PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR

Neal Chen, M.D

PROTOCOL TITLE

Treating Depression in Patients with De Quervain's tenosynovitis; An integrated web based skills intervention and decision aid

FUNDING

N/A

VERSION DATE

1.17.19

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

Aim 1: To develop a feasible and acceptable decision aid (DA) combined with a web-based depression treatment (Toolkit-depression) to help patients with de Quervain's tenosynovitis make informed choices with regard to their treatment, for de Quervain's tenosynovitis and comorbid depression.
Hypothesis: NA

Aim 2: To conduct an RCT of patients with de Quervain's tenosynovitis and compare patients who screen in for depression and are randomized to the Toolkit-depression versus patients who screen in for depression and undergo enhanced usual care (EUC). Primary outcomes are: pain intensity (NRS pain) and disability (DASH). Secondary outcomes are depression and catastrophic thinking about pain.

Hypothesis 1a: The DA will be feasible (>75% of participants will agree to participate) and accepted by patients (scores on the Client Satisfaction Scale above median split).

Hypothesis 1b: The Toolkit-depression will be feasible (>75% participants randomized to the Toolkit-depression will agree to participate and complete at least 3 out of the 4 web modules) and accepted by patients (scores on the Client Satisfaction Scale above median split).

Hypothesis 2: Patients randomized to Toolkit-depression will show short-term (pre to post) improvements in both primary and secondary outcomes when compared to those randomized to enhanced usual care. Improvements will be both statistically and clinically significant.

Hypothesis 3: Patients randomized to Toolkit-depression will show similar improvement (pre to post) in both primary and secondary outcomes when compared to those who did not screen in for depression and did not use the Toolkit.

Aim 3: To determine if improvements are durable at 6 month follow up.

Hypothesis 3: Among patients who screen in for depression, those randomized to Toolkit-depression will show sustained (post 6 months) improvements in both primary and secondary outcomes when compared to those randomized to EUC. Improvements will be both statistically and clinically significant.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

De Quervain's tenosynovitis is prevalent and treated with discretionary medical approaches. De Quervain's tenosynovitis is a self-limiting condition involving tendinosis of the abductor pollicis longus (APL) and extensor pollicis brevis (EPB) tendons within the first extensor compartment of the wrist. It has a prevalence of 1.3-2.1% in women and 0.5-0.6% in men. The standard care treatment for de Quervain's tenosynovitis includes a variety of medical options including nonsteroidal anti-inflammatory medication (NSAIDs), orthoses, corticosteroid injections and surgery. One study showed a significant variation in use of corticosteroid injection and surgery between 10 hand surgeons in 2 medical centers. Because de Quervain's tenosynovitis is a self-limiting condition surgery is discretionary.

Depression and coping explain the challenges faced by many patients in managing de Quervain's. Research has shown that there is limited correlation between impairment and disability is in many orthopedic conditions. A biopsychosocial model that considers the complex interactions of biological, psychological and social variables may explain this discrepancy. Indeed, studies have shown that depression affects patient reported outcome measures in de Quervain's tenosynovitis. Disability is significantly correlated with symptoms of depression, anxiety, pain-escaping behavior, and catastrophizing. Multivariable linear regression models showed symptoms of depression accounted for 32% of the variability in functional outcomes, suggesting that depression is a risk factor for poor outcomes in patients with de Quervain's tenosynovitis.

Psychosocial skills interventions that target depression may improve outcomes in patients with de Quervain's. A number of studies have shown that psychosocial treatments that are focused on teaching coping skills are effective in improving depression as well as decreasing disability across many conditions from fibromyalgia, tinnitus distress to chronic pain. Depression also predicts outcomes after elective minor surgeries include de Quervain's. The multidisciplinary team at MGH has developed a 4 session psychosocial skills intervention (Toolkit for Optimal Recovery) for patients with acute musculoskeletal trauma at risk for persistent pain and disability, which has been shown to improve pain at rest function, pain with activity, pain catastrophizing, depression and pain anxiety when compared to standard care. This intervention may also be beneficial for individuals with de Quervain's who also report depression. To date, there are no studies of psychosocial interventions to improve outcome in individuals with de Quervain's tenosynovitis. Treating depression represents an unexplored opportunity to improve outcomes for patients with de Quervain's tenosynovitis regardless of the medical treatment modality they choose.

