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Protocol for a randomized trial evaluating the comparative effectiveness of strategies to promote shared decision making for hip and knee osteoarthritis

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ABSTRACT

Introduction:

Shared decision making (SDM) is increasingly recommended for patients considering elective procedures, such as hip and knee replacement surgery. There are several different interventions that may promote SDM including patient decision aids (DA) and provider-directed tools. However, little is known about the comparative effectiveness of different decision support interventions. The goal of this clinical trial is to examine the impact of patient- and physician-directed decision support strategies on the quality of treatment decisions for hip and knee osteoarthritis (OA).

Methods and Analysis:

The multi-site study is a 2x2 factorial randomized controlled trial. Patients are randomly assigned to receive one of two different DAs. Surgeons are randomly assigned to receive a report detailing patients' goals and treatment preferences at the time of the visit or not. The enrollment targets are eight surgeons and 1,120 patient subjects. Eligible patients receive the DA before their new patient consultations and complete three surveys: (T1) before the visit, (T2) 1 week after the visit, and (T3) six months from either the visit or from the date of surgery for patients who underwent surgery. The primary study outcome is decision quality, the percentage of patients who are well-informed and received their preferred treatment. Secondary outcomes include involvement in decision making, surgical rates, health outcomes, decision regret and satisfaction. A logistic regression model with the Generalized Estimating Equations approach will be used to compare rates of decision quality between the groups and account for the clustering of patients within providers.

Ethics and Dissemination: Ethics approval was obtained through the institutional review board at all three participating sites. The findings will be published in peer-reviewed journals.

Keywords: shared decision making, comparative effectiveness, decision aid, surgery, osteoarthritis

Strengths and Limitations of the Study:

1. This large, multi-site randomized controlled trial will provide important evidence on the comparative effectiveness of two leading patient decision aids that vary in the amount of detail, level of interactivity, and use of patient narratives.
2. The study also includes a clinician-focused intervention, as the literature suggests that intervention strategies directed at both patients and clinicians may have the biggest impact.
3. Data will be collected from patients before the initial visit with the surgeon, shortly after the visit with the surgeon, and again about six months later to shed light on short and longer term impacts of the decision support strategies.
4. The study is adequately powered to examine the impact in key subgroups, including older patients and patients with low literacy, as well as to examine whether there are differences in those who review the patient decision aids online versus on paper.
5. The study staff and participating surgeons are not blinded to the interventions which is a limitation; however, the statistician conducting the analyses will be blinded to the arms.

Clinical trial registration: Clinicaltrials.gov #: NCT02729831.

1. INTRODUCTION

Hip and knee osteoarthritis (OA) are among the most prevalent chronic diseases in the U.S.[1] Joint replacement surgery is a common treatment for osteoarthritis with a recent estimate indicating that 600,000 knee replacements are performed in the U.S. each year alone.[2] Clinical guidelines for the treatment of OA highlight the importance of informing patients about their surgical and non-surgical treatment options.[3,4] Engaging in shared decision making (SDM) is recognized as an integral strategy to help patients choose the best treatment for them.[5]

Patient decision aids (DA) can help inform patients about their relevant treatment options and promote shared decision making.[6,7] Although there are more than 105 randomized controlled trials of DAs, the literature comparing different DAs is sparse.[8, 9] Further, while DAs can help prepare patients to participate in SDM, it is also important to support surgeons to engage in SDM during a medical visit.[10] There is only one small randomized controlled trial that has examined the impact of patient- and surgeon-directed interventions on decision making in hip and knee osteoarthritis.[11]

The purpose of this randomized controlled trial study is to compare the effectiveness of two DAs for treatment of hip and knee OA and a surgeon-directed intervention.

2. METHODS AND ANALYSIS:

This clinical trial protocol follows the SPIRIT guidelines (see SPIRIT checklist in supplemental files).[12, 13] The underlying protocol follows the CONSORT guidelines and the Standards for Universal Reporting of Decision Aid Evaluations (SUNDAE) guidelines (see SUNDAE checklist in supplemental files).[14-17] The trial was registered on clinicaltrials.gov (NCT02729831).

2.A. Specific Aims

Aim 1: Evaluate comparative effectiveness of two patient DAs (DA-A vs. DA-B) and a surgeon-focused intervention (usual care vs. Patient Preference Report (PPR), which includes patients' goals and treatment preferences) on their ability to achieve high decision quality.

Hypothesis 1.1: Overall, patients who receive DA-A will have higher decision quality than those who receive DA-B.

Hypothesis 1.2: Patients who receive DA-A, with more comprehensive information and videos to make the information more salient, will have higher knowledge scores than those who receive DA-B.

Hypothesis 1.3: More patients who receive DA-B, with the explicit values clarification exercise, will have a clear treatment preference than those who receive DA-A.

Hypotheses 1.4: The PPR group will have higher rate of concordance, i.e. more patients who receive treatments that match their goals, compared to usual care group.

Aim 2: Follow participants for 6-12 months to determine the impact of the decision support strategies on treatment choices and health outcomes, specifically, overall quality of life and functional status.

Hypothesis 2.1: Patients with high decision quality (i.e. informed and received preferred treatments) at one week from their visit will have better health outcomes at one year compared to those with low decision quality.

Hypothesis 2.2: Patients with high decision quality at one week will have lower surgical rates at one year compared to those with low decision quality.

Aim 3: Identify patient-, physician- and intervention-level factors associated with effectiveness for the DAs. These factors include (1) patient characteristics (e.g. age, gender, education level, and joint (hip or knee), (2) provider characteristics (e.g. years since graduation, surgical volume),

(3) intervention compliance (e.g. whether patients reviewed the DAs and amount of time spent reviewing the DAs) and (4) mode of delivery (online or hardcopy).

2.B. Study Design

This study compares two high quality DAs that differ in the format, amount of content, and level of interactivity, and will examine the impact on decision quality, treatment selection and health outcomes. The study also examines the impact of a surgeon-focused intervention—a PPR detailing patients' goals and treatment preferences—vs usual care. Because the patient DA and the provider PPR may work together to improve decisions better than each on their own, we selected a 2X2 factorial randomized trial design to compare the interventions. Factorial studies allow for efficient examination of multiple interventions and are also particularly well-suited when two interventions have a potential interaction, as the design enables the examination of the benefits of each intervention separately as well as both interventions together.[18]

2.C. Conceptual framework

The study is based on the conceptual framework of SDM as outlined in Mulley [19] and Sepucha and Mulley [20, 21] that views SDM as a systems approach to enable continuous improvement in clinical decision making. The framework recognizes the fundamentally social nature of the decision-making task; it cannot be completed by the health care provider or patient alone but rather requires productive interactions between them. The interventions chosen for this study address the key elements of the conceptual framework. The DAs help surgeons convey the evidence to patients in ways that they can access and understand. The surgeon intervention will help patients communicate their treatment preferences to the surgeons in a structured manner.

Together, these interventions will work to ensure high quality decisions that are evidence-based and patient-centered.

2.D. Participants, interventions and outcomes:

Participants and setting:

Patients and physicians were recruited from the orthopedic departments of three sites: a large academic medical center in an urban setting, a community hospital in suburban environment, and an orthopedic specialty hospital in an urban setting. Two of the three sites were selected because of their access and use of DAs as part of routine care, as well as their common electronic medical record. A third site was added to meet recruitment targets. Patients scheduled for an appointment with an orthopedic surgeon were screened two weeks prior to their visit date (pre-visit screening) for study eligibility. Study staff called patients, as needed, to collect eligibility information that was not available in the medical record.

The eligibility criteria for patients are:

- Diagnosis of knee or hip osteoarthritis (confirmed via x-ray)
- Age 21 or older
- Attends visit with a participating orthopedic specialist

Patients with the following will be ineligible:

- Partial or total knee or hip replacement surgery within 5 years of being screened
- Received patient decision aid within 1 year of visit
- Hip fracture or aseptic necrosis in 12 months prior to visit
- Rheumatoid arthritis or psoriatic arthritis diagnosis
- Does not read or write in English or Spanish

- Cognitive impairment (unable to consent for self)
- Non-osteoarthritis related reason for visit

Interventions**:**

The DAs are not publicly available. Two of the sites had existing licenses to use the DAs, and the PI obtained a license agreement to use the DAs as part of the study at all sites. Table 1 provides details of the various elements of the two DAs.

- Decision Aid-A: *Treatment Choices for Knee Osteoarthritis* ©Health Dialog is a 42-minute DVD and 38-page booklet (Over the course of the study the DA was updated, and the following versions were used: English: Booklet V08/DVD V07 ©2016 and Booklet V07A/DVD V06A ©2014; Spanish Booklet V07/DVD V07 ©2014; Booklet V08/DVD V08 ©2016) and *Treatment Choices for Hip Osteoarthritis* ©Health Dialog is a 44-minute DVD and 40-page booklet (English: booklet V06A/DVD V06A ©2014 and booklet V07/DVD V07 ©2016; Spanish: booklet V06/DVD V07 ©2014 and booklet V07/DVD V08 ©2016). The same content is also available online through Health Dialog's secure website. Health Dialog has 40 different decision aids that have been evaluated in 20 randomized controlled trials. The DAs have been shown to increase knowledge, reduce decisional conflict and increase decision quality. Spanish language versions were also available online or in paper booklet form.[22]
- Decision Aid-B: *Knee Osteoarthritis: Is it time to think about surgery?* ©Healthwise 2016 and *Hip Osteoarthritis: Is it time to think about surgery?* ©Healthwise 2016 are available online or as a 17-page printed brochure. They include 6 sections (get facts, compare options, your feelings, your decision, quiz, and summary).[23, 24] Healthwise has more than 180 *Decision Points* and these were accessed over five million times in 2014. The hip and knee

arthritis *Decision Points* were among the top five accessed topics. English and Spanish versions of Healthwise decision aids were made available for this trial.

- Patient Preference Report (PPR): a one-page sheet that includes patients' goals for the visit, impact of disease on activities, and treatment preference. The sheet was developed with input from a patient advisory group (n=6), an expert in decisions sciences, a primary care physician, a nurse practitioner and two orthopedic surgeons.

Table 1. Design features of Decision Aid-A and Decision Aid-B

Design feature	Decision Aid-A	Decision Aid-B
Format	Paper and DVD or online	Paper or online
Treatment options	*Nonsurgical options*: • Lifestyle changes; Physical therapy; Walking aids; Pain medications; Injections (**knee only**); Complementary approaches *Total Joint Replacement* *Partial Joint Replacement* (**knee only**)	*Nonsurgical options*: • Generic discussion of nonsurgical options *Total Joint Replacement*
Essential information by itself, first[a]		X
Video to improve salience of patient narratives and information[a]	X	
Components in PDA		
• Explicit description of the decision	X	X
• Description of health problem	X	X
• Information on options and their benefits, harms, and consequences	X	X

Design feature	Decision Aid-A	Decision Aid-B
• Values clarification (implicit or explicit)	Implicit, patient narratives	Explicit, rating of goals and concerns
• Numerical probabilities	X	X
• Tailoring of information or probabilities		
• Guidance in deliberation	X	X
• Guidance in communication	X	X
• Personal stories	X	
• Reading level or other strategies to help understanding	Not available	Not available

[a]These design features have been shown to be effective in low literacy populations.[25]

Sample Size:

The sample size calculations considered both the potential for interaction effects between the two sets of interventions as well as the potential impact of clustering of patient participants within surgeons. In the situation where an interaction between DAs and PPR report is unlikely, the patients from both usual care and PPR groups will be combined for the comparisons between the two DAs. We planned to have eight surgeons at the sites enroll patients. With an average of 140 patients in each provider cluster, the inflation factor was estimated to be 1.96 based on the assumption of an intraclass correlation coefficient (ICC) of 0.01. A sample size of 280 participants in each group at the T1 survey is equivalent to an effective sample size of 117. Similarly, a sample size of 210 at the T2 survey is equivalent to an effective sample size of 100 patients per group and a sample size of 178 participants in each group at T3 survey is equivalent to an effective sample size of 95 patients per group. Details on sample size and power calculations for hypotheses within each aim are included in the analysis plan.

Outcomes:

Our primary outcome is decision quality, defined as the percentage of patients who are well informed and received their preferred treatment. The Hip or Knee Decision Quality Instruments will be used to measure the primary outcome.[26] Secondary outcomes include involvement in decision making, surgical rates, patient-reported health outcome measures, decision regret and satisfaction.

Delivery of interventions and assessments**:**

The study activities including screening, recruitment, and intervention and survey delivery. The sequence of activities within the orthopedic clinic flow is illustrated in Figure 1.

- *Decision aid delivery*: Trained study staff screened new patients from the orthopedic clinical schedule across the three sites. Eligible patients received their assigned DA two weeks prior to their visit. The DA was sent electronically to patients who are enrolled in the site's online patient portal and mailed to all others.
- *First survey at Timepoint 1 (T1)*: A mailed packet was sent to all participants which included a cover letter, information sheet and the T1 survey. The DA was included in the same packet as the T1 survey for patients receiving a paper copy. For patients receiving the DA online, instructions for how to access the online portal was included with the T1 survey.
- *Patient Preference Report (PPR) delivery*: For patients seeing a surgeon in the PPR group, the PPR was included as part of the T1 survey. In the waiting room before the patient's visit, study staff collected the completed survey from patients, made two copies of the PPR page, and gave one to the patient and the other to the surgeon in advance of the visit.

- *Second survey at Timepoint (T2)*: After the visit, study staff screened visit notes for enrolled patients to confirm eligibility. Eligible patients received the T2 survey either via mail or email (depending on patient preference as indicated on the T1 survey) approximately one week after their visit.
- *Third survey at Timepoint 3 (T3)*: Approximately 6 months after initial visit, study staff called patients to remind them about the study follow up assessment, confirm surgical status and their preferred method for receiving the T3 survey (mail or email). Patients were sent the T3 survey 6 months after their date of surgery, or 6 months after their visit if they did not have surgery within 6 months.

Recruitment Strategies**:**

Figure 2 is the CONSORT Flow diagram and includes estimates for screening, enrollment and response rates. To meet our sample size requirements, we needed 1,120 patients to complete the T1 survey, 840 to complete the T2 survey, and 716 to complete the T3 survey. Several strategies were implemented during the enrollment period to achieve the target sample size. After sending out the DA with the invitation to participate, study staff called patients who did not opt out prior to their visit date to answer any questions about the study. This call also served as a reminder to the patients to review the DA before the visit and to complete the T1 survey. Study staff also offered to administer the survey over the phone. On the day of the visit, the study staff met with eligible patients in clinic waiting room. Staff answered questions and brought extra copies of the T1 surveys to administer the survey in clinic if needed.

2.E. Randomization and blinding:

Two randomizations occurred: one at the patient-level and one at the surgeon-level. Within each site, surgeons were divided into two groups stratified by years in practice and patient volume, then the two groups were randomly assigned to usual care or PPR by the statistician. Patients were randomized to DA-A or DA-B, using a computer-generated allocation sequence, prior to enrollment in the study. For any patient participant found to be ineligible for the study after randomization, the original assignment was re-assigned to the next eligible patient.

Patient participants were not blinded to the DA assigned to them; however, they were not given any explicit information on the other DA or their surgeon's assignment. Likewise, surgeons were not blinded to their intervention group, but they were not given any specific information on the type of DA the patient received. It was possible for surgeons to find out their patients' assignment; patients may have brought the DA with them to the visit, or surgeons could have opened the patient education note in the electronic medical record that included the specific title of the DA.

Study staff who recruited participants and approached them in clinic were not blinded to the DA assignment, as they were responsible for mailing the DAs to patients. However, the study staff responsible for data entry did not have information on the DA assignment when entering the paper surveys. The analytic data set will be de-identified to maintain blinding during the analysis process.

2.F. Data collection, management and analysis

Data collection:

Paper and online surveys were used to collect patient reported outcomes. The first (T1) survey was mailed to patients before their visit. The second (T2) and third (T3) surveys were sent to patients either via mail or email based on patient preference. Study staff followed-up with a phone reminder about one week after sending the surveys, followed by a mailed reminder or up to three email reminders, and a second phone reminder for all the participants who did not complete the surveys. Participants who received the survey by email also got the survey in the mail if they did not complete it online within two weeks. During the reminder calls, study staff gave participants the option to complete the survey by phone. A $5 cash incentive was included with the T2 and T3 assessments. A study database tracked all participant contact and was used to monitor the consistency of the reminder protocols.

