INTERVENTIONAL
RESEARCH PROTOCOL TEMPLATE
(HRP-503a)

STUDY INFORMATION

- **Title of Project:**
  Utilization of Video as Preoperative Education for Meniscectomy Surgery Patients

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- **Protocol Version and Date:**
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1.0 Research Design

1.1 Purpose/Specific Aims

The purpose of the proposed study is to compare the effectiveness of video instructions versus a patient handout as method for patient comprehension and opioid usage for meniscectomy patients.

A. Objectives

The primary objective is to compare the effectiveness of video instructions versus a patient handout as method for patient comprehension of concept areas such as how to care for the incision, how to safely manage pain with and without opioids, the side effects of opioids. The secondary objective is to evaluate whether the utilization of video instructions versus a patient handout will lead to lower post-operative use of opioid medications.

B. Hypotheses / Research Question(s)

The use of video for pre-operative education for meniscectomy surgery will improve patient comprehension of operative instructions compared to paper handout. Secondarily, the use of video will help to minimize opioid usage post-operatively.

1.2 Research Significance

Several studies have shown the utility of video relating to patient comprehension and experience surrounding orthopedic surgery. These studies have been done in knee and shoulder arthroscopy, joint replacement surgery, and hand surgery. A recent project referenced below that was presented at NYSSH meeting showed that using video compared to a paper handout for operative instructions showed improved patient comprehension, particularly as it relates to patient knowledge surrounding opioid usage. However, that study did not quantify the number of opioids in the video and paper handout groups. To date, there is no study that compares video instructions versus a paper handout for patient comprehension and opioid usage for meniscectomy patients.

1.3 Research Design and Methods

This is a single-blinded prospective randomized controlled clinical trial. Patients 18 or older, undergoing a meniscectomy procedure at University Center for Ambulatory Surgery, LLC (UOA), who are English speaking, with intact decision-making capacity, and have access to the required technology to participate in this study (cell phone to receive text messages and view the instructional video), will be reviewed for eligibility. Patients who did not speak English and/or had documented cognitive impairment or neurological disorder affecting word processing or memory will be excluded from the study. Once identified, potential study subjects will be asked whether they are interested in participating in the project. If the patient agrees, the subject will be given the informed consent to read and sign.

A. Research Procedures

Preoperative Visit: All patients who consent will have operative instructions explained by the study surgeon and his assistants. Patients will then be allocated to either the video or handout group with the use of a computer-generated block randomization sequence, with the study surgeon blinded to patient allocation. Due to the nature of the material provided, it is not possible to blind the patients to the allocation. Patients in the control group will be given a physical copy of the handout of operative guidelines at the time they book their surgery in the office. Those in the study group will receive a link at the same time point when they book their surgery in the office, via email, which will provide access to a video on YouTube outlining the same operative instructions. A research assistant will confirm patients in the study group receive the video by email and that the link was playable/ accessible to them.

Patients in both groups will be aware that they would be asked questions regarding the contents of the instructions. Patients had unlimited access to the video once they were provided the link. The

video was less than 10 minutes long, and it was accessible by computer, tablet, or cell phone. The content of the video and paper handout mirrored each other and consisted of general operative instructions, incision and dressing care, symptom monitoring, and pain management (Video 1, Appendix 1).

Day of Surgery: All patients will be receiving the same preoperative care, undergo meniscectomy via the same surgical technique, and same postoperative care in the post-anesthesia care unit (PACU) after surgery. In the PACU, patients in the control group will again be given a physical copy of the handout of operative guidelines. Likewise, patients in the study group will also be sent a link by email, again in the PACU after surgery.

After surgery: At the first postoperative visit, 10 to 14 days after surgery, patients will be given a questionnaire to evaluate their comprehension of concepts which were outlined in the video or the handout. The questionnaire will consist of 12 multiple choice questions with concepts including areas such as how to care for the incision, how to safely manage pain with and without opioids, the side effects of opioids (Questionnaire in supplemental section of eIRB). Patients will also be asked to rate how helpful they found the information in the assigned instructions on a scale of 1 to 5 (1 = not at all helpful, 5 = extremely helpful), how many times they viewed the instructions, and at what time point the instructions were most helpful to read (before the procedure, at the surgical center, or after the procedure). Lastly, patients will be asked to report the number of opioid and other analgesic medications they took following surgery.

B. Data Points

Age, injury type, surgery performed, use of narcotic and other analgesic pain medication, number of times instructions viewed or read

C. Study Duration

The study will be conducted from time of IRB approval until the minimum number of participants shown below have completed the study. Each subject will participate in the study from their pre-operative appointment until 14 days after surgery.

