Reducing the Transition from Acute to Chronic Musculoskeletal Pain among Older Adults (BETTER from Pain)

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Reducing the Transition from Acute to Chronic Musculoskeletal Pain among Older Adults (BETTER from Pain)

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ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE	Adverse Event
ANCOVA	Analysis of Covariance
ED	Emergency Department
EHR	Electronic Health Record
ICER	Incremental Cost Effectiveness Ratio
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
IRB	Institutional Review Board
IT	Information Technology
ITT	Intention-to-Treat
MSP	Musculoskeletal Pain
NA	Nursing Assistant
NC TraCS	North Carolina Translational and Clinical Services Institute
NIA	National Institute on Aging
NIH	National Institutes of Health
NSAID	Nonsteroidal Anti-inflammatory Drug
PCP	Primary Care Provider
PP	Per Protocol
PI	Principal Investigator
RA	Research Assistant
RCT	Randomized Clinical Trial
REDCap	Research Electronic Data Capture
RI	Research Interventionist
RMSEA	Root Mean Square Error of Approximation
RN	Research Nurse
SAE	Serious Adverse Event
SC	Study Coordinator

SDM	Shared Decision-Making
SO	Safety Officer
UNC	The University of North Carolina at Chapel Hill

Data Collection Time Period	**Definition of Time Period (days = calendar days)**
48-72 hours (Telecare)	*48-72 hours after ***study enrollment*** with an extension of 5 days. This call can take place anytime beginning 48 hours and through the 7th day after study enrollment. ^48-72 hours after ***hospital discharge*** with a 5-day extension. This call can take place anytime beginning 48 hours and through the 7th day after hospital discharge.
1 Week	*7 days after the patient's ***study enrollment*** and includes an extension to 12 days. This call can take place anytime between the 7th and 12th day after study enrollment. ^7 days after the patient's ***hospital discharge*** and includes an extension to 12 days. This call can take place anytime between the 7th and 12th day after hospital discharge.
1 Month	*^30 days from ***study enrollment*** *+/-* 7 days. Data collection can occur anytime from the 23rd to 37th day after study enrollment.
3 Months	*^90 days from ***study enrollment*** +/- 7 days. Data collection can occur anytime from the 83rd to 97th days after study enrollment.
6 Months	*^180 days from ***study enrollment*** +/- 7 days. Data collection can occur anytime from the 173rd to 187th day after study enrollment if admitted.
12 Months	*^360 days from ***study enrollment*** +/- 7 days. Data collection can occur anytime from the 353rd to 367th day after study enrollment if admitted.

*Subjects enrolled in the study and discharged from the ED/OrthoNow without being admitted to the hospital.
^Subjects enrolled in the study who were admitted to the hospital.
*^All subjects (discharged and admitted).

PROTOCOL SYNOPSIS

Study Title	Reducing the Transition from Acute to Chronic Musculoskeletal Pain among Older Adults (BETTER from Pain)
Funder	NIH National Institute on Aging
Clinical Phase	Phase III
Study Rationale	The NIH has identified reducing the transition from acute to chronic musculoskeletal pain (MSP) and reducing opioid use among older adults as public health priorities. The most common site of care for older adults with acute MSP is the emergency department (ED); ~9 million adults ≥50 years of age present to US EDs with MSP annually. While most of these patients are discharged home, 10-25% of discharged patients transition to chronic MSP, and these patients are at risk for functional decline and long-term opioid use. Interventions are urgently needed to prevent this transition, reduce suffering, and maintain independence. Effective treatment of acute MSP can reduce progression to chronic MSP in older adults but is often not achieved for two major reasons. First, education on the use of commonly used analgesics is rarely provided, despite the fact that individual contraindications to specific medicines frequently exist and substantial medication-related adverse events are common (e.g., constipation, falls, addiction). Second, recovery-promoting behaviors are rarely discussed by providers, despite evidence that they are effective. Therefore, we have developed an intervention to address these gaps which uses an educational video, telecare, and communication with a patient's primary care provider to improve patient education regarding medication use and recovery-promoting behaviors.
Study Objective(s)	Primary • To determine the effectiveness of two shared decision-making (SDM), ED-based interventions (full intervention and video-only) compared to usual care in reducing the transition from acute to chronic MSP in older adults Secondary • To test the efficacy of two SDM interventions in reducing long-term opioid use in older adults • To assess the mechanisms by which the interventions influence outcomes (*why are they effective or ineffective?)* • To compare the cost-effectiveness of a full SDM-based intervention and a video-only intervention for managing acute MSP relative to usual care

Test Article(s)	• Video: ~15-minute interactive video focused on education related to acute pain management strategies • Telecare: ~15-minute follow-up phone call by a nurse occurring 48-72 hours after the ED visit to assess patient's pain management strategies and provide recommendations • Primary Care Provide (PCP) Communication: summary of patient's ED visit and telecare call will be provided to patient's PCP
Study Design	This is a three-arm, parallel group, randomized controlled trial.
Subject Population **Key Criteria for Inclusion and Exclusion:**	Inclusion Criteria 1. ED patients age 50 and older 2. Primary complaint of acute musculoskeletal pain 3. If in the ED, expected discharge Exclusion Criteria 1. Pain located in the head, chest, or abdomen or due to ischemia, infection 2. Patients who are critically ill 3. Self-reported daily opioid use for more than 2 weeks prior to the acute care visit
Number of Subjects	400
Study Duration	Each subject's participation will last 12 months. The entire study is expected to last 5 years.
Study Phases **Screening** **Study Treatment** **Follow-Up**	1. Screening: screening for eligibility, obtaining consent and HIPPA agreement will occur over the phone at the time of enrollment 2. Baseline: data collection will occur for subjects in all arms of the study over the phone within 24 hours of their ED or OrthoNow visit 3. Randomization: subjects will be randomly assigned to 1 of 3 study arms at enrollment 4. Intervention: a. an educational video shown to subjects in the full and video-only intervention arms of the study b. telecare phone call ~48 -72 hours after study enrollment for subjects in the full intervention group c. PCP communication for subjects in the full intervention group 5. Follow up: data collection will occur via phone interview for subjects in all arms of the study at 1 week, 1, 3, 6, and 12 months
Efficacy Evaluations	The Brief Pain Inventory-Short Form (BPI-SF), which uses 11 questions each assessed on a 0-10 scale measures patient's pain severity and pain interference over the past week. The BPI-SF will be used to assess intervention efficacy. An average score will be calculated from the patients' answers to 11 questions. The primary outcome is a composite