The patient surveys and time administered are as follows:

- *Hip OA and Knee OA Decision Quality Instruments (DQI) (T1, T2)*: Each DQI contains 5 decision-specific, multiple-choice knowledge items, 5 decision-specific goals and concerns (rated on an 11-point importance scale), and one treatment preference item. The DQI results in a knowledge score (0-100%) and a concordance score (0-100%) indicating the percentage of patients who received treatments that matched their stated preference. The minimal important changes in knowledge and concordance scores are 10%.[26]
- *Shared Decision-Making Process Survey (T2, T3)*: 7 items that assess discussion of four elements of shared decision-making: options, pros, cons and preferences. A total score is generated (0-4) with higher scores indicating more shared decision making.[6]

- *Functional goals (T1/T2, T3)*: Participants listed the top three things that they needed or wanted to do but were unable to do because of their knee or hip pain (at T1 for the PPR group and at T2 for the usual care group). Then at T3, they indicated to what extent they were able to do those three things and how important those goals still were.
- *SURE scale (T2)*: A brief, 4-item version of the widely used Decisional Conflict Scale that measures patients' uncertainty about which treatment to choose and factors contributing to uncertainty (feeling uninformed, unclear values, and unsupported in decision making).[27, 28]
- *Decision regret (T3)*: A 5-item Likert scale that measures distress or remorse after a decision. A total score (0-100) is calculated with higher scores indicating more regret. The scale has demonstrated strong internal consistency (0.81-0.92) and correlates with decision satisfaction and quality of life.[29]
- *EQ-5D (T1, T3)*: A 6-item summary measure of overall health status.[30] It generates a single index value for health status on which full health is assigned a value of 1 and death a value of 0. In conjunction with weights established for the 243 different combinations, the EQ-5D can be used to obtain quality-adjusted life years.[31] The minimum important change is 0.1 points.[32]
- *Knee injury and osteoarthritis score (KOOS) (T1, T3)*: The KOOS was developed to assess patients' opinions about their knee and associated problems and has been used extensively.[33-41] Three subscales were used in this study: pain, symptoms, and functional status. A normalized score (100 indicating no pain/symptoms and 0 indicating extreme pain/symptoms) is calculated for each subscale.

- *Harris Hip Score (HHS) (T1, T3)*: The HHS assesses pain, function, range of motion and deformity for each hip. Pain receives 44 points, function 47 points, range of motion 5 points, and deformity 4 points for a total of 100 points. Function is subdivided into activities of daily living (14 points) and gait (33 points). The higher the HHS, the less dysfunction. A total score of 70 is considered a poor result; 70 – 80 is considered fair, 80 –90 is good, and 90 – 100 is an excellent result. No normative values are available.[42, 43]
- *Decision aid usage (T1, T2)*: 1 item assessed how much of the DVD, booklet and/or website was reviewed (all, most, some, none).
- *Treatment received (T3, chart review)*: Surgical and non-surgical treatments tried since the consultation visit were self-reported by patients and collected via chart review.
- *Expectations (T2, T3)*: 10 items assessed expectations at T2 for pain relief and limitations in daily activities. At T3, patients are asked if their function after surgical or non-surgical treatment is worse, about, or better than they expected.[44]
- *Demographics (T2)*: Information such as education, race, and ethnicity will be self-reported.
- *Satisfaction (T3)*: Two questions assess overall satisfaction with quality of visit and treatment outcome.
- *Collaborate score (T2)*: Three item patient-reported measure of shared decision making and patient satisfaction at a clinical encounter.[45]
- *Single-item literacy screener (T1)*: One question assessing how often patients need help reading and understanding medical paperwork.[46]

Data management:

Study staff reviewed surveys within a week of receipt and flagged any missing answers or comments that suggested a problem with the survey to discuss with the PI and study team. The staff contacted patient participants up to three times to acquire answers to missing items. Study staff were responsible for data entry of the paper surveys into Research Electronic Data Capture (REDCap), a HIPAA-approved web application. Study staff conducted double coding on 10% of surveys collected over the first 6 months of the recruitment period. We stopped double coding after a 99.5% rate of agreement between entered and double-coded surveys was achieved.

Analysis Plan:

As the first step, responders and non-responders will be compared across groups to examine non-response bias. For patient reported outcomes, missing data will be handled according to established protocols for the validated surveys. We will conduct sensitivity analyses to determine the impact of missing imputation.[47] The hypotheses will be evaluated using an **intention to treat approach.** The analysis plan for the primary outcome (Hypothesis 1.1) will first calculate the rate of decision quality in each group, as the percentage of patients who meet or exceed the knowledge threshold *and* receive treatment that matches their preference. A logistic regression model with the Generalized Estimating Equations (GEE) approach will be used to compare the rates of decision quality of the DA-A and DA-B groups and account for the clustering of patients within providers. [48] Analysis will start by testing the interaction between the two intervention factors. It is plausible that an interaction between DAs and type of surgeon report exists for this analysis. As a result, the effective sample size will be limited to 117 per group when the comparisons are stratified by the type of surgeon report. The study has 89%

power to detect a difference in the percentage of patients with high decision quality of 18%, from 65% in DA-B group to 83% in DA-A group.

For Hypothesis 1.2, an interaction between DAs and PPR report is unlikely so there is no need to account for clustering within the same provider, as a result, we will use a two-sample t-test to compare the mean knowledge score between the two groups. For Hypothesis 1.3, patient's treatment preference will be assessed before the surgeon visit so again, there is no need to account for clustering. A chi-square test will be used to compare the percentage of patients with clear treatment preference between the two groups. Hypotheses 2.1 will use a linear regression model with the GEE approach and 2.2 will use logistic regression with GEE approach to account for clustering of patients within surgeons for these analyses.

The heterogeneity of the treatment effect will be explored by testing the interaction between interventions and different factors on study outcomes. These factors include (1) patient characteristics (e.g. age, gender, education level, joint (hip or knee), health literacy, and severity of disease), (2) provider characteristics (gender, years since graduation, surgical volume), (3) intervention compliance (whether patients reviewed the DAs) and (4) mode of DA delivery (online or hardcopy). Linear or logistic regression models (with the GEE approach in the case of clustering within providers) will be used to test the interaction between interventions and these factors. We will also report treatment effect in each subpopulation if there are strong evidence of interactions between interventions and these factors. Some of the hypothesis testing here might be exploratory in nature. The study will have sufficient power for testing interaction for continuous outcomes (e.g. detecting meaningful 'differences in differences' for knowledge scores, EQ-5D scores) but not categorical outcomes (e.g. rate of high decision quality, surgical rate).

2.G. Data Monitoring

Data monitoring and auditing:

Due to the minimal risk nature of the study, there is no external data and safety monitoring board. The PI, co-investigators and study staff monitored data internally. Study staff, co-investigators and PI met weekly in person or by phone to ensure the project proceeded as intended, per protocol. All participant enrollment was tracked including recruitment rates and survey response rates. The study staff completed all required items required by the IRB regarding data monitoring. The internal data monitoring committee is independent from the funder. Reports detailing study progress and milestones were submitted every 6 months to Patient-Centered Outcomes Research Institute (PCORI), the funder.

The central site controlled the randomization and data storage for the study. Limited data was kept on all non-responders across sites including joint, age, gender, physician, DA assignment, and all elements in the eligibility screener. This information will be used to examine non-response bias. There are no planned interim analyses for this study. Study outcomes will be analyzed by the statistician who will have a de-identified, blinded dataset.

Adverse events:

There were minimal risks to participating individuals; the main risks were the time and effort involved in completing the surveys. Study staff reviewed surveys within a week of receipt and notified the PI and clinical investigators about any adverse events at regularly scheduled meetings. Study staff kept records of any feedback, questions, concerns and/or complaints that were received and addressed them as needed. Staff were trained on how to address adverse events with the PI according to IRB protocol.

3. ETHICS AND DISSEMINATION:

Ethics approval and consent to participate:

Research ethics approval:

Institutional Review Board approval was obtained centrally through main IRB site. All other sites ceded review to the central IRB.

Protocol version:

This study protocol was approved on 3/15/16 and this manuscript details the protocol on the latest version approved on 12/21/17.

Protocol amendments to IRB:

All changes to the study protocol were reviewed by the IRB and then reported to funder at the 6-month reports. The participating providers and co-investigators were sent regular emails with updates on the study recruitment timeline and any major protocol changes during the enrollment period. All significant protocol changes were noted on ClinicalTrials.gov.

Study participant consent:

- *Surgeon consent*: The PI and co-investigators met with potential surgeons individually or as part of faculty meetings to discuss the study and to answer any questions. The surgeons were given a copy of the PPR, the patient and surgeon surveys, and both DAs to review. Surgeons provided verbal and email consent to the PI to indicate their willingness to participate.
- *Patient consent*: There are no formal written consent procedures for patients as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required. Consent for patient participants was implied by completion of the first survey. Two weeks prior to their

surgical consultation, eligible patients were mailed (1) a cover letter from the patient's surgeon inviting them to be part of the study; (2) an information sheet explaining the study involvement, risks, and benefits, and how to "opt out" prior to the visit; (3) their assigned DA and (4) the T1 survey. Three days prior to the visit, study staff called all patients who did not opt out to answer any questions about the study, and to remind them to review the DA and complete the survey. On the day of the visit, the study staff met the patients in clinic, answered any questions, and collected T1 surveys.

Confidentiality**:**

Special efforts are made to protect the privacy of subjects. All personal identifying information (PII), such as names, addresses, phone numbers and email addresses are kept in a secure Access database. PII on eligibility screeners collected at each site will be sent securely using a secure file transfer to the central study staff. Any paper that includes PII is kept in a locked cabinet or at a secure offsite storage facility.

Data management for the study will be done through REDCap. Study staff assigned to manage data will have access to the REDCap application and will be required to login via an individualized username and password combination. Study staff located at other institutions will only have access to the data collected at their sites. De-identified survey data will be entered into REDCap. All paper surveys and electronic surveys (collected via REDCap) include a patient Study ID number and do not have any identifying information. The access database that links the Study ID number to patient name and contact information will be kept separately on a password-protected server.

Dissemination Plan:

The PI and study team have developed a plan to promote dissemination and implementation of the study findings to consumer, clinical and payer stakeholders. The patient advisory committee (PAC) will facilitate dissemination of the study and results to patient, advocate and community audiences. One key role the PAC will play is to develop and maintain relationships with local and regional organizations that may assist in disseminating the results. Presentations at local meetings (e.g. grand rounds), at national meetings (e.g. American Academy of Orthopaedic Surgeons) as well as publications in leading journals will be used to reach physicians more broadly. In addition, the team will convene an external advisory board made up of clinician, payer, researcher and consumer representatives to guide dissemination and implementation efforts. This group will convene for one in-person meeting and two calls over the study period. These external advisors are experts across different domains (clinical care, payers, patient advocacy and consumer groups) who can help disseminate study findings more broadly.

Availability of data and material:

Within three months of the end of the final year of funding a description of the study dataset, including a code book, a SAS file of the code used for creating the final study sample, the final study variables, and plan for conducting the outcomes analyses outlined in the study protocol will be made available. The investigators will create a complete, cleaned, de-identified copy of the final data set that will include T1, T2, and T3 data. A section in the MGH Health Decision Sciences Center website will be created to hold study materials and it will include information for investigators interested in accessing these materials and replicating the findings.

The PI will share a de-identified data set with outside investigators according to the policies in the approved IRB protocol. Investigators may be required to provide evidence of IRB approval (or exemption) and/or complete a data sharing agreement.

4. PATIENT ADVISOR AND STAKEHOLDER ENGAGEMENT:

We have the ongoing participation of a patient advisory committee (PAC) throughout this study. The group includes six orthopedic patients recommended by physicians from one site who showed interest in contributing to patient-centered research in orthopedic care. The PAC meets quarterly with the study team and members provide feedback on the design of workflows, the communication and messaging to patients, and the type of data to collect.

5. PROCESS EVALUATION:

A process evaluation was designed to help understand how and why the interventions work. The study staff gathered data on differences in clinic structure and operations, institutional processes, clinicians and staff that may influence study outcomes. Before enrolling patients, study staff observed the clinic at each surgeon's practice and documented the standard patient flow, who patients met with during a visit, any patient information available at intake, and any standard patient education materials provided to support the visit and the decision-making process. Staff tracked delivery and receipt of the interventions including patient DAs and surgeon PPR sheets and documented any deviations in a study database along with reasons for the deviations. Participating surgeons were surveyed for a random sample of about 30% of their study patients. The surgeon survey had six questions including the surgeon's treatment recommendation, satisfaction and their perception of the patient's preferred treatment.

Orthopedic fellows who were involved in the initial visit with participating patients also completed a short survey assessing their confidence in certain SDM skills such as risk communication and eliciting patients' goals and preferences, as well as their perceptions of the attending surgeons' SDM skills. Exit interviews are also planned with surgeons, administrators, and clinic staff to assess gather reflections on the study protocol, acceptability, and feasibility in order to support dissemination and implementation of findings.

6. DISCUSSION:

This study protocol outlines the methodology for a multi-centered, randomized trial comparing two different decision aids and a patient preference report on SDM in orthopedic care. DAs are tools that communicate complex medical information to patients and families and have been shown to improve decision quality. As DAs proliferate and efforts to integrate SDM into routine care expand, understanding the comparative effectiveness of different interventions is critical. While the value of DA delivery in orthopedics has been highlighted in past studies, this study builds on those findings and will provide rigorous data on the impact of variations in DA format. The study will help answer several key questions that are aligned with the funder, PCORI's mission, as well as our patient partners and stakeholders, including (1) Which decision aid is most effective for patients who are considering elective hip or knee replacement surgery? Does the effectiveness vary by patient characteristics (such as age or literacy) or other factors? (2) What is the impact of providing surgeons information about their patients' experience with the disease and their goals for treatment? Does it help ensure more patient-centered treatment decisions? And (3) Do patients who make high quality decisions have better health related outcomes? Does it change the kind of treatments received?

In general, to assure that patients get the treatment they need and no less—and the treatment they want and no more—doctors and patients must share in decision making and collaborate in the care that follows. By contributing evidence on the value of patient and provider decision support strategies, we are eager to offer insights on promoting patient engagement and more patient-centered care. This fits with recent trends in health care policy that emphasize increasing consumer involvement in many aspects of care, from selecting a plan or provider to selecting treatments. The results of this study will provide critical evidence for health care administrators who are often tasked with making decisions about offering decision support technologies.

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Authors contributions:

Each author has contributed significantly to, and is willing to take public responsibility for, one or more aspects of the study. KS, AF, HB, and YC participated integrally in the study design. All authors contributed to implementation of the study protocol, data acquisition and analysis, and interpretation of the study data. MM, SD, SM, HV, and KS drafted the initial manuscript; all other authors provided critical revisions and approved the final revisions.

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Competing interests statement:

Dr. Sepucha (PI) has received salary support as a medical editor for the Informed Medical Decisions Foundation (IMDF). From 1997-2014, the IMDF was associated with Health Dialog, from 2014-2017 the IMDF was part of Healthwise, and in 2017, the IMDF became part of Massachusetts General Hospital. Dr. Freiberg reports other from Zimmer Biomet, other from ArthroSurface, other from CeramTec, other from Orthopaedic Technology Group, outside the submitted work. Dr. Bedair reports personal fees from Smith & Nephew, personal fees from Conformis, outside the submitted work. Dr. Dwyer, Dr. Talmo, Dr. Chang, Ms. Mangla, Ms. Daggett, Ms. Mwangi, and Ms. Vo declare that they have no competing interests.

