

**Patient Education to Improve Pain Management in Older Adults with
Acute Musculoskeletal Pain: A Pilot Randomized Trial**

Protocol

**July 27, 2015
NCT02438384**

SCEENING / ED INTERVIEW

Participant Selection: To identify potential participants for this trial, monitor the ED Track Board in EPIC to find patients likely to be experiencing musculoskeletal pain. Eligibility criteria are listed below. Consult with Dr. Platts-Mills if you are unsure about a patient's potential eligibility.

- 50 years old or older
- Chief Complaint of musculoskeletal pain
- Can read and understand English
- Has a home phone or cell phone
- Score of ≥ 4 on Six Item Screener

Screening: Print out PDF copies of both the Screener and ED Interview. The other two tools will be used later and are not printed. The screener outlines the eligibility criteria. The last section of the Screener asks for verbal consent from the patient for enrollment in the trial. Completion of this form will determine whether or not the patient is eligible for and consenting to enrollment.

ED Interview: Ask all questions on this questionnaire and then follow the steps listed to randomize patients to treatment groups. Provide the brief explanation listed for the selected treatment group and show the BETTER Video to all patients selected for either "Video only" or "Video + Follow-up"

TABLET SETUP & USE

Two HP Stream 8 tablets are designated for use in this study. These tablets run the Windows 8.1 OS including full desktop capabilities. Information on important identification numbers for each of these tablets is available in the document titled BETTER Tablet Info. The tablets have already been set up specifically for use in this project.

Basic Setup: It is recommended that these tablets are setup with a local account rather than linked to someone's Microsoft account. Initially, a local account should be created with the username: BETTER and the password: better

1. Set the IE home page to UNC Better. Open the desktop and use Internet Explorer (IE) to navigate to <https://media.med.unc.edu/emergmed/better/index.html> Select the gear (options) icon in the top right corner and select "Internet Options." Under the General tab, tap "Use current" and then "Apply" on the bottom of the options box to set the new home page.
2. Create a desktop link to the BETTER site. Open IE and navigate to the UNC Better page (it should be the home page). Tap the gear icon in the top right corner and select "Add site to Apps." Tap the home button (Windows logo) and you are taken back to the start screen. Swipe up to view

all apps then press and hold the app labeled “UNC Better.” Select “Pin to Start” and this link will now be accessible from the start screen.

3. Unpin all other apps from the start screen. Press and hold over any app to edit. Select all apps except UNC Better and then tap “Unpin from Start” in the bottom left corner.
4. Put IE in full screen mode. From the UNC Better homepage, select the gear icon in the top right corner, tap File, and select Full screen.

Advanced Features: Along with the basic features listed above, these tablets have been customized for use in the BETTER project. All backgrounds and lock screens have been set to an image pulled from the video. The desktop has been cleared of all icons other than a link to the video and the taskbar is hidden. This helps to ensure that patients and providers do not accidentally alter the basic setup listed above. Because this setup does not use the traditional desktop display, a battery meter app has been installed on the start page. Lastly, these tablets have been set to NOT receive automatic updates. While we appreciate Microsoft’s dedication to providing almost a constant stream of updates for its devices, these tablets only experience a very specific type of use and are not likely to benefit from the vast majority of system updates.

Use:

- Turning the tablet on: Press and hold the small button on the side of the device.
- Turning the tablet off: You can either press and hold the small button on the side followed by swiping down, or swipe in from the right side of the screen, select “Settings,” then tap the Power icon and select Shut down.
- Logging in: After turning the tablet on, swipe up to reveal the Login screen. If correctly setup on the BETTER local account, the password will be “better”
- Connecting to Wi-Fi: To connect to a wireless network, swipe in from the right on any screen, select Settings, and then tap the Wi-Fi icon. You can select your network from here. “UNCH-Guest” is recommended.
- Volume control: The larger button on the side of the tablet is actually a two-way volume button.
- Opening the better video: From either the start screen or the desktop, select the UNC BETTER icon and you will be taken to the video website.
- Trouble shooting: All standard features (e.g. task manager, updates, system preferences) can be found with the search feature. To Search, swipe in from the right at any time and select “Search.” Have you tried turning it off and then back on?

RANDOMIZATION

Development of the Random Number Lists

Stratification: The two variables that we are adjusting distribution for in the BETTER Trial are gender and age (dichotomized into 50-64 years and 65 years or older). Age was selected as the primary variable

because of its association with short term knowledge gained from the video demonstrated in the BETTER video validation study.

