Patient reported outcomes from patients seen in virtual phone visits compared to in-person physical visits for post-operative follow-up at a sports medicine clinic: a prospective randomized controlled trial

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1) Protocol Title

Patient reported outcomes from patients seen in virtual phone visits compared to in-person physical visits for post-operative follow-up at a sports medicine clinic: a prospective randomized controlled trial

2) HSC Review History

None

3) Investigator

Principle Investigator: Dr. John Andrawis, MD MBA

Study Coordinator at Harbor-UCLA: Dr. Jonathan Wu, DO MPH

4) Objectives

Objectives: This study will compare patient reported outcomes (PROs) and patient satisfaction scores of patients seen at virtual phone visits with patients seen at in-person visits for post-operative follow up at 6 weeks, 12 weeks, and 6 months at a sports medicine clinic. This study will determine if there is a difference in PROs and satisfaction scores between these two groups of patients.

Research hypothesis: Patients who are seen during a virtual phone visit will report different PRO and patient satisfaction scores compared to patients who are seen during an in-person visit for post-operative follow-up at 6 weeks, 12 weeks, and 6-months.

5) Background

Since the WHO declared the coronavirus disease 2019 (COVID-19) a global pandemic on March 11, 2020, health systems have had to reorganize and change the way healthcare is provided to patients [1]. An emphasis has been placed on social distancing to limit the spread of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In the past several months, healthcare has rapidly shifted towards telemedicine to limit the COVID-19 spread. Telemedicine is defined as healthcare where clinicians utilize technology and telecommunications to treat and diagnose patients [2]. Benefits of telemedicine has been found to include decrease healthcare costs, decrease overall appointment times, and similar patient satisfaction [3-4]. During the age of COVID-19, telemedicine has played a vital role in allowing the conservation of resources like personal protective equipment (PPE), decrease in risk of clinician exposure to COVID-19, and maintain social distancing.

Telemedicine has been researched in various medical specialties and have been associated with good outcomes and patient satisfaction scores [5]. Based on the literature, the use of telemedicine in orthopedics has not been extensively studied. There are studies on virtual fracture clinics which have grown in use in the United Kingdom and Ireland, however, they do not utilize a live assessment model [6-8]. One study looks at patient satisfaction of those seen at a regional medical center in rural Norway through telemedicine [9]. Also, there are studies exploring the use of telemedicine to provide follow-up care after

total hip and knee arthroplasty [10-13] and the role of telemedicine by physical therapists as a viable option for virtual rehabilitation [14]

However, there are few studies looking at PROs in patients receiving orthopaedic care through telemedicine. PROs are an important marker of quality distinct from patient satisfaction because PROs are standardized metrics of healthcare delivery. One study looked at the accuracy of physical exams and patient satisfaction from post-operative follow up for arthroscopic knee procedures [15]. A study by Sathiyakumar et al looked at patient satisfaction scores during follow up from operative and non-operative management of orthopedic trauma injuries and found similar satisfaction scores between both groups [4]. Two studies collected both PROs and patient satisfaction scores of patients who attended telemedicine orthopaedic appointments. In Sharareh et al's study, telemedicine visits are used to supplement physical follow up visits for patients that receive total joint arthroplasty [13]. In the other study by Grandizio et al, patients are seen for post-operative follow-up for upper extremity orthopaedic injuries and had similar patient satisfaction scores, however PROs are not compared [16].

Before the COVID-19 pandemic, the standard of care was that after surgery, patients are seen for in-person follow up. Due to the COVID-19 pandemic, the standard of care has changed. Currently, at Harbor-UCLA Medical Center, many clinics and providers have started utilizing virtual phone appointments to see patients to allow social distancing amidst the COVID-19 pandemic. The providers have been determining if a patient requires an in-person visit or if a virtual phone visit would be appropriate. Virtual phone visits have been used for post-operative appointments, to complete pre-surgical history and physicals, and assessment of chronic medical conditions. With this study, we are creating controlled circumstances to determine if patients who receive virtual phone visits are satisfied with their care and report similar outcomes.