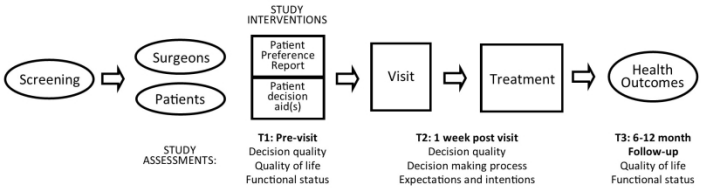

Figure 1. Flow of study interventions and assessments

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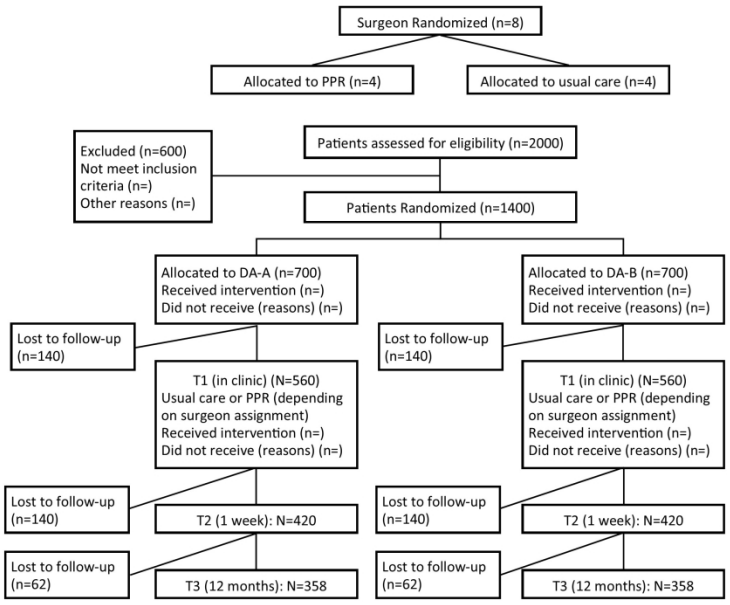

Figure 2: CONSORT diagram with estimates for screening and enrollment rates Figure Legend: PDA=patient decision aid, T1=pre-visit/in clinic before surgeon visit, PPR=patient preference report; T2=1-week post visit; T3=6-12-month post visit

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	20
Funding	4	Sources and types of financial, material, and other support	30
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	30
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	30
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	1, 30

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4-5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6-7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	1
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-12, 14-16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11-12, Figure 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13-14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13-14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13-14
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14-16
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14, 19

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	20
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	19- 20
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20-21
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	21
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	30
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	22-23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	22
	31b	Authorship eligibility guidelines and any intended use of professional writers	22
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	22
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Table 2: SUNDAE Checklist for evaluation studies of patient decision aids

Section/Topic	Page No.	Item No.	Checklist Item
Title and Abstract			
	1-2	1	Use the term patient decision aid in the abstract to identify the intervention evaluated and, if possible, in the title.
	1-2	2	In the abstract, identify the main outcomes used to evaluate the patient decision aid.
Introduction	**As part of standard introduction (the problem, gaps, purpose)**		
	4	3	Describe the decision that is the focus of the patient decision aid.
	7-8	4	Describe the intended user(s) of the patient decision aid.
	4	5	Summarize the need for the patient decision aid under evaluation.
	4-6	6	Describe the purpose of the evaluation study with respect to the patient decision aid.
Methods	**Studies with a comparator should also address Items 7-13 for the comparator if possible**		
	N/A	7	Briefly describe the development process for the patient decision aid (and any comparator), or cite other documents that describe the development process. At a minimum include: • Participation of stakeholders in its development • The process for gathering, selecting and appraising evidence to inform its content • Any testing that was done
	8-9	8	Identify the patient decision aid evaluated in the study (and any comparator) by including: • Name or information that enables it to be identified • Date and/or version number • How it can be accessed, if available
	9-10	9	Describe the format(s) of the patient decision aid (and any comparator) (e.g. paper, online, video).
	9	10	List the options presented in the patient decision aid (and any comparator).
	9-10	11	Indicate the components in the patient decision aid (and any comparator) including: • Explicit description of the decision* • Description of health problem* • Information on options and their benefits, harms, and consequences* • Values clarification (implicit or explicit)* • Numerical probabilities • Tailoring of information or probabilities • Guidance in deliberation • Guidance in communication • Personal stories • Reading level or other strategies to help understanding • Other components *These components are **needed to meet** the definition of a patient decision aid.
	10	12	Briefly describe the components from Item 11 that are included in the patient decision aid (and any comparator) or cite other documents that describe the components.

Section/Topic	Page No.	Item No.	Checklist Item
Methods (cont.)	11-12	13	Describe the delivery of the patient decision aid (and any comparator) including: • How it was delivered (e.g. by whom and/or by what method) • To whom it was delivered • Where it was used • When it was used in the pathway of care • Any training to support delivery • Setting characteristics and system factors influencing its delivery
	16; 23-24	14	Describe any methods used to assess the degree to which the patient decision aid was delivered and used as intended (also known as fidelity).
	23-24	15	Describe any methods used to understand how and why the patient decision aid works (also known as process evaluation) or cite other documents that describe the methods.
	6-7	16	Identify theories, models or frameworks used to guide the design of the evaluation and selection of study measures.
	11-12 14-16	17	For all study measures used to assess the impact of the patient decision aid on patients, health professionals, organization, and health system: • Identify the measures • Indicate the timing of administration in relation to exposure to the patient decision aid and health care interventions
	14-16	18	For any instruments used: • Name the instrument and the version (if applicable) • Briefly describe the psychometric properties, or cite other documents
Results	**In addition to standard reporting of results**		
	___	19	Describe the characteristics of the patient, family, and carer population(s) (e.g. health literacy, numeracy, prior experience with treatment options) that may affect patient decision aid outcomes.
	___	20	Describe any characteristics of the participating health professionals (e.g. relevant training, usual care vs. study professional, role in decision making) that may affect decision aid outcomes.
	___	21	Report any results on the use of the patient decision aid: • How much and which components were used • Degree to which it was delivered and used as intended (also known as fidelity)
	___	22	Report relevant results of any analyses conducted to understand how and why the patient decision aid works (also known as process evaluation).
	___	23	Report any unanticipated positive or negative consequences of the patient decision aid.
Discussion	**As part of the standard discussion section (summary of key findings, interpretation, limitations and conclusions):**		
	___	24	Discuss whether the patient decision aid worked as intended and interpret the results taking into account the specific context of the study including any process evaluation.
	___	25	Discuss any implications of the results for patient decision aid development, research, implementation, and theory, frameworks or models.
Conflict of Interest			
	___	26	All study authors should disclose if they have an interest (professional, financial or intellectual) in **any of the** ~~one~~ option**s** ~~over any others~~ included in the patient decision aid **or a financial interest in the decision aid itself**.

BMJ Open

Protocol for a randomized trial evaluating the comparative effectiveness of strategies to promote shared decision making for hip and knee osteoarthritis

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Title: Protocol for a randomized trial evaluating the comparative effectiveness of strategies to promote shared decision making for hip and knee osteoarthritis

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ABSTRACT

Introduction:

There are several different interventions available to promote shared decision making (SDM); however, little is known about the comparative effectiveness of different approaches.

Objective:

To examine the impact of patient- and physician-directed decision support strategies on the quality of treatment decisions for hip and knee osteoarthritis (OA).

Trial Design:

A 2x2 factorial randomized controlled trial.

Setting:

One academic medical center, one community hospital, and one orthopedic specialty hospital.

Participants and interventions:

The enrollment targets were eight surgeons and 1,120 patients diagnosed with hip or knee OA. Patients were randomly assigned to receive one of two different decision aids (DAs) stratified by site. The DAs varied in length, content and the level of detail regarding treatment options. Both DAs were available by paper or online.

Surgeons were randomly assigned to receive a report detailing patients' goals and treatment preferences at the time of the visit or not. Eligible patients received their assigned DA before their visit and completed three surveys: before the visit (T1), 1-week post-visit (T2), and six months from either the visit date or surgery date for patients who underwent surgery (T3). Study staff and participating surgeons were not blinded, but the statistician conducting the analyses was blinded to the arms.

Main outcome measure and analysis:

The primary study outcome was decision quality, the percentage of patients who were well informed and received their preferred treatment. Secondary outcomes included involvement in decision making, surgical rates, health outcomes, decision regret and satisfaction. A logistic regression model with the Generalized Estimating Equations approach was used to compare rates of decision quality between the groups and account for the clustering of patients within providers.

Ethics and Dissemination:

Ethics approval was obtained through the institutional review board at the main site. The findings will be published in peer-reviewed journals.

Keywords: shared decision making, comparative effectiveness, decision aid, surgery, osteoarthritis

Strengths and Limitations of the Study:

1. This large, multi-site randomized controlled trial will provide important evidence on the comparative effectiveness of two leading patient decision aids that vary in the amount of detail, level of interactivity, and use of patient narratives.
2. The study also includes a clinician-focused intervention, as the literature suggests that intervention strategies directed at both patients and clinicians may have the biggest impact.
3. Data will be collected from patients before the initial visit with the surgeon, shortly after the visit with the surgeon, and again about six months later to shed light on short and longer term impacts of the decision support strategies.

4. The study is adequately powered to examine the impact in key subgroups, including older patients and patients with low literacy, as well as to examine whether there are differences in those who review the patient decision aids online versus on paper.

5. The study staff and participating surgeons are not blinded to the interventions which is a limitation; however, the statistician conducting the analyses will be blinded to the arms.

Clinical trial registration: Clinicaltrials.gov #: NCT02729831.

1. INTRODUCTION

Hip and knee osteoarthritis (OA) are among the most prevalent chronic diseases in the U.S.[1] Joint replacement surgery is a common treatment for OA with a recent estimate indicating that 600,000 knee replacements are performed in the U.S. each year alone.[2] Clinical guidelines for the treatment of OA highlight the importance of informing patients about their surgical and non-surgical treatment options.[3,4] Engaging in shared decision making (SDM) is recognized as an integral strategy to help patients choose the best treatment for them.[5]

Patient decision aids (DAs) can help inform patients about their relevant treatment options and promote SDM.[6,7] There are more than 105 randomized controlled trials of DAs that find the tools improve knowledge, accuracy of risk perceptions, reduce decisional conflict and increase the match between choices and values.[8] Although considerable evidence exists to support effectiveness over usual care, the literature comparing different DAs is sparse.[8, 9] Further, while DAs can help prepare patients to participate in SDM, it is also important to support surgeons to engage in SDM during a medical visit.[10] There is only one small randomized controlled trial that has examined the impact of patient- and surgeon-directed interventions on decision making in hip and knee OA.[11]

The purpose of this randomized controlled trial study is to compare the effectiveness of two DAs for treatment of hip and knee OA and a surgeon-directed intervention.

2. METHODS AND ANALYSIS:

This clinical trial protocol follows the SPIRIT guidelines (see SPIRIT checklist in supplemental files).[12, 13] The underlying protocol follows the CONSORT guidelines and the Standards for Universal Reporting of Decision Aid Evaluations (SUNDAE) guidelines (see

SUNDAE checklist in supplemental files).[14-17] The trial was registered on clinicaltrials.gov (NCT02729831).

2.A. Study Design

This study compared two high quality DAs that differ in the format, amount of content, and level of interactivity, and will examine the impact on decision quality, treatment selection and health outcomes. Patients were randomly assigned to receive one of two different DAs stratified by site. The study also examined the impact of a surgeon-focused intervention—a patient preference report (PPR) detailing patients' goals and treatment preferences—vs usual care. Because the patient DA and the provider PPR may work together to improve decisions better than each on their own, we selected a 2X2 factorial randomized trial design to compare the interventions. Factorial studies allow for efficient examination of multiple interventions and are also particularly well-suited when two interventions have a potential interaction, as the design enables the examination of the benefits of each intervention separately as well as both interventions together.[18]

2.B. Specific Aims

Aim 1: Evaluate comparative effectiveness of two patient DAs (DA-A vs. DA-B) and a surgeon-focused intervention (usual care vs. PPR), which includes patients' goals and treatment preferences, on their ability to achieve high decision quality.

Hypothesis 1.1: Overall, patients who receive DA-A will have higher decision quality than those who receive DA-B.

Hypothesis 1.2: Patients who receive DA-A, with more comprehensive information and videos to make the information more salient, will have higher knowledge scores than those who receive DA-B.

Hypothesis 1.3: More patients who receive DA-B, with the explicit values clarification exercise, will have a clear treatment preference than those who receive DA-A.

Hypotheses 1.4: The PPR group will have higher rate of concordance, i.e. more patients who receive treatments that match their goals, compared to usual care group.

Aim 2: Follow participants for 6-12 months to determine the impact of the decision support strategies on treatment choices and health outcomes, specifically, overall quality of life and functional status.

Hypothesis 2.1: Patients with high decision quality (i.e. informed and received preferred treatments) at one week from their visit will have better health outcomes at one year compared to those with low decision quality.

Hypothesis 2.2: Patients with high decision quality at one week will have lower surgical rates at one year compared to those with low decision quality.

Aim 3: Identify patient-, physician- and intervention-level factors associated with effectiveness for the DAs. These factors include (1) patient characteristics (e.g. age, gender, education level, and joint (hip or knee), (2) provider characteristics (e.g. years since graduation, surgical volume), (3) intervention compliance (e.g. whether patients reviewed the DAs and amount of time spent reviewing the DAs) and (4) mode of delivery (online or hardcopy).

2.C. Conceptual framework

The study was based on the conceptual framework of SDM as outlined in Mulley [19] and Sepucha and Mulley [20, 21] that views SDM as a systems approach to enable continuous improvement in clinical decision making. The framework recognizes the fundamentally social nature of the decision-making task; it cannot be completed by the health care provider or patient alone but rather requires productive interactions between them. The interventions chosen for this study address the key elements of the conceptual framework. The DAs help surgeons convey the evidence to patients in ways that they can access and understand. The surgeon intervention will help patients communicate their treatment preferences to the surgeons in a structured manner. Together, these interventions will work to ensure high quality decisions that are evidence-based and patient-centered.

2.D. Participants, interventions and outcomes:

Participants and setting:

Patients and physicians were recruited from the orthopedic departments of three sites: a large academic medical center in an urban setting, a community hospital in suburban environment, and an orthopedic specialty hospital in an urban setting. Two of the three sites were selected because of their access and use of DAs as part of routine care, as well as their common electronic medical record (EMR). A third site was added to meet recruitment targets.

Patients scheduled for an appointment with an orthopedic surgeon were screened two weeks prior to their visit date (pre-visit screening) for study eligibility. Study staff called patients, as needed, to collect eligibility information that was not available in the EMR.

The eligibility criteria for patients are:

- Diagnosis of knee or hip OA (confirmed via x-ray or visit note)
- Age 21 or older
- Attends visit with a participating orthopedic specialist

Patients with the following will be ineligible:

- Partial or total knee or hip replacement surgery within 5 years of being screened
- Received patient DA within 1 year of visit
- Hip fracture or aseptic necrosis in 12 months prior to visit
- Rheumatoid arthritis or psoriatic arthritis diagnosis
- Does not read or write in English or Spanish
- Cognitive impairment (unable to consent for self)
- Non-OA related reason for visit

Interventions:

The DAs are not publicly available. Two of the sites had existing licenses to use the DAs, and the PI obtained a license agreement to use the DAs as part of the study at all sites. These DAs were selected because they are commercially available, have been certified by Washington state for use with hip and knee patients, and vary in content and format. Table 1 provides details of the various elements of the two DAs.

- DA-A: *Treatment Choices for Knee Osteoarthritis* ©Health Dialog is a 42-minute DVD and 38-page booklet (over the course of the study the DA was updated, and the following versions were used: English: Booklet V08/DVD V07 ©2016 and Booklet V07A/DVD V06A ©2014; Spanish Booklet V07/DVD V07 ©2014; Booklet V08/DVD V08 ©2016) and *Treatment Choices for Hip Osteoarthritis* ©Health Dialog is a 44-minute DVD and 40-page booklet (English: booklet V06A/DVD V06A ©2014 and booklet V07/DVD V07 ©2016;

Spanish: booklet V06/DVD V07 ©2014 and booklet V07/DVD V08 ©2016). The same content is also available online through Health Dialog's secure website. Health Dialog has 40 different DAs that have been evaluated in 20 randomized controlled trials. The DAs have been shown to increase knowledge, reduce decisional conflict and increase decision quality. Spanish language versions were also available online or in paper booklet form.[22] The authors reviewed the DAs for International Patient Decision Aid Standards (IPDAS) criteria and found they met 7 of 7 qualifying criteria to be defined as a DA and 8 out of 9 criteria to lower the risk of making a biased decision.

- DA-B: *Knee Osteoarthritis: Is it time to think about surgery?* ©Healthwise 2016 and *Hip Osteoarthritis: Is it time to think about surgery?* ©Healthwise 2016 DAs are available online or as a 17-page printed brochure. They include 6 sections (get facts, compare options, your feelings, your decision, quiz, and summary).[23, 24] Healthwise has more than 180 *Decision Points* and these were accessed over five million times in 2014. The knee and hip arthritis *Decision Points* were among the top five accessed topics. The Ottawa inventory of decision aids published IPDAS ratings for these DAs and found they met 7 out of 7 criteria to be defined as a DA and 8 out of 9 criteria to lower the risk of making a biased decision.[25,26] English and Spanish versions of Healthwise DAs were made available for this trial.