Block Randomization: In each of the two random number lists, random distributed blocks of three and six will be used to ensure that screeners will not be able to guess the next study participant group assignment while still maintaining a high degree of even group distribution. A computer program developed by Dr. Mark Weaver was used to randomly assign numbers one through three in an even distribution into each block. This program works by randomly permuting the two lists 1,2,3 and 1,1,2,2,3,3 depending on the desired block size.

For a better understanding of the purpose of block randomization and blinding in small studies, refer to pages 156-159 in Designing Clinical Research

<https://books.google.com/books?id=7UWxJ5erSsC&q=157#v=snippet&q=157&f=false>

Random Number List: There are two random number lists used in this trial, one for each of the two age groups being assessed. Each list is created 21 numbers at a time and any list can be made again following the complete allocation of a block of six numbers.

Block Size Randomization: Blocks are randomized to contain either three or six numbers when each random number list (twenty-one numbers) is created.

Assignment of treatment group in the field

Master List The master list is actually two different random number lists, one for each strata of the distribution. These lists are randomized to block sizes and numbers are edited using the method described above to ensure equitable distribution. To keep the randomization process blinded, these lists should not be accessed by screeners who are actively enrolling patients.

Envelopes: Two sets of folded sticky notes labeled x01 through x21 are required for the blinded assignment of patients to treatment groups. Each card in one set is labeled "Younger" (101-121) corresponding to the 50-64 year old age group. Each card in the other set is labeled "Older" (201-221) corresponding to the 65 and older age group. Inside each folded sticky note is the corresponding number from that set's Random number list (i.e. envelope "Younger 101" has a piece of paper in it with the number that identifies the randomly assigned treatment arm for the first 50-64 year old enrolled in the study)

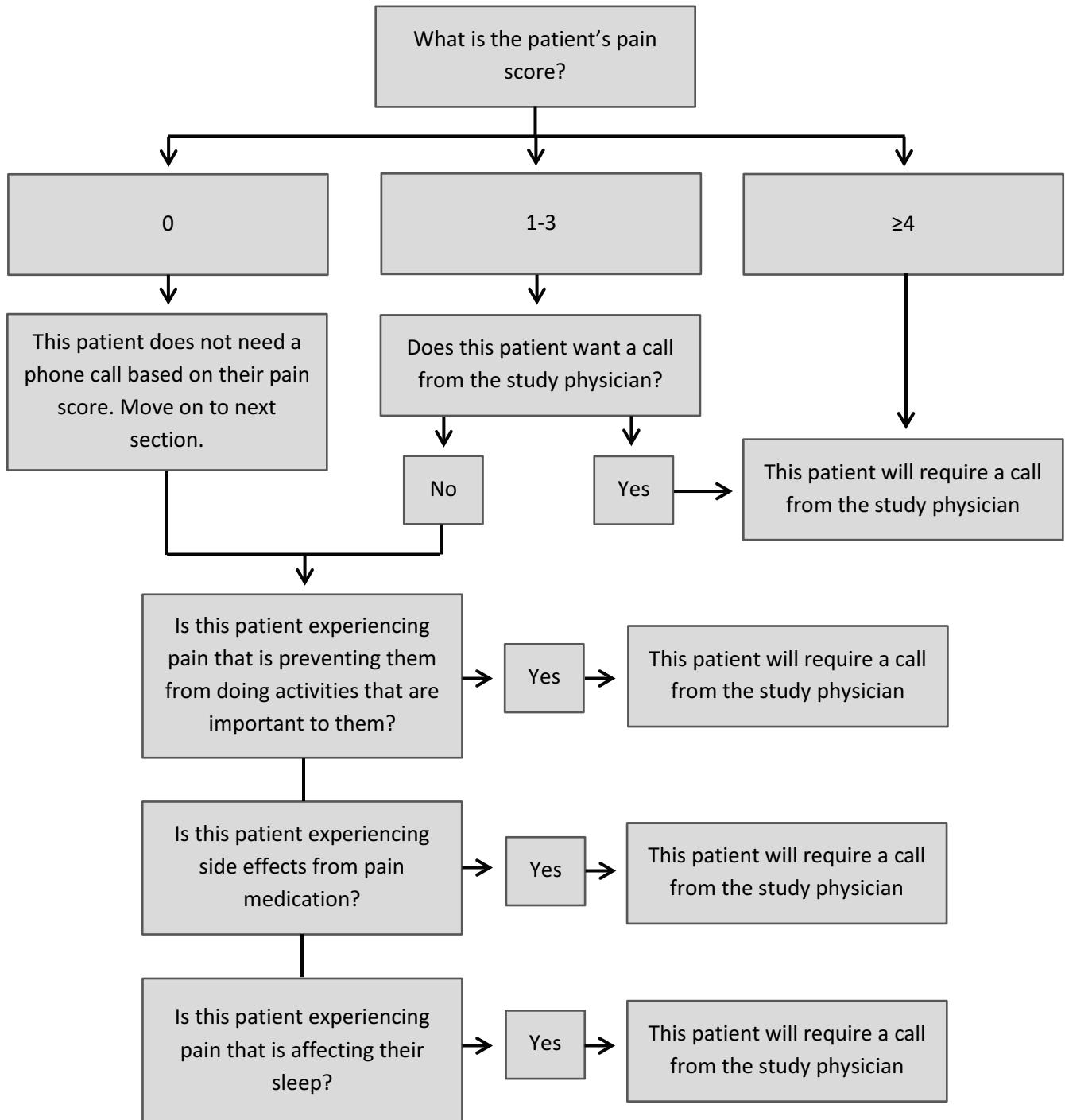
Assignment: This method requires that the screener carries the box containing both number lists (sticky note sets) with them when enrolling participants. After a prospective participant is deemed eligible, consents to participation in the trial, and completes the ED Interview, the screener will pull out the set of folded sticky notes that corresponds to the participant's age group. The next unopened sticky note in that category is opened and number of the treatment group found inside will determine which treatment group the participant will be assigned to.

