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Development And Pilot Testing Of A Behavioral Intervention For Chronic Pain Tailored To Individuals With Hiv

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DEVELOPMENT AND PILOT TESTING OF A BEHAVIORAL INTERVENTION FOR CHRONIC PAIN TAILORED TO INDIVIDUALS WITH HIV

by

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A DISSERTATION

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DEVELOPMENT AND PILOT TESTING OF A BEHAVIORAL INTERVENTION FOR CHRONIC PAIN TAILORED TO INDIVIDUALS WITH HIV

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HEALTH EDUCATION AND PROMOTION

ABSTRACT

Chronic pain is a chronic condition with a unique neurobiologic basis, which has a substantial impact on physical and emotional function. Chronic pain in HIV-infected patients is common, and associated with serious health consequences, including up to 10 times greater odds of impaired physical function. Many pharmacologic therapies, including opioids, often do not lead to improved pain and function, and carry significant risk. Evidence-based behavioral interventions are among the most effective and safe non-pharmacologic chronic pain treatments investigated in the general medical population. Therefore, behavioral interventions to improve pain, physical, and emotional function in HIV-infected patients are needed. There is much to be learned from existing interventions. However, the success of a behavioral intervention is heavily influenced by how well it is tailored to the target population's biological, psychological, and social environment. Therefore, the Specific Aims of this project were as follows: Aim 1: Use intervention mapping to systematically develop and pre-test a tailored behavioral intervention for chronic pain in HIV-infected patients. Aim 2: Conduct a two-arm pilot randomized controlled trial of the behavioral intervention compared to routine HIV and pain care, to determine feasibility, acceptability, and preliminary impact. The first two papers presented in this dissertation address Aim 1: the first paper addresses patient preferences for intervention delivery and the second paper uses Social Cognitive Theory-based intervention mapping to incorporate these and other patient needs/preferences into

the content of the intervention. The third paper reports the results of the randomized pilot trial. This research represents the first study to address chronic pain as a chronic disease in HIV-infected patients, and to develop and test a behavioral intervention specifically tailored to this population. Next steps will include a full scale randomized trial to evaluate the intervention's efficacy.

Key words: HIV, chronic pain, intervention mapping, behavioral interventions, intervention development

DEDICATION

To my husband Scott, who has supported me throughout this process.

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INTRODUCTION

Chronic Pain is a Chronic Illness

Chronic pain is defined as persistent pain lasting longer than 3 months, beyond the period of normal tissue healing. (1, 2) It often occurs in patients with complex chronic illness**,** including medical, psychiatric, and substance use comorbidities. (3-6) However, chronic pain is not simply a symptom of these comorbid conditions. Rather, it has a unique neurobiologic basis. Chronic pain involves processes that heighten sensitivity in peripheral receptors, and cause perception of pain in the absence of local inflammation. (7-9)

Prevalence estimates of chronic pain in the general population vary widely depending on the methodology used. Based on the 2016 U.S. Department of Health and Human Services (USDHHS) National Pain Strategy, many investigators have begun to use research definitions of chronic pain that incorporate not only pain duration, but also severity and/or impact on function (e.g., work, social/recreational activities).(10) Using this approach, the most contemporary estimates of chronic pain in the general population are 11% based on a sample from the National Health Interview Survey, (11) and 14% based on a mail survey of adult health plan enrollees.(12) In the United States, chronic pain costs more than heart failure or cancer,(13) and is associated with substantial disability.(14) A recent report by the Institute of Medicine described chronic pain as a chronic illness in itself and a “public health crisis,” and called for research among populations most affected.(13)

Chronic Pain in People Living with HIV (PLWH)

The classically described syndrome of HIV neuropathy – caused by HIV itself, common comorbidities (e.g., alcohol use), and old antiretroviral drugs – occurs in as many as 40% of chronic pain in people living with HIV (PLWH) in the current treatment era.(15) However, recent studies suggest a predominance of musculoskeletal pain. For example, Jiao et al conducted a diagnostic code-based study of chronic pain in a large HIV primary care clinic, and found that the most common type of chronic pain was musculoskeletal, occurring in 39% of participants. (16)