- Patient Preference Report (PPR): a one-page sheet that includes patients' goals for the visit, impact of disease on activities, and treatment preference (*see in supplemental files*). The sheet was developed with input from a patient advisory group (n=6), an expert in decisions sciences, a primary care physician, a nurse practitioner and two orthopedic surgeons.

Table 1. Design features of Decision Aid-A and Decision Aid-B

Design feature	Decision Aid-A	Decision Aid-B
Format	Paper and DVD or online	Paper or online
Treatment options	*Nonsurgical options*: • Lifestyle changes; Physical therapy; Walking aids; Pain medications; Injections (**knee only**); Complementary approaches *Total Joint Replacement* *Partial Joint Replacement* (**knee only**)	*Nonsurgical options*: • Generic discussion of nonsurgical options *Total Joint Replacement*
Essential information by itself, first[a]		X
Video to improve salience of patient narratives and information[a]	X	
Components in decision aid		
• Explicit description of the decision	X	X
• Description of health problem	X	X
• Information on options and their benefits, harms, and consequences	X	X
• Values clarification (implicit or explicit)	Implicit, patient narratives	Explicit, rating of goals and concerns
• Numerical probabilities	X	X
• Tailoring of information or probabilities		
• Guidance in deliberation	X	X
• Guidance in communication	X	X
• Personal stories	X	
• Reading level or other strategies to help understanding	Not available	Not available

[a]These design features have been shown to be effective in low literacy populations.[27]

Sample Size:

The sample size calculations considered both the potential for interaction effects between the two sets of interventions as well as the potential impact of clustering of patient participants within surgeons. In the situation where an interaction between DAs and PPR report is unlikely, the patients from both usual care and PPR groups will be combined for the comparisons between the two DAs. We planned to have eight surgeons at the sites enroll a total of 1120 of their patients (T2). We anticipated a 25% attrition rate at T2 (N=840), and another 15% attrition rate at T3 (N=716). Based on our previous estimate, we assumed an intraclass correlation coefficient (ICC) of 0.01.[6, 28] Using the formula of Design factor =1+(m-1)**ICC,* where m is the average number of observations in each cluster, a sample size of 280 participants in each group at the T1 survey is equivalent to an effective sample size of 117, a sample size of 210 per group at the T2 survey is equivalent to an effective sample size of 103 patients, and a sample size of 178 participants in each group at T3 survey is equivalent to an effective sample size of 95 patients. Thus, the effective sample size varies depending on the hypotheses within each aim as dictated by analysis plan. Using Hypothesis 1.1 as an example, it is plausible that an interaction between DAs and type of surgeon report exists for this analysis. As a result, the effective sample size will be limited to 117 per group when the comparisons are stratified by the type of surgeon report. The study will have 89% power to detect a difference in the percentage of patients with high decision quality of 18%, from 65% in DA-B group to 83% in DA-A group.

With an average of 140 patients in each provider cluster, the inflation factor was estimated to be 1.96 based on the assumption of an ICC of 0.01. A sample size of 280 participants in each group at the T1 survey is equivalent to an effective sample size of 117. Similarly, a sample size of 210 at the T2 survey is equivalent to an effective sample size of 100 patients per group and a sample size of 178 participants in each group at T3 survey is equivalent

to an effective sample size of 95 patients per group. Details on sample size and power calculations for hypotheses within each aim are included in the analysis plan.

Outcomes:

Our primary outcome is decision quality, defined as the percentage of patients who are well informed (at least three out of five knowledge questions correct) and received their preferred treatment (surgical or non-surgical). The Hip or Knee Decision Quality Instruments were used to measure the primary outcome.[29] Secondary outcomes include involvement in decision making, surgical rates, patient-reported health outcome measures, decision regret and satisfaction.

- *Hip OA and Knee OA Decision Quality Instruments (DQI) (T1, T2)*: Each DQI contains 5 decision-specific, multiple-choice knowledge items, 5 decision-specific goals and concerns (rated on an 11-point importance scale), and one treatment preference item. The DQIs were developed with considerable input from patients and a multidisciplinary team of providers [30] and followed best practices in survey research methods.[31,32] They have demonstrated strong psychometric properties (e.g. retest reliability, validity, sensitivity to change) and clinical sensibility (e.g. acceptability and feasibility).[7, 29, 33] Respondents get a knowledge score (0-100%) and a concordance indicator (yes or no) depending on whether the patient received treatment that matched their stated preference. High decision quality is a binary indicator variable calculated as the percentage of patients whose knowledge score met or exceeded the knowledge threshold and received treatment that matched their preference. The minimal important changes in knowledge and concordance scores are 10%.[29]

- *Shared Decision-Making Process Survey (T2, T3)*: 7 items that assess discussion of four elements of SDM: options, pros, cons and preferences. A total score is generated (0-4) with higher scores indicating more SDM.[6]
- *Functional goals (T1/T2, T3)*: Participants listed the top three things that they needed or wanted to do but were unable to do because of their knee or hip pain (at T1 for the PPR group and at T2 for the usual care group). Then at T3, they indicated to what extent they were able to do those three things and how important those goals still were.
- *SURE scale (T2)*: A brief, 4-item version of the widely used Decisional Conflict Scale that measures patients' uncertainty about which treatment to choose and factors contributing to uncertainty (feeling uninformed, unclear values, and unsupported in decision making).[34-35]
- *Decision regret (T3)*: A 5-item Likert scale that measures distress or remorse after a decision. A total score (0-100) is calculated with higher scores indicating more regret. The scale has demonstrated strong internal consistency (0.81-0.92) and correlates with decision satisfaction and quality of life.[36]
- *EQ-5D (T1, T3)*: A 6-item summary measure of overall health status.[37] It generates a single index value for health status on which full health is assigned a value of 1 and death a value of 0. In conjunction with weights established for the 243 different combinations, the EQ-5D can be used to obtain quality-adjusted life years.[38] The minimum important change is 0.1 points.[39]
- *Knee injury and osteoarthritis score (KOOS) (T1, T3)*: The KOOS was developed to assess patients' opinions about their knee and associated problems and has been used extensively.[40-46] Three subscales were used in this study: pain, symptoms, and functional

status. A normalized score (100 indicating no pain/symptoms and 0 indicating extreme pain/symptoms) is calculated for each subscale.

- *Harris Hip Score (HHS) (T1, T3)*: The HHS assesses pain, function, range of motion and deformity for each hip. Pain receives 44 points, function 47 points, range of motion 5 points, and deformity 4 points for a total of 100 points. Function is subdivided into activities of daily living (14 points) and gait (33 points). The higher the HHS, the less dysfunction. A total score of 70 is considered a poor result; 70 – 80 is considered fair, 80 –90 is good, and 90 – 100 is an excellent result. No normative values are available.[47-50]
- *DA usage (T1, T2)*: 1 item assessed how much of the DVD, booklet and/or website was reviewed (all, most, some, none).
- *Treatment received (T3, chart review)*: Surgical and non-surgical treatments tried since the consultation visit were self-reported by patients and collected via chart review.
- *Expectations (T2, T3)*: 10 items assessed expectations at T2 for pain relief and limitations in daily activities. At T3, patients were asked if their function after surgical or non-surgical treatment is worse, about, or better than they expected.[51]
- *Demographics (T2)*: Information such as age, gender and insurance were collected from the EMR and education, race, and ethnicity were self-reported.
- *Satisfaction (T3)*: Two questions assess overall satisfaction with quality of visit and treatment outcome.
- *Collaborate score (T2)*: Three item patient-reported measure of SDM and patient satisfaction at a clinical encounter.[52]
- *Single-item literacy screener (T1)*: One question assessing how often patients need help reading and understanding medical paperwork.[53]

Delivery of interventions and assessments:

The study activities included screening, recruitment, and intervention and survey delivery. The sequence of activities within the orthopedic clinic flow is illustrated in Figure 1.

- *DA delivery*: Trained study staff screened new patients from the orthopedic clinical schedule across the three sites. Eligible patients received their assigned DA two weeks prior to their visit. The DA was sent electronically to patients who are enrolled in the site's online patient portal and mailed to all others.
- *First survey at Timepoint 1 (T1)*: Two weeks before the initial visit, a mailed packet was sent to all participants which included a cover letter, information sheet and the T1 survey. The DA was included in the same packet as the T1 survey for patients receiving a paper copy. For patients receiving the DA online, instructions for how to access the online portal was included with the T1 survey. The T1 survey was collected from the patient on the day of the visit in the waiting room before they saw the surgeon.
- *Patient Preference Report (PPR) delivery*: For patients seeing a surgeon in the PPR group, the PPR was included as part of the T1 survey. In the waiting room before the patient's visit, study staff collected the completed survey from patients, made two copies of the PPR page, and gave one to the patient and the other to the surgeon in advance of the visit.
- *Second survey at Timepoint (T2)*: After the visit, study staff screened visit notes for enrolled patients to confirm eligibility. Eligible patients received the T2 survey either via mail or email (depending on patient preference as indicated on the T1 survey) approximately one week after their visit.

- *Third survey at Timepoint 3 (T3)*: Follow-up assessment was collected between 6 and 12 months post initial visit. Approximately 6 months after initial visit, study staff called patients to remind them about the study follow up assessment, confirm surgical status and their preferred method for receiving the T3 survey (mail or email). Patients who did not have surgery within 6 months were sent the T3 survey at this time; patients who had surgery were sent the T3 survey 6 months after their date of surgery.

Recruitment Strategies:

Figure 2 is the CONSORT Flow diagram and includes estimates for screening, enrollment and response rates. To meet our sample size requirements, we needed 1,120 patients to complete the T1 survey, 840 to complete the T2 survey, and 716 to complete the T3 survey. Several strategies were implemented during the enrollment period to achieve the target sample size. After sending out the DA with the invitation to participate, study staff called patients who did not opt out prior to their visit date to answer any questions about the study. This call also served as a reminder to the patients to review the DA before the visit and to complete the T1 survey. Study staff also offered to administer the survey over the phone. On the day of the visit, the study staff met with eligible patients in clinic waiting room. Staff answered questions and brought extra copies of the T1 surveys to administer the survey in clinic if needed.

Recruitment Status and Trial Dates:

Patient enrollment started April 2016 at Sites 1 and 2 and July 2017 at Site 3 and was completed in December 2017. The T3 surveys were collected from December 2016 through November 2018.

2.E. Randomization and blinding:

Two randomizations occurred: one at the patient-level and one at the surgeon-level. Within each site, surgeons were divided into two groups stratified by years in practice and patient volume, then the two groups were randomly assigned to usual care or PPR by the statistician. Patients were randomized to DA-A or DA-B, using a computer-generated allocation sequence, prior to enrollment in the study.

A study database was set up to support allocation and concealment. Study staff entered information for each eligible patient one at a time and the randomization assignment was revealed once the study staff clicked the "randomize" button for each patient. Study staff did not know in advance what the assignment was. For any patient participant found to be ineligible for the study after randomization, the original assignment was put back into the study database and re-assigned to the next eligible patient. Study staff did not know when this re-assignment occurred as the allocation sequence was kept hidden.

Patient participants were not blinded to the DA assigned to them; however, they were not given any explicit information on the other DA or their surgeon's assignment. Likewise, surgeons were not blinded to their intervention group, but they were not given any specific information on the type of DA the patient received. It was possible for surgeons to find out their patients' assignment; patients may have brought the DA with them to the visit, or surgeons could have opened the patient education note in the EMR that included the specific title of the DA.

Study staff who recruited participants and approached them in clinic were not blinded to the DA assignment, as they were responsible for mailing the DAs to patients. However, the study staff responsible for data entry did not have information on the DA assignment when entering the

paper surveys. The analytic data set will be de-identified to maintain blinding during the analysis process.

2.F. Data collection, management and analysis

Data collection:

Paper and online surveys were used to collect patient reported outcomes. The first (T1) survey was mailed to patients before their visit. The second (T2) and third (T3) surveys were sent to patients either via mail or email based on patient preference. Study staff followed-up with a phone reminder about one week after sending the surveys, followed by a mailed reminder or up to three email reminders, and a second phone reminder for all the participants who did not complete the surveys. Participants who received the surveys by email also got the survey in the mail if they did not complete it online within two weeks. During the reminder calls, study staff gave participants the option to complete the survey by phone. A $5 cash incentive was included with the T2 and T3 assessments. A study database tracked all participant contact and was used to monitor the consistency of the reminder protocols. Table 2 shows which outcomes were administered at each timepoint:

Table 2. Outcomes collected at different timepoints

Outcomes	**T1**	**T2**	**T3**
Hip Osteoarthritis and Knee Osteoarthritis Decision Quality Instruments	X	X	
Shared decision making process survey		X	X
Functional goals	X+	X+	X
SURE scale		X	
Decision regret			X
EQ-5D	X		X
Knee injury and osteoarthritis score	X		X
Harris Hip Score	X		X
Decision aid usage	X	X	

Treatment received			X
Expectations		X	X
Demographics		X	
Satisfaction			X
CollaboRATE		X	
Single-item literary screener	X		

+ T1 for patient preference report group, T2 for usual care group

Data management:

Study staff reviewed surveys within a week of receipt and flagged any missing answers or comments that suggested a problem with the survey to discuss with the PI and study team. The staff contacted patient participants up to three times to acquire answers to missing items. Study staff were responsible for data entry of the paper surveys into Research Electronic Data Capture (REDCap), a HIPAA-approved web application.[54] Study staff conducted double coding on 10% of surveys collected over the first 6 months of the recruitment period. We stopped double coding after a 99.5% rate of agreement between entered and double-coded surveys was achieved.

Analysis Plan:

For patient reported outcomes (decision quality, quality of life, etc.), missing data items will be handled according to established protocols for the validated surveys (e.g. missing knowledge items are considered incorrect). For item-specific analysis, our primary analyses will be conducted excluding patients with missing data. The treatment received (surgical vs. non-surgical) will be assessed through chart review and confirmed via patient report (T3); therefore is not subject to missing data.

Even though we cannot test the Missing at Random (MAR) assumption, we will first compare patients with and without missing data to gain insights. As a sensitivity analysis, we

will conduct several missing imputation techniques: (1) last value carried forward (LVCF), (2) single imputation with EM algorithm, and (3) multiple imputation. The LVCF approach applies to follow-up missing data, which is essentially the same as assuming no change over time. Compared to single imputation, the appealing aspect of the multiple imputation approach is incorporating the variability across imputation so that the statistical uncertainty due to missing is more properly accounted for. We will compare our findings from the primary analyses to the findings from different imputation strategies to determine whether our findings are stable across different assumptions. We will also report the uncertainty associated with the treatment effect as indicated in the standard error estimates from the multiple imputation analysis.

As the first step, responders and non-responders will be compared across groups to examine non-response bias. For patient reported outcomes, missing data will be handled according to established protocols for the validated surveys. We will conduct sensitivity analyses to determine the impact of missing imputation.[55] The hypotheses will be evaluated using an intention to treat approach**.** The analysis plan for the primary outcome (Hypothesis 1.1) will first calculate the rate of decision quality in each group, as the percentage of patients who meet or exceed the knowledge threshold *and* receive treatment that matches their preference. A logistic regression model with the Generalized Estimating Equations (GEE) approach will be used to compare the rates of decision quality of the DA-A and DA-B groups and account for the clustering of patients within providers.[56] Analysis will start by testing the interaction between the two intervention factors. It is plausible that an interaction between DAs and type of surgeon report exists for this analysis. As a result, the effective sample size will be limited to 117 per group when the comparisons are stratified by the type of surgeon report. The study has 89%

power to detect a difference in the percentage of patients with high decision quality of 18%, from 65% in DA-B group to 83% in DA-A group.

For Hypothesis 1.2, an interaction between DAs and PPR report is unlikely so there is no need to account for clustering within the same provider, as a result, we will use a two-sample t-test to compare the mean knowledge score between the two groups. With approximately 560 patients from each group, we can invoke the Central Limit Theorem and use a two-sample t-test to compare mean knowledge score between the two groups, even if the knowledge score is not normally distributed. The study will have 80% power to detect a difference as small as 3.3% in total knowledge scores assuming the SD is 20%.

For Hypothesis 1.3, patient's treatment preference will be assessed before the surgeon visit so again, there is no need to account for clustering. A chi-square test will be used to compare the percentage of patients with clear treatment preference between the two groups. Hypotheses 2.1 will use a linear regression model with the GEE approach and 2.2 will use logistic regression with GEE approach to account for clustering of patients within surgeons for these analyses.

