

**A randomized trial measuring the effect of
Decision Aids on patients' satisfaction,
conflict of decision-making and clinical
outcome.**

NCT03181724

Version Date of the Document: 16 September 2016

PARTNERS HUMAN RESEARCH COMMITTEE DETAILED PROTOCOL

A randomized trial measuring the effect of Decision Aids on patients' satisfaction, conflict of decision-making and clinical outcome.

DETAILED PROTOCOL

VERSION 9/16/2016

PI: Neal Chen, MD

I. BACKGROUND AND SIGNIFICANCE

Decision aids are tools that help patients participate in making decisions by providing detailed, specific, and personalized information regarding the benefits and risks of various potential treatment options for a diagnosis. Decision aids can reduce the level of uncertainty and mental anguish associated with choosing a particular course of action, i.e. '**decisional conflict**'.¹ The most common manifestations of decisional conflict include verbalized uncertainty about choices or undesired consequences of alternatives, vacillation between choices, and delayed decision making.

Patient decision aids or "shared decision making programs" are interventions meant to prepare patients to make better or more informed decisions about their health care. By being involved in the decision-making process, patients can have a greater understanding of the risks and benefits of treatment options and the ability to make well-informed choices. In order to do this, however, patients need adequate, clear, and balanced information. Based on research in other fields, decision aids have been shown to decrease decisional conflict increase confidence with decisions, increase knowledge and may improve satisfaction with the process of decision making and the overall treatment outcome.² Decision aids have also been shown to have positive effects on shared decision making.³

A Cochrane systematic review of 86 randomized control trials (RCT's) evaluating patient decision aids (largely in medical subspecialties) showed that these tools increased patients'

knowledge, risk perception, and participation. Furthermore it helped them clarify their values and preferences, and prepare them for the encounter with their physician and deciding on a course of action.¹⁴ In addition, patients who used decision aids were less anxious and more likely to prefer nonoperative treatment, while outcomes were unaffected.³ Most often a decision aid addresses treatment opportunities and tailors questions to clarify patients' wishes, as recommended by the Ottawa Decision Support Framework.¹⁴

Although the literature is clear about the advantages of decision aids in the process of decision-making, studies are inconclusive about the effect of decision aids on patient satisfaction.¹⁵ Of the 86 RCT's identified by Stacey et al., eleven studies measured satisfaction.³ Of these, four studies reported that people exposed to decision aids had higher satisfaction with their choice compared to usual care, and the remaining seven reported no statistically significant difference.¹⁶

Studies that have directly investigated the effect of decision aids in orthopaedic practice are limited and further study is necessary to determine the best way to implement decision aids in a clinical orthopedic practice.⁵⁷⁻¹² Randomized trials evaluating the impact of decision aids on patient knowledge, decisional conflict, satisfaction, and outcomes may have substantial impact in hand surgery where most treatments are elective and address quality of life.

II. SPECIFIC AIMS (Research Objectives)

Primary Study Question:

The objective is to apply decision aids, which are based on the Ottawa Framework and International Patient Decision Aids Standards (IPDAS) criteria, to two randomly selected patient cohorts (Cohort I and Cohort II) for each diagnosis. The diagnoses will include patients with trapeziometacarpal (TMC) arthrosis, carpal tunnel syndrome (CTS), cubital tunnel syndrome (CTD), distal radius fractures (DRF) and trigger finger (TF). Cohort I is comprised of patients managed with a decision aid, and Cohort II is comprised of patients managed without a decision aid. This distinction is made to evaluate whether the use of a decision aid results in different scores on variables reflective of the decision-making process, behavior, health outcomes, communication, and healthcare system.

Primary Null Hypothesis:

We plan a prospective randomized controlled study with a null hypothesis that patients randomized to a newly developed decision aid in addition to usual care have no difference in decisional conflict compared to patients treated with usual care and the ASSH brochures.

Secondary Null Hypotheses:

Our second aim is to determine if decision aids influence patient satisfaction, clinical outcomes and regret. To address this second aim, we will test the null hypothesis, which is that there is no difference in the rate of satisfaction, clinical outcomes and regret between patients treated with and without a decision aid.

III. SUBJECT SELECTION

Participants will be recruited among patients presenting to Orthopedic Hand Service of Massachusetts General Hospital with moderate or severe TMC arthrosis or CTS or CTD or DRF and or TF. The study physician will confirm the diagnosis and introduce the study to the patient. Each participant following the explanations by the interventionist will sign a detailed consent form at the time of their baseline diagnostic assessment. The consent form will include all of the study procedures, information about potential risks and benefits of participation, and information regarding who they can contact for further questions. It also will state that participation is voluntary, that participants can refuse to answer any question, and that they can withdraw from the study at any time, and that study participation is in no way related to their care. For follow-up, participants may be contacted by mail, phone and email.