Decision aids may help patients make a more informed choice about their treatment for de Quervain's and depression. Decision aids (DA; shared decision making tools—websites, videos, or pamphlets) are interventions to prepare patients to make more informed and satisfying decisions that match their preferences and values. DA's are designed to provide patients with balanced, complete and understandable information about their options as well as risks and benefits, in order to help them determine their preferences according to their values[16]. A systematic review of decision aids for treatment or screening decisions found participants felt more knowledgeable and better informed with a more active role in decision making[17]. A decision aid component that educates patients about their depressive symptoms and association with symptoms and disability may also be a more sensitive and cost effective way to get timely treatment for patients in need. By being more involved in the treatment choice, patients can feel empowered and may show better recovery.

This study aims to develop a decision aid (DA) for helping patients with de Quervain's tenosynovitis to determine their preferences for treatment (including treatment for depression for those with clinical depression) according to their values and relationship with pain and disability.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

This is a prospective randomized controlled trial of Toolkit depression compared to enhanced standard care with a decision aid for patients with de Quervain's tenosynovitis and symptoms of major depression.

Inclusion criteria
Adults (≥18 years) diagnosed with de Quervain's tenosynovitis
English fluency and literacy
Ability to give informed consent

Exclusion criteria
Inability or unwillingness to participate in decision aid (DA) and/or Toolkit-depression
Major medical comorbidity expected to worsen in the next 6 months
Comorbid chronic pain condition
Antidepressant medications changes in the past 6 months
Severe and untreated mental health conditions or active substance dependence
Secondary gains such as litigations or worker compensation procedures that may interfere with patients' motivation for treatment
No online device available to use the DA and Toolkit-depression

We expect to enroll 90 patients diagnosed with de Quervain's tenosynovitis. The primary outcome measure is change in QuickDASH score. A minimum sample size of 54 patients would allow the study 90% power to detect a difference of 15 points in QuickDASH score between patients who received the Toolkit-depression intervention and those that did not. Therefore we would want to enroll a minimum of 27 patients in each group.

In an RCT of the Toolkit, 14% did not complete the intervention at 6 weeks. If we anticipate experiencing similar levels, we will need to recruit a minimum sample size of 90 patients (30 patients in each group) to maintain sufficient power at 6 months follow up.

In a study of depression in patients with common hand diagnoses, 46% of patients with de Quervain's tenosynovitis had a PHQ-9 or CES-D score consistent with symptoms of major depression. However, while some studies found almost 50% of their patients with de Quervain's tenosynovitis had symptoms of major depression, this may be as low as 10%.

A study of de Quervain's tenosynovitis at Massachusetts General Hospital (MGH) and Brigham and Women's Hospital (BWH) recruited 2513 patients over 12 years equating to approximately 200 patients per year. Therefore, it may take between 6 months and just over 3 years to recruit 70 participants to our trial.

It is also possible that patients may choose to answer the HADS questionnaire in a way that underestimates their symptoms of depression. This would then further reduce the rate of recruitment of participants to our study.

Participants will complete the base measures at their initial clinical visit, then they receive email invitations to complete online surveys at 6 weeks and 6 months. Patients unable to fill out the survey will be contacted by telephone and assisted with completion of the questionnaire.

Nested Feasibility Study

As this study involves introduction of a new concept - a decision aid that introduces the concept of depression as a factor affecting the outcome of patients with de Quervain's tenosynovitis, we propose a nested feasibility study. During recruitment of the first 10 patients into the study, we review their satisfaction scores to see how acceptable they found the DA and if there are any ways that we could improve the DA or the recruitment process.

Additionally, we would like to administer 2 questionnaires that ask about symptoms of depression at enrolment to these first 10 participants in the study. The PHQ-9 and Hospital Anxiety and Depression Scale (HADS) are both used widely in the research literature, and it would be useful to know preference of participants so that we can use the preferred questionnaire for future studies. We would like to use both questionnaires at enrolment for the first 10 people recruited to the study, and ask them which questionnaire they prefer. After the first 10 people recruited, we would select the most popular questionnaire and continue with this one alone.

After the first 10 people were recruited, the HADS was chosen as the questionnaire to be used for symptoms of depression in the rest of the study. Participants who score ≥7 on the HADS will be eligible to be randomized to the Toolkit intervention. Where a participant HADS score indicates symptoms of severe depression (HADS ≥15), REDCap will notify Dr Vranceanu who will be able to conduct a psychological assessment of the patient's safety (including suicidality).

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

Patients will be prescreened by clinical notes and referrals and either contacted before their appointment or approached in clinic. Potential subjects will be pre-screened for inclusion and exclusion criteria by a questionnaire and questions asked by study staff. Those eligible who wish to participate will complete the informed consent process to enroll in the study. Additional detail is available in the Recruitment Procedures section of this document.

