Development of a Behavioral Intervention for Chronic Pain in Individuals With HIV
NCT02824562

STUDY PROTOCOL

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Send Questions or Comments to:
Jessica Merlin merlinjs@pitt.edu
Riddhi Modi rmodi@uabmc.edu

I. STUDY OVERVIEW

Defined as pain lasting longer than three months, chronic pain affects up to 30% of the US population. It often occurs in patients with complex chronic illness, including medical, psychiatric, and substance use comorbidities. However, chronic pain is not simply a symptom of these comorbidities. Its distinct neurobiologic basis and substantial impact on physical and emotional function make it a serious illness in itself. In recognition of its importance, the Institute of Medicine has called chronic pain a “public health crisis,” and identified research on chronic pain, particularly in populations most burdened by this condition, to be a priority.

The burden of chronic pain in HIV-infected patients is substantial. Prevalence estimates of chronic pain in HIV-infected patients are as high as 39-85%. Mounting evidence suggests that chronic pain in HIV is often associated with psychiatric illness, especially mood disorders such as depression, and has serious health consequences, including up to 10 times greater odds of functional impairment.

Non-pharmacologic, behavioral interventions to decrease pain and improve physical and emotional function in HIV-infected patients with chronic pain are needed. A consensus panel identified pain, physical, and emotional function to be the most important outcomes of chronic pain interventions. Commonly used pharmacologic therapies, including opioids, often do not result in substantial improvement in these outcomes, and carry risks including misuse, abuse, and addiction. In HIV, opioids may

actually be associated with worse pain, and adversely interact with antiretrovirals. Behavioral interventions are among the most effective and safe non-pharmacologic treatments for chronic pain in the general medical population.

II. OBJECTIVES

In this study we will conduct a two-arm pilot randomized controlled trial of the chronic pain behavioral intervention to investigate feasibility, acceptability, and when possible, preliminary impact.

III. STUDY ACTIVITIES

a) STUDY POPULATION

A total of 40 patients (up to 60) who are patients at the UAB 1917 clinic, enrolled in CNICS, experiencing chronic pain (Brief Chronic Pain Screening Questionnaire (BCPQ) = at least moderate pain for at least 3 months) and moderately severe and impairing chronic pain (PEG pain questionnaire = average of all three times is 4 or greater).

Inclusion Criteria

1. Enrolled in CNICS
2. Age ≥ 18 years
3. Chronic pain (Brief Chronic Pain Screening Questionnaire (BCPQ) = at least moderate pain for at least 3 months)
4. Moderately severe and impairing chronic pain (PEG pain questionnaire = average of all three times is 4 or greater)

Exclusion Criteria

1. Do not speak or understand English
2. Are planning a new pain treatment like surgery

3. Cannot attend the group sessions

Recruitment of participants will take place in the 1917 clinic. Participants will be recruited via word-of-mouth by clinic staff or providers, calls generated from flyer tear-offs, and responses to the flyer on the TV monitors.

b) PRE-SCREENING

Potential participants will be prescreened over the phone using our prescreening phone script. If the individual passes the telephone prescreen, he or she will be scheduled for an in-person pre-screening visit by a member of the STOMP recruitment team. The date and time of the pre-screening visit along with the participant contact information and preferred method of contact will be recorded on the Prescreening Visit Appointment Form. About 48 hours prior to the in-person prescreen visit, a reminder call from the research staff will be made to remind the potential participant of the prescreening visit.

On the day of the prescreen, the research staff member conducting the prescreen will log onto Redcap and establish a unique RedCap instance for this participant and complete the prescreen section only. At the end of the prescreen, the research tech will record the participant's eligibility on the Prescreening Visit Appointment Form. If the participant is eligible for enrollment, a Screening and Enrollment Visit will be scheduled and recorded on a Screening and Enrollment Visit form. The participant will also be thanked and given their $25 incentive.

If the participant is not eligible, he or she will be thanked for their time and give their $25 incentive.

c) SCREENING AND ENROLLMENT

The Screening and Enrollment Visit will be scheduled approximately 2-4 weeks from the date of the pre-screen visit and recorded on a Screening and Enrollment Visit form. Participants will receive a reminder call at about a week and 48 hours prior to the scheduled screening visit. At the beginning of the screening and enrollment visit, the participant will complete the informed consent process.

Informed Consent Procedures

Informed consent will be administered by staff trained in accordance to the University of Alabama at Birmingham Institutional Review Boards guidelines for obtaining informed consent. The staff member obtaining consent must verify the following: protocol name, version number, dates for use, and institution. The Study team member will also ensure that the most recent informed consent is being used for the study. Initial informed consent must be completed and documented before any other study related procedures are done.