	score at 1, 3, and 6 months using a longitudinal comparison. We will adjust for baseline pain severity.
Statistical and Analytic Plan	To evaluate the primary outcome by intervention arm, we will use a linear mixed model to conduct an analysis of covariance (ANCOVA), controlling for site type (emergency department vs. urgent care) index visit pain severity, age, gender, race, medical comorbidities (as the Gagne score), baseline intermittent opioid use, a history of chronic pain, and access to a PCP. This model will include all BPI-SF average scores (1, 3, and 6) as outcomes, will include fixed effects for group, time, and group-by-time, as well as all of the control variables, and will use an unstructured covariance matrix for the error terms. We will specify a 6 degrees of freedom (df) linear contrast to test the overall null hypothesis of no mean difference in BPI-SF score at any follow-up visit across the 3 groups at the 5% significance level. If the overall null hypothesis is rejected, we will then conduct separate 3 df contrasts to compare each of the intervention groups with the control group using a Bonferroni-adjusted 2.5% significance level. We will estimate mean pairwise differences along with 95% confidence intervals at each time point. Missing BPI-SF data will be ignored for the primary comparison. The primary analysis will be conducted using the intention-to-treat (ITT) population but will also be repeated using the per protocol (PP) population.
Data and Safety Monitoring Plan	Please see separate Data and Safety Monitoring Plan. Briefly, a Safety Officer (Dr. Eugenia Quackenbush) will review the protocol and interventions prior to initiating the study. The Safety Officer (SO) will also review adverse events. Criteria and procedures for recording adverse events are described in the Data and Safety Monitoring Plan.

1 BACKGROUND AND RATIONALE

1.1 Introduction

The NIH has identified reducing the transition from acute to chronic musculoskeletal pain (MSP) and reducing opioid use among older adults as public health priorities.[1-3] The most common site of care for older adults with acute MSP is the emergency department (ED); ~9 million adults ≥50 years of age present to US EDs with MSP annually.[4,5] While most of these patients are discharged home, 10-25% of discharged patients transition to chronic MSP, and these patients are at risk for functional decline[6-8] and long-term opioid use.[9] Interventions are urgently needed to prevent this transition, reduce suffering, and maintain independence.

Effective treatment of acute MSP can reduce progression to chronic MSP in older adults,[10-12] but is often not achieved for two major reasons. First, education on the use of commonly-used analgesics is rarely provided,[13] despite the fact that individual contraindications to specific medicines frequently exist[14,15] and substantial medication-related adverse events are common (e.g., constipation[16], falls[4,16,17], addiction[9,18]). Second, recovery-promoting behaviors are rarely discussed by providers, despite evidence that they are effective.[19-23]

We have developed a simple, scalable intervention that addresses these gaps. The intervention addresses knowledge about analgesics and encourages recovery-promoting behaviors using a shared decision-making (SDM) approach. SDM offers an ideal clinical approach for older adults with acute MSP because (1) multiple treatment options exist, (2) patient experiences, values, and preferences should inform their MSP treatment decisions, (3) most decisions regarding MSP management occur after the ED visit and reflect a mix of physician advice and patient choice, and (4) observational studies indicate SDM is associated with improved recovery for ED patients with MSP.[13,24]

Patients will be recruited and enrolled from emergency departments at UNC Medical Center in Chapel Hill, Hillsborough, and UNC REX Healthcare. Patients will also be enrolled from UNC OrthoNow clinics in Chapel Hill, NC. Eligibility screening, baseline data, intervention, and social support data will be collected over the phone within 24 hours of the patient's acute care visit. Telecare and follow-up data collection at 1 week, 1, 3, 6, and 12 months after discharge will occur by phone.

1.2 Name and Description of Intervention

The intervention entails an educational video, Brief Educational Tool to Enhance Recovery (BETTER from Pain), in addition to telecare and primary care provider (PCP communication).

BETTER from Pain Video: A ~15-minute interactive educational video sent to patients via email or text after study baseline questions are completed. Patients watch the video within 24 hours of their acute care visit. The video provides information about acute pain management strategies that can be used at home including medications (acetaminophen, NSAIDs, opioids) and behaviors (sleep, staying active, relaxation, and social support).

Telecare: A ~15-minute protocol-guided phone call from a research nurse ~48-72 hours after the patient's enrollment in the study. Telecare is designed to assess the patient's pain severity and interference with daily activities, review analgesic and opioid use and side effects, review recovery-promoting behaviors discussed in the video (sleep, staying active, relaxation, and social support), discuss adjustments to the patient's treatment, and link the patient to PCP follow-up.

PCP Communication: The research nurse will provide a summary of the ED/OrthoNow visit and telecare call to the patient's primary care provider (PCP) in order to convey information about the patient's condition and treatment plan with the intent of supporting a transition of care. Patients without a PCP provider will be provided resources for one.

This study entails two intervention groups: **Full intervention** and **video-only intervention**. The Full intervention group will receive all three components of the intervention (video + telecare + PCP communication) while the video-only group will only receive the video.

1.3 Non-Clinical and Clinical Study Findings

Potential Benefits: It is our hypothesis that older adults that receive video education and telecare regarding effective and safe pharmacologic and non-pharmacologic therapies for acute MSP will have less pain over the following 6 months than patients viewing the video-only; video-only patients will have less pain than usual care patients. If this study establishes the value of the video plus/minus telecare, this information may be used to improve emergency care for patients with acute MSP by limiting the transition to chronic pain, reducing side effects, and potentially reducing long-term opioid use. Patients that receive the video education intervention plus telecare may potentially benefit due to an increased understanding of the effective and safe use of pharmacologic and non-pharmacologic therapies for acute MSP. Whether and to what extent there is a benefit is unknown, which is the reason for the study.

Potential Risks: This trial entails interventions to support shared decision-making between provider and patients to enhance recovery for older patients with acute MSP. As such, the risks to subjects participating in the study are low. However, the risk of breach of confidentiality exists because human subjects are giving personal information. The following steps have been taken to minimize this risk. Research personnel collecting data will have completed all required CITI trainings, including Good Clinical Practice. Research activities and follow-up data collection will occur in areas where the conversation with the patient cannot be overheard by others. Follow-up data will be collected via phone interviews in a private setting and entered directly into REDCap. When conducting analyses, only de-identified data will be downloaded from REDCap. The UNC REDCap data system meets or exceeds all NIH security requirements. Any paper documents associated with the study will be destroyed 3 years after the completion of the study. De-identified data from the study will be made publicly available within 12 months of study completion and archived on the Open Science Framework.

Completing the baseline and follow-up interviews may be inconvenient for some respondents, but it requires approximately 20 minutes of their time for each interview. Viewing the video takes approximately 15 minutes, thus, patients randomized to view the video will spend about 35 minutes engaged in these study activities.

The consent process will describe these risks and is designed to ensure comprehension prior to patient enrollment. Patients will also be informed that 1) participation is voluntary and will not affect any medical care they receive, and 2) they may choose not to answer any questions for any reason and can withdraw from the study at any point.