At enrollment, patients will be asked to complete a questionnaire on symptoms of depression (HADS) and the DA for de Quervain's tenosynovitis. Additionally, demographic data will be collected, including age, gender, ethnicity, race, marital status, current work status, consulting hand surgeon, occupation, education, hand dominance, affected side and current analgesia intake. They will also be asked to complete surveys to assess pain intensity (NRS), disability (QuickDASH), depression (HADS) and catastrophic thinking (PCS-13) in REDCap.

During their consultation, a hand surgeon will confirm the diagnosis of de Quervain's. Patients that do not have de Quervain's tenosynovitis will be excluded from the study. After their consultation, participants randomized to Toolkit-depression will be given a link to access the Toolkit online at home.

At 2 weeks, participants will be contacted via REDCap to record initial choice of treatment (observation, NSAIDs, orthoses, corticosteroid injection, surgery), acceptability of the decision aid (Client Satisfaction Scale CSQ-3) and decisional conflict (Decisional Conflict Scale).

At 6 weeks, participants will be contacted to assess pain intensity (NRS), disability (QuickDASH), depression (HADS), catastrophic thinking (PCS-13) and decisional conflict (DCS) online on REDCap. Participants randomized to the Toolkit-depression will also be asked about its acceptability (CSQ-3).

At 6 months, participants will be contacted to assess pain intensity (NRS), disability (QuickDASH), depression (HADS), catastrophic thinking (PCS-13) and decisional conflict (DCS) online in REDCap. All participants will be asked about their final choices of treatment (observation, NSAIDs, orthoses, corticosteroid injection, surgery) and satisfaction with the DA and Toolkit if used (SCQ-3).

In a single-center study of patient-centered care for de Quervain's tenosynovitis, 57% of patients who opted for non-operative treatment noted resolution of symptoms within 6 months. In an RCT of full-time compared to as-desired splint wearing for patients with de Quervain's tenosynovitis, DASH score only improved by a mean of 7 points at follow up after 8 weeks. The minimum clinically important difference in DASH score is approximately 10 so it would be better to wait until 6 months when symptoms are more likely to have resolved.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Enhanced Standard Care includes; options for management explained as observation (see if it goes away on its own), NSAIDs, orthoses, corticosteroid injection and surgery in the DA. This may include follow up visits with surgeons as required.

Toolkit-depression includes: a web-based intervention with 4 sessions focused on teaching relaxation strategies as well as cognitive and behavioral aspects of acute pain.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

We do not foresee major additional risks for patients participating in this study. Patients receive usual care, regardless of their participation.

There is the possibility that some patients are initially identified as having de Quervain's tenosynovitis and complete enrollment questionnaires, but having seen the Specialist Hand Surgeon it is determined that they do not have de Quervain's tenosynovitis. This may be distressing for some patients. However, this did not pose any problems in a recent study at this center (IRB Protocol Number 2015P002550) when 12 patients were excluded after initial likely diagnosis of thumb carpometacarpal joint arthritis but were later excluded due to a different diagnosis.

The only other discomfort participants may endure is the time required to complete the questionnaires and for those randomized to the Toolkit-depression there will be additional time required to complete these sessions. There are 4 sessions that will each take approximately 30 minutes to complete.

In the event that a patient has a severe adverse emotional disturbance while in the study, the patient will meet with a psychologist for diffusion and or referral.

Questionnaires will require approximately 20 minutes at the time of the in person visit, and online at 6 weeks and 6 months.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

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

Where a participant HADS score indicates symptoms of severe depression (HADS $\geq$15), REDCap will notify Dr Vranceanu who will be able to conduct a psychological assessment of the patient's safety (including suicidality).

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

Since all patients will receive the usual care, participation in this trial does not impose additional risks to the patients. This trial does not interfere with the surgical process or postoperative care. If the completion of questionnaires causes discomfort for patients, study physicians will be readily accessible for consultation.

Where a participant HADS score indicates symptoms of severe depression (HADS ≥15), REDCap will notify Dr Vranceanu, a clinical psychologist, who will be able to conduct a psychological assessment of the patient's safety (including suicidality).