Comprehension will be assessed by asking the participant to summarize the study activities or some general open ended questions will be asked like what can you tell me about this study, can you tell me about how long the study may last, etc.

The consent process is estimated to take around 30 minutes.

Study staff will ensure that the participant has signed and dated the consent form including the HIPAA form.

All signed consent forms will be stored in locked file cabinets under respective participant files.

Baseline Assessment

The research staff will then administer the baseline assessment which includes a confirmatory set of screening questions via RedCap. Confirmation of the participant's eligibility will be recorded in RedCap.

Following completion of the baseline assessment, participants will be thanked for coming and given their $50 incentive payment for their time. Completion of Baseline assessment will be recorded in excel logs.

d) RANDOMIZATION

Our team will utilize a 1:1 ratio for allocation to the treatment and control arms at each participating site. The UAB statistician will generate a list of random arm assignments for each site. Randomization list will be provided to the study coordinator to create sealed envelopes with participant ids on it in chronological order.

Once the participant completes the enrollment procedures, study staff will open the sealed envelope and will show the random arm assignment to participant and record it in the excel logs.

e) ASSIGNMENT OF ARM OF STUDY

Approximately, 20 intervention arm and 20 control (standard of care) participants will be randomly assigned. Recruiting staff and research personnel will be masked to treatment arm assignment at the initial study visit. After the initial study visit, study coordinator will inform the participant of the follow-up assessments and thank the participant for their time. Staff personnel doing the assessment will still be blinded to the arm assignment.

If the participant is randomized to the intervention group, the participant will be informed of the next steps which includes the first group session. If the date of the first group

session has been established, the participant will be informed of the date and time. If it has not been scheduled, the participant will be informed that s/he will receive a call within the next two weeks informing his/her with the date and the time of the first group session

f) INTERVENTION

This behavioral intervention consists of 12 intervention sessions (6 group and 6 individual sessions). The sessions will be completed over a period of 12-16 weeks from enrollment. The first intervention session will be a group session for all participants followed by individual and then alternating group and individual session for the rest of the sessions.

Group intervention Sessions

A total of 6 group sessions will be conducted over a period of 12-16 weeks from study enrollment date. These sessions will be led by a peer. A peer is an HIV-infected patient of the UAB 1917 Clinic living with chronic pain, who has completed all ten of the one-on-one sessions offered, received training to co-facilitate the six group sessions with the interventionist, and is successfully self-managing his/her chronic pain.

Participants will receive a reminder call/text approximately 48 hours before the group session to remind them of the upcoming session. Participants will also be notified of the upcoming group sessions at the end of each one-on-one intervention. Group sessions will be conducted in UAB 1917 clinic building or the Bevill Biomedical Research Building (BBRB). A sign-in sheet will be used to document attendance. Session notes will be used to document any major issues presented or any anecdotal nuances identified. The date, start time and end time of the session will also be documented. Participants will

complete an anonymous session feedback form at the end of each session. Each session will be audio recorded and transcribed later using a third party.

Individual Intervention Sessions

A total of 6 individual sessions will be conducted over a period of 12-16 weeks from study enrollment date.

Each individual intervention session will be scheduled by the staff interventions preferably prior to next group session. The intervention date and time will be recorded on the Individual Intervention Session Form along with the intervention no. and topic. The participant will receive a reminder communication about the upcoming session approximately 48 hours before the session. An Intervention Session Form will be used to record the date, time, length of session, topic covered, homework, next steps, and any nuances identified during the session. An adverse event form will be completed if any physical, social or psychological issues arise a result of participating in this study and warrant immediate attention. The date of the next group session will be announced and the date of the next one-on-one session will be recorded at the bottom of the Intervention Session Form. Participants will complete an anonymous session feedback form at the end of each session. Each session will be audio recorded and later transcribed using a third party.

Each session will be reviewed by a member of the research team not participating in the session for fidelity using the fidelity checklist.

Reminder calls

Study staff will conduct up to 5 reminder calls to remind about their upcoming intervention session. Please note the purpose of these calls is to remind about

appointments but in case patient initiates the conversation regarding intervention or other related to the study staff will talk to participant regarding intervention.

If a participant misses a session, they will receive up to 5 reminder calls asking why and what we can do to help. If there are things we can do to help that are reasonable (e.g., more reminders, more transportation assistance, or other things), we will provide them. If they miss more than one visit, they may receive a call asking about their future participation in the study and whether, if they are unwilling to participate in intervention sessions, they would willing to just complete outcome assessments.