The heterogeneity of the treatment effect will be explored by testing the interaction between interventions and different factors on study outcomes. These factors include (1) patient characteristics (e.g. age, gender, education level, joint (hip or knee), health literacy, and severity of disease), (2) provider characteristics (gender, years since graduation, surgical volume), (3) intervention compliance (whether patients reviewed the DAs) and (4) mode of DA delivery (online or hardcopy). Linear or logistic regression models (with the GEE approach in the case of clustering within providers) will be used to test the interaction between interventions and these factors. We will also report treatment effect in each subpopulation if there are strong evidence of

interactions between interventions and these factors. Some of the hypothesis testing here might be exploratory in nature. The study will have sufficient power for testing interaction for continuous outcomes (e.g. detecting meaningful 'differences in differences' for knowledge scores, EQ-5D scores) but not categorical outcomes (e.g. rate of high decision quality, surgical rate).

2.G. Data Monitoring

Data monitoring and auditing:

Due to the minimal risk nature of the study, there is no external data and safety monitoring board. The PI, co-investigators and study staff monitored data internally. Study staff, co-investigators and PI met weekly in person or by phone to ensure the project proceeded as intended, per protocol. All participant enrollment was tracked including recruitment rates and survey response rates. The study staff completed all required items required by the IRB regarding data monitoring. The internal data monitoring committee is independent from the funder. Reports detailing study progress and milestones were submitted every 6 months to Patient-Centered Outcomes Research Institute (PCORI), the funder.

The central site controlled the randomization and data storage for the study. Limited data was kept on all non-responders across sites including joint, age, gender, physician, DA assignment, and all elements in the eligibility screener. This information will be used to examine non-response bias. There are no planned interim analyses for this study. Study outcomes will be analyzed by the statistician who will have a de-identified, blinded dataset.

Adverse events:

There were minimal risks to participating individuals; the main risks were the time and effort involved in completing the surveys. Study staff reviewed surveys within a week of receipt and notified the PI and clinical investigators about any adverse events at regularly scheduled meetings. Study staff kept records of any feedback, questions, concerns and/or complaints that were received and addressed them as needed. Staff were trained on how to address adverse events with the PI according to IRB protocol.

2.H. Patient and Public Involvement

We have the ongoing participation of a patient advisory committee (PAC) throughout this study. The group includes six orthopedic patients recommended by physicians from one site who showed interest in contributing to patient-centered research in orthopedic care. The PAC meets quarterly with the study team and members provide feedback on the design of workflows, the communication and messaging to patients, and the type of data to collect. Specifically, this study question was informed by the views of our PAC who wanted to explore the variation in how new orthopedic patients educate themselves about their treatment options. They showed interest in how different DAs might influence patients' treatment decisions differently. The PAC reviewed all the interventions — both DAs, patient surveys, and the surgeons' PPR. They were particularly involved in designing our patient outreach plan, including how we would send study materials and contact study patients. The PAC offered insight on the best ways to engage patients over phone and email. Through their recommendation, when the trial is completed, study data will be shared on our website in our "For Patients and Families" section so participants can see the results of their involvement.

2.I. Limitations

There are some potential limitations to note in this study. First, study staff are not blinded to the interventions as they are responsible for mailing them to patients. However, staff entering the survey data will be blinded to the DA assignment, and the statistician will also be blinded to the arms. Second, we expect a number of post-randomization exclusions due to patients not showing up for their appointment and due to limited data available to assess eligibility before the visit. Third, we expect a modest amount of attrition over the course of the study and have put into place standard protocols to maximize response rates to all surveys. Fourth, the follow-up period of 6 months may be too short to capture the full benefit of surgery on quality of life. Finally, the surgeons at two of the sites had prior exposure to patients using one of the DAs.

3. ETHICS AND DISSEMINATION:

Ethics approval and consent to participate:

Research ethics approval:

Institutional Review Board approval was obtained centrally through main IRB site. All other sites ceded review to the central IRB.

Protocol version:

This study protocol was approved on 3/15/16 and this manuscript details the protocol on the latest version approved on 12/21/17.

Protocol amendments to IRB:

All changes to the study protocol were reviewed by the IRB and then reported to funder at the 6-month reports. The participating providers and co-investigators were sent regular emails

with updates on the study recruitment timeline and any major protocol changes during the enrollment period. All significant protocol changes were noted on ClinicalTrials.gov.

Study participant consent:

- *Surgeon consent*: The PI and co-investigators met with potential surgeons individually or as part of faculty meetings to discuss the study and to answer any questions. The surgeons were given a copy of the PPR, the patient and surgeon surveys, and both DAs to review. Surgeons provided verbal and email consent to the PI to indicate their willingness to participate.
- *Patient consent*: There are no formal written consent procedures for patients as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required. Consent for patient participants was implied by completion of the first survey. Two weeks prior to their surgical consultation, eligible patients were mailed (1) a cover letter from the patient's surgeon inviting them to be part of the study; (2) an information sheet explaining the study involvement, risks, and benefits, and how to "opt out" prior to the visit; (3) their assigned DA and (4) the T1 survey. Three days prior to the visit, study staff called all patients who did not opt out to answer any questions about the study, and to remind them to review the DA and complete the survey. On the day of the visit, the study staff met the patients in clinic, answered any questions, and collected T1 surveys.

Confidentiality:

Special efforts are made to protect the privacy of subjects. All personal identifying information (PII), such as names, addresses, phone numbers and email addresses are kept in a secure Access database. PII on eligibility screeners collected at each site are sent securely using a

secure file transfer to the central study staff. Any paper that includes PII is kept in a locked cabinet or at a secure offsite storage facility.

Data management for the study was done through REDCap. Study staff assigned to manage data have access to the REDCap application and are required to login via an individualized username and password combination. Study staff located at other institutions only have access to the data collected at their sites. De-identified survey data is entered into REDCap. All paper surveys and electronic surveys (collected via REDCap) include a patient Study ID number and do not have any identifying information. The access database that links the Study ID number to patient name and contact information is kept separately on a password-protected server.

Dissemination Plan:

The PI and study team have developed a plan to promote dissemination and implementation of the study findings to consumer, clinical and payer stakeholders. The patient advisory committee (PAC) will facilitate dissemination of the study and results to patient, advocate and community audiences. One key role the PAC will play is to develop and maintain relationships with local and regional organizations that may assist in disseminating the results. Presentations at local meetings (e.g. grand rounds), at national meetings (e.g. American Academy of Orthopaedic Surgeons) as well as publications in leading journals will be used to reach physicians more broadly. In addition, the team will convene an external advisory board made up of clinician, payer, researcher and consumer representatives to guide dissemination and implementation efforts. This group will convene for one in-person meeting and two calls over the study period. These external advisors are experts across different domains (clinical care,

payers, patient advocacy and consumer groups) who can help disseminate study findings more broadly.

Availability of data and material:

Within three months of the end of the final year of funding a description of the study dataset, including a code book, a SAS file of the code used for creating the final study sample, the final study variables, and plan for conducting the outcomes analyses outlined in the study protocol will be made available. The investigators will create a complete, cleaned, de-identified copy of the final data set that will include T1, T2, and T3 data. A section in the MGH Health Decision Sciences Center website will be created to hold study materials and it will include information for investigators interested in accessing these materials and replicating the findings. The PI will share a de-identified data set with outside investigators according to the policies in the approved IRB protocol. Investigators may be required to provide evidence of IRB approval (or exemption) and/or complete a data sharing agreement.

4. PROCESS EVALUATION:

A process evaluation was designed to help understand how and why the interventions work. The study staff gathered data on differences in clinic structure and operations, institutional processes, clinicians and staff that may influence study outcomes. Before enrolling patients, study staff observed the clinic at each surgeon's practice and documented the standard patient flow, who patients met with during a visit, any patient information available at intake, and any standard patient education materials provided to support the visit and the decision-making process. Staff tracked delivery and receipt of the interventions including patient DAs and

surgeon PPR sheets and documented any deviations in a study database along with reasons for the deviations. Participating surgeons were surveyed for a random sample of about 30% of their study patients. The surgeon survey had six questions including the surgeon's treatment recommendation, satisfaction and their perception of the patient's preferred treatment. Orthopedic fellows who were involved in the initial visit with participating patients also completed a short survey assessing their confidence in certain SDM skills such as risk communication and eliciting patients' goals and preferences, as well as their perceptions of the attending surgeons' SDM skills. Exit interviews are also planned with surgeons, administrators, and clinic staff to assess gather reflections on the study protocol, acceptability, and feasibility to support dissemination and implementation of findings.

5. DISCUSSION:

This study protocol outlines the methodology for a multi-centered, randomized trial comparing two different DAs and a PPR on SDM in orthopedic care. DAs are tools that communicate complex medical information to patients and families and have been shown to improve decision quality. As DAs proliferate and efforts to integrate SDM into routine care expand, understanding the comparative effectiveness of different interventions is critical. While the value of DA delivery in orthopedics has been highlighted in past studies, this study builds on those findings and will provide rigorous data on the impact of variations in DA format. The study will help answer several key questions that are aligned with the funder, PCORI's mission, as well as our patient partners and stakeholders, including (1) Which DA is most effective for patients who are considering elective hip or knee replacement surgery? Does the effectiveness vary by patient characteristics (such as age or literacy) or other factors? (2) What is the impact of

providing surgeons information about their patients' experience with the disease and their goals for treatment? Does it help ensure more patient-centered treatment decisions? And (3) Do patients who make high quality decisions have better health related outcomes? Does it change the kind of treatments received?

In general, to assure that patients get the treatment they need and no less—and the treatment they want and no more—doctors and patients must share in decision making and collaborate in the care that follows. By contributing evidence on the value of patient and provider decision support strategies, we are eager to offer insights on promoting patient engagement and more patient-centered care. This fits with recent trends in health care policy that emphasize increasing consumer involvement in many aspects of care, from selecting a plan or provider to selecting treatments. The results of this study will provide critical evidence for health care administrators who are often tasked with making decisions about offering decision support technologies.

Figure Legends

Figure 1. Flow of study interventions and assessments

Figure 2. CONSORT Flow diagram estimating patient screening, enrollment and response rate

Figure 2 Legend:

DA = decision aid
PPR = patient preference report
T1 = pre-visit/in clinic before surgeon visit
T2 = 1-week post-visit
T3 = 6-12 months post-visit

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Authors contributions:

Each author has contributed significantly to, and is willing to take public responsibility for, one or more aspects of the study. KS, AF, HB, and YC participated integrally in the study design. All authors contributed to implementation of the study protocol, data acquisition and analysis, and interpretation of the study data. MM, SD, SM, HV, and KS drafted the initial manuscript; all other authors including MD and CT provided critical revisions and approved the final revisions.

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We would also like to acknowledge members of our patient advisory committee who provided insight for the study design and recommendations for dissemination of findings.

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Competing interests statement:

Dr. Sepucha (PI) has received salary support as a medical editor for the Informed Medical Decisions Foundation (IMDF). From 1997-2014, the IMDF was associated with Health Dialog, from 2014-2017 the IMDF was part of Healthwise, and in 2017, the IMDF became part of Massachusetts General Hospital. Dr. Freiberg reports other from Zimmer Biomet, other from ArthroSurface, other from CeramTec, other from Orthopaedic Technology Group, outside the submitted work. Dr. Bedair reports personal fees from Smith & Nephew, personal fees from

Conformis, outside the submitted work. Dr. Dwyer, Dr. Talmo, Dr. Chang, Ms. Mangla, Ms. Daggett, Ms. Mwangi, and Ms. Vo declare that they have no competing interests.

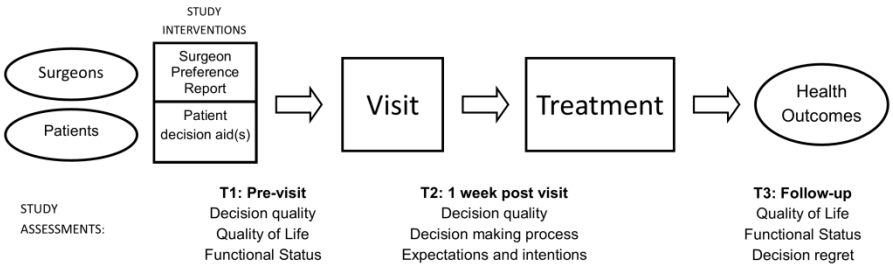

Figure 1: Flow of study interventions and assessments

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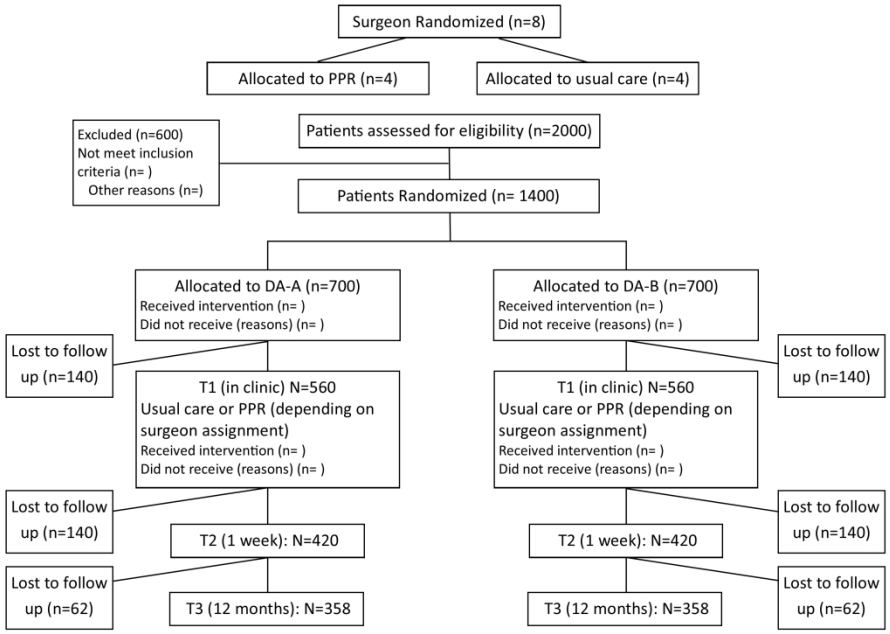

Figure 2: CONSORT diagram with estimates for screening and enrollment rates Figure Legend: DA=decision aid, T1=pre-visit/in clinic before surgeon visit, PPR=patient preference report; T2=1-week post visit; T3=6-12-month post visit%"

279x215mm (300 x 300 DPI)

Patient Preference Report

TREATMENT DECISIONS FOR [HIP/KNEE] OSTEOARTHRITIS

1. What are three important activities that you want or need to do that you cannot do now due to your [hip/knee]?

a. Activity1._____

b. Activity 2._____

c. Activity 3._____

2. At this time, what treatment do you feel will work best for your [hip/knee]?

- ☐ [Hip/Knee] replacement surgery
- ☐ Non-surgical treatment
- ☐ I am not sure

3. What is your hope for what will happen at your visit today?

_____

_____

_____

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	20
Funding	4	Sources and types of financial, material, and other support	30
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	30
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	30
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	1, 30

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4-5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6-7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	1
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-12, 14-16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11-12, Figure 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13-14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13-14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13-14
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14-16
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14, 19

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	20
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	19- 20
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20-21
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	21
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	30
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	22-23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	22
	31b	Authorship eligibility guidelines and any intended use of professional writers	22
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	22
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

SUNDAE Checklist for evaluation studies of patient decision aids

Section/Topic	Page No.	Item No.	Checklist Item
Title and Abstract			
	1-2	1	Use the term patient decision aid in the abstract to identify the intervention evaluated and, if possible, in the title.
	1-2	2	In the abstract, identify the main outcomes used to evaluate the patient decision aid.
Introduction	**As part of standard introduction (the problem, gaps, purpose)**		
	4	3	Describe the decision that is the focus of the patient decision aid.
	7-8	4	Describe the intended user(s) of the patient decision aid.
	4	5	Summarize the need for the patient decision aid under evaluation.
	4-6	6	Describe the purpose of the evaluation study with respect to the patient decision aid.
Methods	**Studies with a comparator should also address Items 7-13 for the comparator if possible**		
	N/A	7	Briefly describe the development process for the patient decision aid (and any comparator), or cite other documents that describe the development process. At a minimum include: • Participation of stakeholders in its development • The process for gathering, selecting and appraising evidence to inform its content • Any testing that was done
	8-9	8	Identify the patient decision aid evaluated in the study (and any comparator) by including: • Name or information that enables it to be identified • Date and/or version number • How it can be accessed, if available
	9-10	9	Describe the format(s) of the patient decision aid (and any comparator) (e.g. paper, online, video).
	9	10	List the options presented in the patient decision aid (and any comparator).
	9-10	11	Indicate the components in the patient decision aid (and any comparator) including: • Explicit description of the decision* • Description of health problem* • Information on options and their benefits, harms, and consequences* • Values clarification (implicit or explicit)* • Numerical probabilities • Tailoring of information or probabilities • Guidance in deliberation • Guidance in communication • Personal stories • Reading level or other strategies to help understanding • Other components *These components are **needed to meet** the definition of a patient decision aid.
	10	12	Briefly describe the components from Item 11 that are included in the patient decision aid (and any comparator) or cite other documents that describe the components.