Inclusion criteria:

All adult (>18years old) English-speaking patients presenting to one of the participating hand surgeons, Dr. Mudgal, Dr. Jupiter, Dr. Chen and Dr. Herndon from the Massachusetts General Hospital with moderate or severe TMC arthrosis, CTS, CTD, DRF and TF will be invited to enroll.

Exclusion criteria include:

1. Patients with prior operative treatment or corticosteroid injection for TMC, CTS, CTD, DRF and TF on the same limb.
2. Patients that have previously used the Decision Aids

IV. SUBJECT ENROLLMENT

The study will be described in detail and the treating physician/study staff will obtain informed consent. Patients will be given a copy of the consent form and be informed that their participation is voluntary and that they may refuse at anytime. The enrolling physician will emphasize that participation is voluntary.

All patients will be randomized to either a cohort managed with a decision aid (Cohort I) or to a cohort managed without a decision aid (Cohort II). A research fellow does the randomization after the first consult at the outpatient clinic with a computer generated simple randomization sequence.

V. STUDY PROCEDURES

This study will employ a randomized, prospective design. The baseline data are gathered at enrollment. The patients will be randomly assigned to two different cohorts after the encounter with the physician. The physician will be informed that the patient is participating in this study, but will not know to which cohort the patient will be randomized.

Cohort I will be managed with standard care plus a decision aid (henceforth “DA”), and cohort II will be managed without one. The patients in Cohort I will receive the DA, which they can complete in a separate room and take home. The decision aids include information on the disease/condition, treatment options, benefits, risks, scientific uncertainties, and probabilities of potential outcomes tailored to the patient’s health risks factors. Additionally, it includes values clarifications such as describing outcomes in functional terms, asking patients to consider which benefits and risks matter most to them, and guidance in the steps of decision making and

discussing their decision with family/friends. It is interactive and dynamic, helping patients clarify their preferences and come to a decision that feels best to them.

Cohort II will receive the standard care including—at the surgeon’s discretion--the American Society of Surgery of the Hand (ASSH) informational brochure. The patients will have the opportunity to read the brochure in a separate, quiet room or take it home. The ASSH - brochure contains anatomic illustrations of the injury and a discussion of surgical and non-surgical treatments for the diseases, and a general description of expected outcomes. Similar to the patients in cohort II, the patients in cohort I can read and complete the DA in a separate quiet room and take the decision aid home.

After randomization all patients will complete the REDCap questionnaires about the conflict in decision-making, which will take approximately 20 minutes. After completing the study procedures, the physician will return to the room and continue with the visit with the patient. The visit will be timed by a member of the study staff.

Outcome: Measured variables at enrollment – with REDCap, which will take approximately 20 minutes to fill out:

Demographic Questionnaire:

- Age
- Sex
- Ethnicity
- Race
- Marital status
- Education
- Current work status
- Current or previous occupation
- Hand dominance

Primary outcome:

- Decision conflict scale (DCS) – quantifies the state of uncertainty about a course of action.
- 11-point ordinal satisfaction scale – quantifies the satisfaction with overall treatment.
- 11-point ordinal satisfaction scale – quantifies the satisfaction with decision-making.

Secondary outcome

- Knowledge questionnaire
- Stage of decision making
- Decision Self-efficacy Scale
- Acceptability (Cohort 1 will not receive this questionnaire)
- Pain Self efficacy Questionnaire (PSEQ)
- 9-item Shared Decision Making Questionnaire (SDM-Q-9)

Primary health outcomes variables:

- Quick-DASH
- EQ-5D

At follow-up 1 week-1 month and 6 months after enrollment we will have patients complete the following online REDCap questionnaires, which will take approximately 20 minutes:

The decision-making process variables:

- Quick-DASH
- PROMIS Upper Extremity CAT
- DCS
- 11-point ordinal satisfaction scale – quantifies the satisfaction with overall treatment and decision-making.