2 STUDY OBJECTIVES

2.1 **Primary Objective:** The primary objective of this project is to test the efficacy of this intervention to reduce the transition from acute to chronic MSP and reduce long-term opioid use and other key secondary outcomes. The primary outcome will be pain, measured using the 11-item Brief Pain Inventory-Short Form (BPI-SF), assessed longitudinally over the course of 6 months following the ED/OrthoNow visit (i.e., at 1, 3, and 6 months).

2.2 **Secondary Objective:** Secondary outcomes will include individual components of the BPI-SF (at 1, 3, and 6 months for longitudinal analysis), opioid use, physical function, and overall health at 1, 3, 6, and 12 months; analgesic side effects at 1 week and 1 month; and healthcare utilization through 6 and 12 months. The long-term goal of this work is to identify and implement effective interventions into clinical care to improve outcomes for older adults with acute musculoskeletal pain.

3 INVESTIGATIONAL PLAN (brief overview)

3.1 Study Design

This 5-year longitudinal study will encompass the conduct and analysis of an assessor-blinded three-arm randomized controlled trial and includes the following study phases:

Screening: screening for eligibility, obtaining consent and HIPAA agreement will occur within 24 hours of the ED/OrthoNow visit.

Baseline: data collection will occur for subjects in all arms of the study over the phone within 24 hours of the ED/OrthoNow visit.

Randomization: subjects will be randomly assigned to 1 of 3 study arms: full intervention, video-only intervention, and usual care.

Intervention: video intervention will occur within 24 hours of the acute care visit for subjects assigned to the full and video-only intervention. Telecare will occur via phone call ~48 hours – 72 hours after subject's enrollment for those in the full intervention arm. Communication with PCP will occur after telecare for subjects in the full intervention arm.

Follow up: data collection will occur via phone interview for subjects in all arms of the study at 1 week, 1, 3, 6, and 12 months.

3.2 Allocation to Treatment Groups and Blinding

Patients will be randomly assigned to one of three groups: full intervention, video-only, and usual care. Assignment will occur via 1:1:1 randomization, stratified by access to a PCP (patients with and without access to a PCP within 2 weeks of study enrollment) and age (50-64 and over 65). The randomization sequence will be generated in SAS, version 9.4, using computer-generated random numbers. The original randomization program will be written by the Principal Statistician; however, the study Data Manager will change the randomization program seed and then use the program to generate the final randomization lists in order to keep the Principal Statistician blinded to true treatment group until after the primary analyses have been programmed. Primary analyses will initially be programmed using dummy treatment codes to maintain blinding. The generated randomization lists will be imported into REDCap's integrated randomization module.

Anyone who conducts the study enrollment call and randomizes the patient or who becomes unblinded to the participant's treatment arm will not conduct follow-up calls.

3.3 Study Duration, Enrollment and Number of Subjects

The entire study is expected to last 60 months with each subject's participation lasting 12 months. The targeted enrollment goal is 400 subjects with ~133 subjects randomized to each study arm.

3.4 Study Population

Four hundred patients aged 50 years and older presenting to UNC EDs or OrthoNow clinics with acute MSP will be recruited for the study. Subjects will be recruited from all gender/race/ethnic groups. The video intervention is presented in English via an oral format and uses graphics with written text to emphasize key points. In addition, data measures are in English and will be collected via interview with subjects. As a result, patients who are unable to read or speak English or have difficulty seeing or hearing will not be included in the study.

Inclusionary Criteria

- ≥50 years of age
- primary complaint of acute MSP
- if in the ED, discharge to home is anticipated
- average pain score ≥4 (0-10 scale) since pain onset

Exclusionary Criteria

- patient does not speak English
- primary pain located in the head, chest, or abdomen
- pain due to ischemia, infection, or some other cause not due to MSP (blood clot, kidney stone, etc.)
- primary pain due to self-injury
- patient is critically ill determined by an acuity score of 1 in the tracking board[25]
- diagnosis of somatoform disorder, schizophrenia, dementia, or bipolar disorder
- patient is a prisoner or in police custody
- self-reported daily opioid use for more than 2 weeks prior to the acute care visit
- resides in a nursing home or is homeless
- at-risk alcohol use[26]
- speech, hearing, vision problems
- cognitively impaired (6-item Brief Screener)[27]
- nonworking phone number (follow-up occurs via phone calls)

*Note: It is possible that a small number of patients with pain thought to be musculoskeletal will be enrolled in the study but later found to have non-MSP; they will remain in the study. Similarly, patients who had access to a technological device to watch the video, but who do not watch the video within 24 hours of their acute care visit will also remain in the study. The primary analysis will be of the intention-to-treat population. Thus, all subjects, including those with non-MSP, those who do not watch the video within 24 hours of their visit, or those who are later found to meet any other exclusionary criteria, will be included in the primary analysis. We will also define *a priori* a per-protocol analysis that excludes patients who were enrolled but later found to meet exclusionary criteria.

4 STUDY PROCEDURES (what will be done)

4.1 Recruitment

Recruitment Screening: Recruitment will occur via a two-step process. In the first step, potential subjects will be identified for recruitment using the electronic health record (EHR) to determine if they meet the initial recruitment criteria. Patients who meet all recruitment inclusionary criteria and do not meet any of the exclusionary criteria will be contacted by phone by SC or an RA to explore their interest in participating in the study. No further recruitment will occur for patients who are not eligible based on the criteria obtained from the EHR.

Recruitment Inclusionary Criteria from EHR

- ≥50 years of age
- primary complaint of acute MSP
- discharge from ED to home is anticipated

Recruitment Exclusionary Criteria from EHR

- language other than English
- primary pain located in the head, chest, or abdomen
- pain due to ischemia, infection, or some other cause not due to MSP (blood clot, kidney stone, etc.)
- primary pain due to self-injury
- patient is critically ill determined by an acuity score of 1 in the ED tracking board[25]
- diagnosis of somatoform disorder, schizophrenia, dementia, or bipolar disorder
- patient is a prisoner

4.2 **Eligibility Screening Interview:** The second step of the recruitment process, entails an eligibility screening interview and will occur for patients meeting the initial recruitment criteria noted above. Patients will be contacted by phone within 24 hours after their acute care visit. The purpose of the study will be explained, and verbal assent will be sought in order to conduct the eligibility screening interview. The inclusionary/exclusionary criteria addressed in the interview is noted below:

Inclusionary Criteria Assessed via Screening Interview

- average pain score ≥4 (0-10 scale) since pain onset

Exclusionary Criteria Assessed via Screening Interview

- self-reported daily opioid use for more than 2 weeks prior to the acute care visit
- resides in a nursing home or is homeless
- at-risk alcohol use[26]
- speech, hearing, vision problems
- cognitively impaired (6-item Brief Screener)[27]
- no internet connection needed to watch the video

There may be additional reasons a potential subject is deemed ineligible that we have not anticipated. As a result, we will consider for exclusion anything that, in the opinion of the research screener or investigator, would place the patient at increased risk or preclude the potential subject's full compliance with or completion of the study.