Section/Topic	Page No.	Item No.	Checklist Item
Methods (cont.)	11-12	13	Describe the delivery of the patient decision aid (and any comparator) including: • How it was delivered (e.g. by whom and/or by what method) • To whom it was delivered • Where it was used • When it was used in the pathway of care • Any training to support delivery • Setting characteristics and system factors influencing its delivery
	16; 23-24	14	Describe any methods used to assess the degree to which the patient decision aid was delivered and used as intended (also known as fidelity).
	23-24	15	Describe any methods used to understand how and why the patient decision aid works (also known as process evaluation) or cite other documents that describe the methods.
	6-7	16	Identify theories, models or frameworks used to guide the design of the evaluation and selection of study measures.
	11-12 14-16	17	For all study measures used to assess the impact of the patient decision aid on patients, health professionals, organization, and health system: • Identify the measures • Indicate the timing of administration in relation to exposure to the patient decision aid and health care interventions
	14-16	18	For any instruments used: • Name the instrument and the version (if applicable) • Briefly describe the psychometric properties, or cite other documents
Results	**In addition to standard reporting of results**		
	___	19	Describe the characteristics of the patient, family, and carer population(s) (e.g. health literacy, numeracy, prior experience with treatment options) that may affect patient decision aid outcomes.
	___	20	Describe any characteristics of the participating health professionals (e.g. relevant training, usual care vs. study professional, role in decision making) that may affect decision aid outcomes.
	___	21	Report any results on the use of the patient decision aid: • How much and which components were used • Degree to which it was delivered and used as intended (also known as fidelity)
	___	22	Report relevant results of any analyses conducted to understand how and why the patient decision aid works (also known as process evaluation).
	___	23	Report any unanticipated positive or negative consequences of the patient decision aid.
Discussion	**As part of the standard discussion section (summary of key findings, interpretation, limitations and conclusions):**		
	___	24	Discuss whether the patient decision aid worked as intended and interpret the results taking into account the specific context of the study including any process evaluation.
	___	25	Discuss any implications of the results for patient decision aid development, research, implementation, and theory, frameworks or models.
Conflict of Interest			
	___	26	All study authors should disclose if they have an interest (professional, financial or intellectual) in **any of the** ~~one~~ option**s** ~~over any others~~ included in the patient decision aid **or a financial interest in the decision aid itself**.

BMJ Open

Protocol for a randomized trial evaluating the comparative effectiveness of strategies to promote shared decision making for hip and knee osteoarthritis (DECIDE-OA study)

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Title: Protocol for a randomized trial evaluating the comparative effectiveness of strategies to promote shared decision making for hip and knee osteoarthritis (DECIDE-OA Study)

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ABSTRACT

Introduction:

There are several different interventions available to promote shared decision making (SDM); however, little is known about the comparative effectiveness of different approaches.

Objective:

To examine the impact of patient- and physician-directed decision support strategies on the quality of treatment decisions for hip and knee osteoarthritis (OA).

Trial Design:

A 2x2 factorial randomized controlled trial.

Setting:

One academic medical center, one community hospital, and one orthopedic specialty hospital.

Participants and interventions:

The enrollment targets were eight surgeons and 1,120 patients diagnosed with hip or knee OA. Patients were randomly assigned to receive one of two different decision aids (DAs) stratified by site. The DAs varied in length, content and the level of detail regarding treatment options. Both DAs were available by paper or online.

Surgeons were randomly assigned to receive a report detailing patients' goals and treatment preferences at the time of the visit or not. Eligible patients received their assigned DA before their visit and completed three surveys: before the visit (T1), 1-week post-visit (T2), and six months from either the visit date or surgery date for patients who underwent surgery (T3). Study staff and participating surgeons were not blinded, but the statistician conducting the analyses was blinded to the arms.

Main outcome measure and analysis:

The primary study outcome was decision quality, the percentage of patients who were well informed and received their preferred treatment. Secondary outcomes included involvement in decision making, surgical rates, health outcomes, decision regret and satisfaction. A logistic regression model with the Generalized Estimating Equations approach was used to compare rates of decision quality between the groups and account for the clustering of patients within providers.

Ethics and Dissemination:

Ethics approval was obtained through the institutional review board at the main site. The findings will be published in peer-reviewed journals.

Keywords: shared decision making, comparative effectiveness, decision aid, surgery, osteoarthritis

Strengths and Limitations of the Study:

1. The DECIDE-OA study is a large, multi-site randomized controlled trial and will provide important evidence on the comparative effectiveness of two leading patient decision aids that vary in the amount of detail, level of interactivity, and use of patient narratives.
2. The study also includes a clinician-focused intervention, as the literature suggests that intervention strategies directed at both patients and clinicians may have the biggest impact.
3. Data will be collected from patients before the initial visit with the surgeon, shortly after the visit with the surgeon, and again about six months later to shed light on short and longer term impacts of the decision support strategies.

4. The study is adequately powered to examine the impact in key subgroups, including older patients and patients with low literacy, as well as to examine whether there are differences in those who review the patient decision aids online versus on paper.

5. The study staff and participating surgeons are not blinded to the interventions which is a limitation; however, the statistician conducting the analyses will be blinded to the arms.

Clinical trial registration: Clinicaltrials.gov #: NCT02729831.

1. INTRODUCTION

Hip and knee osteoarthritis (OA) are among the most prevalent chronic diseases in the U.S.[1] Joint replacement surgery is a common treatment for OA with a recent estimate indicating that 600,000 knee replacements are performed in the U.S. each year alone.[2] Clinical guidelines for the treatment of OA highlight the importance of informing patients about their surgical and non-surgical treatment options.[3,4] Engaging in shared decision making (SDM) is recognized as an integral strategy to help patients choose the best treatment for them.[5]

Patient decision aids (DAs) can help inform patients about their relevant treatment options and promote SDM.[6,7] There are more than 105 randomized controlled trials of DAs that find the tools improve knowledge, accuracy of risk perceptions, reduce decisional conflict and increase the match between choices and values.[8] Although considerable evidence exists to support effectiveness over usual care, the literature comparing different DAs is sparse.[8, 9] Further, while DAs can help prepare patients to participate in SDM, it is also important to support surgeons to engage in SDM during a medical visit.[10] There is only one small randomized controlled trial that has examined the impact of patient- and surgeon-directed interventions on decision making in hip and knee OA.[11]

The purpose of this randomized controlled trial (DECIDE-OA Study) is to compare the effectiveness of two DAs for treatment of hip and knee OA and a surgeon-directed intervention.

2. METHODS AND ANALYSIS:

This clinical trial protocol follows the SPIRIT guidelines (see SPIRIT checklist in supplemental files).[12, 13] The underlying protocol follows the CONSORT guidelines and the Standards for Universal Reporting of Decision Aid Evaluations (SUNDAE) guidelines (see

SUNDAE checklist in supplemental files).[14-17] The trial was registered on clinicaltrials.gov (NCT02729831).

2.A. Study Design

The DECIDE-OA study compared two high quality DAs that differ in the format, amount of content, and level of interactivity, and will examine the impact on decision quality, treatment selection and health outcomes. Patients were randomly assigned to receive one of two different DAs stratified by site. The study also examined the impact of a surgeon-focused intervention—a patient preference report (PPR) detailing patients' goals and treatment preferences—vs usual care. Because the patient DA and the provider PPR may work together to improve decisions better than each on their own, we selected a 2X2 factorial randomized trial design to compare the interventions. Factorial studies allow for efficient examination of multiple interventions and are also particularly well-suited when two interventions have a potential interaction, as the design enables the examination of the benefits of each intervention separately as well as both interventions together.[18]

2.B. Specific Aims

Aim 1: Evaluate comparative effectiveness of two patient DAs (DA-A vs. DA-B) and a surgeon-focused intervention (usual care vs. PPR), which includes patients' goals and treatment preferences, on their ability to achieve high decision quality.

Hypothesis 1.1: Overall, patients who receive DA-A will have higher decision quality than those who receive DA-B.

Hypothesis 1.2: Patients who receive DA-A, with more comprehensive information and videos to make the information more salient, will have higher knowledge scores than those who receive DA-B.

Hypothesis 1.3: More patients who receive DA-B, with the explicit values clarification exercise, will have a clear treatment preference than those who receive DA-A.

Hypotheses 1.4: The PPR group will have higher rate of concordance, i.e. more patients who receive treatments that match their goals, compared to usual care group.

Aim 2: Follow participants for 6-12 months to determine the impact of the decision support strategies on treatment choices and health outcomes, specifically, overall quality of life and functional status.

Hypothesis 2.1: Patients with high decision quality (i.e. informed and received preferred treatments) at one week from their visit will have better health outcomes at one year compared to those with low decision quality.

Hypothesis 2.2: Patients with high decision quality at one week will have lower surgical rates at one year compared to those with low decision quality.

Aim 3: Identify patient-, physician- and intervention-level factors associated with effectiveness for the DAs. These factors include (1) patient characteristics (e.g. age, gender, education level, and joint (hip or knee), (2) provider characteristics (e.g. years since graduation, surgical volume), (3) intervention compliance (e.g. whether patients reviewed the DAs and amount of time spent reviewing the DAs) and (4) mode of delivery (online or hardcopy).

2.C. Conceptual framework

The study was based on the conceptual framework of SDM as outlined in Mulley [19] and Sepucha and Mulley [20, 21] that views SDM as a systems approach to enable continuous improvement in clinical decision making. The framework recognizes the fundamentally social nature of the decision-making task; it cannot be completed by the health care provider or patient alone but rather requires productive interactions between them. The interventions chosen for this study address the key elements of the conceptual framework. The DAs help surgeons convey the evidence to patients in ways that they can access and understand. The surgeon intervention will help patients communicate their treatment preferences to the surgeons in a structured manner. Together, these interventions will work to ensure high quality decisions that are evidence-based and patient-centered.

2.D. Participants, interventions and outcomes:

Participants and setting:

Patients and physicians were recruited from the orthopedic departments of three sites: a large academic medical center in an urban setting, a community hospital in suburban environment, and an orthopedic specialty hospital in an urban setting. Two of the three sites were selected because of their access and use of DAs as part of routine care, as well as their common electronic medical record (EMR). A third site was added to meet recruitment targets.

Patients scheduled for an appointment with an orthopedic surgeon were screened two weeks prior to their visit date (pre-visit screening) for study eligibility. Study staff called patients, as needed, to collect eligibility information that was not available in the EMR.

The eligibility criteria for patients are:

- Diagnosis of knee or hip OA (confirmed via x-ray or visit note)
- Age 21 or older
- Attends visit with a participating orthopedic specialist

Patients with the following will be ineligible:

- Partial or total knee or hip replacement surgery within 5 years of being screened
- Received patient DA within 1 year of visit
- Hip fracture or aseptic necrosis in 12 months prior to visit
- Rheumatoid arthritis or psoriatic arthritis diagnosis
- Does not read or write in English or Spanish
- Cognitive impairment (unable to consent for self)
- Non-OA related reason for visit

Interventions:

The DAs are not publicly available. Two of the sites had existing licenses to use the DAs, and the PI obtained a license agreement to use the DAs as part of the study at all sites. These DAs were selected because they are commercially available, have been certified by Washington state for use with hip and knee patients, and vary in content and format. Table 1 provides details of the various elements of the two DAs.

- DA-A: *Treatment Choices for Knee Osteoarthritis* ©Health Dialog is a 42-minute DVD and 38-page booklet (over the course of the study the DA was updated, and the following versions were used: English: Booklet V08/DVD V07 ©2016 and Booklet V07A/DVD V06A ©2014; Spanish Booklet V07/DVD V07 ©2014; Booklet V08/DVD V08 ©2016) and *Treatment Choices for Hip Osteoarthritis* ©Health Dialog is a 44-minute DVD and 40-page booklet (English: booklet V06A/DVD V06A ©2014 and booklet V07/DVD V07 ©2016;

Spanish: booklet V06/DVD V07 ©2014 and booklet V07/DVD V08 ©2016). The same content is also available online through Health Dialog's secure website. Health Dialog has 40 different DAs that have been evaluated in 20 randomized controlled trials. The DAs have been shown to increase knowledge, reduce decisional conflict and increase decision quality. Spanish language versions were also available online or in paper booklet form.[22] The authors reviewed the DAs for International Patient Decision Aid Standards (IPDAS) criteria and found they met 7 of 7 qualifying criteria to be defined as a DA and 8 out of 9 criteria to lower the risk of making a biased decision.

- DA-B: *Knee Osteoarthritis: Is it time to think about surgery?* ©Healthwise 2016 and *Hip Osteoarthritis: Is it time to think about surgery?* ©Healthwise 2016 DAs are available online or as a 17-page printed brochure. They include 6 sections (get facts, compare options, your feelings, your decision, quiz, and summary).[23, 24] Healthwise has more than 180 *Decision Points* and these were accessed over five million times in 2014. The knee and hip arthritis *Decision Points* were among the top five accessed topics. The Ottawa inventory of decision aids published IPDAS ratings for these DAs and found they met 7 out of 7 criteria to be defined as a DA and 8 out of 9 criteria to lower the risk of making a biased decision.[25,26] English and Spanish versions of Healthwise DAs were made available for this trial.

- Patient Preference Report (PPR): a one-page sheet that includes patients' goals for the visit, impact of disease on activities, and treatment preference (*see in supplemental files*). The sheet was developed with input from a patient advisory group (n=6), an expert in decisions sciences, a primary care physician, a nurse practitioner and two orthopedic surgeons.

Table 1. Design features of Decision Aid-A and Decision Aid-B

Design feature	Decision Aid-A	Decision Aid-B
Format	Paper and DVD or online	Paper or online
Treatment options	*Nonsurgical options*: • Lifestyle changes; Physical therapy; Walking aids; Pain medications; Injections (**knee only**); Complementary approaches *Total Joint Replacement* *Partial Joint Replacement* (**knee only**)	*Nonsurgical options*: • Generic discussion of nonsurgical options *Total Joint Replacement*
Essential information by itself, first[a]		X
Video to improve salience of patient narratives and information[a]	X	
Components in decision aid		
• Explicit description of the decision	X	X
• Description of health problem	X	X
• Information on options and their benefits, harms, and consequences	X	X
• Values clarification (implicit or explicit)	Implicit, patient narratives	Explicit, rating of goals and concerns
• Numerical probabilities	X	X
• Tailoring of information or probabilities		
• Guidance in deliberation	X	X
• Guidance in communication	X	X
• Personal stories	X	
• Reading level or other strategies to help understanding	Not available	Not available

[a]These design features have been shown to be effective in low literacy populations.[27]

Sample Size:

The sample size calculations considered both the potential for interaction effects between the two sets of interventions as well as the potential impact of clustering of patient participants within surgeons. In the situation where an interaction between DAs and PPR report is unlikely, the patients from both usual care and PPR groups will be combined for the comparisons between the two DAs. We planned to have eight surgeons at the sites enroll a total of 1120 of their patients (T2). We anticipated a 25% attrition rate at T2 (N=840), and another 15% attrition rate at T3 (N=716). Based on our previous estimate, we assumed an intraclass correlation coefficient (ICC) of 0.01.[6, 28] Using the formula of Design factor =1+(m-1)**ICC,* where m is the average number of observations in each cluster, a sample size of 280 participants in each group at the T1 survey is equivalent to an effective sample size of 117, a sample size of 210 per group at the T2 survey is equivalent to an effective sample size of 103 patients, and a sample size of 178 participants in each group at T3 survey is equivalent to an effective sample size of 95 patients. Thus, the effective sample size varies depending on the hypotheses within each aim as dictated by analysis plan. Using Hypothesis 1.1 as an example, it is plausible that an interaction between DAs and type of surgeon report exists for this analysis. As a result, the effective sample size will be limited to 117 per group when the comparisons are stratified by the type of surgeon report. The study will have 89% power to detect a difference in the percentage of patients with high decision quality of 18%, from 65% in DA-B group to 83% in DA-A group. Details on sample size and power calculations for hypotheses within each aim are included in the analysis plan.