Studies of PLWH seeking treatment for chronic pain also suggest an emergence of the importance of regional musculoskeletal pain. For example, we found that the most common cause of chronic pain in individuals presenting to an HIV-focused pain clinic was back pain (21%), followed by neuropathic pain (12%); the remainder had other types of musculoskeletal pain (e.g., leg, hip, shoulder, neck, and joints, <10% each). Others have found similar results.(17)

Notably, chronic pain in PLWH is often more complex than pain of one type or pain in just one location. Rather, many PLWH have widespread pain. For example, Miaskowksi et al reported the median number of locations of pain in a cohort of indigent PLWH to be five. (18) Jiao et al again found that 40% of participants with chronic pain had more than one pain diagnosis.(16)

Chronic Pain is an Important Comorbidity in PLWH

Chronic pain is very common in PLWH. We are not aware of any studies whose aim is to directly compare chronic pain prevalence between PLWH and the general popu-

lation. However, studies of chronic pain clinical epidemiology in PLWH suggest prevalence estimates that are high and vary widely, from 30%-85%. This range is likely due to varying methodologies as described above, and also differences between clinical cohorts and other samples. For example, chronic pain prevalence is closer to 30% in cohorts of patients engaged in HIV primary care (16, 19, 20), and closer to 85% in cohorts like the REACH cohort, in whom patients are recruited primarily from soup kitchens and homeless shelters and experience a greater degree of psychiatric and addiction comorbidities (which are associated with chronic pain)(18). Regardless, even if the true prevalence of chronic pain in HIV was 30%, this is still substantially higher than is reported in the general population.

Investigation of **t**he relationship between chronic pain and key outcomes in PLWH is an emerging area. Our prior work suggests that chronic pain is associated with up to 10 times greater odds of impairment in mobility, self-care, and usual activities.(21) Additionally, we found that pain was associated with reduced odds of retention in HIV primary care in individuals without current substance use (OR 0.5, 95% CI 0.2-0.9). These studies are limited by their cross-sectional nature, but point to the importance of chronic pain in this population. Other studies have shown that chronic pain in PLWH is associated with increased emergency room utilization(16), suboptimal adherence to antiretroviral therapy(22), and the use of heroin and prescription opioids.(23)

Studying the Treatment of Chronic Pain: PLWH vs. General Population

It can be asked why should the treatment of chronic pain in PLWH be studied as distinct from chronic pain in the general population? The answer to this question can be

summed up that regardless of the etiology, chronic pain in PLWH is unique from chronic pain in the general population. This is the case for three reasons.

First, chronic pain in PLWH is biologically distinct from chronic pain in HIV-uninfected individuals. Several studies have established that the HIV virus causes inflammation around peripheral neurons.(24-27) A growing body of basic science literature has also found a specific biologic basis for the development of both neuropathic and non-neuropathic chronic pain in HIV-infected patients, involving activation of astrocytes in the spinal dorsal horn.(28, 29) Some of our pilot work suggests that PLWH with a detectable viral load have higher levels of pain sensitivity than PLWH with an undetectable viral load, who in turn have a higher level of pain sensitivity than HIV-negative controls. This suggests that PLWH, especially those who are viremic, have a predilection to develop chronic pain, and that the virus itself plays a role in pain processing. Additionally, we have conducted a pilot study that suggests PLWH and chronic multisite pain have higher circulating levels of IL1-β, a cytokine that is involved in pain processing, than PLWH without chronic pain.