We would like to analyze PROs and patient satisfaction scores of patients that attend virtual phone visits for sports medicine injuries and compare them to scores from in-person physical visits. We will collect PROs and patient satisfaction scores from patients who attend appointments at their 6-week, 12-weeks and 6-month post-operative appointments.

6) Setting of the Human Research

Harbor-UCLA Department of Orthopaedic Surgery Sports Medicine Clinic

7) Resources Available to Conduct the Human Research

Based on patient scheduling, there are approximately 4-6 new patients every week who would be a potential Patient. We will need to recruit 50% of those potential Patients over a 6-month course.

It will only be those doctors (residents) and research assistants listed on the study involved in recruiting patients. Once COVID is over, we will have research assistant involvement outside of residents and will make an addendum to the application to include them in the future.

Our facilities will offer tablets which Participants can use to answer surveys. The tablets are approved by HUMC Hospital Admin for use in clinic. The tablets belong

to HUMC and the IT department will help us set them up. The tablets will be secured in the physician work area under lock and key.

The facilities staff will be notified that this study is taking place, so that if a Participant contacts the staff about the study, they know who to redirect and call.

The surveys are to be completed by all participants of the study. Surveys are on REDCaps hosted by Lundquist (https://research.lundquist.org/redcap/surveys/?s=NK3YH4NWL3) and are done online. This study will deliver the surveys in the same manner to participants that attend in-person visits and virtual visits. REDCaps will allow us to collect participants' clinical data. The REDCap administrator is aware that these surveys are collected for research purposes. The surveys will result in a score. This score from REDCaps will be part of the DHS medical record. Any Participant that is part of the study and present for an in-person post-operative appointment will receive a tablet to complete the survey after their appointment. Any Participant in the virtual phone group will receive an email with the survey to complete after attending a virtual phone visit or if the Participant is having difficulty, one of the research staff go through the questions with the Participant over the phone.

8) Prior Approvals

No prior approvals are needed for this study.

9) Study Design

a) Recruitment Methods

When: Participants will be recruited at the pre-op visit, day of surgery, or in-person 2-week post-operative visit.

Where: The Participant will be recruited at Harbor-UCLA Medical Center in-person.

Researchers want to allow patients to have enough time to read the information sheet and consider participation in this study.

In-person consent will be done at any in-person visit including the pre-operative appointment, day of surgery, and at the routine 2-week postop visit.

How: The Participant will be recruited in-person.

Source of the Participants: Patients that present to the Harbor-UCLA Medical Center sports medicine clinic that have scheduled operative intervention.

Methods to identify potential Participants: When patients of the sports medicine clinic have planned operative intervention, study team member will go through the patient charts to see if patient meets criteria and then discuss and consent the Participant in-person.

Materials to recruit Participants: Patients who meet criteria will be given the information study sheet to review on their own.

There are no payments to any of the Participants.

b) Inclusion and Exclusion Criteria

Inclusion criteria:

Participants are at least 18 years of age. Participants who are seen at Harbor-UCLA Medical Center sports medicine clinic. Participants have agreed to have operative intervention. Participants must own a phone with reliable calling capabilities. The Participants must have access to reliable internet to fill out the online survey. The Participants must be able to provide consent. Participants may include pregnant patients. Participants who start out in the virtual phone pathway, and the clinician deems person to require an in-person appointment at the 2-week follow-up visit can be moved to the in-person pathway.

Exclusion criteria:

Patients that are under the age of 18, any cognitive impaired adult, and any adult unable to provide consent.

c) Local Number of Participants

For a statistical significance of 0.05, Power of 80%, and assuming a medium effect size of 0.8, 26 patients are required per group for a total of 52 Participants.

The number of Participants need to complete the research procedure are 52.

