Timm[2,5], Karina Dahl Steffensen[2,6], Claus Varnum[1,2] [1] Department of Orthopaedic Surgery, Lillebaelt Hospital, University Hospital of Southern Denmark, Vejle, Denmark. [2] Department of Regional Health Research, University of Southern Denmark, Odense, Denmark. [3] Orthopaedic Research Unit, Clinical Institute, University of Southern Denmark, Denmark. [4] Department of Orthopaedic Surgery and Traumatology, Odense University Hospital, Odense, Denmark. [5]Department of Oncology, University Hospital of Southern Denmark, Vejle, Denmark. [6] Center for Shared Decision Making, Lillebaelt Hospital, University Hospital of Southern Denmark, Vejle, Denmark.
1.3	Principal investigator/project lead	Trine Ahlmann Pedersen, PhD-student
1.4	Statistician/data analyst	Signe Timm / Simon Kornvig[1,2]
1.5	Reference to protocol version being used	
1.6	SAP version and revision history	**Original SAP 0007 with Revision Version 0007.1** The revision pertains to the analysis of the primary outcome. The original analysis is not feasible due to the structure of the IPC data. The original analysis methods were designed for continuous data, whereas the IPC data is categorical. The revision has been added to Section 6.2: *Primary Analysis Methods*.
1.7	Date for approval of final SAP version	01.02.2024 Revision 04.12.2024
1.8	Timeframe for conducting the proposed analysis	Vinter 2024

Section 2: Introduction

2.1	Describe briefly background, research	Osteoarthritis (OA) is the most common joint disease and a major cause of disability worldwide(1). The condition typically affects the hip or knee, and as the condition progresses it

	questions and rationale behind the study	frequently causes debilitating pain and stiffness in the affected joints; thus impairing mobility, and decreasing function and quality of life (QoL)(2, 3). Approximately 25,600 primary hip (THA) and knee arthroplasties (TKA/UKA) were performed in Denmark in 2022 (4-6). For the majority of patients with severe osteoarthritis, evidence shows that joint replacement surgery is life-changing (7, 8). Despite this documented effect, not all patients achieve optimal results. Patient dissatisfaction following THA and TKA has been reported as 7 % and 11-18%, respectively (9-11). It is hypothesized that a lack of adequate information and patient involvement in the decision process might lead to the misalignment of patients' expectations and subsequent dissatisfaction (12, 13). This strongly supports the concept that patients need to be actively involved in treatment decisions(11, 14). Accordingly, increasing patient involvement in healthcare decisions may be beneficial. Shared decision-making (SDM) supports patients' active involvement in the process and improves the quality of decisions (15, 16). SDM can be facilitated using an in-consult Patient Decision Aid (PtDA), which has shown significant benefits in a range of patient groups(17). However, research on SDM and PtDAs in patients with severe hip or knee OA is lacking (18, 19). The overall aim of this project is to investigate if an in-consultation PtDA increases the decision quality for patients with severe OA of the hip or knee.
2.2	Describe briefly objectives and/or hypotheses	**Primary objective:** 1. To investigate whether using an in-consult PtDA enhances the decisional quality for patients with severe OA of the hip or knee referred for treatment. **Secondary objectives:** 2. To investigate whether an in-consult PtDA increases patient-experienced involvement in SDM. 3. To compare durations between consultations using SDM with an in-consult PtDA and standard consultations and explore the learning curve in using the in-consult PtDA, expressed as the consultation duration. **Tertiary objectives:** 4. To determine whether consultations using the in-consult PtDA are superior to standard consultations regarding the level of changes in the patient-reported outcomes of pain, physical function and QoL at 3 and 12 months following surgery 5. To determine the association between informed patient-centred (IPC) decisions and the level of changes in the

		patient-reported outcomes of pain, physical function and QoL at 3 and 12 months after surgery. 6. To evaluate whether consultations using a PtDA are superior to standard consultations regarding patient satisfaction at 3 and 12 months after surgery. **Figure 1:** Summary of outcomes, measurement instruments and time of measurement