The eligibility screening interview will be completed in full even if a subject meets an exclusion criterion. These data will be retained in order to help track and characterize patients who pass/fail the eligibility screening stage of the study.

Patients not meeting eligibility screening criteria will be informed they do not meet the criteria for the study and recruitment/screening activities will end. Patients meeting criteria for the study will be informed if they are eligible and the consent process will begin.

4.3 Baseline procedures

Baseline data collection will begin after a subject gives consent to participate in the study. The SC or RA who conducted eligibility screening and obtained verbal consent will conduct the baseline interview questionnaire during the same enrollment call. Data collection will entail questionnaires and data abstracted from the

patient's medical record. The questionnaires will be administered in an interview format. Data abstracted from the patient's EHR in Epic will occur after the enrollment phone call.

After consent is obtained and baseline data is collected by the SC or RA, the SC/RA will randomize the patient and provide a video link and instructions on how to watch the video if the patient is randomized to watch it. This is to ensure that any RA who is blind to the patient's study arm remains blinded and is able to complete follow-up interviews.

4.4 Intervention procedures (by visits)

1. Administering the BETTER from pain video (Full intervention and Video-only arms)

At the end of the enrollment call, the SC/RA will send the video link to the participant via text on an encrypted study phone and/or by secure email. Patients are asked to watch the video within 24 hours of their acute care visit. Patients are asked to send their answers or number of correct answers to the video multiple-choice questions within 24 hours of their acute care visit. If the participant does not provide their answers to the multiple-choice questions within 24 hours, they will be placed into the intention-to-treat analysis and excluded from the per-protocol analysis.

2. Conducting the telecare call (Full intervention arm)

   The full intervention group will also receive telecare following a protocol-guided phone call from a research nurse (RN) ~48 - 72 hours after study enrollment (or after discharge from the hospital if the subject was admitted) with an extension of 5 days if contact is not made within the 72-hour time frame. Thus, the RN will have a total of 7 days to contact the subject.

   Prior to the call, the RN will review the EHR data abstraction instrument in REDCap, which provides a summary of the patient's medical visit, co-morbid conditions, allergies, prescribed medications, and a treatment plan. The RN will also review any pertinent notes in the EHR. The RN will then call the patient and proceed through the telecare script, addressing pain management goals, current analgesic use, and non-pharmacologic methods of pain management. Based on the patient's answers, the RN will make recommendations as needed. The patient's responses and the RN's recommendations will be recorded in REDCap under the telecare instrument as well as the number of minutes of the call.

   The telecare call is designed to last ~15 minutes, and the RN will be trained on how to conduct the call. At the conclusion of the call, the RN will summarize their recommendations and encourage the patient to follow up with their PCP. Patients without a PCP will be provided a referral, including local free or low-cost medical clinics for uninsured patients.

3. PCP Communication (Full intervention arm)

   Following the telecare call, the RN will enter a note in the subject's EHR that documents the patient's current clinical status, information reviewed, and any recommendations or referrals made. The RN will report the (1) Date, time, location and reason for the ED/OrthoNow visit; (2) Results of diagnostics studies; (3) Discharge prescriptions/recommendations; (4) Summary of and link to the video; (5) Summary of the telecare conversation; and (6) Encouragement for follow-up. If the patient's PCP is a UNC-affiliated provider, they will send the note through an electronic message in the EHR. If the patient's PCP is not affiliated with UNC, the RN will send the note via the US Postal Service. At the end of the note, PCPs will be asked to confirm the note has been received and reviewed by the PCP.

4.5 Follow- up procedures (by time points)

Follow-up data will be obtained for subjects in all arms of the study by a RA who is blind to the subject's group allocation. Data collected at all follow-up time points will include a phone interview with the patient and data obtained from the patient's EHR. Prior to each phone interview, data will be extracted from the patient's EHR by an RA using standardized questions with explanations in REDCap.

1-Week Follow-up: This call can take place anytime from the 7th day through the 12th day after study enrollment (or hospital discharge if subject was admitted). Following the phone script, the RA will make a total of 10 attempts via phone call, text, or email to reach the subject for the follow-up interview. This phone interview will take ~20 minutes and include the questionnaires noted below. The purpose of this call is to assess the mechanisms that might contribute to patient recovery. However, some outcomes (pain, healthcare use) will also be assessed at this time point.

1-week questionnaires

- Brief Pain Inventory-short form[28]
- Patient Global Impression of Change[29]Preparedness and Confidence Questions
- Pain Self Efficacy Questionnaire 4-item[30]
- Analgesic and Opioid use
- Other (Nonpharmacological) pain management strategies used
- Opioid-Related Symptom Distress Scale[31]
- Pittsburg Sleep-2[32]
- International Physical Activity Questionnaire-short form[33]
- Healthcare Utilization Questions
- Opioid prescribed (obtained from EHR)

Longitudinal Follow-up: Follow-up data collection via phone interviews will occur at 30 days, 90 days, 180 days, and 360 days +/- 7 days following study enrollment. Following the phone script, the RA will make a total of 10 phone calls to reach the subject at each data point for the follow-up interview. These phone interviews will take ~20 minutes each and include the questionnaires noted below:

1, 3, 6, and 12-month follow-up questionnaires

- Brief Pain Inventory-short form[28]
- Patient Global Impression of Change[29]
- PROMIS Global Health-Physical 2a[34]
- PROMIS-Physical Function-4[35]
- Pittsburg Sleep-2[32]
- Analgesic and Opioid use
- Other (Nonpharmacological) pain management strategies used
- Opioid-Related Symptom Distress Scale[31]
- Healthcare Utilization Questions
- Opioid prescribed (obtained from EHR)

4.6 Withdrawal procedures

Subjects may withdrawal from the study at any time. If such a request is made, no further contact with the subject will be made. Data that was collected prior to withdrawal will be retained unless the subject requests that all data be removed from the study.

Screen failure procedures

Subjects who fail the eligibility screening interview will be thanked for their time and informed they do not meet the criteria for the study. Data collected during the screening interview will be retained and used to report screen fail characteristics.