Second, PLWH who have chronic pain experience not only a unique biological, but also a distinct psychological and social context,(30, 31) which we have described in our adapted Biopsychosocial Framework for Chronic Pain in HIV (BPS).(32) The BPS is an explanatory framework that has been applied to medical and psychiatric diseases,(33, 34) including chronic pain.(35) To explain the unique context experienced by HIV-infected individuals with chronic pain, we deliberately cast a broad net and identified biological, psychological, and social factors common to PLWH and individuals with chronic pain.(32) Based on this process, we describe chronic pain in HIV within the context of

pain diagnosis, comorbid medical(36-38) and psychiatric illness,(3, 38-42) chronic opioid use,(19, 43, 44) substance use(39, 42, 45-48), HIV-related stigma,(49, 50) traumatic life events,(51-55) and environmental challenges such as housing,(56, 57) employment,(58-61) and social support.(62-65) We hypothesized that this unique psychosocial milieu in PLWH is likely to impact patients' pain experience, and preferences for treatment, especially behavioral treatments. This hypothesis is supported by our formative work using the BPS framework to develop and tailor a Social Cognitive Theory (SCT)-based chronic pain behavioral intervention to PLWH.(66)

Third, PLWH generally receive health care in different settings than the general population. The Ryan White HIV/AIDS Program ("Ryan White") is a federal program that provides comprehensive medical care, including primary care, specialty care, mental health, and social services, often in the setting of a patient-centered medical home This program provides care to 512,000 or 52% of individuals diagnosed with HIV in the United States. Additionally, PLWH require monitoring of their disease at least every 6-12 months(67). This combination of a relatively uniform approach to comprehensive care through the Ryan White program, and the need for frequent monitoring, provides the perfect platform for the implementation and dissemination of efficacious chronic pain interventions.

Limited Studies in Chronic Pain Interventions for PLWH

Despite the importance of chronic pain in PLWH, few studies have investigated interventions to address it. This is a critical barrier in the field. We recently conducted a systematic review of all chronic pain interventions – pharmacologic and non-

pharmacologic – in PLWH.(68) Only 11 total interventions met our inclusion criteria. Nine of the studies were of low or very low quality (GRADE 1 or 2; i.e., due to designs that were non-randomized, had short duration of follow-up, or were not blinded). Despite the preponderance of musculoskeletal pain in the current treatment era, six studies focused exclusively on neuropathic pain. Across the board, effect sizes were small. This body of literature is insufficient in size and scope to address the large burden of chronic pain in PLWH.

Need for Non-Pharmacologic, Behavioral Interventions for Chronic Pain in PLWH

Medications are commonly used to treat individuals with chronic pain, but have significant limitations. The most commonly prescribed medications for pain in the United States are opioids, which have increased in use dramatically over the past 10 years.(69) Opioids are more commonly prescribed for HIV-infected individuals with chronic pain than HIV-uninfected individuals.(70) Despite their frequency of use, two recent systematic reviews(44, 71) suggest only weak evidence to support improvement in pain and insufficient evidence to support improvement in function. Furthermore, no study evaluated the long-term use of opioids beyond a year. Likewise, HIV-infected individuals with chronic pain on long-term opioid therapy have worse pain than those not on chronic opioid therapy.(43) In addition to lack of compelling evidence of efficacy in general and in PLWH, opioids carry serious risks. These include medical complications such as cardiovascular disease,(72, 73) fractures,(74) hypogonadism,(75) and misuse and overdose(76) (especially in individuals with a history of substance use(76, 77)).

Perhaps most importantly, several studies have now shown that opioids are associated with significantly higher odds of mortality, especially at high doses (> 100mg equivalents of morphine per day) and when combined with benzodiazepines(78-81). For these reasons, the 2016 CDC Opioid Guideline for Prescribing Opioids for Chronic Pain states, "Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred [over opioid therapy] for chronic pain.**"**(1) Recent evidence also suggests that PLWH who are prescribed opioids are particularly vulnerable to this mortality risk.(82) In addition, opioids disrupt gut homeostasis, potentially leading to HIV disease progression(83), and can adversely interact with antiretrovirals.(84)