Section 3: Study methods

3.1	Study design Describe type of study (i.e. experimental/observational, parallel group/cross over, singlecenter/multicenter ect.) and describe briefly interventions	This study is a superiority, pragmatic two-armed, multicentre (two sites) cluster randomized controlled trial. **Standard consultation:** For patients consulting with a surgeon in the control group, standard preliminary examinations and information, according to the usual practices at each of the two orthopaedic surgery outpatient clinics, will be provided. **Intervention consultation:** Patients in the intervention group will participate in the decision-making process through SDM. This involvement is facilitated by using an in-consult PtDA, developed priori for this trial, and incorporation of standard preliminary examinations.
3.2	Randomization details (if applicable) Describe randomization i.e. allocation ratio, potential factors randomization will be stratified for and describe how and when randomization will be performed	Each cluster consisting of one hip or knee surgeon will be randomized 1:1, stratified (by site), to either continue with standard consultations or to use SDM and incorporate a newly developed in-consultation PtDA. Cluster randomization was implemented using a computer-generated randomization schedule. The randomization was stratified based on the surgeons' employment site and involved two permuted blocks, each consisting of 10 numbers. Additional blocks, each containing two numbers, were introduced to accommodate potential changes in clinical practice, such as surgeons leaving the departments or new hires during the trial period. An independent data manager developed a computer-generated list of random numbers using the randomization tool in Research Electronic Data Capture (REDCap)(20). The administrator of the randomization procedure remained blinded to block size and randomisation sequence throughout the trial period. The randomization code is securely stored in REDCap. The randomization of the clusters was disclosed to the two orthopaedic departments before the trial.

3.3	Sample size Describe calculation of sample size or reference to sample size calculation in study protocol	The required sample size was estimated, assuming a total of 15 clusters (surgeons) and an interclass correlation coefficient (ICC) of 0.02. A superiority difference between groups of 0.15 based on data from a comparable American setting, indicating a proportion of 0.40 of patients in the intervention group with high decisional quality compared to 0.25 in the control group (21, 22). To achieve a statistical power of 80%, using a two-sided significance level of 0.05, a total sample size of 615 patients will be enrolled. This corresponds to 41 patients in each cluster, with 287 in the intervention group and 328 in the control group, while accounting for an expected 20% loss to follow-up.
3.4	Hypotheses framework Describe hypotheses framework i.e. superiority, equivalence or noninferiority hypothesis testing and which group comparisons will be analysed	**Primary hypothesis** *Hypothesis 1*: Patients receiving consultations using an in-consult PtDA will achieve higher decisional quality than those receiving standard consultations. **Secondary hypothesis** *Hypothesis 2*: Patients receiving consultations using an in-consult PtDA will report greater involvement in SDM than those who receive standard consultations. *Hypothesis 3.1*: The duration will not differ between consultations using the in-consult PtDA and standard consultations. *Hypothesis 3.2*: The duration of consultations using the in-consult PtDA will decrease over time, indicating a learning curve associated with PtDA integration.
3.5	Statistical interim analyses and stopping guidelines (if applicable) Describe how and when interim analyses will be performed, and potential planned adjustment of significance level due to interim analyses. Describe guidelines for stopping the trial early.	No interim analyses are planned.
3.6	Timing of outcome assessments and follow-up Describe time points at which outcomes/covariates	**Figur 2:** Flow of study interventions and assessments ➢ **First survey at T1:** One week after visiting the orthopedic outpatient clinic, eligible patients will receive the (T1) survey in their electronic digital mailbox.

	will be measured (consider a figure to visualize the time windows of measurements – see appendix)	➢ **Second survey at T2:** Follow-up assessments (T2) will be collected through patients' digital mailboxes three months after receiving either surgical or non-surgical treatment. **Treatment received:** Six months after enrolment, project nurses will register the received treatment by reviewing the patients' electronic journals. ➢ **Second survey at T3:** The final follow-up assessments will be sent out twelve months after receiving treatment, via the patients' electronic digital mailbox.
3.7	Timing of final analysis i.e. all outcomes analysed collectively or analyses performed according to planned follow-ups	Outcomes on primary and secondary objectives will be analysed in august – december 2024