5 STUDY EVALUATIONS AND MEASUREMENTS (how measurements will be made)

5.1 Variables to be abstracted from medical charts

Summary of Data to be Abstracted from EHR at Baseline:

- Final diagnosis
- Final disposition (was patient admitted or not)
    - If patient was admitted, hospital discharge date
- Whether the patient was hospitalized up to 30 days before ED/OrthoNow visit.
- Comorbidity data will be abstracted in order to calculate a Gagne score.[36]
- Treatment (any allergies to medications, medications prescribed, recommendations)
- Opioids and/or pain medications prescribed

Summary of Data to be Abstracted from EHR at Follow-up (1 week & 1, 3, 6, 12 month):

- Healthcare Utilization since last visit/call
    - Number of hospitalizations, days spent in hospital, name and location of hospital
    - Number of ER or Urgent Care visits, name of facility and location
    - Number of Primary Care office and telehealth visits and how many of the visits were with UNC providers
    - Number of non-physician (physical therapist, occupational therapist, chiropractors, etc.) visits
- Opioids prescribed

5.2 Baseline evaluation (conducted during ED/OrthoNow visit)

How measures will be taken

Baseline questionnaires will be conducted with subjects in all arms of the study over the phone during the enrollment call. The baseline questionnaires will occur immediately after the patient has verbally consented to participate in the study. A description of the questions (non-standardized internal items) and assessment measures are summarized below:

Baseline Questions and Measures

- Access to Primary Care question
    - Question which asks whether the patient has a primary care provider

- Analgesic and Opioid use questions
    - Analgesic and opioid use questions which assess opioid use in the ED and pain medications in the past week

- Nonpharmacological pain management use questions (e.g., deep breathing)
    - Questions to assess strategies patients have used besides medication to manage pain such as mindfulness, meditation, imagery, yoga, or visiting a chiropractor

- Brief Pain Inventory-Short Form[28]
  - The BPI-SF is an 11-item measure that rates pain severity and interference over the past week on a 0-10 numeric scale with higher scores reflecting more pain severity and more pain interference.

- Recovery Questions
  - Two questions to measures how well patients expect to recover from their pain and how long they estimate recovery will take.

- Prior History of Chronic Pain
  - Two questions based on the 2010 National Health Interview survey[37] to assess if patients have a history of chronic pain.

- ENRICHD Social Support Inventory (ESSI): item 4 and 5[38]
  - The two items on the ESSI will assess perceived social support (how much a patient feels supported) and embedded social support (whether a patient has practical help with everyday tasks)

- Single Item Literacy Screen[39]
  - The SILS uses one question to identify limited reading ability, which is a component of health literacy. It assesses how often one needs assistance reading materials provided by a doctor or pharmacy, on a scale from "never" to "always."

- Tobacco Screening Measure[40]
  - This tool was developed by the University of Maryland School of Medicine and entails 2 questions to screen whether the patient has smoked cigarettes or used tobacco products ever or in the past 30 days.

- Pain Catastrophizing Scale 4-item version[41]
  - The PCS-4 measures rumination, magnification, and helplessness related to one's pain experience by having patients rate the degree to which thoughts and feelings are associated with their pain on a 5-point scale, ranging from "not at all" to "all the time."

- Pain Self-efficacy Questionnaire-4 item version[30]
  - The PSEQ 4-item questionnaire measures how confident a patient feels they can accomplish activities despite their pain on a 6-point scale where 0 is "not at all confident" and 6 is "completely confident.

- Patient Health Questionnaire-2[42]
  - The PHQ-2 is a two-question assessment to measure the frequency of depressed mood on a 4-point scale.

- Generalized Anxiety Disorder-2 item[43]
  - GAD-2 is a two-question assessment to measure the frequency of anxious mood, on a 4-point scale.

- Control Preferences Scale[44]
  - The CPS measures shared decision-making regarding a patient's treatment. It consists of 5 statements and patients pick which statement best describes the level of involvement they prefer in treatment decisions.

- PROMIS Global Health-Physical 2a[34]

- The Patient-Reported Outcomes Measurement Information System (PROMIS) includes 2 questions related to the general physical health and ability to carry out physical activities on a 5 point-scale with higher scores reflecting better health and ability.

- PROMIS-Physical Function-4[45]
  - The Patient-Reported Outcomes Measurement Information System (PROMIS) report of physical function includes four items that measure ability to do chores, ability to use stairs, walking, and running errands on a 5-point scale with higher scores reflecting less difficulty.

5.3 Follow-up evaluations

How measures will be taken
All follow-up questionnaires will be conducted with subjects in all arms of the study via a phone interview at 1 week and 1, 3, 6, and 12 months. A description of the questions (non-standardized internal items) and various assessment measures are summarized below:

Questions and Measures conducted at 1 Week

- Brief Pain Inventory-short form
  - *See Baseline assessment*

- Patient Global Impression of Change
  - The PGIC is a 1-item measure of how much patients feel their pain has improved since their ED visit on a 7-point scale ranging from "much better" to "much worse."

- Preparedness and Confidence Questions
  - Assesses how prepared patients feel about their ability to manage their pain with 6 questions on a 5-point scale, from "not at all" to "very well."

- Pain Self Efficacy Questionnaire 4-item
  - *See baseline assessment*

- Analgesic and Opioid use
  - *See baseline assessment*

- Nonpharmacological pain management use questions (e.g., deep breathing)
  - *See baseline assessment*

- Opioid-Related Symptom Distress Scale
  - The OR-SDS assesses subject-reported levels of frequency and severity concerning 10 side effects known to be associated with opioid medication. Added to this measure are 5 additional symptoms reflecting side effects for patients taking NSAIDs or acetaminophen. Symptom frequency and severity will be rated on a 4-point scale with higher scores reflecting increased frequency and greater severity.

- Pittsburgh Insomnia Rating Scale-2
  - The PIRS measures patient's sleep quality in the past week via two questions on a 4-point scale.

- International Physical Activity Questionnaire-short form
    - The IPAQ is a 7-item measure to assess the intensity of physical activity and sitting time that the patient engages in as part of their daily life, measured in minutes/per week and time spent sitting.

- Healthcare Utilization Questions
    - Questions pertaining to the number of days in the hospital, number of visits to an ED or urgent care, and number of visits to non-ED or urgent care physicians since the patient's ED visit.

Questions and Measures conducted at 1, 3, 6, 12 months

- Brief Pain Inventory-short form
    - *See Baseline assessment*

- PROMIS Global Health 2a
    - *See 1-week assessment*

- PROMIS Physical Function-4
    - *See Baseline assessment*

- Pittsburgh Insomnia Rating Scale-2
    - *See 1-week assessment*

- Opioid and Analgesic Use Questions
    - *See baseline assessment*

- Nonpharmacological pain management use questions (e.g., deep breathing)
    - *See baseline assessment*

- Opioid-Related Symptom Distress Scale (side effects)
    - *See 1-week assessment*