Unfortunately, non-opioid pharmacologic therapies are barely more promising than opioids. Long-term use of other pharmacologic therapies such as non-steroidal anti-inflammatory drugs and acetaminophen is also challenging because of cardiovascular, renal, hematologic, and gastrointestinal risks (85-90), especially in populations like PLWH with a high burden of medical comorbidities. Anticonvulsants such as gabapentin are only modestly effective for neuropathic pain,(91) and are ineffective in musculoskeletal pain. Antidepressants such as duloxetine may be beneficial, but have only modest effect sizes in some populations,(92) and are ineffective in others.(93) Furthermore, our systematic review found very few studies of non-opioid pharmacologic therapies for pain in PLWH. All such studies focused on peripheral neuropathy: one was negative study of gabapentin(91), one was negative study of pregabalin(94), and two were promising studies of capsaicin for peripheral neuropathy with modest effect sizes and a follow-up time of 12 weeks.(95, 96)

Therefore, a purely pharmacologic approach is limited by the safety and efficacy concerns described above, and does not help patients learn how to overcome disability associated with chronic pain.(97, 98) Behavioral interventions that educate patients about pain and also help to build adaptive behaviors and self-management skills, such as addressing cognitions about pain, managing stress and mood symptoms, and pacing oneself to improve physical activity, are among the most efficacious chronic pain treatments in the general population.(14) They are specifically highlighted by both the CDC Guideline and the USDHHS National Pain Strategy as key to the management of chronic pain.

Target Population and Behavioral Interventions

The success of a behavioral intervention is heavily influenced by how well it is tailored to the target population. This assertion is a basic premise of the field of health behavior. As Green and Kreuter articulate in their formative textbook, *The Principal of Intervention Specificity* states that "there is nothing inherently superior about any intervention method…it always depends on the appropriate fit of the intervention with the person or population and their circumstances, and the delivery setting."(99) This is reflected directly in the 2016 USDHHS National Pain Strategy, which underscores the urgent need to develop and test pain self-management (PSM) programs tailored to the unique needs of vulnerable populations, particularly PLWH, that can be implemented and disseminated in health care systems and networks nationwide.

In our systematic review, we found only two behavioral interventions for chronic pain that have been studied in PLWH.(100, 101) Both investigated psychologist-delivered cognitive behavioral therapy (CBT) programs. Despite the critical importance

of tailoring behavioral interventions to their target population, it is unclear to what degree these programs were tailored to PLWH. Both studies were rated GRADE 1 (very low quality), suffered from poor participation rates, and the interventions they tested have not been investigated further. Since the publication of that review, two relevant pilot trials have been published. One was a 32-participant pilot trial of a mindfulness-based stress reduction intervention,(102) and the other was a 23-participant psychologist-delivered CBT-based intervention ("behavioral activation") addressing both depression and pain.(103) These studies also suffered from several limitations. Neither were developed using formative work intended to tailor the intervention to PLWH, CBT was delivered by a psychologist (out of the reach of most HIV primary care settings), and neither have been tested in full scale efficacy trials. Therefore, there is an immediate need for additional work in this area.

Pain Self-Management (PSM) Programs

Pain Self-Management (PSM) programs are SCT-based behavioral interventions that are widely regarded as both efficacious and scalable. SCT-based cognitive behavioral interventions for chronic pain have been developed and tested in the general population and can inform our work.

SCT is a learning theory, and asserts that even in the setting of stressors such as pain, people can learn to change their behavior (e.g., physical activity). Additionally, behaviors are influenced by personal and environmental factors (e.g., mood, socials support). Reciprocal determinism argues that individuals have the power to change these personal and environmental factors (e.g., engage in treatments that improve mood and

cultivate social support) and furthermore, that changes in personal and environmental factors can influence each other and influence behaviors. Importantly, SCT asserts that this behavior change is governed by three key constructs. Self-efficacy is the belief that one has the ability to perform a behavior, outcome expectations are the belief that something good will come from participating in the intervention, and self-regulation is the ability to put one's present desires aside to achieve something important in the long-run.