Locally we will attempt to recruit at least 104 Participants. This will allow room in case of patients are removed or fall from the study.

d) Study-Wide Number of Participants

This is not a multicenter study.

e) Study Timelines

The study will be ongoing until the appropriate number of Participants are recruited from this site.

The duration of an individual Participant's participation in the study will be from initial visit where consent is asked until completion and submission of the surveys at their 6-month post-operative appointment.

The duration anticipated to enroll all study Participants will be 6 months.

The estimated date for the investigators to complete this study (complete primary analyses) is December 2023.

f) Study Endpoints

Primary study endpoints: Participant reported outcome scores through PROMIS Global.

Secondary study endpoints: Patient survey scores for knee injuries via KOOS, and shoulder and elbow injuries via QuickDash. Patient appointment satisfaction scores will be surveyed.

g) Procedures Involved in the Human Research

There are no procedures performed.

The mentioned above surveys will be attached to this document.

Study Design:

In this prospective study, we will enroll patients undergoing operative intervention at a Sports Medicine clinic.

The patient will arrive at the 2 week post-operative appointment to sign the consent form in the presence of study team member and a witness in order to be eligible to participate in the study.

After consent is obtained, the Participant will be randomized to either in-person follow up or virtual phone follow up to take place after the 2-week post-op visit. The virtual visits will occur using the same platforms that they are currently taking place in accordance and required by LA County DHS/HUMC.

The randomization process will utilize block randomization and be conducted by an online program called http://www.randomization.com.(Wichmann and Hill, 1982, as modified by McLeod, 1985). The Participant will be assigned a number based on the order the Participant is enrolled in the study and that number will be randomly assigned to a follow-up group based on that number.

The Participant will be notified at the 2-week post-op or after if they will receive in-person follow up or virtual phone follow-up. If the Participant in the virtual phone group feel they need an in-person visit, the Participant will be free to make an in-person follow-up. After each follow up visit (6-week, 12-week, and 6-month), the Participant will be asked to fill out 30-minute surveys.

The surveys the Participant will be asked to fill out are the following:

1. KOOS- a knee specific survey
2. Quick Dash Outcome Measure
3. PROMIS Global
4. General Health Questionnaires (2)
5. Patient Satisfaction Survey -We will have the patient complete this also after every visit to see if their preferences change over time as their recovery changes.

If a Participant attends an in-person post-operative follow up visit, then the study team member will check to see if the participant is on the in-person list. If the participant is on the list, then he or she will be given a tablet to fill out the online survey after the appointment. The tablet will be set up so a link to the surveys can be accessed and participants can fill out the surveys. The surveys are on REDCaps (https://research.lundquist.org/redcap/surveys/?s=NK3YH4NWL3). Patients will be able to fill out the survey at home. For Participants that attend a virtual appointment, an online

link to the survey on REDCap will be sent to the Participant's email. Members of the study team can also call the participant to conduct the survey over the phone. The emails will be made secure by having them sent out from an official DHS email that uses Microsoft outlook and requires double verification to logon. The content of the email message is included in the IRB submission as a separate document.

The first page of the survey asks for the Participant's name, date of birth, and preferred language (English or Spanish), how comfortable filling out the form, who is completing the form, which joints, amount of pain, and amount of back pain. The second page of the survey will be a joint specific survey and will depend on the joint selected on the first page and the language chosen. It can be the KOOS, QuickDash Outcome Measure, or PROMIS Global. There is a separate patient satisfaction survey that the patient will complete.

Participants will have appointments with the surgeon for suture removal (10 to 14 days after surgery), and evaluation at 6 weeks, 12 weeks, and 6 months after surgery per usual practice.

The source records that will be used to collect data about the Participants are the surveys, and type of surgery, and results of follow up visits. The data collected will be asked on the surveys which include demographic information- Participants' injury region, age, gender, and time since operative intervention.