- Health Utilization Questions
    - *See 1-week assessment*

5.4 Schedule of Events

Procedures	Enrollment / Baseline	Telecare (48-72 hrs after enrollment)	Week 1 Follow-up Call	1, 3, 6, and 12 Month Follow-up Call
Demographics	X			
Obtain verbal informed consent	X			
Randomization	X			
Administer educational video	i, ii			
Call with research nurse		i		
Data Collection Measures/Questions				
Assess access to primary care provider question	X			
Overview of analgesic use (opioid and non-opioid)	X		X	X
Use of other pain management strategies	X		X	X
Brief Pain Inventory-short form (pain severity only)	X			
Brief Pain Inventory-short form (pain severity and pain interference)			X	X
Pain recovery questions	X			
Prior history of chronic pain questions	X			
Pain Catastrophizing Scale-short form	X			
PROMIS Global Health-2a (prior to pain)	X			
PROMIS Physical Function (prior to pain)	X			
PROMIS Global Health-2a (including pain)	X		X	X
PROMIS Physical Function (including pain)	X		X	X
Patient Health Questionnaire (Prior to pain)	X			
Generalized Anxiety Disorder-2 (Prior to pain)	X			
Control Preference Scale	X			
Pain Self-efficacy questionnaire-4 item version	X		X	
Single Item Literacy Screen	X			
Tobacco Screening Measure	X			
Global Impressions of Change			X	X
Preparedness and Confidence questions			X	
Opioid specific questions*	X		X	X
Non-opioid analgesic questions	X		X	X
Analgesic side effects			X	X
Pittsburgh Insomnia Rating Scale			X	X
International Physical Activity Questionnaire			X	
Health Utilization questions*	X		X	X
COVID-19 activity questions				X**

i Subjects in Full intervention arm

ii Subjects in Video-only intervention arm

*Data obtained through Electronic Health Record AND Questionnaires

** month 3 only

6 STATISTICAL CONSIDERATION

6.1 Statistical Methods

Analysis Plan Summary: A detailed Statistical Analysis Plan will be developed and approved by the Principal Statistician, PI, and other key members of the study team prior to summarizing any data by unblinded study arm; the following is a summary of the proposed plan.

Preliminary analyses of complete data will describe the sample and compare characteristics of study participants with individuals who were eligible but declined consent. Baseline variables will then be tabulated by study arm. For outcomes that are based on patient self-report, we will calculate the loss to follow-up rate for each arm and assess for non-response bias by comparing baseline characteristics of patients who did and did not complete follow-up.

Analysis Populations: We will define the following two analysis populations:

- *Intention-to-treat (ITT) Population*: This population will include all randomized patients based on the arm to which they were randomized, regardless of the extent of intervention actually received and regardless of whether they were at a later point found to meet an exclusion criterion.
- *Per-Protocol (PP) Population*: This population will be a subset of the Intention-to-Treat Population, and will exclude patients who received the incorrect intervention (e.g., viewed less than 50% of the video, were not reached for the telecare call) or who meet an exclusion criteria after randomization (e.g., were admitted to the hospital from the primary ED visit, had non-MSP).

Objective 1:

To evaluate the primary outcome by intervention arm, we will use a linear mixed model to conduct an analysis of covariance (ANCOVA), controlling for site type (ED vs. Urgent Care), index visit pain severity, age, gender, race, medical comorbidities (as the Gagne score), baseline intermittent opioid use, a history of chronic pain, and access to a PCP. These control variables were selected *a priori* based on prior evidence of prognostic value and will not be subjected to significance testing. This model will include all BPI-SF average scores (1, 3, and 6) as outcomes, will include fixed effects for group, time, and group-by-time, as well as all of the control variables, and will use an unstructured covariance matrix for the error terms. We will specify a 6 degrees of freedom (df) linear contrast to test the overall null hypothesis of no mean difference in BPI-SF score at any follow-up visit across the 3 groups at the 5% significance level. If the overall null hypothesis is rejected, we will then conduct separate 3 df contrasts to compare each of the intervention groups with the control group using a Bonferroni-adjusted 2.5% significance level. We will estimate mean pairwise differences along with 95% confidence intervals at each time point. Missing BPI-SF data will be ignored for the primary comparison. The primary analysis will be conducted using the ITT Population, but will also be repeated using the PP Population.

We will also conduct a sensitivity analysis of the primary comparisons using a multiple imputation approach. Pain scores for patients taking analgesics in the past week will be imputed using demographic characteristics, history of chronic pain, pain location, pain etiology (traumatic vs. not traumatic), baseline pain severity, analgesics used, and treatment group.

We will use similar ANCOVA models to test the intervention effects on the secondary outcomes. For continuous or ordinal outcomes, we will use generalized estimating equations models and contrast tests. For any binary variables (e.g., opioid use or non-use) we will also use ANCOVA model but will fit mixed-effect logistic regression models.

To assess whether some groups of patients are more likely to benefit from the intervention, we will estimate and compare effects using tests of interaction for *a priori* identified subgroups based on gender, race, health literacy, access to a PCP, and preference for control over decision-making. To assess for differential intervention effects on the primary outcome across each of the subgroups, we will use similar ANCOVA models, but with the addition of appropriate terms representing the interactions between intervention groups and the subgroup of interest. Separate models will be used to assess each interaction. Interpretation of differential effects of the intervention will be limited to subgroups for which an interaction is significant at the 5% level. (Because available data suggest that Hispanics will constitute ~2.5% of the study sample, we do not anticipate the ability to analyze differential effects by ethnicity in this study.)

Objective 2:

To examine potential mechanisms by which the intervention influences outcomes, we will apply a structural equation model (specifically, a path analysis with manifest variables) with all variables incorporated appropriately for their scale. The model will use data from all patients and will control for demographic and clinical characteristics used for adjusting the Objective 1 model. The primary model will include direct and indirect effects of the interventions on the outcome through potential mediating variables (self-efficacy, use of specific analgesics or behaviors) to allow for assessment of whether mediation is present, and if so, if it is complete or partial. No structural relationship will be imposed relating the mediating variables to one another, beyond simple correlations. We will first test each of the path coefficients from the interventions to the mediator variables separately at the p=0.05 level using chi-squared difference tests. We will then test indirect paths to assess mediation. Standard model fit indices (i.e., RMSEA, Bollen's Incremental Index, and the Tucker-Lewis index) will be reported.

As an exploratory analysis, to assess whether the use of specific medications or recovery promoting behaviors during the first week or the first month mediate pain recovery, these variables will also be examined as potential mediators following the methods described above.

6.2 Sample Size and Power

STATISTICAL CONSIDERATIONS

Sample Size Calculation: We calculated power for comparing mean change in pain severity across the three trial arms using a standard approach for linear mixed models.[46] We used data from a previous study by our group,[6] restricted to participants with ED/OrthoNow visit pain severity of at least 4, to obtain mean pain values for our usual care condition as well as variance and covariance values for an unstructured covariance matrix (see Figures X and Y).