SCT-based CBT interventions are the most widely studied behavioral approach to chronic pain.(104, 105) CBT is a therapeutic approach typically delivered by a psychologist that helps individuals change behavior by identifying and disputing maladaptive thoughts and cognitive distortions.(106) CBT for chronic pain promotes an individual's acceptance of responsibility for change and development of adaptive behaviors (e.g., engagement in physical activity), while addressing their maladaptive counterparts (e.g., avoiding physical activity due to fear of pain or re-injury(104, 107)) In practice, CBT interventions accomplish these behavior changes by utilizing key SCT constructs: they explicitly focus on building self-efficacy, improving outcome expectations, and practicing self-regulation for these behaviors. While CBT interventions for chronic pain have been developed and tested in HIV, none have been specifically developed for or tailored PLWH; not surprisingly, the majority have suffered from poor adherence; and a psychologist is often out of reach of typical HIV primary care clinic settings.

PSM interventions address these shortcomings of CBT. PSM interventions are based on CBT, and incorporate SCT constructs in the same way. However, PSM programs have several notable differences from SCT. Improving coping skills and addressing adaptive and maladaptive behaviors remain a focal point of PSM. However, PSM

programs are manualized interventions that may be delivered by health professionals more commonly found in primary care settings than psychologists (e.g., social workers, health educators). Additionally, the focus of PSM programs is on the desired outcome of the intervention (self-management) rather than its cognitive and behavioral components. PSM programs also have a long history of being developed for and tailored to specific populations. For example, PSM interventions have been developed for use in specific chronic pain syndromes, including low back pain, arthritis, and fibromyalgia, and specific populations, such as Veterans. Numerous RCTs and meta-analyses of effective PSM interventions have been published.(108-111)

The USDHHS National Pain Strategy mentions PSM programs 24 times. In fact, the National Pain Strategy's Prevention and Care Section's second objective, right after "Characterize the benefits and costs of current prevention and treatment approaches," is "Develop nationwide pain self-management programs," particularly those tailored to the needs of vulnerable populations. These programs are regarded by the National Pain Strategy as efficacious and scalable. The National Pain Strategy outlines a 5-year plan to focus on the following:

> implement, evaluate, and disseminate nationally evidence-based pain self-management programs that are effective, as documented by high quality research methods, and that have developed materials and a structure enabling them to be transferred to one or more additional sites. (10)

We have developed just such a PSM program, and the purpose of this proposal is to evaluate its efficacy, mechanisms, and cost-effectiveness. If successful, this would allow our program to be implemented and disseminated across Ryan White care settings nationally.

Dissertation Objective

The long-term goal of this line of research is to implement an efficacious PSM intervention in HIV care settings. The overall objective of this dissertation is to develop and pilot test a behavioral intervention for chronic pain tailored to individuals with HIV.

Specific Aims

The specific aims for this dissertation are as follows

Aim 1: Use intervention mapping to systematically develop and pre-test a tailored behavioral intervention for chronic pain in HIV-infected patients.

Aim 2: Conduct a two-arm pilot randomized controlled trial of the behavioral intervention compared to routine HIV and pain care, to determine feasibility, acceptability, and preliminary impact.

The first two papers presented in this dissertation address Aim 1. In the first paper, qualitative inquiry was used to investigate preferences for chronic pain intervention delivery among PLWH. The importance of a group component to provide social support around chronic pain, ensuring groups were comprised solely of PLWH due to stigma, and the need for peer co-facilitation of these groups, stood out as important themes. In the second paper, intervention mapping was used to systematically develop the intervention sessions by integrating existing PSM interventions with key SCT constructs (self-efficacy, outcome expectations, and self-regulation) and the project's qualitative work. This rigorous development process is essential to the intervention's robustness. The third paper will be a 40-participant 2-arm randomized pilot trial of the intervention as compared to usual care.

Summary and Next Steps

This research represents the first study to address chronic pain as a chronic disease in HIV-infected patients, and to develop and test a behavioral intervention specifically tailored to this population. Next steps will include a full scale randomized trial to evaluate the intervention's efficacy, mechanism, and cost-effectiveness.