Section 4: Statistical principles and protocol deviations

4.1	Confidence intervals and P-values Specification of level of statistical significance and confidence intervals to be reported. Describe, if relevant, rationale for adjustment for multipel testing and how type 1 error will be controlled for	95% CI, $p<0.05$
4.2	Adherence/compliance and protocol deviations Define adherence/compliance and how this is assessed in the study. Define protocol deviations and which protocol deviations will be summarized and presented	In the baseline survey, concerning demographics, patients are asked whether they were introduced to an in-consult PtDA during their consultation and if they brought the PtDA home with them. Patients who are documented as receiving SDM facilitated with an in-consult PtDA and who respond “no” to both questions above are treated as a protocol deviation.
4.3	Analysis populations Define analysis population i.e. intention-to-treat, per-protocol,	All analysis wil be performed as intention-to-treat and in case of cross over, per-protocol analysis will be performed as sensitivity analysis

	complete case, safety population	

Section 5: Study population

5.1	Screening (if applicable) Describe screening data to determine eligibility (i.e. scoring and scales)	All patients with servere osteoarthritis in their hip or knee. See the consort flowchart in figure 3.
5.1	Eligibility Summarize in- and exclusion criteria	**The eligibility criteria for patients are** ➢ Patients diagnosed with severe primary OA eligible for primary THA/TKA/UKA ➢ Age>18 years ➢ Able to understand and read Danish ➢ Give informed consent ➢ Able to receive digital posts in E-boks **Patients with the following will be ineligible** ➢ Previous THA, TKA, or UKA on the contralateral side ➢ Cognitive impairment ➢ Non-OA-related reason for the visit
5.2	Recruitment and flow chart Specification of steps in the recruitment process i.e. enrollment, screening allocation for use in flow chart (see appendix)	**Enrolment:** Surgeons in both groups are tasked with screening, recruiting, obtaining informed patient consent, and handing written information to eligible patients. Eligible patients will be enrolled irrespective of their chosen treatment option and for patients treated with non-surgical treatment, their treatment start date was set to the enrolment date. Figur 1. Flow of study interventions and assessments and Figur 3. Consort Flowchart Local project nurses are responsible for ensuring that all enrolled patients were recorded, in the electronic database within Research Electronic Data Capture (REDCap).
5.3	Withdrawal/loss to follow-up Specification on how reason and timing of withdrawal or loss to follow-up will be recorded and presented (i.e. in the flow chart – see appendix)	Withdrawal/loss to follow-up will be registred in RedCap and presented in a Consort flowchart. Figur 3.
5.4	Baseline patient characteristics List of baseline characteristics and how these data will be	**Patient level**: • Introduced to SDM, facilitated with a in-consult PtDA (Were you introduced to a PtDA during the consulation and did you bring it with you home, yes/no) • Sex: (male vs. female, others) • Age at enrolment: (years)

	descriptively summarized in a “Table 1” (see appendix)	• Inclusion site: (OUH, Svendborg or SLB, Vejle). • Joint: (Knee, Hip) • Treatment form: (surgery or other treatment) • Education level: (9th grade/11-12 years, short college education, long college education, bachelor education, Master, PhD or other) • Civil status: (married, living with a partner or alone) • Income status: (Salery, other income, other) • Pain score (no pain, little pain, some pain, moderate pain, strong pain) **Cluster level:** • Surgical experience (years), • Surgeons age, (years) • Sex, (male, female, others) • Surgical joint speciality (hip, knee)

Section 6: Analysis

6.1	<u>Exposure and outcome definitions</u> Describe details on exposure i.e. assessment, definitions, units and thresholds or the intervention/treatment under study. List and describe details on primary and secondary outcomes i.e. definition of outcome and timing, specific clinical measurements and units (i.e. mmol/mol) or any calculation or transformation of data to derive the outcome (i.e. sum score, change from baseline, logarithm, quality-of-life scoring algorithm)	**Figure 1**. Summary of outcomes, measurement instruments and time of measurement Primary and secondary outcomes will be analysed and pubilsed in the main article. Tertiary objectives will be analysed three and twelve months after recived treatment, and will be publised in two follow up articles. **Primary outcome** ➢ *Hip/Knee Osteoarthritis Decision Quality Instrument (HK-DQI)* (T1) is a patient-centered questionnaire evaluating decision-making quality for arthroplasty decisions. Comprising three sections, it assesses decision-specific goals and concerns, decision-specific knowledge, and the decision-making process (21). The questionnaires were developed with significant input from patients and is a multidisciplinary team of providers, the HK-DQIs demonstrated robust psychometric properties, including retest reliability, validity, sensitivity, acceptability, and feasibility (21, 23). Both HK-DQIs have been recently translated into a Danish version and their psychometric properties rigorously tested. ➢ *Informed, Patient–Centered Decision (IPC*) (T1) is calculated as the percentage of patients who are well-informed (answering at least three out of five knowledge questions correctly) and received their preferred treatment, a concordance score. IPC is based on data from HK-DQI presenting the knowledge score and concordance score together (22).