D. Endpoints

Primary endpoints: The number of questions answered correctly, and patient-reported helpfulness of the material, on a scale of 1-5 to detect clinically significant difference in patient comprehension.

Secondary endpoint: Number of opioid and other analgesic medications taken

1.4 Preliminary Data

There is currently no relevant preliminary data collected at University Orthopaedic Associates.

1.5 Sample Size Justification

PG Power Table			Primary 2 Arm Treatment Comparison		Primary 2 Arm Treatment + Anesthesia Subgroup Comparison	
Statistical Significance	Power	Desired Effect Size	N per Treatment Type (2 Groups) 0% Drop-Out Inflation	N per Treatment Type (2 Groups) 20% Drop-Out Inflation	N per Treatment Type (4 Groups) 0% Drop-Out Inflation	N per Treatment Type (4 Groups) 20% Drop-Out Inflation
0.05	0.80	0.50 (medium)	64	80	128	160
0.05	0.80	0.60 (medium)	45	57	90	114
0.05	0.80	0.70 (medium)	34	43	68	86
0.05	0.80	0.80 (large)	26	33	52	66

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables
Independent Variable: video containing operative instructions

B. Dependent Variables or Outcome Measures
Dependent Variable: number of questions answered correctly, and patient-reported helpfulness of the material, on a scale of 1-5 at the first post-operative visit (day 10-14)

1.7 Drugs/Devices/Biologics

A. Schedule and Administration
Patients in the control group will be given a physical copy of the handout of operative guidelines at the time they book their surgery in the office, and again in the post-anesthesia care unit (PACU) after surgery. Those in the study group will receive a link at the same time-points by email, when they book their surgery in the office and again in the PACU after surgery, which provides access to a video on YouTube outlining the same operative instructions.

B. Drug/Device Accountability and Storage Methods
Not Applicable

1.8 Specimen Collection

A. Primary Specimen Collection
Not Applicable

B. Secondary Specimen Collection
Not Applicable

1.9 Data Collection

A. Primary Data Collection

B.

- **Location**: Data will be collected via online survey/questionnaire utilizing RedCAP
- **Process of Data Collection**: Patients will be educated on how to access the online survey and a research assistant will ensure patient access.
- **Timing and Frequency**: The survey will be accessible to patients at their first post-operative visit, day 10-14.
- **Procedures for Audio/Visual Recording**: ***N/a***
- **Study Instruments**: Qualitative data will be collected via a questionnaire created by the researchers.
- **Ethnographic Studies, Interviews, Or Observation**: Patients will be provided with questionnaires via the app/web based system including pain scores, number of narcotic and non-narcotic pain medications used, as well as any adverse events.
- **Subject Identifiers**: Patient data will not include any identifiers.

C. Secondary Data Collection
Not Applicable

1.10 Timetable/Schedule of Events

This study will have two groups that will each go through the timetable below. Patients will receive operative instructions at the first preoperative clinic visit when they book their procedure. Patients in the control group will be given a physical copy of the handout of operative guidelines at the time they booked their surgery in the office, and again in the post-anesthesia care unit (PACU) after surgery. Those in the study group will receive a link at the same time-points by email, when they booked their surgery in the office and again in the PACU after surgery, which provided access to a video on YouTube outlining the same operative instructions. At the first postoperative visit, 10 to 14 days after surgery, patients will be given a questionnaire to evaluate their comprehension of concepts which were outlined in the video or the handout.

2.0 Project Management

2.1 Research Staff and Qualifications

Project Lead: Charles Gatt, MD
Faculty: Kenneth Swan, MD, Patrick Buckley, MD, Cristobal Beiro, MD
Resident: Jeremy Silver, MD, PGY-4 Orthopaedic Resident
UOA Staff: Eric Nussbaum, MEd, ATC, LAT
Medical Students: Peter Filtes, PharmD; Alioune Diane, BS

2.2 Research Staff Training

Research Staff Training: All research staff has successfully completed CITI Training (Collaborative Institutional Training Initiative).

2.3 Other Resources

Facilities: The research will be conducted at University Orthopaedic Associates, LLC (UOA). Medical or Psychological Resources: Medical treatment related to orthopaedics can be provided by the study physicians. Other required medical care can be referred to the appropriate clinician. Psychological assistance can be referred to an appropriate mental health professional.

2.4 Research Sites

All research will be conducted at University Orthopaedics Associates, LLC outpatient surgery center located at 2 Worlds Fair Drive, Somerset, NJ 08873.