USING PATIENT PERSPECTIVES TO INFORM THE DEVELOPMENT OF A BEHAVIORAL INTERVENTION FOR CHRONIC PAIN IN PATIENTS WITH HIV: A QUALITATIVE STUDY

by

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Abstract

Background. Chronic pain is a common and disabling comorbidity in individuals living with HIV. Behavioral interventions are among the most effective and safe nonpharmacologic treatments for chronic pain. However, the success of a behavioral intervention is influenced by how well it is tailored to the target population's biological, psychological, and social context. Given well-documented psychosocial vulnerabilities among persons with HIV, it is critical to develop a behavioral intervention for chronic pain tailored to this population.

Objective. To use qualitative methods to investigate patient preferences for the structure and delivery of a behavioral intervention for chronic pain in individuals with HIV.

Methods. Interviews and focus groups were used to elicit participant preferences. A thematic analysis approach, with an initial round of open coding, was used to develop the codebook and analyze the data.

Results. Qualitative data from 12 interviews and 3 focus groups with patients living with HIV and chronic pain (total N = 24) were analyzed. Emergent themes fell into four major categories: perceived value of group sessions, incorporating peer leadership, and two key elements of how the intervention should be delivered: the HIV status of group participants and views on phone-delivered intervention content.

Discussion. This study provides a framework for the structure and delivery of a behavioral intervention for chronic pain in individuals with HIV based on patient preferences. We will use these results to design our intervention, and hope that our approach informs the work of investigators in other disciplines who seek to incorporate patient preferences during intervention development.

Introduction

Chronic pain—pain lasting longer than 3 months, beyond the period of normal tissue injury [1]—is a common comorbid condition in individuals living with HIV. Prevalence estimates vary widely, but range from 39% to 85% [2–10], higher than estimated in the general population [11]. In individuals living with HIV, chronic pain causes substantial disability; it is associated with mood and substance use disorders [9], and up to 10 times greater odds of functional impairment [12].

Nonpharmacologic, behavioral interventions to decrease pain and improve physical and emotional function in HIV-infected patients with chronic pain are needed. Commonly used pharmacologic therapies, including opioids, often do not result in substantial improvement in pain or physical and emotional function [13,14], and carry risks including misuse, addiction, and overdose [14]. For people living with HIV, opioids may actually be associated with worse pain [15], and may adversely interact with antiretroviral medications [16]. Behavioral interventions are among the most effective and safe nonpharmacologic treatments for chronic pain in the general population. These include Social Cognitive Theory (SCT)–based cognitive behavioral interventions that focus on self-management strategies to relieve pain and achieve functional goals [17–19].

The success of a behavioral intervention is heavily influenced by how well it is tailored to the target population's biological, psychological, and social context [20]. Given well-documented psychosocial vulnerabilities among persons with HIV [21], it is critical to develop a behavioral intervention specifically tailored to HIV-infected patients with chronic pain. We are aware of only two randomized controlled trials of SCT-based behavioral interventions (manualized cognitive behavioral therapy delivered by a

psychologist) in HIV-infected individuals with chronic pain [22,23]. However, neither intervention was systematically tailored to individuals with HIV; both suffered from poor attendance at intervention sessions and had only a small effect on patients' pain and function.

The current study proceeded from the view that a population's unique biopsychosocial context is likely to influence its preferences for intervention structure and delivery, which ultimately informs the best way to deliver the intervention and determines the intervention's success. Previously, we have described an adapted biopsychosocial framework for chronic pain in HIV [24], which can serve as a useful starting point for intervention development. To develop this framework, we identified biological, psychological, and social factors common to both HIV and chronic pain that are likely to contribute to pain and therefore important to consider in intervention development. For example, depression, stigma, and social isolation are associated with both HIV [21] and chronic pain [25], and these factors may be compounded in individuals who experience both conditions. Therefore, these factors may influence preferences for intervention structure and delivery in ways that cannot be assumed in advance; individuals may be socially isolated and therefore prefer group sessions to achieve social support; or they may be so depressed and stigmatized that they prefer individual sessions.