		➢ *Treatment received (T3)* is recorded using a self-designed assessment tool assessing whether surgical or non-surgical treatments were received after consultation visits. ➢ *Demographics (T1*) includes information including age, gender, education level, income status, PtDA handout (yes, no), and a single-item self-reported pain score. **Secondary outcome** ➢ *Collaborate (T1*) is a three-item patient-reported outcome measure assessing the level of SDM in the clinical encounter, evaluating healthcare quality and provider performance (24). ➢ Duration of consultation *(T1)* is measured by documenting the time duration of consultations.
6.2	Primary analysis methods Describe in details which statistical methods will be used (i.e. regression), how treatment effects will be presented (i.e. which effect measure - OR, HR etc.) and if estimates will be adjusted for covariates (see appendix). If analyses will be adjusted for covariates, describe how the sufficient adjustment set will be defined (i.e. using DAGs) Describe methods used to check assumptions (i.e. normality, proportional hazards) behind the statistical models, and alternative methods if assumptions about distribution do not hold.	Analysis are only decribed on primary and secondary objectives. **Primary objective:** 1. Analysed in mixed effect linear regression models using surgeon as random effects. **Revisions:** Due to the structure of the IPC, the original analyses are not feasible, as the IPC data is categorical. 1. Analysed in a multilevel mixed-effects logistic regression, using surgeons as random effects. The odds ratio for the intervention will be reported with a 95% confidence interval and p-value to determine whether the effect is significant. **Secondary objectives:** 2. Analysed in mixed effect linear regression models using surgeon as random effects. 3. In case of normal distribution, consultation time will be analysed using t-test comparing mean consultation time among surgeons using PtDA and not using PtDA. Normality will be checked using histograms. In case of non-normality, consultation time will be analysed using Wilcoxon Ranksum test. The learning curve will be explored in descriptive analysis.
6.3	Additional analysis methods Describe any planned sensitivity and subgroup analysis including how	Since ceiling effects are common in several assessment scores of SDM, mixed effect Tobit regression(25) will be applied as sensitivity analysis to investigate the potential influence of ceiling effects.

	subgroups will be defined (see appendix).	
6.4	Missing data Describe how missing data will be explored and which assumptions and methods will be used to handle missing data (i.e. multiple imputation)	Data will be analyzed according to the amount of missing data. If missing data is <5%, a complete case will be performed. If >5% is missing, an investigation of missing structures will be carried out with a view to a possible potential imputation.
6.5	Harms (only applicable in experimental studies) Describe the collection of safety data i.e. data on severity, expectedness, causality. Describe grouping and analyses planned i.e. incidence analyses on grade 3-4 events only.	N.A.
6.6	Statistical software Specify statistical packages to be used for the analyses	STATA18

Appendix: Figure and tables

Figure 1 Summary of outcomes, measurement instruments and time of measurement

Outcome Domain	Measurement instruments	Objectives	Consultation	(T1)	(T2)	Six months post-consultation	(T3)	Score range	Items: *N* (range)
Demographics	**Demographic questionnaire**			X				-	
IPC decision	**Concordance** and **Knowledge scores (HK-DQI)** (21)	1, 6		X				Cat (yes [0]/no [1])	Concordance score Knowledge sum score (0–1)
Knowledge score	**Knowledge score (HK-DQI)** (21)	1		X				Con (0–100)	Five items (0–5)
Treatment received	**Patient journal**	1				X		Cat (non-surgical [0]/surgical [1])	One item (0–1)
Patient involvement	**Decisional process score (HK-DQI)** (21)	2		X				Con (0–100)	Five items (0–4)
Patient-reported engagement	**CollaboRATE** (26)	2		X				Con (0–100)	Three items (0–9)
Time duration	**Self-documented**	3	X					Con (minutes)	-
Quality of life	**EQ-5D-5L** (27)	4, 6		X	X		X	Con (−0.757–1.000)	Five items (1–5)
Physical function	**OHS** (28)	4, 6		X	X		X	Con (0–48)	12 items (0–4)