3.0 Multi-Center Research

University Orthopaedic Associates (Somerset), 2 Worlds Fair Drive, Somerset, NJ 08873

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects
Patients 18 or older, undergoing a meniscectomy procedure at University Center for Ambulatory Surgery, LLC (UOA) will be reviewed for eligibility.

B. Recruitment Details
Recruitment will take place at the UOA office during patient visits. Patients will be provided with educational pamphlet. Recruitment will take place by study staff.

C. Subject Screening
Subjects will be screened by attending physicians in the office setting as patients are being indicated for surgery as per standard of care.

- **Inclusion Criteria**
  - Patients 18 or older
  - Undergoing a meniscectomy procedure
  - English speaking
  - Intact decision-making capacity
  - Have access to the required technology to participate in this study (cell phone to receive text messages and view the instructional video)
- **Exclusion Criteria**
  - Patients who did not speak English
  - Patients with documented cognitive impairment or neurological disorder affecting word processing or memory
  - Patients who do not have access to a cell phone to view the video

D. Privacy Protections
Data collected via an online questionnaire that is protected by HIPPA regulations. Data will be de-identified prior to statistical analysis.

4.2 Obtaining Identifiable Information About Non-Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects
80-160 patients targeted to be recruited to account for study dropout

B. Total Number of Subjects If Multicenter Study
N/a

C. Feasibility
University Orthopaedic Associates is a high-volume orthopaedic center. Physicians including Drs. Gatt, Swan, Buckley, and Beiro see a high volume of patients undergoing meniscectomy and it is therefore reasonable to accrue the required number of patients to achieve statistical significance for this study.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
  Consent will take place in person at University Orthopaedics Associates, LLC outpatient surgery center located at 2 Worlds Fair Drive, Somerset, NJ 08873.
- **Ongoing Consent**
  Patients are free to remove themselves from the study at any time. Unenrolling from the study will not affect their care in any way.
- **Individual Roles for Researchers Involved in Consent**
  Physicians listed in study staff will be primarily involved in identification of patients and consent. Study staff including anesthesiologist, resident, and support staff listed will also be able to discuss study with patients. Potential study participants will be led through the consent process by research coordinator or study investigators, using an IRB-approved consent form.
- **Consent Discussion Duration**
  The consent discussion will be given as much time as is needed for the potential subject to make an informed decision. We estimate that each patient will require around 20 minutes to complete the consent process, but patients are free to extend the duration as needed.
- **Coercion or Undue Influence**
  In order to minimize the potential for coercion or undue influence, all participants will be given ample time to ask questions and to make an informed decision about study participation. A member of the study team will ensure that the potential participant fully understands the details of the study and comprehends the significance of his/her decision to consent for participation. Participating in this study will determine how they receive their instructions for surgery. Lastly, all potential participants will be assured that their current or future care will not be affected by their decision to participate.
- **Subject Understanding**
  The "teach-back method" will be implemented. The study team member leading the consent discussion will ensure the subject's understanding of the study by asking them to paraphrase the information conveyed in the consent form. Potential subjects will also be encouraged to ask questions throughout the consent process to clarify any points of confusion that arise.
- **Protecting Privacy**
  Consent will take place privately in the private examination room at the UOA office.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
  N/A
- **Destruction of Identifiers**
  N/A
- **Use of Deception/Concealment**
  N/A
  a. **Minimal Risk Justification**
     N/A
  b. **Alternatives**
     N/A
  c. **Subject Debriefing**
     N/A

C. Documentation of Consent

- **Documenting Consent**
  Potential subjects will have an informative conversation with the surgeon and research coordinator/ancillary staff at their preoperative visit to assess their interest in participating in

the study. The subject will be given the opportunity to read the study informed consent and to ask any questions. If the subject agrees to participate and signs the informed consent, the subject will be given a copy of the informed consent.

- **Waiver of <u>Documentation</u> of Consent (i.e., will not obtain subject's signature)**
  N/A

4.5 Special Consent Populations

A. Enrolling Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
  All participants will be above the age of 18 and will provide informed consent for themselves.
- **Non-Parental Permission**
  N/A
- **Assent Process**
  N/A
- **Documentation of Assent**
  N/A
- **Reaching Age of Majority During Study**
  N/A

B. Enrolling Wards of the State

N/A

- **Research Outside of NJ Involving Minors**
  N/A

C. Enrolling Non-English-Speaking Subjects

Non-English speaking patients will be excluded from the study.

- **Process for Non-English-Speaking Subjects**
  N/A
- **Short Form Consent for Non-English Speakers**
  N/A

D. Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)

Patients who lack decision-making capacity will be excluded from the study.