The greatest discomfort associated with participation is the time required to complete the Toolkit-depression. This is anticipated to take approximately 30 minutes to complete each of the 4 sessions. Additionally, the questionnaires at enrolment, 6 weeks and 6 months will take approximately 20 minutes to complete, but this can be done online via REDCap at home.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

For subjects receiving enhanced standard care, using the DA may improve satisfaction with their decision making with reduced decisional conflict. We hope that patients managed with the Toolkit-depression may experience improvement in their symptoms of depression as well as improvement in pain intensity and disability in terms of their de Quervain's tenosynovitis. The study may also benefit society as a whole by providing a better understanding of the factors that influence patient-reported outcomes in de Quervain's tenosynovitis.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

All adult subjects who satisfy the inclusion/exclusion criteria are eligible for enrollment in this study regardless of sex, race or ethnicity. Vulnerable populations will not be recruited.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

We must restrict the study to English speaking patients because the web based intervention Toolkit-depression is only in English. Additionally many of our questionnaires are validated in English only.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.1.10.pdf

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

We will use three recruitment methods in this study: 1. First contact via invitation letters to patients with specific mention of de Quervain's or symptoms thereof per referral or clinical notes; 2. First contact during clinical visit for patients with possible de Quervain's per symptoms documented in referral or clinical notes; and 3. First contact made by patients to study staff in response to study advertisement on clinicaltrials.partners.org

Recruitment by screening clinic schedule
Potential subjects will be identified by screening the schedule of the Hand and Arm Center at Massachusetts General Hospital. For patients referred to a hand surgeon with a probable diagnosis of de Quervain's tenosynovitis, a recruitment letter may be sent to them by mail or via Patient Gateway. The letter explains the purpose of the research - study procedures, and duration of participation.

Patients who opt in to the study and will be contacted by study staff to explain the study, obtain consent from the subject and answer all remaining questions. Subjects that agree to participate will electronically sign the consent form in REDCap. Subjects will receive a copy of the consent form via e-mail.

Patients will therefore have the opportunity to start working with the decision-aid prior to their appointment and be able to make a more informed decision making process with the specialist. They will also be asked to complete enrollment questionnaires, including HADS for symptoms of depression.

Recruitment at first clinical visit
Patients whose referrals do not mention de Quervain's specifically but that could be presenting for de Quervain's or patients whose appointments are made close enough in the future that it is not logistically feasible to contact them for pre-screening will be approached in clinic by study staff. Study staff will briefly describe the study and ask if the patient may be interested in participating if eligible. If the patient agrees, they will be asked to sign the consent form and proceed with the pre-screening questionnaire (HADS) and DA. They will also be asked to complete enrollment questionnaires if they have time before their consultation.

For all patients, during their consultation a hand surgeon will confirm the diagnosis of de Quervain's. Patients that do not have de Quervain's tenosynovitis will be excluded from the study.

Patients that do have de Quervain's tenosynovitis but do not score 7 or above on the HADS will be invited to participate in the study to evaluate the decision aid and allow comparison with patients who do have symptoms of major depression.

After the initial appointment with the specialist, patients with a diagnosis of de Quervain's tenosynovitis and symptoms of major depression will be randomized to the Toolkit-depression (Cohort 1) or Standard Care (Cohort 2). The randomization is done within REDCap via generated randomization sequence. Subjects randomized to the Toolkit-depression will be given the online link to the Toolkit.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Subjects will not receive monetary remuneration for their participation in this study, and patients will return to the Hand and Arm Center for their usual practice follow-up examination.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Recruitment_Of_Research_Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Guidelines_For_Advertisements.1.11.pdf

Remuneration for Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Remuneration_for_Research_Subjects.pdf

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Recruitment by screening clinic schedule

For those patients receiving a letter prior their appointment and deciding to opt in, they will be asked to send their contact information (name, date of birth, e-mail address, and phone number) to the principal investigator and study coordinator. A member of the study staff will then get in touch with the subject to explain the study.

Subjects that agree to participate will electronically sign the consent form in REDCap. Subjects will receive a copy of the consent form via e-mail.

Recruitment at first clinic visit
For those patients recruited at first clinic visit, study staff will briefly describe the study and ask if the patient may be interested in participating if eligible. If the patient agrees to participate, they will be asked to sign the consent form and proceed with the pre-screening questionnaire (HADS) and DA.

Advertisements on clinicaltrials.partners.org
For those patients recruited via a study card on Partners' clinicaltrials.partners.org website, subjects that agree to participate will electronically sign the consent form in REDCap. Subjects will receive a copy of the consent form via e-mail.

For all patients, during their consultation a hand surgeon will confirm the diagnosis of de Quervain's. Patients that do not have de Quervain's tenosynovitis will be excluded from the study.

After the patient is included in the study, a member of study staff will be available to help subjects complete questionnaires and for those randomized to the Toolkit-depression will give them the link to access it online.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects:
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Informed_Consent_of_Research_Subjects.pdf

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

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. Subjects can log in to complete online questionnaires.

REDCap enables customization of items 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 that includes databases which store confidential, personal health information. All of the questionnaires, including the questionnaires filled out by the subject, will be stored on Partners encrypted computers and only members of the study staff will have access to this information. If paper copies are used, they will be stored in locked filing cabinets or converted to certified digital copies and originals shredded, and only the study staff will have access to the documents.