Physical function	**OKS** (29)	4, 6		X	X		X	Con (0–48)	12 items (0–4)
Physical function	**FJS** (30)	4, 6		X	X		X	Con (0–100)	12 items (1–5)
Patient satisfaction	**One question on satisfaction with received treatment**	5			X		X	Cat (yes/no)	One item (0–1)
Decision regret	**Decision regret scale** (31)	5			X		X	Con (0–100)	Five items (0–4)

Categorical (Cat); Continues (Con). T1: 1-week post visit. T2: 3 months after treatment received. T3: 12 months after treatment received.

Figure 2: Study interventions and assessments timeline for surgical and non-surgical patients

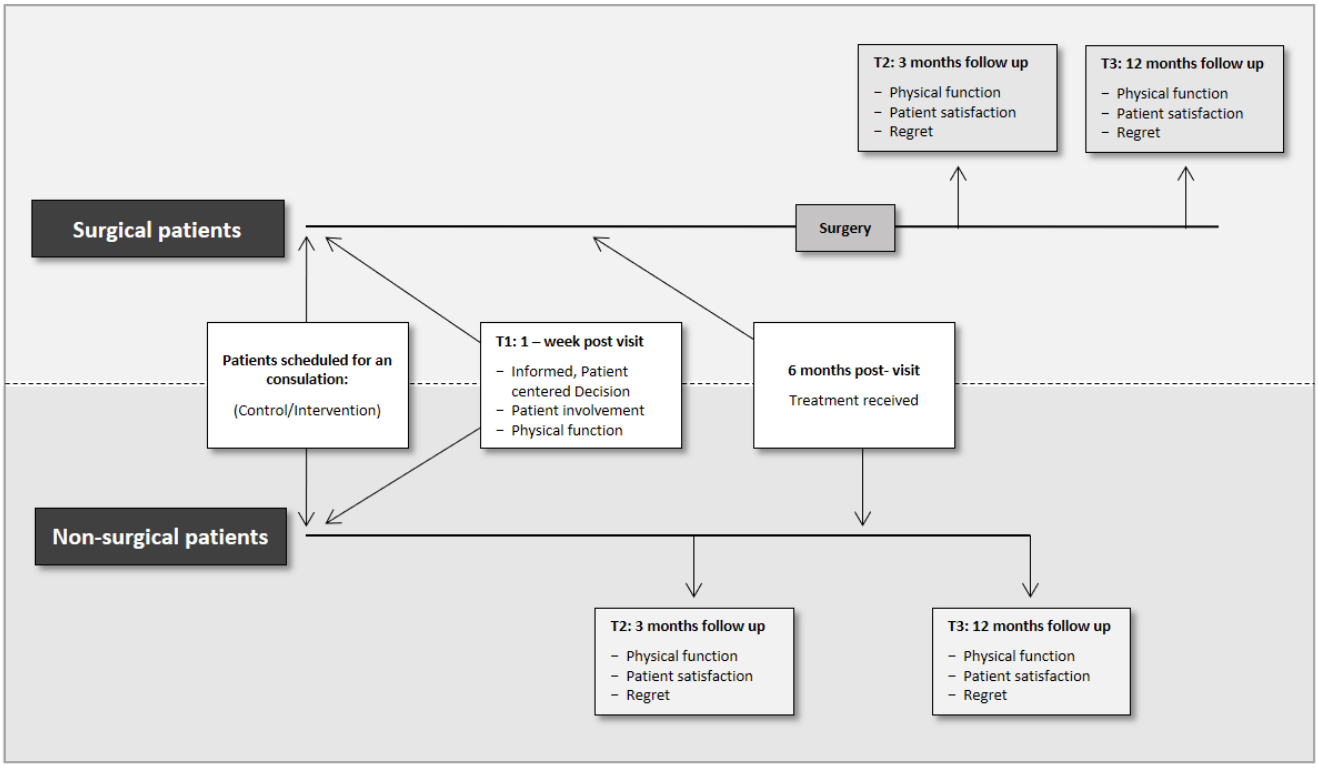

Figure 3: Flow chart template for randomized trials

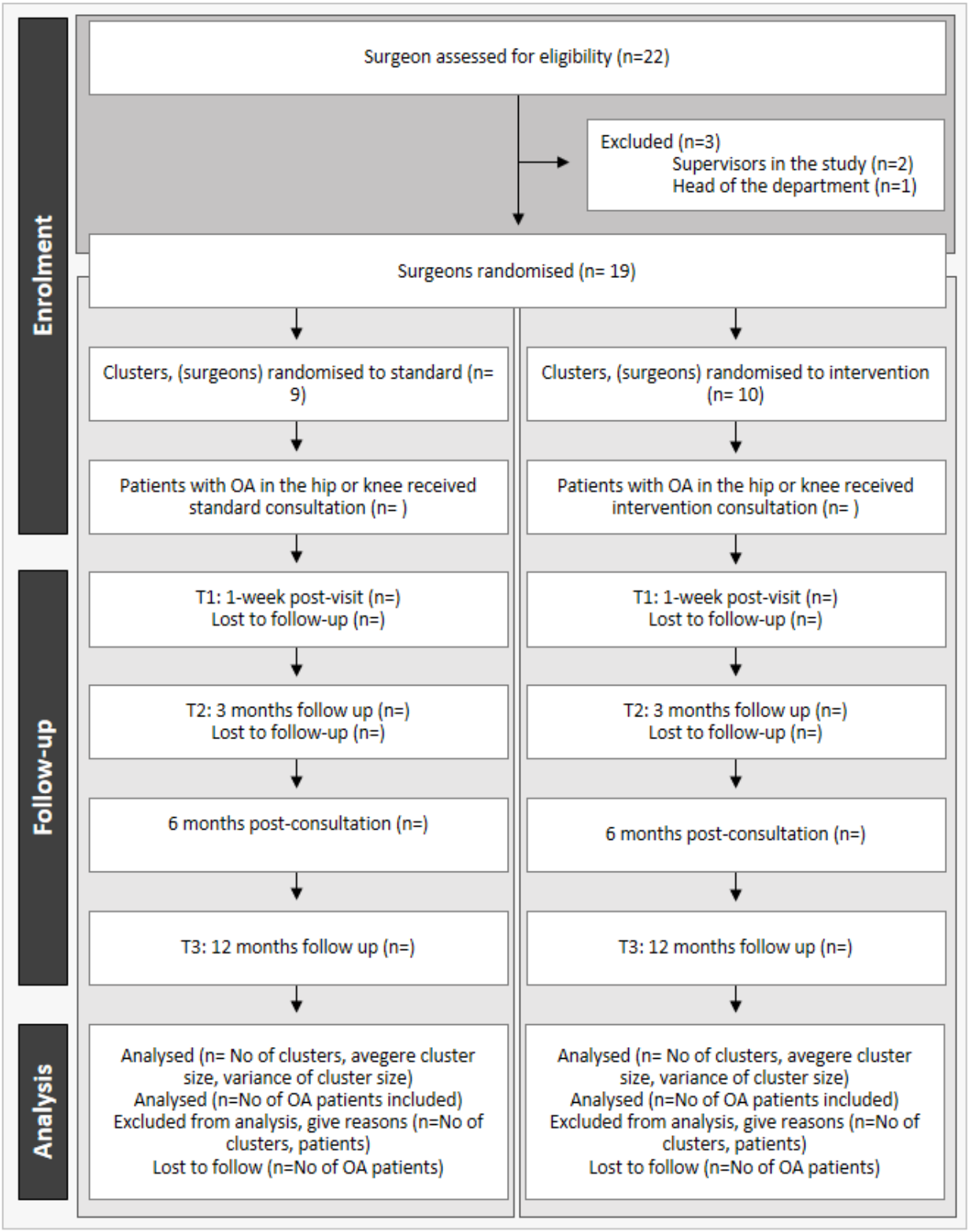

Fig. 3 CONSORT flow diagram, extended version for C-RCTs at both cluster and individual levels. Clusters: surgeons; T1: one-week post-visit; T2: three months after treatment; T3: 12