Study coordinator will check the upcoming Participant schedule and ensure the correct appointment is scheduled.

h) Data and Specimen Banking

None. No data or specimen banking will be done.

i) Data Management/Statistical Analysis

Statistical analysis will be conducted to compare the total scores of each survey results from participants in the in-person group with participants in the virtual phone group. Each Participant outcomes scores will be averaged with standard deviation calculated.

Participant outcomes scores from each appointment time frame (6-week, 12 week, and 6 months) will be compared across the in-patient group and virtual phone group using Student t-test. Statistical significance will be based on an α level of 0.05.

To determine if there is a difference among the Participants' preference for an in-person visit or telemedicine visit, we will conduct a chi-squared test comparing the percentage of Participant responses from the in-patient group with responses from virtual phone group.

Within each category, to determine if Participant's satisfaction changed as time progressed, we will conduct an Analysis of Variance. This will help us determine

if Participants who experience virtual phone visits start to have changing satisfaction the longer time has elapsed since initial operative intervention.

The PROMIS Global is used to calculate the required sample size as it as the largest range of the outcome measures resulting in the most conservative estimates.

For a statistical significance of 0.05, Power of 80%, and assuming a large effect size of 0.8, 26 Participants are required per group for a total of 52 Participants.

At the end, study data will be exported into excel sheets. All the data collected will be on an excel spreadsheet for purposes of the study. Individual surveys will not be downloaded. At that time, all identifiers will be removed and a de-identified data set is maintained and analyzed. At this time, the study team will not be able to identify which data belongs to which participant. Once this occurs, a subject will not be able to request removal of their data. This spreadsheet will be stored on the secure One Drive Microsoft account which uses double authentication and is provided to all DHS employees. Data originating from the surveys will also be kept in a password-protected location on the Harbor-UCLA One Drive Microsoft account. Data will be stored for 3 years after study completion. Access to the data will be given only to those registered with the study.

Signed consent documents any other paper records are kept in a locked cabinet in a locked office with limited access. The data will be stored for 3 years after completion of the research project.

The only individuals with access to the information will be members of the study team.

j) Confidentiality

A list of Participants participating in the study will include the Participant's name, element of dates, which experiment group the Participant is a part of, MRN, and phone number and email, and study ID number. No health information is recorded with this list This list is be kept on the Harbor-UCLA One Drive Microsoft account and available to the research team. All health data required will be recorded in REDCap hosted by Lundquist and the data will include direct identifiers such as name.

k) Provisions to Monitor the Data to Ensure the Safety of Participants

This research does not result in more than minimal risk to the Participants.

l) Withdrawal of Participants

Participants can withdraw from the study at any time.

The procedure for orderly termination is that the Participant will notify any staff member including nurses or providers. The study coordinator will be notified and the Participant's name, MRN, and email will be removed from the data list.

The Participant's survey responses will be linked to Patient identifiers so it will be possible to eliminate the Participant's responses.

10) Risks to Participants

Participants may feel inconvenienced having to stay 30 minutes longer to complete the survey on the tablets if you are attending an in-person visit.

Participants may also experience inconvenience or frustration if the survey system freezes and does not operate appropriately. You may also feel bored or tired.

Risk Mitigation

The exclusion criteria exclude any minors, prisoners, and adults who cannot give consent, from participating in the study.

Participants will be given the opportunity to pick a time convenient for them to answer the questionnaires after the virtual phone visit. Participants part of the in-person visit will answer surveys after the visit. Participants are encouraged to answer all questions. If they skip any questions or the survey is not answered completely, their survey may be removed. Participants may stop at any time. They may skip any questions they do not wish to answer, and they may stop at any time. Participants may withdraw from the study at any time. To decrease risk mitigation, the data will be kept on REDCap hosted by Lundquist. Only members of the research team will have access to the data information.

11) Potential Benefits to Participants

We cannot promise any benefits to Participants or others from taking part in this research. We cannot promise any benefits to others from taking part in this research.