The information collected during the study will not become part of the patient's medical record. Only the investigators and member of the study staff will have access to this information. Hardcopies of study related data and forms will be stored in a lockable file cabinet or converted to certified digital copies and originals shredded. 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 password-protected computers to which only research coordinator and persons involved with the research project will have access.

All subjects are given a participation number/code at time of enrollment for this study. While the data remains in REDCap it will be stored with subjects' identifiers, but can be exported into deidentified reports. Subject information is only accessible by Partners authorized investigators and will not be shared with outside entities.

Subject information will not be accessible to any of the referring hand surgeons at non-Partners sites. Each referring hand surgeon will only provide the x-rays and diagnostic information for the surgeon's own patients.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

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 in compliance with Partners policy as they are discovered by any study staff member and discussed with the PI or designee. The research coordinator, supervised by the principal investigator will be responsible for cataloging and tallying adverse events. Serious adverse events (SAEs) will be reported to the PHRC in accordance with Partners policy. 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). Fluctuations in depressed mood (that do not involve suicidality) are not considered adverse events.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

There will be a full-time research coordinator and principal investigator responsible for adherence to all IRB rules and guidelines and for the accuracy and completeness of all forms, entries, and informed consent.

Study data will be maintained in a locked filing cabinet and on password protected computers. Questionnaires and self-reported responses will not become part of the subject's medical record. Hardcopies of study related data and forms will be stored in a lockable file cabinet or converted to certified digital copies and originals shredded. Subject information will remain confidential by keeping identifying information (name and subject number) in a separate locked file cabinet or password protected computer or approved database (REDCap). Only the investigators and study staff specified on the protocol will have access to this information. Any magnetic or electronic information will be saved in password-protected computers to which only research coordinator and persons involved with the research project will have access. REDCap, secure and HIPAA-compliant, will be used to collect all answers. The Principal Investigator oversees and monitors this process.

For guidance, refer to the following Partners policies:
Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Reporting_Unanticipated_Problems_including_Adverse_Events.pdf

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

Care will be taken to preserve the confidentiality of patient information. Research data will not become part of the medical record. Patient information specific to the study will be maintained in a private database on a secure network, to which access is limited. Hardcopies of study related data and forms will be stored in a lockable file cabinet or converted to certified digital copies and originals shredded. All participants are given a participation number/code at the time of enrollment. Subject information is only accessible by Partners authorized investigators and outside investigators who have been approved by the data use agreement process by the IRB and Research Management. Subject information will not be accessible to any of the referring hand surgeons at non-Partners sites.

All data will be maintained at MGH in accordance with Partners policy. Data may be shared and stored as a limited data set with non-Partners investigators through a Data Use Agreement (DUA) with approval of the IRB and Research management. Non-Partners investigators may temporarily store the data on password protected, encrypted laptops.

Once the research is complete, all direct patient identifiers will be destroyed.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

Limited data sets (LDS) may be shared with outside collaborators for the study, including current study staff who return to their institution but will continue to collaborate on the study to prepare

the work for publication and presentation at scientific meetings. Data use agreements will be executed as necessary for the sharing of any data to comply with current Partners policy.

Institutions and Responsible Researchers	Type of Data	Explanation
Massachusetts General Hospital (Dr. Neal Chen) University of Bristol (Dr. Julia Blackburn)	Participant information (including marital status, education level, current work status, occupation, household income, hand dominance), affected side, pain medication currently taken, QuickDASH score, VAS pain score, Pain Catastrophizing Scale score, Hospital Anxiety and Depression Scale score, Decision Conflict Scale score, arm of the trial that the participant is in, treatment choice, satisfaction with the Decision Aid and Toolkit interventions	This data will be collected at MGH by a researcher in coordination with Dr. Chen. Dr. Chen would like to continue the research project with a researcher at the University of Bristol. Dr. Neal Chen is the PI for the protocol under which the data was collected at MGH. Dr. Julia Blackburn is the responsible PI at the University of Bristol. Use of data: Data will be analysed and used to produce publication(s) for peer reviewed journals and poster or podium presentations at conferences.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

Data will be stored at the receiving institution for the purpose of conducting research as outlined in this protocol. Data at the receiving institution will be stored on a password-protected computer, and only study staff will have access to the shared data. Once data is shared, it will be stored and records maintained in accordance with the receiving institution's IRB policies. Subjects may withdraw their data by contacting the MGH Arm and Hand Center, who can exclude the specified data or contact the receiving institution to delete the specified data.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

N/A