- 11-point ordinal satisfaction scale – quantifies the satisfaction with decision-making.
- Decision Regret scale (measures distress or remorse after a health care decision)

VI. BIOSTATISTICAL ANALYSIS

Statistical issues

Based on previous studies, scores of 25 or lower on the DCS (0-100) are associated with low decisional conflict and following-through with decisions.¹⁵ On the other hand, scores of 39 or higher are associated with heightened mental conflict resulting in a delay in the decision making.¹⁵ Our study will measure the rate of patients having a conflict in decision-making. A sample size of 126 total patients was chosen to measure our primary outcome with 80% power, 0.5 effect size and an alpha of 0.05. Chi-square tests will be conducted to determine the differences between two categorical variables. Independent Student's t-tests will be performed to determine the differences between continuous and dichotomous variables. Paired samples T-test will be used to compare the mean scores for the same group on different occasions. Pearson's correlation or Spearman correlation will be used to explore the strength of the relationship between the conflict of decision-making and the use of decision aids. Wherever the minimum expected cell frequency is less than five, the Fisher's exact test will be used instead of the Pearson's Chi-square test. All variables with significant ($p < 0.05$) or near significant ($p < 0.08$) relationships will be evaluated with backwards multivariate/binary logistic regression (depending on the outcome variable) Descriptive statistics will be summarized in terms of means, standard deviations or frequencies, and will be calculated at each time point. Incomplete data will be adequately described and mean imputation will be used when deemed necessary. We will use IBM SPSS ® (19) to perform the data analysis.

VII. RISKS AND DISCOMFORTS (Stratify by common and uncommon)

The greatest discomfort associated with participation is the time required to fill out the decision aid and complete the questionnaires. Completing the DA will require approximately 20

minutes, but this can be done at home. The Questionnaires will require approximately 20 minutes at the time of enrollment.

VIII. POTENTIAL BENEFITS

Individuals managed without a DA will not experience any additional benefits, but will also not have any extra risks. Patients managed with a DA, on the other hand, may experience less decisional conflict and improved knowledge about their disease. The study will benefit society as a whole by providing a better understanding of the factors that influence patient decision-making and surgical outcomes for orthopedic problems.

Subjects will not receive monetary remuneration for their participation in this study. Since the patients have to return to the Hand and Upper Extremity Service for their regularly scheduled follow-up and the questionnaires are being sent online via REDCap, there are no additional monetary costs associated with participation in this study.

IX. MONITORING AND QUALITY ASSURANCE

Patients are not obligated to answer any questions. The patient's participation will not affect their medical care. Patients can withdraw from the study at any time. Patients who are disturbed by any of the questions will be offered psychological counseling, referral to a psychiatrist, or immediate transfer to the emergency room for psychiatric evaluation, depending upon the severity of the reaction.

Study physicians will be readily accessible for consultation should a study patient experience increasing discomfort while completing the questionnaire.

In the unlikely event that a patient has a severe adverse emotional disturbance while completing the questionnaire, we will contact the Acute Psychiatric Service and immediately take the patient to the Emergency Department for treatment. Subjects transported to the Emergency Department for additional care will not be asked to complete the questionnaires and will be dropped from the study.

Adverse events are defined as harmful occurrences to study participants, either study related or non-study related. These events may include an exacerbation of a pre-existing illness, increase in frequency or intensity of pre-existing episodic event or condition, condition detected or diagnosed even though it may have been present prior to the start of the study, or the worsening of the disease or symptom that was present before study participation. As a result of participant self-report, study staff discovery, or routine study assessments, the study staff may become aware of an adverse event. Fluctuations in depressed mood (that do not involve suicidality) are not considered adverse events.

The principal investigator will be responsible for insuring that any adverse events are reported to the IRB or federal agencies as necessary. Adverse events will be reported to the IRB as soon as they are discovered by any study staff member and discussed with the PI or designee (within 24 hours). The research coordinator, supervised by the principal investigator will be responsible for cataloguing and tallying adverse events. Serious adverse events (SAEs) will be reported to the MGH IRB within 24 hours of their detection using the necessary written forms provided by the MGH IRB. All proposed staff have participated in the NIH required trainings in participation and conduct of studies that involve human subjects, and any future study staff will do so upon hiring. If any study staff discovers any untreated condition (e.g. onset of substance abuse or physical condition), they will refer participants to appropriate treatment immediately. Study staff will follow Massachusetts's laws regarding mandated reporting for psychologists (i.e. discovery of abuse to a child, elder, or disabled person, participant is imminent danger of hurting themselves or an identifiable other person).

All participants are given a participation number/code at the time of enrollment. This code is kept on all data sheets instead of the patient name. Subject information is only accessible by Partners authorized investigators and will not be shared with outside entities. The final results after statistical analysis will not be shared with any other institution.