Assignment – phone call alternative: This method requires a second research assistant that can be contacted by phone call. Following participant eligibility assessment, consent for participation in the trial, and the ED Interview, the screener calls the second research assistant to complete the randomized assignment. The person that is contacted by phone has the box containing both sets of sticky notes. Using the set that represents the participant's age group, the person on the phone will open the next sticky note to reveal the number of the treatment group that the participant will be assigned to. The phone call alternative will be used exclusively when multiple research assistants are screening participants at the same time.

RA FOLLOW-UP CALL

Phone calls are made to patients in the “video + follow-up” and “follow-up only” treatment arms. These calls must be made between 48 and 72 hours from patient enrolment. Refer to the REDcap data collection instrument titled “Follow-Up Call” to see the scripted introduction and questions that need to be asked to each patient. Using the answers given, evaluation of whether or not the patient will receive a phone call from Dr. Platts-Mills is made before terminating the call. The result of this decision is explained to the patient and a time-frame is set up for Dr. Platts-Mills to call the patient if it is deemed necessary. Before terminating the call, patients are asked about the status of any appointments that might have been scheduled with their primary care providers (PCP).

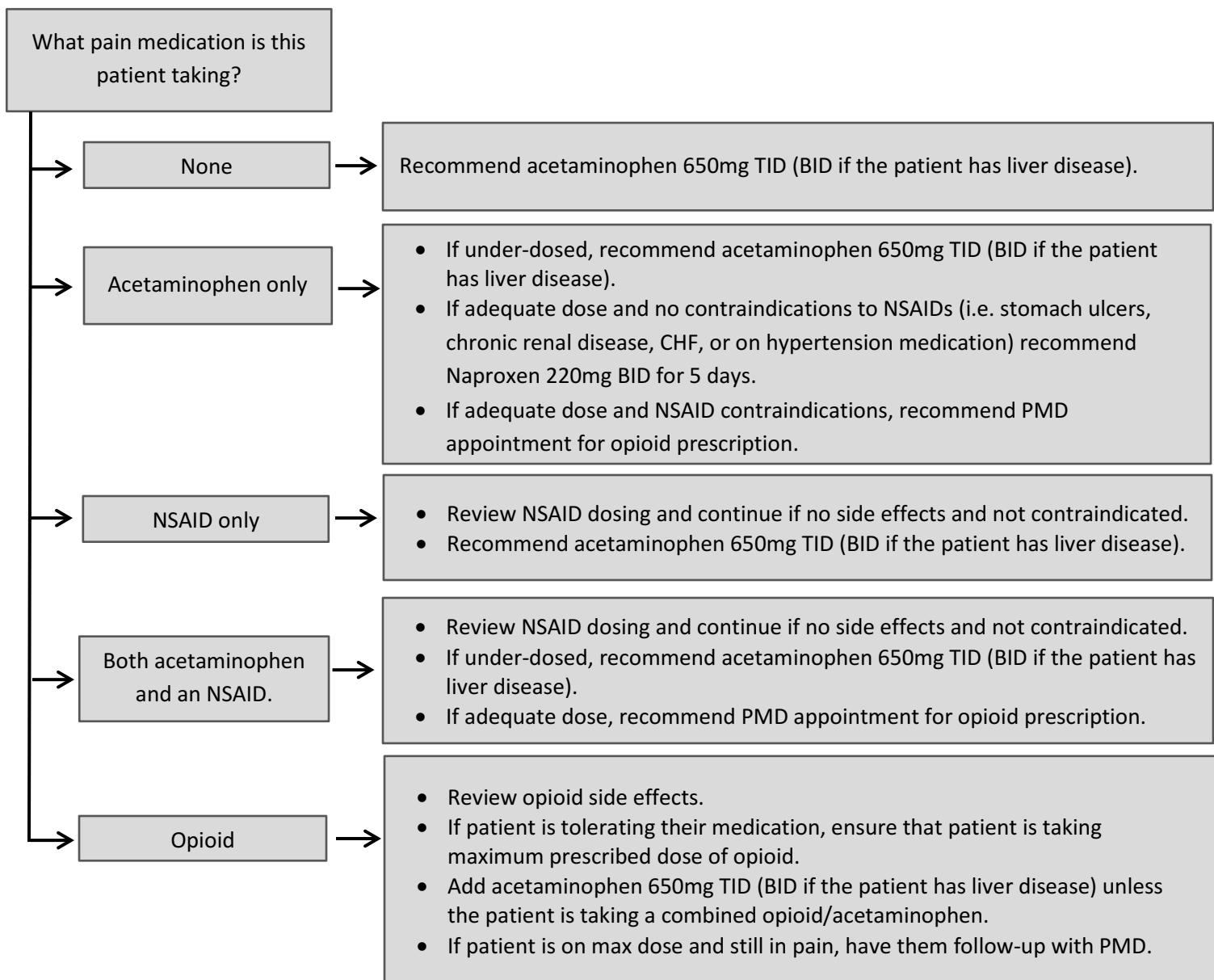
Study Physician Call Assessment: Based on the answers given patients in the “video + follow-up” and “follow-up only” treatment arms will be designated one of three status options, referred to here as Clear, Requesting, or Automatic. All patients assigned the “Clear” status meet the criteria answered “No” to all Assessment Survey questions and they either have no pain or they have pain in the 1-3 range but stated that they did not want to talk to a doctor when asked. Patients assigned the “Requested” status answered “No” to all Assessment Survey, have pain in the 1-3 range, and stated that they did what to talk to a doctor when asked. Patients assigned the “Automatic” status either had pain ≥ 4 and/or answered “Yes” to any of the survey questions (not include PCP appointment questions). Flow chart shown below.