Figure X

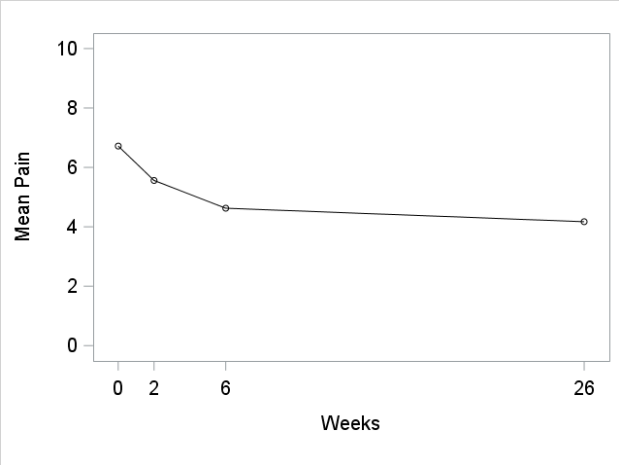


Figure Y

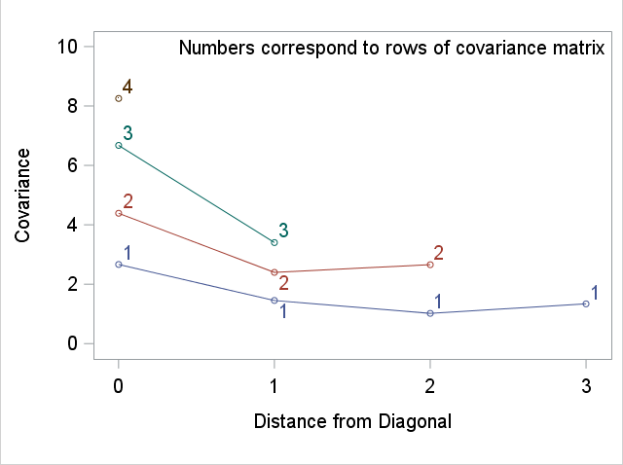
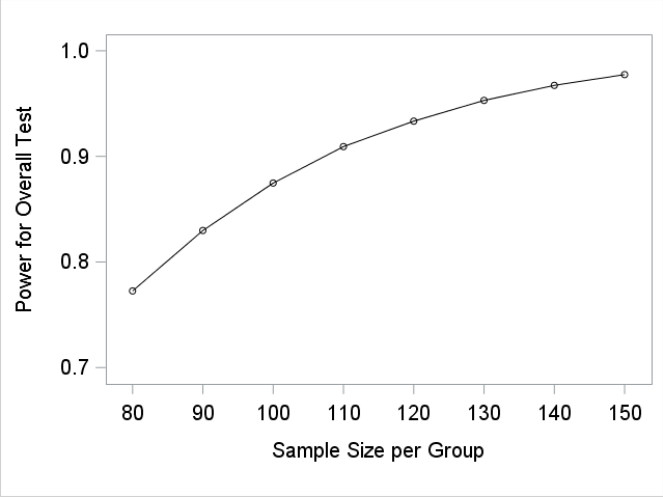


Figure Z



Thus, we created an exemplary dataset in which participants in the full intervention and video-only groups experienced post-randomization mean pain scores of 20% or 15%, respectively, lower than that in the usual care group. We assumed that loss-to-follow-up times would be exponentially distributed such that the total loss would be 20% at 12 months. Under these assumptions, randomizing 120 participants to each group would provide at least 90% power for testing the overall null hypothesis of no difference across the three groups in mean change from baseline to any follow-up visit through the 6-month visit using linear contrast tested at the 5% significance level (Figure Z). Furthermore, this sample size would provide about 93% power for the comparison between the full intervention and the usual care group and 67% power for the comparison between the video-only group and the usual care group under these same assumptions, each tested at Bonferroni-adjusted 2.5% significance levels. Because we would like our sample size to support both the intention to treat analysis and the per protocol analysis (restricted to non-admitted patients) and assuming that up to 10% of enrolled patients will be admitted, we plan to enroll 400 patients. The sample size is not calculated based on secondary outcomes. In order to avoid selective reporting of secondary outcomes, we will register and report all secondary outcomes regardless of what is found. The MIXED Procedure in SAS, version 9.4 (SAS Institute, Cary, NC) was used for calculations.

7 STUDY INTERVENTION (intervention details)

Full Intervention (Video + Telecare + PCP Communication)

BETTER from Pain Video: The educational video is designed to educate individuals about pharmacologic management of acute MSP pain and recovery-promoting behaviors (see video script). Each section of the video is followed by a multiple-choice question to promote interaction and reinforce learning. The actress for the ~15-minute video is a 56-year-old mixed-race woman who presents herself as a healthcare provider.

Telecare: The full intervention group will also receive telecare following a protocol-guided phone call (see telecare protocol) from a research nurse (RN) 48-72 hours after study enrollment. If contact is not made within 72 hours, the time frame will be extended to 7 days. The call is designed to support patient decision-making regarding analgesics and behaviors following the content presented in the video. The telecare script is guided by an SDM framework in which the nurse first asks for information from the patient, then discusses alternative strategies, and actively elicits feedback from the patient. Patients will be encouraged to follow-up with their PCP. Patients without a PCP will be provided a referral, including local free or low-cost medical clinics for uninsured patients. The telecare call is designed to last ~15 minutes.
PCP Communication: Following the telecare conversation, the RN will send a message to the subject's PCP through the EHR using a standard template that documents the subject's current clinical status, information reviewed, and any recommendations or referrals made. If the PCP cannot be contacted through the EHR, the RN will send a letter to the PCP through US mail. This communication will also include: (1) Date, time, location and reason for the visit; (2) Results of ED diagnostics studies; (3) Discharge prescriptions/recommendations; (4) Summary of and link to the video; (5) Summary of the telecare conversation; and (6) Encouragement for follow-up. PCPs or their representatives will be asked to confirm the message has been received and reviewed by the PCP.

Video-only
Subjects in the video-only arm will watch the BETTER from Pain video (same video shown to subjects in the full intervention) and the SC/RA will implement all the same procedures noted above in the full intervention.

Usual Care
Patients randomized to the usual care arm will receive education, prescriptions, and advice on recovery promoting behaviors as typically provided by medical providers. We have chosen not to include a sham intervention or enhanced usual care because the intent of the study is to determine if the intervention improves upon what is typically done for these patients.[47] Consistent with this intent, no restrictions will be placed on the care from providers for any of the study arms.

8 STUDY INTERVENTION ADMINISTRATION

8.1 Randomization procedures

Patients will be assigned to one of the three treatment arms using 1:1:1 randomization, stratified by access to a PCP within (patients with and without access to a PCP within 2 weeks) and age (50-64 and over 65). The randomization sequence will be generated in SAS, version 9.4, using computer-generated random numbers. The original randomization program was written by the Principal Statistician; however, the study Data Manager will change the randomization program seed and then use the program to generate the final randomization lists in order to keep the Principal Statistician blinded to true treatment group until after the primary analyses have been programmed. Primary analyses will initially be programmed using dummy treatment codes to maintain blinding. The generated randomization lists will be imported into REDCap's integrated randomization module.