Outcomes:

Our primary outcome is decision quality, defined as the percentage of patients who are well informed (at least three out of five knowledge questions correct) and received their

preferred treatment (surgical or non-surgical). The Hip or Knee Decision Quality Instruments were used to measure the primary outcome.[29] Secondary outcomes include involvement in decision making, surgical rates, patient-reported health outcome measures, decision regret and satisfaction.

- *Hip OA and Knee OA Decision Quality Instruments (DQI) (T1, T2)*: Each DQI contains 5 decision-specific, multiple-choice knowledge items, 5 decision-specific goals and concerns (rated on an 11-point importance scale), and one treatment preference item. The DQIs were developed with considerable input from patients and a multidisciplinary team of providers [30] and followed best practices in survey research methods.[31,32] They have demonstrated strong psychometric properties (e.g. retest reliability, validity, sensitivity to change) and clinical sensibility (e.g. acceptability and feasibility).[7, 29, 33] Respondents get a knowledge score (0-100%) and a concordance indicator (yes or no) depending on whether the patient received treatment that matched their stated preference. High decision quality is a binary indicator variable calculated as the percentage of patients whose knowledge score met or exceeded the knowledge threshold and received treatment that matched their preference. The minimal important changes in knowledge and concordance scores are 10%.[29]
- *Shared Decision-Making Process Survey (T2, T3)*: 7 items that assess discussion of four elements of SDM: options, pros, cons and preferences. A total score is generated (0-4) with higher scores indicating more SDM.[6]
- *Functional goals (T1/T2, T3)*: Participants listed the top three things that they needed or wanted to do but were unable to do because of their knee or hip pain (at T1 for the PPR group and at T2 for the usual care group). Then at T3, they indicated to what extent they were able to do those three things and how important those goals still were.

- *SURE scale (T2)*: A brief, 4-item version of the widely used Decisional Conflict Scale that measures patients' uncertainty about which treatment to choose and factors contributing to uncertainty (feeling uninformed, unclear values, and unsupported in decision making).[34-35]
- *Decision regret (T3)*: A 5-item Likert scale that measures distress or remorse after a decision. A total score (0-100) is calculated with higher scores indicating more regret. The scale has demonstrated strong internal consistency (0.81-0.92) and correlates with decision satisfaction and quality of life.[36]
- *EQ-5D (T1, T3)*: A 6-item summary measure of overall health status.[37] It generates a single index value for health status on which full health is assigned a value of 1 and death a value of 0. In conjunction with weights established for the 243 different combinations, the EQ-5D can be used to obtain quality-adjusted life years.[38] The minimum important change is 0.1 points.[39]
- *Knee injury and osteoarthritis score (KOOS) (T1, T3)*: The KOOS was developed to assess patients' opinions about their knee and associated problems and has been used extensively.[40-46] Three subscales were used in this study: pain, symptoms, and functional status. A normalized score (100 indicating no pain/symptoms and 0 indicating extreme pain/symptoms) is calculated for each subscale.
- *Harris Hip Score (HHS) (T1, T3)*: The HHS assesses pain, function, range of motion and deformity for each hip. Pain receives 44 points, function 47 points, range of motion 5 points, and deformity 4 points for a total of 100 points. Function is subdivided into activities of daily living (14 points) and gait (33 points). The higher the HHS, the less dysfunction. A total

score of 70 is considered a poor result; 70 – 80 is considered fair, 80 –90 is good, and 90 – 100 is an excellent result. No normative values are available.[47-50]

- *DA usage (T1, T2)*: 1 item assessed how much of the DVD, booklet and/or website was reviewed (all, most, some, none).
- *Treatment received (T3, chart review)*: Surgical and non-surgical treatments tried since the consultation visit were self-reported by patients and collected via chart review.
- *Expectations (T2, T3)*: 10 items assessed expectations at T2 for pain relief and limitations in daily activities. At T3, patients were asked if their function after surgical or non-surgical treatment is worse, about, or better than they expected.[51]
- *Demographics (T2)*: Information such as age, gender and insurance were collected from the EMR and education, race, and ethnicity were self-reported.
- *Satisfaction (T3)*: Two questions assess overall satisfaction with quality of visit and treatment outcome.
- *Collaborate score (T2)*: Three item patient-reported measure of SDM and patient satisfaction at a clinical encounter.[52]
- *Single-item literacy screener (T1)*: One question assessing how often patients need help reading and understanding medical paperwork.[53]

Delivery of interventions and assessments:

The study activities included screening, recruitment, and intervention and survey delivery. The sequence of activities within the orthopedic clinic flow is illustrated in Figure 1.

- *DA delivery*: Trained study staff screened new patients from the orthopedic clinical schedule across the three sites. Eligible patients received their assigned DA two weeks

prior to their visit. The DA was sent electronically to patients who are enrolled in the site's online patient portal and mailed to all others.

- *First survey at Timepoint 1 (T1)*: Two weeks before the initial visit, a mailed packet was sent to all participants which included a cover letter, information sheet and the T1 survey. The DA was included in the same packet as the T1 survey for patients receiving a paper copy. For patients receiving the DA online, instructions for how to access the online portal was included with the T1 survey. The T1 survey was collected from the patient on the day of the visit in the waiting room before they saw the surgeon.
- *Patient Preference Report (PPR) delivery*: For patients seeing a surgeon in the PPR group, the PPR was included as part of the T1 survey. In the waiting room before the patient's visit, study staff collected the completed survey from patients, made two copies of the PPR page, and gave one to the patient and the other to the surgeon in advance of the visit.
- *Second survey at Timepoint (T2)*: After the visit, study staff screened visit notes for enrolled patients to confirm eligibility. Eligible patients received the T2 survey either via mail or email (depending on patient preference as indicated on the T1 survey) approximately one week after their visit.
- *Third survey at Timepoint 3 (T3)*: Follow-up assessment was collected between 6 and 12 months post initial visit. Approximately 6 months after initial visit, study staff called patients to remind them about the study follow up assessment, confirm surgical status and their preferred method for receiving the T3 survey (mail or email). Patients who did not have surgery within 6 months were sent the T3 survey at this time; patients who had surgery were sent the T3 survey 6 months after their date of surgery.

Recruitment Strategies:

Figure 2 is the CONSORT Flow diagram and includes estimates for screening, enrollment and response rates. To meet our sample size requirements, we needed 1,120 patients to complete the T1 survey, 840 to complete the T2 survey, and 716 to complete the T3 survey. Several strategies were implemented during the enrollment period to achieve the target sample size. After sending out the DA with the invitation to participate, study staff called patients who did not opt out prior to their visit date to answer any questions about the study. This call also served as a reminder to the patients to review the DA before the visit and to complete the T1 survey. Study staff also offered to administer the survey over the phone. On the day of the visit, the study staff met with eligible patients in clinic waiting room. Staff answered questions and brought extra copies of the T1 surveys to administer the survey in clinic if needed.

Recruitment Status and Trial Dates:

Patient enrollment started April 2016 at Sites 1 and 2 and July 2017 at Site 3 and was completed in December 2017. The T3 surveys were collected from December 2016 through November 2018.

2.E. Randomization and blinding:

Two randomizations occurred: one at the patient-level and one at the surgeon-level. Within each site, surgeons were divided into two groups stratified by years in practice and patient volume, then the two groups were randomly assigned to usual care or PPR by the statistician. Patients were randomized to DA-A or DA-B, using a computer-generated allocation sequence, prior to enrollment in the study.

A study database was set up to support allocation and concealment. Study staff entered information for each eligible patient one at a time and the randomization assignment was revealed once the study staff clicked the "randomize" button for each patient. Study staff did not know in advance what the assignment was. For any patient participant found to be ineligible for the study after randomization, the original assignment was put back into the study database and re-assigned to the next eligible patient. Study staff did not know when this re-assignment occurred as the allocation sequence was kept hidden.

Patient participants were not blinded to the DA assigned to them; however, they were not given any explicit information on the other DA or their surgeon's assignment. Likewise, surgeons were not blinded to their intervention group, but they were not given any specific information on the type of DA the patient received. It was possible for surgeons to find out their patients' assignment; patients may have brought the DA with them to the visit, or surgeons could have opened the patient education note in the EMR that included the specific title of the DA.

Study staff who recruited participants and approached them in clinic were not blinded to the DA assignment, as they were responsible for mailing the DAs to patients. However, the study staff responsible for data entry did not have information on the DA assignment when entering the paper surveys. The analytic data set will be de-identified to maintain blinding during the analysis process.

2.F. Data collection, management and analysis

Data collection:

Paper and online surveys were used to collect patient reported outcomes. The first (T1) survey was mailed to patients before their visit. The second (T2) and third (T3) surveys were

sent to patients either via mail or email based on patient preference. Study staff followed-up with a phone reminder about one week after sending the surveys, followed by a mailed reminder or up to three email reminders, and a second phone reminder for all the participants who did not complete the surveys. Participants who received the surveys by email also got the survey in the mail if they did not complete it online within two weeks. During the reminder calls, study staff gave participants the option to complete the survey by phone. A $5 cash incentive was included with the T2 and T3 assessments. A study database tracked all participant contact and was used to monitor the consistency of the reminder protocols. Table 2 shows which outcomes were administered at each timepoint:

Table 2. Outcomes collected at different timepoints

Outcomes	**T1**	**T2**	**T3**
Hip Osteoarthritis and Knee Osteoarthritis Decision Quality Instruments	X	X	
Shared decision making process survey		X	X
Functional goals	X+	X+	X
SURE scale		X	
Decision regret			X
EQ-5D	X		X
Knee injury and osteoarthritis score	X		X
Harris Hip Score	X		X
Decision aid usage	X	X	
Treatment received			X
Expectations		X	X
Demographics		X	
Satisfaction			X
CollaboRATE		X	
Single-item literary screener	X		

+ T1 for patient preference report group, T2 for usual care group

Data management:

Study staff reviewed surveys within a week of receipt and flagged any missing answers or comments that suggested a problem with the survey to discuss with the PI and study team. The staff contacted patient participants up to three times to acquire answers to missing items. Study staff were responsible for data entry of the paper surveys into Research Electronic Data Capture (REDCap), a HIPAA-approved web application.[54] Study staff conducted double coding on 10% of surveys collected over the first 6 months of the recruitment period. We stopped double coding after a 99.5% rate of agreement between entered and double-coded surveys was achieved.

Analysis Plan:

For patient reported outcomes (decision quality, quality of life, etc.), missing data items will be handled according to established protocols for the validated surveys (e.g. missing knowledge items are considered incorrect). For item-specific analysis, our primary analyses will be conducted excluding patients with missing data. The treatment received (surgical vs. non-surgical) will be assessed through chart review and confirmed via patient report (T3); therefore is not subject to missing data.

Even though we cannot test the Missing at Random (MAR) assumption, we will first compare patients with and without missing data to gain insights. As a sensitivity analysis, we will conduct several missing imputation techniques: (1) last value carried forward (LVCF), (2) single imputation with EM algorithm, and (3) multiple imputation. The LVCF approach applies to follow-up missing data, which is essentially the same as assuming no change over time. Compared to single imputation, the appealing aspect of the multiple imputation approach is incorporating the variability across imputation so that the statistical uncertainty due to missing is more properly accounted for. We will compare our findings from the primary analyses to the

findings from different imputation strategies to determine whether our findings are stable across different assumptions. We will also report the uncertainty associated with the treatment effect as indicated in the standard error estimates from the multiple imputation analysis.

As the first step, responders and non-responders will be compared across groups to examine non-response bias. For patient reported outcomes, missing data will be handled according to established protocols for the validated surveys. We will conduct sensitivity analyses to determine the impact of missing imputation.[55] The hypotheses will be evaluated using an intention to treat approach. The analysis plan for the primary outcome (Hypothesis 1.1) will first calculate the rate of decision quality in each group, as the percentage of patients who meet or exceed the knowledge threshold *and* receive treatment that matches their preference. A logistic regression model with the Generalized Estimating Equations (GEE) approach will be used to compare the rates of decision quality of the DA-A and DA-B groups and account for the clustering of patients within providers.[56] Analysis will start by testing the interaction between the two intervention factors. It is plausible that an interaction between DAs and type of surgeon report exists for this analysis. As a result, the effective sample size will be limited to 117 per group when the comparisons are stratified by the type of surgeon report. The study has 89% power to detect a difference in the percentage of patients with high decision quality of 18%, from 65% in DA-B group to 83% in DA-A group.

For Hypothesis 1.2, an interaction between DAs and PPR report is unlikely so there is no need to account for clustering within the same provider, as a result, we will use a two-sample t-test to compare the mean knowledge score between the two groups. With approximately 560 patients from each group, we can invoke the Central Limit Theorem and use a two-sample t-test to compare mean knowledge score between the two groups, even if the knowledge score is not

normally distributed. The study will have 80% power to detect a difference as small as 3.3% in total knowledge scores assuming the SD is 20%.

For Hypothesis 1.3, patient's treatment preference will be assessed before the surgeon visit so again, there is no need to account for clustering. A chi-square test will be used to compare the percentage of patients with clear treatment preference between the two groups. Hypothesis 2.1 will use a linear regression model with the GEE approach and Hypothesis 2.2 will use logistic regression with GEE approach to account for clustering of patients within surgeons for these analyses.

The heterogeneity of the treatment effect will be explored by testing the interaction between interventions and different factors on study outcomes. These factors include (1) patient characteristics (e.g. age, gender, education level, joint (hip or knee), health literacy, and severity of disease), (2) provider characteristics (gender, years since graduation, surgical volume), (3) intervention compliance (whether patients reviewed the DAs) and (4) mode of DA delivery (online or hardcopy). Linear or logistic regression models (with the GEE approach in the case of clustering within providers) will be used to test the interaction between interventions and these factors. We will also report treatment effect in each subpopulation if there are strong evidence of interactions between interventions and these factors. Some of the hypothesis testing here might be exploratory in nature. The study will have sufficient power for testing interaction for continuous outcomes (e.g. detecting meaningful 'differences in differences' for knowledge scores, EQ-5D scores) but not categorical outcomes (e.g. rate of high decision quality, surgical rate).

2.G. Data Monitoring

Data monitoring and auditing:

Due to the minimal risk nature of the study, there is no external data and safety monitoring board. The PI, co-investigators and study staff monitored data internally. Study staff, co-investigators and PI met weekly in person or by phone to ensure the project proceeded as intended, per protocol. All participant enrollment was tracked including recruitment rates and survey response rates. The study staff completed all required items required by the IRB regarding data monitoring. The internal data monitoring committee is independent from the funder. Reports detailing study progress and milestones were submitted every 6 months to Patient-Centered Outcomes Research Institute (PCORI), the funder.

The central site controlled the randomization and data storage for the study. Limited data was kept on all non-responders across sites including joint, age, gender, physician, DA assignment, and all elements in the eligibility screener. This information will be used to examine non-response bias. There are no planned interim analyses for this study. Study outcomes will be analyzed by the statistician who will have a de-identified, blinded dataset.

Adverse events:

There were minimal risks to participating individuals; the main risks were the time and effort involved in completing the surveys. Study staff reviewed surveys within a week of receipt and notified the PI and clinical investigators about any adverse events at regularly scheduled meetings. Study staff kept records of any feedback, questions, concerns and/or complaints that were received and addressed them as needed. Staff were trained on how to address adverse events with the PI according to IRB protocol.

2.H. Patient and Public Involvement

We have the ongoing participation of a patient advisory committee (PAC) throughout this study. The group includes six orthopedic patients recommended by physicians from one site who showed interest in contributing to patient-centered research in orthopedic care. The PAC meets quarterly with the study team and members provide feedback on the design of workflows, the communication and messaging to patients, and the type of data to collect. Specifically, this study question was informed by the views of our PAC who wanted to explore the variation in how new orthopedic patients educate themselves about their treatment options. They showed interest in how different DAs might influence patients' treatment decisions differently. The PAC reviewed all the interventions — both DAs, patient surveys, and the surgeons' PPR. They were particularly involved in designing our patient outreach plan, including how we would send study materials and contact study patients. The PAC offered insight on the best ways to engage patients over phone and email. Through their recommendation, when the trial is completed, study data will be shared on our website in our "For Patients and Families" section so participants can see the results of their involvement.