A critical first step in intervention tailoring is to broadly investigate participant preferences for the general structure and delivery of the intervention. Little has been written to guide investigators developing behavioral interventions on how such formative work might inform intervention design. We hope that this report will not only guide the

design of our intervention, but will also inform other efforts to tailor interventions by incorporating patient preferences.

Methods

Individuals with HIV and chronic pain were recruited from an outpatient HIV clinic in the southeastern United States. This clinic serves a population that is made up of predominantly Black and White patients (59% and 36%, respectively). Twenty-five percent are female. Patients' primary insurers include private insurance (26%), Medicare (27%), and Medicaid (13%) [26]. Pre–Affordable Care Act, 34% were "uninsured" [26]; such patients are often covered under either the Federal Ryan White HIV/AIDS Program or by an Affordable Care Act–based insurance plan [26–28]. Most clinic patients are enrolled in the Center for AIDS Research Network of Integrated Clinical Systems (CNICS) cohort, which routinely collects electronic data on a variety of patient-reported outcome (PRO) measures at the point of care [29]. Study recruitment was based on identifying individuals who reported either moderate or severe pain on the EuroQOL quality of life measure [30] in the past 6 months. Additionally, participants were purposively sampled to include those who self-reported depression or anxiety symptoms (PHQ-9 $\geq$ 10 [31], PHQ-Anxiety module-anxiety symptoms, panic [31]) and/or current substance use (the Alcohol, Smoking, and Substance Involvement Screening Test [ASSIST] items pertaining to cocaine; amphetamines; hallucinogens; inhalants; opioids, stimulants, or sedatives purchased illicitly or taken for nonmedical purposes; does not include marijuana [32]). We used this recruitment strategy to represent individuals who may have had chronic pain that was more challenging to address due to these comorbid

symptoms and behaviors. Potentially eligible participants were recruited by phone; further screening was conducted using the Brief Chronic Pain Questionnaire (BCPQ) [33,34]. Individuals who reported at least moderate pain for at least 3 months were invited to participate. When participants arrived for their study visit, the BCPQ was repeated to confirm at least moderate pain severity.

We also administered the Brief Pain Inventory (BPI) [35], which asks about pain severity at its worst, least, "on average," and right now, and how that pain interferes with a variety of functional domains (general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life). Both pain severity and interference are measured on a scale ranging from 0–10, with a score of 4–6 considered moderate pain or interference and 7–10 severe pain or interference [35].

Qualitative Data Collection

Qualitative data from these participants were collected in two stages. First, we conducted one-on-one in-depth interviews with 12 participants using a semistructured interview guide. In order to build rapport, participants were initially asked to give a general overview of their experiences with chronic pain. Then, they were broadly asked to describe their vision for a chronic pain program for patients with HIV. Participants were subsequently probed as to the format of the sessions (e.g., individual, group), who should deliver the sessions (e.g., doctor, nurse, social worker, peer), and the HIV status of group participants; open-ended questioning was used to allow participants to expand on their thoughts. After providing their overview, participants were also shown sample sections from a previously published chronic pain intervention manual for their

impressions [36]. After initial qualitative data analysis of the individual interview data, we conducted three focus groups (n = 20 participants; six to eight participants per group). One focus group included eight participants drawn from those who had already participated in interviews; the remaining focus group participants were recruited in the same fashion described above.

The interview and focus group guides were piloted with patient volunteers in the clinic by a trained interviewer and refined prior to use with participants. Interviews and focus groups were conducted by a member of the study team experienced in qualitative data collection (WA). All interviews and focus groups were audio recorded and transcribed by a professional transcription service. Transcriptions were uploaded into NVivo software for analysis. For each of the interview rounds, a similar analysis processes was used, which is described in detail here.