- **Assessing Adult Capacity to Consent**
  N/A
- **Selecting a Surrogate & Consent Process**
  N/A
- **Subject Assent**
  N/A
- **Selecting a Witness to the Surrogate Consent Process**
  N/A
- **Removing a Subject**
  N/A

E. Special Consent Considerations

N/A

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses

There will be no additional costs to the patient. Each patient who enrolls will need to have a cell phone that can be used to receive messages and view the instructional video. These messages and videos will not cost the patient any money. Any patient that does not have access to a cell phone will be excluded from the study.

B. Compensation/Incentives

There is no compensation for participation in this study.

C. Compensation Documentation

N/A

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
  There are no risks associated with participation in this study.
- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  N/A
- **Other Foreseeable Risks of Harm**
  N/A
- **Observation and Sensitive Information**
  N/A

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects

N/A

C. Risks of Harm to Non-Subjects

N/A

D. Assessment of Social Behavior Considerations

N/A

E. Minimizing Risks of Harm

N/A.

- **Certificate of Confidentiality**
  N/A
- **Provisions to Protect the Privacy Interests of Subjects**
  Patient confidentiality will be maintained by storing collected data on a password protected document and stored on the Rutgers approved Office cloud - OneDrive. Only the research team will have access to this information. Any publication that may come of this research study will not reveal any identifying information about the subjects.

F. Potential Direct Benefits to Subjects

The goal of this research is to provide patients with an ideal/ effective method of perioperative education that will improve patient comprehension of operative instructions. Effective patient education on care for surgical incision, how to safely manage pain with and without opioids, the side effects of opioids, may minimize risks associated with opioids including adverse effects and the risk of developing an opioid dependence in the post-operative setting.

5.0 Special Considerations

Complete each sub-section that applies to the research; if not applicable, replace instructional text with N/A.

5.1 Health Insurance Portability and Accountability Act (HIPAA)

All patients will be provided with a standard HIPAA practices agreement at the office visit.

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

N/A

A. Special Populations

- N/A

5.4 General Data Protection Regulation (GDPR)

N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)

N/A

6.0 Data Management Plan

6.1 Data Analysis

Data will be analyzed by the statisticians. Statistical comparisons will be made between patients receiving paper instructions vs. video instructions. The mean number of questions answered correctly for both the groups were compared using the student t-test. For secondary variables and baseline characteristics, statistical testing was performed based on the type of variable: the chi-square test for categorical variables and the student t-test (parametric) or Mann-Whitney U test (nonparametric) for continuous variables. For the ordinal variable of patient-reported helpfulness, the Mann-Whitney U test was used.

6.2 Data Security

Describe the steps that will be taken to secure the data through all phases of the research—from the time of its collection, to its storage, use and study closure— such as staff training, transporting or transmitting data from the study site or 'field' to Rutgers, methods to restrict access, password protection, encryption, use of key codes to separate identifiers from the data, and state how and when identifiers will be deleted from the data. Identify who will be responsible for each of these tasks.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan

N/A

B. Data/Safety Monitoring Board Details

Data will be stored on a password protected document and stored on the Rutgers approved Office Cloud - OneDrive. Only the research team will have access to this information. All members of the research team are CITI-trained.

6.4 Reporting Results

A. Individual Subjects' Results

If patients wish to be notified of the findings of this study, information will be disseminated through a mailing to their preferred address.

B. Aggregate Results

If patients wish to be notified of the findings of this study, information will be disseminated through a mailing to their preferred address.

C. Professional Reporting
The findings of this study are intended to be presented both at professional meeting of health care specialists, as well as be published as a scientific manuscript.

D. Clinical Trials Registration, Results Reporting and Consent Posting
N/A

6.5 Secondary Use of the Data
N/A.

7.0 Research Repositories – Specimens and/or Data

Neither data nor specimens will be stored as a part of this study. Data will be deleted at the completion of this study.

8.0 Approvals/Authorizations

No additional approvals or authorizations will be needed as a part of this study.

9.0 Bibliography

1. Katt B, Tawfik A, Imbergamo C, Silver J, McEntee R, Beredjiklian P, Ilyas A. Patient comprehension of Operative Instructions with a Handout versus Video: A Prospective Randomized Control Trial. NYSSH Residents and Fellows Research Conference. May 11, 2011.
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3. Hoppe DJ, Denkers M, Hoppe FM, Wong IH. The use of video before arthroscopic shoulder surgery to enhance patient recall and satisfaction: a randomized-controlled study. J shoulder Elb Surg. 2014;23(6):e134-9. doi:10.1016/j.jse.2013.09.008
4. Kamdar PM et al. Opioid Use After Knee Arthroscopy. Arthrosc Sports Med Rehabil. 2020 Apr; 2(2):e77-81.