Table 1 Baseline demographics characteristic

	Intervention (N = xx)	Control (N = xx)	All (N = xx)	Missing
Patient level				
Age, mean ±SD	xx (xx)	xx (xx)	xx (xx%)	xx (xx%)
Gender, N (%F)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Joint, N (%F)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Knee	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Hip	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Income status (%)	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Salary	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Other income (pension, ect)	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Other	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Education (%)	xx (x%)	xx (x%)	xx (x%)	xx (x%)
High school or less	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Some college	xx (x%)	xx (x%)	xx (x%)	xx (x%)
≥ College graduate	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Other	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Civil status (%)				
Married/ Living with a partner	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Living alone	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Other	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Treatment scheduled (%)				
Operation	xx (x%)	xx (x%)	xx (x%)	xx (x%)

Other treatment	xx (x%)	xx (x%)	xx (x%)	xx (x%)
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
OKS/OHS overall score **mean ±SD**	xx (xx)	xx (xx)	xx (xx%)	xx (xx%)
Cluster level				
Surgeon age **mean ±SD**	xx (xx)	xx (xx)	xx (xx%)	xx (xx%)
Surgical experience, age **mean ±SD**	xx (xx)	xx (xx)	xx (xx%)	xx (xx%)
Gender, N (%F)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Joint speciality, N (%F)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Knee	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Hip	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

SD= standard deviation**. Education:** The Danish education system are converted into the international education system.

References

1. Steinmetz JD, Culbreth GT, Haile LM, Rafferty Q, Lo J, Fukutaki KG, et al. Global, regional, and national burden of osteoarthritis, 1990–2020 and projections to 2050: a systematic analysis for the Global Burden of Disease Study 2021. Lancet Rheumatol. 2023;5(9):e508-e22.

2. Hunter DJ, Bierma-Zeinstra S. Osteoarthritis. Lancet. 2019;393(10182):1745-59.

3. Katz JN, Arant KR, Loeser RF. Diagnosis and treatment of hip and knee osteoarthritis: A review. J Am Med Assoc. 2021;325(6):568-78.

4. Højgaard B. Fem megatrends der udfordrer fremtidens sundhedsvæsen.: KORA 2017; [Available from: https://www.vive.dk/da/udgivelser/fem-megatrends-der-udfordrer-fremtidens-sundhedsvaesen-8760/.

5. (DHR) TDHAR. The Danish Hip Arthroplasty Register (DHR), 2022, National Annual Report. http://www.dhr.dk/2022 [Available from: https://www.sundhed.dk/content/cms/98/4698_dhr_aarsrapport_2022.pdf.

6. (DHR) TDKAR. The Danish Knee Arthroplasty Register (DHR), 2022, National Annual Report. http://www.dhr.dk/2022 [Available from: https://www.sundhed.dk/content/cms/99/4699_dkr-aarsrapport-2022_udgivet2023_offentliggjort_version.pdf.

7. Lovelock TM, Broughton NS, Williams CM. The popularity of outcome measures for hip and knee arthroplasties. The Journal of arthroplasty. 2018;33(1):273-6.

8. Beswick AD, Wylde V, Gooberman-Hill R, Blom A, Dieppe P. What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients. BMJ Open. 2012;2(1):e000435.

9. Okafor L, Chen AF. Patient satisfaction and total hip arthroplasty: a review. Arthroplasty. 2019;1(1):6.

10. Kahlenberg CA, Nwachukwu BU, McLawhorn AS, Cross MB, Cornell CN, Padgett DE. Patient satisfaction after total knee replacement: A systematic review. HSS journal : the musculoskeletal journal of Hospital for Special Surgery. 2018;14(2):192-201.

11. Neuprez A, Delcour JP, Fatemi F, Gillet P, Crielaard JM, Bruyère O, et al. Patients' Expectations Impact Their Satisfaction following Total Hip or Knee Arthroplasty. PloS one. 2016;11(12):e0167911.