Assessments

All participants in the intervention group will also receive a baseline, post-intervention (after all sessions are completed), and at about 3 months (1 month leeway) assessment. These may be conducted by phone or in person. They will also participate in an audio-recorded in –person qualitative interview at the mid-point and end of the trial which will be transcribed using a third party company.

Qualitative interviews

Participants assigned to intervention arm, peers and interventionists of the study will be interviewed at mid-point of the study and end of the study to provide their feedback on the STOMP intervention. These interviews will be audio-recorded and later transcribed using third party.

g) CONTROL

The control group will receive “treatment as usual”. The “treatment as usual” or control arm refers to the standard of care that patients receive at the UAB 1917 clinic. This standard of care is for patients to discuss chronic pain with their providers at their

discretion. Although highly variable, providers can recommend and prescribe pharmacologic (e.g., opioid and other pain medication), non-pharmacologic (e.g., physical therapy, referral to psychology) approaches for pain. This study will not interfere in any way with usual care. No additional treatment will be provided to participants allocated to the control group. The control group participants will complete the baseline assessment and around 12 week follow-up (1 month leeway) assessment.

h) <u>SNAP SHOT OF STUDY ACTIVITIES</u>

Procedure	**Length of Time Required of Participants**	**Frequency of Repetition**
Individual sessions (intervention group only)	6 sessions, up to approx. 120 minutes each	Maximum of on average every other week
Group sessions (intervention group only)	6 sessions, up to 120 approx minutes each	Maximum of on average every other week
Questionnaire assessments – see attached	Approx 30 minutes	Baseline, end of intervention, and 3 months after intervention
Qualitative interviews (intervention group only)	Approx up to 120 minutes	Midpoint and end of trial
Phone calls (intervention group only)	Approx up to 30 minutes	Average of once weekly

h) SUMMARY OF COMPENSATION

Intervention group

In person for Prescreen	$25
Screening/Enrolment visit	$50
Mid-point qualitative interview	$50
End of study qualitative interview	$50
Post intervention follow up	$50
3 month follow up	$100

Control group

In person for Prescreen	$25
Screening/Enrolment visit	$50
12 week assessment	$50
3 month follow up	$100

Offer parking vouchers/coffee vouchers/bus tickets etc. as required to the participants if that is the standard practice followed over at the clinic.

IV. DATA COLLECTION AND MANAGEMENT

All study documentation will be kept in locked file cabinets in BBRB or CCB in study personnel's offices. RedCap database can only be accessed by STOMP personnel using a UAB computer or encrypted laptop.

V. DATA ANALYSIS

Outcomes were reported as means and standard deviations for continuous variables, and frequencies and percentages for categorical variables. T-tests were used to compare change scores for continuous variables and Fisher's exact

tests were used to compare percentages. Interviews were analyzed thematically by two independent coders. Discrepancies were reconciled, a code book was created, and the lead analyst coded the remaining transcripts with continued input from the other coder. Representative quotes are presented for themes that helped us understand why and how the intervention could work.

VI. CRISIS PROTOCOL

As a general note, referrals can be made for crisis consultation at any time. The research staff will document the findings of his/her evaluation and the course of action taken. Providers for the patient may be informed about the same.

VII. PROTECTION OF HUMAN SUBJECTS

Our team has devised a comprehensive plan for ensuring protection of human subjects throughout the course of the proposed study. We will utilize an English-language consent form with common phrasing that describes that no special privileges or considerations will be conferred as a result of study participation, and that access to medical care will not be affected by the potential participant's decision to enroll in the study. The procedures listed in the following sections detail procedures that have been approved and utilized during recent years of clinical and behavioral trials at each site for collaborative research that utilizes sensitive information from participants. Our team will make every effort to protect all participants' confidential and private information in order to minimize possible study-associated risks.

All findings related to this research will be available and provided to study participants in accordance with standard practices. Clinical and measurement data used for research studies will be released only in de-identified fashion.

In addition, all study personnel are required to renew Human Subjects trainings annually, or in accordance with their site regulatory mandates.

VIII. KEY PERSONNEL AND ROLES

Principal Investigators:

Jessica Merlin	Principal Investigator

Research Team:

Riddhi Modi	Coordinator
Chastity McDavid	Coordinator
Sally Shurbaji	Interventionist
King, Kiko S.	Interventionist
Banasiewicz, Mary K	Research Technician
Hutchins Katelin K	Research Technician
Megan Couture	Research Technician