2.I. Limitations

There are some potential limitations to note in this study. First, study staff are not blinded to the interventions as they are responsible for mailing them to patients. However, staff entering the survey data will be blinded to the DA assignment, and the statistician will also be blinded to the arms. Second, we expect a number of post-randomization exclusions due to patients not showing up for their appointment and due to limited data available to assess eligibility before the visit. Third, we expect a modest amount of attrition over the course of the study and have put into place standard protocols to maximize response rates to all surveys. Fourth, the follow-up

period of 6 months may be too short to capture the full benefit of surgery on quality of life. Finally, the surgeons at two of the sites had prior exposure to patients using one of the DAs.

3. ETHICS AND DISSEMINATION:

Ethics approval and consent to participate:

Research ethics approval:

Institutional Review Board approval was obtained centrally through main IRB site. All other sites ceded review to the central IRB.

Protocol version:

This study protocol was approved on 3/15/16 and this manuscript details the protocol on the latest version approved on 12/21/17.

Protocol amendments to IRB:

All changes to the study protocol were reviewed by the IRB and then reported to funder at the 6-month reports. The participating providers and co-investigators were sent regular emails with updates on the study recruitment timeline and any major protocol changes during the enrollment period. All significant protocol changes were noted on ClinicalTrials.gov.

Study participant consent:

- *Surgeon consent*: The PI and co-investigators met with potential surgeons individually or as part of faculty meetings to discuss the study and to answer any questions. The surgeons were given a copy of the PPR, the patient and surgeon surveys, and both DAs to review. Surgeons provided verbal and email consent to the PI to indicate their willingness to participate.

- *Patient consent*: There are no formal written consent procedures for patients as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required. Consent for patient participants was implied by completion of the first survey. Two weeks prior to their surgical consultation, eligible patients were mailed (1) a cover letter from the patient's surgeon inviting them to be part of the study; (2) an information sheet explaining the study involvement, risks, and benefits, and how to "opt out" prior to the visit; (3) their assigned DA and (4) the T1 survey. Three days prior to the visit, study staff called all patients who did not opt out to answer any questions about the study, and to remind them to review the DA and complete the survey. On the day of the visit, the study staff met the patients in clinic, answered any questions, and collected T1 surveys.

Confidentiality:

Special efforts are made to protect the privacy of subjects. All personal identifying information (PII), such as names, addresses, phone numbers and email addresses are kept in a secure Access database. PII on eligibility screeners collected at each site are sent securely using a secure file transfer to the central study staff. Any paper that includes PII is kept in a locked cabinet or at a secure offsite storage facility.

Data management for the study was done through REDCap. Study staff assigned to manage data have access to the REDCap application and are required to login via an individualized username and password combination. Study staff located at other institutions only have access to the data collected at their sites. De-identified survey data is entered into REDCap. All paper surveys and electronic surveys (collected via REDCap) include a patient Study ID number and do not have any identifying information. The access database that links the Study ID

number to patient name and contact information is kept separately on a password-protected server.

Dissemination Plan:

The PI and study team have developed a plan to promote dissemination and implementation of the study findings to consumer, clinical and payer stakeholders. The patient advisory committee (PAC) will facilitate dissemination of the study and results to patient, advocate and community audiences. One key role the PAC will play is to develop and maintain relationships with local and regional organizations that may assist in disseminating the results. Presentations at local meetings (e.g. grand rounds), at national meetings (e.g. American Academy of Orthopaedic Surgeons) as well as publications in leading journals will be used to reach physicians more broadly. In addition, the team will convene an external advisory board made up of clinician, payer, researcher and consumer representatives to guide dissemination and implementation efforts. This group will convene for one in-person meeting and two calls over the study period. These external advisors are experts across different domains (clinical care, payers, patient advocacy and consumer groups) who can help disseminate study findings more broadly.

Availability of data and material:

Within three months of the end of the final year of funding a description of the study dataset, including a code book, a SAS file of the code used for creating the final study sample, the final study variables, and plan for conducting the outcomes analyses outlined in the study protocol will be made available. The investigators will create a complete, cleaned, de-identified

copy of the final data set that will include T1, T2, and T3 data. A section in the MGH Health Decision Sciences Center website will be created to hold study materials and it will include information for investigators interested in accessing these materials and replicating the findings. The PI will share a de-identified data set with outside investigators according to the policies in the approved IRB protocol. Investigators may be required to provide evidence of IRB approval (or exemption) and/or complete a data sharing agreement.

4. PROCESS EVALUATION:

A process evaluation was designed to help understand how and why the interventions work. The study staff gathered data on differences in clinic structure and operations, institutional processes, clinicians and staff that may influence study outcomes. Before enrolling patients, study staff observed the clinic at each surgeon's practice and documented the standard patient flow, who patients met with during a visit, any patient information available at intake, and any standard patient education materials provided to support the visit and the decision-making process. Staff tracked delivery and receipt of the interventions including patient DAs and surgeon PPR sheets and documented any deviations in a study database along with reasons for the deviations. Participating surgeons were surveyed for a random sample of about 30% of their study patients. The surgeon survey had six questions including the surgeon's treatment recommendation, satisfaction and their perception of the patient's preferred treatment. Orthopedic fellows who were involved in the initial visit with participating patients also completed a short survey assessing their confidence in certain SDM skills such as risk communication and eliciting patients' goals and preferences, as well as their perceptions of the attending surgeons' SDM skills. Exit interviews are also planned with surgeons, administrators,

and clinic staff to assess gather reflections on the study protocol, acceptability, and feasibility to support dissemination and implementation of findings.

5. DISCUSSION:

This study protocol outlines the methodology for the DECIDE-OA study, a multi-centered, randomized trial comparing two different DAs and a PPR on SDM in orthopedic care. DAs are tools that communicate complex medical information to patients and families and have been shown to improve decision quality. As DAs proliferate and efforts to integrate SDM into routine care expand, understanding the comparative effectiveness of different interventions is critical. While the value of DA delivery in orthopedics has been highlighted in past studies, this study builds on those findings and will provide rigorous data on the impact of variations in DA format. The study will help answer several key questions that are aligned with the funder, PCORI's mission, as well as our patient partners and stakeholders, including (1) Which DA is most effective for patients who are considering elective hip or knee replacement surgery? Does the effectiveness vary by patient characteristics (such as age or literacy) or other factors? (2) What is the impact of providing surgeons information about their patients' experience with the disease and their goals for treatment? Does it help ensure more patient-centered treatment decisions? And (3) Do patients who make high quality decisions have better health related outcomes? Does it change the kind of treatments received?

In general, to assure that patients get the treatment they need and no less—and the treatment they want and no more—doctors and patients must share in decision making and collaborate in the care that follows. By contributing evidence on the value of patient and provider decision support strategies, we are eager to offer insights on promoting patient engagement and

more patient-centered care. This fits with recent trends in health care policy that emphasize increasing consumer involvement in many aspects of care, from selecting a plan or provider to selecting treatments. The results of this study will provide critical evidence for health care administrators who are often tasked with making decisions about offering decision support technologies.

Figure Legends

Figure 1. Flow of study interventions and assessments

Figure 2. CONSORT Flow diagram estimating patient screening, enrollment and response rate

Figure 2 Legend:

DA = decision aid
PPR = patient preference report
T1 = pre-visit/in clinic before surgeon visit
T2 = 1-week post-visit
T3 = 6-12 months post-visit

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Authors contributions:

Each author has contributed significantly to, and is willing to take public responsibility for, one or more aspects of the study. KS, AF, HB, and YC participated integrally in the study design. All authors contributed to implementation of the study protocol, data acquisition and analysis, and interpretation of the study data. MM, SD, SM, HV, and KS drafted the initial manuscript; all other authors including MD and CT provided critical revisions and approved the final revisions.

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Competing interests statement:

Dr. Sepucha (PI) has received salary support as a medical editor for the Informed Medical Decisions Foundation (IMDF). From 1997-2014, the IMDF was associated with Health Dialog, from 2014-2017 the IMDF was part of Healthwise, and in 2017, the IMDF became part of Massachusetts General Hospital. Dr. Freiberg reports other from Zimmer Biomet, other from ArthroSurface, other from CeramTec, other from Orthopaedic Technology Group, outside the submitted work. Dr. Bedair reports personal fees from Smith & Nephew, personal fees from

Conformis, outside the submitted work. Dr. Dwyer, Dr. Talmo, Dr. Chang, Ms. Mangla, Ms. Daggett, Ms. Mwangi, and Ms. Vo declare that they have no competing interests.

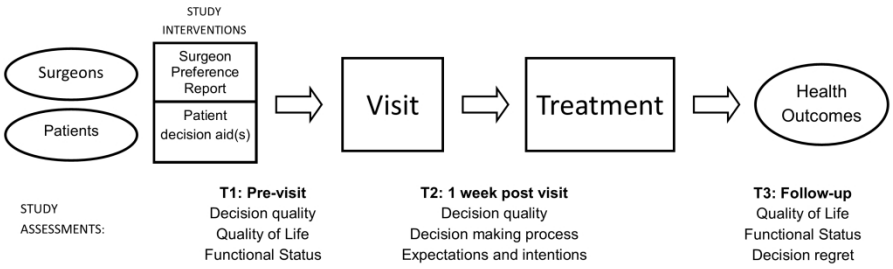

Figure 1: Flow of study interventions and assessments

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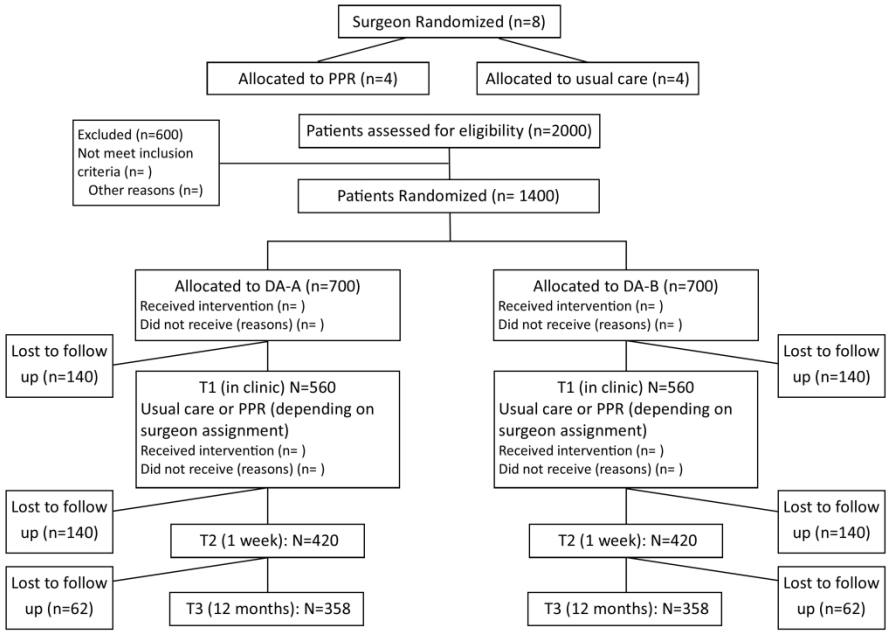

Figure 2: CONSORT diagram with estimates for screening and enrollment rates Figure Legend: DA=decision aid, T1=pre-visit/in clinic before surgeon visit, PPR=patient preference report; T2=1-week post visit; T3=6-12-month post visit%"

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Patient Preference Report

TREATMENT DECISIONS FOR [HIP/KNEE] OSTEOARTHRITIS

1. What are three important activities that you want or need to do that you cannot do now due to your [hip/knee]?

a. Activity1._____

b. Activity 2._____

c. Activity 3._____

2. At this time, what treatment do you feel will work best for your [hip/knee]?

- ☐ [Hip/Knee] replacement surgery
- ☐ Non-surgical treatment
- ☐ I am not sure

3. What is your hope for what will happen at your visit today?

_____

_____

_____

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	20
Funding	4	Sources and types of financial, material, and other support	30
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	30
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	30
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	1, 30

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4-5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6-7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	1
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-12, 14-16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11-12, Figure 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13-14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13-14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13-14
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14-16
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14, 19

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	20
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	19- 20
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20-21
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	21
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	30
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	22-23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	22
	31b	Authorship eligibility guidelines and any intended use of professional writers	22
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	22
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

SUNDAE Checklist for evaluation studies of patient decision aids

Section/Topic	Page No.	Item No.	Checklist Item
Title and Abstract			
	1-2	1	Use the term patient decision aid in the abstract to identify the intervention evaluated and, if possible, in the title.
	1-2	2	In the abstract, identify the main outcomes used to evaluate the patient decision aid.
Introduction	**As part of standard introduction (the problem, gaps, purpose)**		
	4	3	Describe the decision that is the focus of the patient decision aid.
	7-8	4	Describe the intended user(s) of the patient decision aid.
	4	5	Summarize the need for the patient decision aid under evaluation.
	4-6	6	Describe the purpose of the evaluation study with respect to the patient decision aid.
Methods	**Studies with a comparator should also address Items 7-13 for the comparator if possible**		
	N/A	7	Briefly describe the development process for the patient decision aid (and any comparator), or cite other documents that describe the development process. At a minimum include: • Participation of stakeholders in its development • The process for gathering, selecting and appraising evidence to inform its content • Any testing that was done
	8-9	8	Identify the patient decision aid evaluated in the study (and any comparator) by including: • Name or information that enables it to be identified • Date and/or version number • How it can be accessed, if available
	9-10	9	Describe the format(s) of the patient decision aid (and any comparator) (e.g. paper, online, video).
	9	10	List the options presented in the patient decision aid (and any comparator).
	9-10	11	Indicate the components in the patient decision aid (and any comparator) including: • Explicit description of the decision* • Description of health problem* • Information on options and their benefits, harms, and consequences* • Values clarification (implicit or explicit)* • Numerical probabilities • Tailoring of information or probabilities • Guidance in deliberation • Guidance in communication • Personal stories • Reading level or other strategies to help understanding • Other components *These components are **needed to meet** the definition of a patient decision aid.
	10	12	Briefly describe the components from Item 11 that are included in the patient decision aid (and any comparator) or cite other documents that describe the components.

Section/Topic	Page No.	Item No.	Checklist Item
Methods (cont.)	11-12	13	Describe the delivery of the patient decision aid (and any comparator) including: • How it was delivered (e.g. by whom and/or by what method) • To whom it was delivered • Where it was used • When it was used in the pathway of care • Any training to support delivery • Setting characteristics and system factors influencing its delivery
	16; 23-24	14	Describe any methods used to assess the degree to which the patient decision aid was delivered and used as intended (also known as fidelity).
	23-24	15	Describe any methods used to understand how and why the patient decision aid works (also known as process evaluation) or cite other documents that describe the methods.
	6-7	16	Identify theories, models or frameworks used to guide the design of the evaluation and selection of study measures.
	11-12 14-16	17	For all study measures used to assess the impact of the patient decision aid on patients, health professionals, organization, and health system: • Identify the measures • Indicate the timing of administration in relation to exposure to the patient decision aid and health care interventions
	14-16	18	For any instruments used: • Name the instrument and the version (if applicable) • Briefly describe the psychometric properties, or cite other documents
Results	**In addition to standard reporting of results**		
	___	19	Describe the characteristics of the patient, family, and carer population(s) (e.g. health literacy, numeracy, prior experience with treatment options) that may affect patient decision aid outcomes.
	___	20	Describe any characteristics of the participating health professionals (e.g. relevant training, usual care vs. study professional, role in decision making) that may affect decision aid outcomes.
	___	21	Report any results on the use of the patient decision aid: • How much and which components were used • Degree to which it was delivered and used as intended (also known as fidelity)
	___	22	Report relevant results of any analyses conducted to understand how and why the patient decision aid works (also known as process evaluation).
	___	23	Report any unanticipated positive or negative consequences of the patient decision aid.
Discussion	**As part of the standard discussion section (summary of key findings, interpretation, limitations and conclusions):**		
	___	24	Discuss whether the patient decision aid worked as intended and interpret the results taking into account the specific context of the study including any process evaluation.
	___	25	Discuss any implications of the results for patient decision aid development, research, implementation, and theory, frameworks or models.
Conflict of Interest			
	___	26	All study authors should disclose if they have an interest (professional, financial or intellectual) in **any of the** ~~one~~ option**s** ~~over any others~~ included in the patient decision aid **or a financial interest in the decision aid itself**.