8.2 Blinding procedures

Study personnel who collect the follow-up data will be blinded to the subject's study arm and thus, will not run the randomization in REDCap or conduct the video and telecare intervention with subjects. REDCap will be set up to ensure that study personnel are not unblinded when entering data (they will not be able to see which arm the subject was allocated to). See below for study tasks by role:

RAs (blinded): Follow up data collection, collect data from the subject's EHR, and enter data.

SC/RA (unblinded): Recruit, screen for eligibility, consent, conduct baseline data collection, determine which arm of the study the subject will be in (via randomization module in REDCap), conduct the video intervention with subjects in the Full and Video-only intervention arms of the study, and enter data related to intervention, and collect data from the subject's EHR, and enter data. Conduct the telecare portion of the intervention, submit EHR (or secure email) note to subject's PCP summarizing the medical visit and telecare call, and enter telecare data.

Database manager (unblinded): Will create the final randomization list that is loaded into REDCap on a secure server.

Principal Statistician (blinded): Will not have direct access to the accruing study data. Any datasets provided to the Principal Statistician prior to the final analysis of the data will not have any variables indicating the true randomization groups. The primary analysis for the primary objective will be programmed and validated using dummy treatment codes generated by the Principal Statistician. Only after the primary analysis has been finalized and all analytic decisions made regarding a) analysis population membership, b) exclusion of any data from the primary analysis, and c) the structure of the final analysis model will true randomization group be revealed to the Principal Statistician.

PI: (unblinded) Will be notified to any AEs or SAEs that may be related to the intervention; manage any unexpected issues that may arise, which may require knowing to which intervention arm a patient is randomized.

9 SAFETY MANAGEMENT

9. 1 Adverse Event Reporting

All adverse events (AEs) and serious adverse events (SAEs) that are spontaneously reported to study personnel (SC, RN, RAs, or investigators) or elicited by them during subject interviews or contacts will be promptly reported to the PI and RN. The PI or RN will determine if AEs and SAEs are related or unrelated to the research intervention and if they are expected or unexpected occurrences. AEs will be reported to the PI or RN within 24-48 hours of the event; SAEs will be reported to the PI or RN as soon as the event is known. AE/SAE information will be recorded in REDCap. The RN will maintain a tracking log of AEs and SAEs which will be reviewed by the PI on a monthly basis. The tracking log will also be summarized and reported to the IRB annually and to the SO and NIA twice yearly in biannual reports. Serious Adverse events will be reported by the PI or RN to the SO, IRB and NIA within 24 hours of notification.

An AE is any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event. For this trial the most common AE's will include:

- Side effects related to analgesic medications being recommended as part of the study
- Emergency department visits
- Other events about which study personnel are uncertain should be reported to the PI or RN who will discuss and decide if it qualifies as a reportable AE

AEs will be classified according to severity, which is based on their impact on the patient. An AE will be termed "mild" if it does not have a major impact on the patient, "moderate" if it causes the patient some minor inconvenience, and "severe" if it causes a substantial disruption to the patient's well-being. All AEs will be documented in REDCap.

AEs requiring prompt reporting will include the following 3 criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document and (b) the characteristics of the subject population being studied
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. Please note that such events routinely warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or other
- Related or possibly related to the research
    - Adverse events meeting all 3 criteria will be reported by the PI or RN to the IRB and NIA within 1 week of the event.

SAEs are defined as:

- Death
- A life-threatening experience
- Inpatient hospitalization
- Prolongation of hospitalization
- Persistent or significant disability or incapacity
- Congenital anomaly
- Birth defect
- May require medical, surgical, behavioral, social or other intervention to prevent one of the above outcomes.
    - Serious Adverse events will be reported by the PI to the SO, IRB and NIA within 24 hours of notification

9.2 Medical Emergencies: Suicidality

If a subject expresses symptoms of depression during telecare or telephone interviews, the RA or RN will ask a series of questions adapted from the Columbia-Suicide Severity Rating Scale Primary Care Screening with Triage Points to assess for suicidality. Subjects who are determined to be at low risk for suicide will be encouraged by the RA/RN to follow-up with a mental health provider or PCP within 48 hours. Subjects will be contacted again in 48 hours ensure follow-up has taken place. Subjects at moderate risk for suicide will be referred to a mental health provider or PCP for a same day appointment or directed to a local ED if an appointment is unable to be secured. Subjects will be contacted again within 24 hours to ensure they have been seen by a medical provider. Subjects deemed high risk for suicide will be asked to confirm their location and EMS will be called. The RA/RN will remain on the telephone with the subject until EMS arrives.

In all cases, regardless of level of risk, the RA/RN will notify the PI or SO immediately. The subject's PCP will also be notified of the event. All suicide assessments will be documented in REDCap and will be recorded as adverse events.

10 DATA COLLECTION AND MANAGMENT

Several steps have been taken to maximize privacy. All research activity (screening, consent, questionnaire interview) will be completed in a private area where study staff cannot be overheard. Subjects will be informed that at any time during the study, they may choose to not answer a question for any reason. Subjects will be assured that refusal to participate will not affect medical care in any way. Patient identifying information will be flagged in REDCap and will not be downloaded for analyses. All research personnel involved in any way in this

project will complete training in the protection of human research subjects per guidelines issued by the U.S. Department of Health and Human Services, Office for Human Research Protection. Staff training conducted by the PI and UNC study coordinator will include information about the importance of data security, confidentiality, and techniques to maintain confidentiality of all information reported by research participants.

11 CONSENT PROCESS

Verbal informed consent and HIPAA authorization will be obtained from all eligible and willing participants. Consent will take place during the patient's enrollment call following the screening interview. The SC/RA will verbally review each section of the consent and HIPAA authorization with the patient and provide ample time for the patient to ask any questions. The SC/RA will also assess capacity to consent with the following two questions: "What is this study about?" and "Can you drop out of the study at any time?" If necessary, the SC/RA will review relevant information about the study to facilitate subject's comprehension. The subject is determined to have capacity to consent if they correctly answered both questions by the third attempt. Please note that subjects will have already passed a cognitive screener as part of the eligibility screening interview. If a subject passes the capacity to consent and has no further questions, the SC/RA will date and print the patient's name on an electronic verbal HIPPA authorization form. They will also date, sign, and print the patient's name on an electronic verbal consent form. Based on patient preference, a copy of both forms will be sent to the patient via secure email and/or postal mail. Depending on if the patient opted for email or mail, an electronic or paper version will also be retained for study records, secured in a protected area or secured on the study share drive.

12 PLANS FOR PUBLICATION

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, we will publish the primary results within 1 year of data collection in a peer-reviewed journals and will make the final peer-reviewed journal available on PubMed Central in compliance with the NIH Public Access Policy. De-identified data from this study will be made publicly available on the Open Science Framework website within 12 months of study completion.

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