12. Conner-Spady BL, Bohm E, Loucks L, Dunbar MJ, Marshall DA, Noseworthy TW. Patient expectations and satisfaction 6 and 12 months following total hip and knee replacement. Quali Life Res. 2020;29(3):705-19.

13. Jain D, Bendich I, Nguyen LL, Nguyen LL, Lewis CG, Huddleston JI, et al. Do patient expectations influence patient-reported outcomes and satisfaction in total hip arthroplasty? A prospective, multicenter study. The Journal of arthroplasty. 2017;32(11):3322-7.

14. Tilbury C, Haanstra TM, Verdegaal SHM, Nelissen R, de Vet HCW, Vliet Vlieland TPM, et al. Patients' pre-operative general and specific outcome expectations predict postoperative pain and function after total knee and total hip arthroplasties. Scand J Pain. 2018;18(3):457-66.

15. Zikmund-Fisher BJ, Couper MP, Singer E, Levin CA, Fowler FJ, Jr., Ziniel S, et al. The DECISIONS study: a nationwide survey of United States adults regarding 9 common medical decisions. Medical decision making : an international journal of the Society for Medical Decision Making. 2010;30(5 Suppl):20s-34s.

16. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. BMJ (Clinical research ed). 2010;341(oct14 2):c5146-c.

17. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database of Systematic Reviews. 2017(4).

18. Stacey D, Hawker G, Dervin G, Tugwell P, Boland L, Pomey M-P, et al. Decision aid for patients considering total knee arthroplasty with preference report for surgeons: A pilot randomized controlled trial. BMC musculoskeletal disorders. 2014;15(1):54.

19. Van der Sluis G, Jager J, Punt I, Goldbohm A, Meinders MJ, Bimmel R, et al. Current status and future prospects for shared decision making before and after total knee replacement surgery—A scoping seview. Int J Environ Res Public Health. 2021;18(2):668.

20. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(2):377-81.

21. Sepucha K, Stacey D, Clay C, Chang Y, Cosenza C, Dervin G, et al. Decision quality instrument for treatment of hip and knee osteoarthritis: A psychometric evaluation. BMC musculoskeletal disorders. 2011;12:149.

22. Sepucha K. Hip and Knee Osteoarthritis. Informed, Patient-Centered Decision Measure. Users Guide. 2019 [Available from: https://mghdecisionsciences.org/wp-content/uploads/2020/01/2019-hip-and-knee-ipc-user-guide.pdf.

23. Sepucha KR, Levin CA, Uzogara EE, Barry MJ, O'Connor AM, Mulley AG. Developing instruments to measure the quality of decisions: early results for a set of symptom-driven decisions. Patient Educ Couns. 2008;73(3):504-10.

24. Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G. The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. Journal of medical Internet research. 2014;16(1):e2.

25. McBee M. Modeling Outcomes With Floor or Ceiling Effects: An Introduction to the Tobit Model. Gifted Child Quarterly. 2010;54(4):314-20.

26. Elwyn G. CollaboRATE Glyn Elwyn2013 [Available from: http://www.glynelwyn.com/collaborate-measure.html.

27. Jensen CE, Sørensen SS, Gudex C, Jensen MB, Pedersen KM, Ehlers LH. The Danish EQ-5D-5L value set: A hybrid model Using cTTO and DCE Data. Applied Health Economics and Health Policy. 2021;19(4):579-91.

28. Paulsen A, Odgaard A, Overgaard S. Translation, cross-cultural adaptation and validation of the Danish version of the Oxford hip score. Bone & Joint Research. 2012;1(9):225-33.

29. MK AM-P, Nielsen R, Paulsen A, Odgaard A, editors. Translation and classical test theory validation of the Danish version of the Oxford Knee Score. Abstract, Danish Orthopaedic Society, annual congress; 2019.

30. Larsson A, Rolfson O, Kärrholm J. Evaluation of Forgotten Joint Score in total hip arthroplasty with Oxford Hip Score as reference standard. Acta orthopaedica. 2019;90(3):253-7.

31. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, et al. Validation of a decision regret scale. Medical decision making : an international journal of the Society for Medical Decision Making. 2003;23(4):281-92.