The study poses no more than minimal risk with the main risk a breach of confidentiality and the study involves ensuring patient reported outcome surveys completed consistently (which is currently not done in the current clinical setting) and scoring calculated and recorded in the medical record

12) Provisions to Protect the Privacy Interests of Participants

All participation and questionnaires in this study are optional. It is made clear to the Participants that their participation is voluntary. If Participants would like additional appointments, they are free to contact their provider to schedule another one. Participants that are in the virtual phone group are free to contact their provider to schedule an in-person visit if they choose to or if their provider would like to see them for an in-person visit. Participating in the study, completing the surveys will not impact the quality of care provided to the participant.

13) Compensation for Research-Related Injury

This research does not involve more than minimal risk.

14) Economic Burden to Participants

There is no economic burden to Participants. There is the burden of time to participate and fill out the survey.

15) Consent Process

The Participants will be identified as patients presenting at the Harbor-UCLA Orthopaedics Sports medicine clinic who agree to operative intervention. Patients will receive a study consent form to review on their own. The study team member will go through the patient charts to determine patients that meet the inclusion criteria and then provide the patient with the study consent form. At the pre-operative visit for surgical planning and signing of the surgical consents, all patients will be given a study consent form and asked to participate in the study. The study will be explained to the patient, questions will be encouraged and answered, and the patient will be asked to sign the consent if they wish to participate in the study.

A member of the research team will make it clear that the patient can come in for an in-person visit if they wish and at any time for their post-operative care. The patient can also choose to spend more time to considering participating in the study.

Potential Participants who meet the eligibility requirements will be approached by a study team member at a pre-operative visit or their 2-week in-person follow up visit. The participant will be provided a copy of the consent document and PHI authorization and the study team member will engage in a thorough discussion of the study explaining what it entails, risks, benefits, alternatives, etc. and answer all of the participants' questions. The Participants are free to choose not to participate in the study. Participants are told if they decide not to take part in the study, there will be no penalty to them, the study will not affect any of their regular benefits, and they will continue to receive regular care. The participant will be encouraged to discuss the study with his/her family member or friends before deciding. The participant will be given ample time to make his/her decision on whether to participate.

The study team member will ask the Participant questions about the study (e.g., what is the purpose, what they do while in the study, how long participation lasts, etc.) to ensure Participant understands the study. If the Participant is interested in participating, s/he will sign the consent to document their agreement to volunteer to participate in the study.

At any time, potential Participants can request additional time to think about the study, or to decline participation. All questions the Participant have will be answered to the satisfaction of the Participant. The Participant will also have study personnel's phone number in case they have additional questions that come up later.

Patients who are not yet adults will be excluded from the study. Parental permission will not be needed since children under the age of 18 will be excluded from this study. Cognitively impaired adults are excluded from the study. Adults that are unable to consent will not be part of the study.

We will review and follow HRP-090 SOP: Informed Consent Process for Research

Non-English-Speaking Participants

Spanish -speaking Participants are also to be enrolled in the study. We will ensure all documents and surveys are available in Spanish. Oral communication will be provided through a staff member who is compliant and trained to communicate with the Spanish speaking population. The consent document and PHI authorization will be translated by a certified translation service per the IRB requirements. In addition, the PROMIS, KOOS, QuickDash, and Participant surveys will be validated in Spanish.

16) Process to Document Consent in Writing

The research is not FDA regulated.

We will review and follow HRP-091: Written Documentation of Consent

17) Vulnerable Populations

This study does not involve individuals who are vulnerable.

This study will exclude adults unable to consent, individuals under the age of 18, and prisoners.

18) Drugs or Devices

This does not involve drugs or devices.

19) Multi-Site Human Research

This is not a multi-site human research project.

20) Community-Based Participatory Research

None

21) Sharing of Results with Participants

Information will be shared with the Participants if the participant chooses. The information will not be used to guide the participant's care.

22) References:

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