Study data will be collected and managed electronically using REDCap, a free online research management tool. It enables researchers to create study-specific websites for capturing participant data securely. The National Institutes of Health funded Patient Reported Outcomes Measurement Information System (PROMIS) questionnaires use IRT and CAT technology, which makes completing questionnaires less burdensome for patients. This technique uses fewer questions to get the same information on patient-reported health status, since it selects the

questions based on the previous answer. In other words it adapts. Answering questions which are not applicable to a patient's situation might seem unnecessary to patients, which results in a higher chance of questions being left blank, which in turn results in missing data. With the IRT answering technique it is less time consuming to complete questionnaires and thus more patient friendly. Missing questions are encountered frequently and with this technique patients do not need to complete questions which they think are irrelevant. Measures within the REDCap library can be included as well as custom instruments created or entered by the researcher. Patients can log in to complete online questionnaires. When no electronic medium (e.g, computer, laptop, Ipad) is available, we will collect the data through the paper version of the measurements (any PROMIS measure can also be downloaded for administration on paper), and afterwards enter the collected data into the REDCap.

REDCap enables customization of item or instruments (e.g., format, randomization, skip patterns), storage of protected health information in a separate, secure database, automated accrual reports, real-time data export, among many other features. REDCap is well secured and effectively protected and a compliant application which includes databases which store confidential, personal health information.

Questionnaires and self-reported responses will not become part of the patient's medical record and will not contain medical record numbers or names. Hardcopies of study related data and forms will be stored in a lockable file cabinet. Patient information will remain confidential by keeping identifying information (name, medical record number, and subject number) in a separate locked file cabinet. Only the investigators and study staff specified on the consent form will have access to this information.

Any magnetic or electronic information will be saved in Partners password-protected computers to which only research coordinator and persons involved with the research project will have access.

REFERENCES:

1. O'Connor AM, Bennett CL, Stacey D, Barry M, Col NF, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2009(3):CD001431.
2. O'Connor A RA, Fiset V, Tetroe J, Entwistle V, Llewellyn-Thomas H, Holems-Rovner M, Barry M, Jones J. . Decision Aids for patients facing health treatment or Screening Decisions: A cochrane systematic review. . *British Medical Journal* 1993;319:731-34.
3. Stacey D, Bennett CL, Barry MJ, Col NF, Eden KB, Holmes-Rovner M, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2011(10):CD001431.
4. O'Connor AM. Validation of a decisional conflict scale. *Medical decision making : an international journal of the Society for Medical Decision Making* 1995;15(1):25-30.
5. Estabrooks C, Goel V, Thiel E, Pinfold P, Sawka C, Williams I. Decision aids: are they worth it? A systematic review. *J Health Serv Res Policy* 2001;6(3):170-82.
6. Rothert ML, Holmes-Rovner M, Rovner D, Kroll J, Breer L, Talarczyk G, et al. An educational intervention as decision support for menopausal women. *Res Nurs Health* 1997;20(5):377-87.
7. Adam JA, Khaw FM, Thomson RG, Gregg PJ, Llewellyn-Thomas HA. Patient decision aids in joint replacement surgery: a literature review and an opinion survey of consultant orthopaedic surgeons. *Ann R Coll Surg Engl* 2008;90(3):198-207.
8. Barrett PH, Beck A, Schmid K, Fireman B, Brown JB. Treatment decisions about lumbar herniated disk in a shared decision-making program. *Jt Comm J Qual Improv* 2002;28(5):211-9.
9. Braddock C, 3rd, Hudak PL, Feldman JJ, Berekenyi S, Frankel RM, Levinson W. "Surgery is certainly one good option": quality and time-efficiency of informed decision-making in surgery. *The Journal of bone and joint surgery. American volume* 2008;90(9):1830-8.
10. Deyo RA, Cherkin DC, Weinstein J, Howe J, Ciol M, Mulley AG, Jr. Involving patients in clinical decisions: impact of an interactive video program on use of back surgery. *Medical care* 2000;38(9):959-69.
11. Phelan EA, Deyo RA, Cherkin DC, Weinstein JN, Ciol MA, Kreuter W, et al. Helping patients decide about back surgery: a randomized trial of an interactive video program. *Spine* 2001;26(2):206-11;discussion 12.
12. Weng HH, Kaplan RM, Boscardin WJ, Maclean CH, Lee IY, Chen W, et al. Development of a decision aid to address racial disparities in utilization of knee replacement surgery. *Arthritis and rheumatism* 2007;57(4):568-75.
13. Slover J, Shue J, Koenig K. Shared Decision-making in Orthopaedic Surgery. *Clinical Orthopaedics and Related Research* 2011.
14. Towle A, Godolphin W. Framework for teaching and learning informed shared decision making. *BMJ* 1999;319(7212):766-71.
15. O'Connor A, Tugwell, P., Wells, G.A., . A decision aid for women considering hormone therapy after menopause: decision support frame work and evaluation. *Patient education and counseling* 1998;33(267-279).