STUDY PHYSICIAN CALL

If a patient assessed during the RA follow up call is designated to receive a call from the study physician, this call will be made either the same day as the RA call or the next day. This assures that the study physician call always happens within 4 days of the original ER visit. Ideally, the study physician call should be made using REDCap because of the information that is auto-filled from the RA call. The patient intervention flow chart for the study physician call is listed below.

The following protocol applies for patients in treatment arms “video + follow-up” and “follow-up only” who were assigned either the requested or automatic designation after RA follow-up call. Patients assigned the “Requested” status answered “No” to all Assessment Survey, have pain in the 1-3 range, and stated that they did what to talk to a doctor when asked. Patients assigned the “Automatic” status either had pain ≥ 4 and/or answered “Yes” to any of the survey questions (not include PCP appointment questions). Flow chart shown below.



Recommend follow up with primary care provider or UNC clinic for all patients not experiencing adequate pain relief.

UNC Family Medicine: 919-966-0210
UNC Internal Medicine: 919-966-1459
UNC Geriatrics: 919-957-6599
UNC SCHC: 919-843-6841

ONE MONTH EVALUATION

This evaluations requires an RA phone call and should be filled out in REDCap.

REDCap Analysis

Codes: In order to streamline the data analysis process, a series of rules was applied in the coding of answers choices in all redcap forms that will be analyzed. These codes are listed below.

x	This value is designated to answers that reflect that the question is Not Applicable. For example, the choice “No Prescription” for the question “Did you fill your prescription?”
0	This value is primarily designated to all minimum value answers (eg. No, None, Not at all, etc.) If used in a checkbox question, this value represents “Other”
1	If the question is yesno, then this value represents “Yes” If the question is a series, this number represents the next lowest value after “None” If the question is in a checklist or multiple choice, this value represents the first (top) choice
2-n	All other values are used for multiple choice questions and are listed numerically from top to bottom