Analysis

Three study investigators (SRY, JSM, WA) coded the data independently using open coding and thematic analysis [37]. The first cycle of coding was deemed "open" because the researchers assigned first-impression meanings and codes to the data, but were open to the meanings changing as analysis became richer and deeper over time. Thematic analysis, or assigning meaning and/or themes and patterns to the data, was used because of its flexibility in helping to narrow down the data into meaningful key ideas [38,39]. All three independently coded data sets were examined together by one study investigator (SRY) who made comparisons between the three coders and highlighted areas of overlap and disagreement. The three investigators then met to discuss the

comparisons and reach consensus on a reconciled code book. One investigator (SRY) then recoded data from this round using the reconciled code book, and the two others offered feedback, which was discussed by the team and reconciled to produce a final coded set of data.

Interim results were presented to the larger study team after four interviews to confirm that the data being collected would be helpful in informing intervention development. After 12 interviews were completed, the entire study team again reviewed interim results, this time to determine the appropriate next step. At that point, the team agreed that patient focus groups would potentially provide more varied perspectives and further clarification of major themes. Focus groups were presented with an outline of the intervention as developed by the study team based on input received during interviews. Participants were invited to provide feedback on this outline, as well as on other areas requiring clarification. Three focus groups were conducted and analyzed using the same approach described above. The study team reviewed focus group results and determined that theme saturation had been reached. The results presented here are combined from interviews and focus groups.

This study was approved by the Institutional Review Board of the University of Alabama at Birmingham.

Results

Of the 24 interview and focus group participants, 17 were male, 19 were African-American, 5 were white, and the mean age was 48 years (range 33–68). Median CD4+ T-cell count was 569 cells/mm3 (IQR 430–901), and 23 of 24 participants had an

undetectable viral load. Mean pain severity “on average” on the BPI was 6.6 (SD 3, scale 0–10). Mean pain interference ranged from 6.1 (SD 2.8) for interference with relations with other people to 7.8 (SD 2.0) for interference with sleep. Twelve participants reported symptoms of depression (PHQ-9 ≥ 10) or anxiety (PHQ-Anxiety module, anxiety symptoms or panic), and eight reported current substance use within the past 6 months on the ASSIST; of those, four reported both depression/anxiety and substance use. Pain was reported in a variety of locations, including numbness and tingling in hands and feet [11]; headache [10]; and pain in the knee [16], shoulder [13], lower back [12], and hip [10]. The median number of locations of pain reported was 3 (IQR 2–5).

Emergent themes fell into four major categories: perceived value of group sessions, incorporating peer leadership, and two key elements of how the intervention should be delivered: the HIV status of group participants and views on phone-delivered intervention content.

Quotes presented below are accompanied by age, race, and sex for interview participants; individual-level demographics are not available for focus group participants, who are identified via transcription only by their gender.

Perceived Value of Group Sessions

While participants embraced one-on-one sessions to individualize content, many participants viewed group sessions as an additional critical component of the intervention. Various reasons were discussed.

Learning from each other: Some participants said that groups would offer a setting where one could learn strategies for managing chronic pain not only from group leaders, but also from other participants:

> You get to the point where you start to care about people in your group. And so you go home yourself and you put up some stuff and I mean you talked to this person when you all come back to the group and say, "Hey I read this, that and the other," and I tried it and it worked. And it might be something that the peer counselor or the care manager didn't see. So everybody has a part. (Female focus group participant)

> Having other people that have, that started with chronic pain and people that have already had it and have dealt with it and have found things that have made it easier or made it a little lighter on them can then suggest to us things that will help make our load a little bit lighter. (53-year-old African-American female)

Social/emotional support: Participants also described the groups as places where people could draw support from a community of people who have similar struggles. One participant talked about how just attending the group could provide a participant with support:

> A lot of times when I've noticed that we, say if I'm, when I'm hurting. If I'm feeling alone or lonesome, it makes me hurt worse. It makes me feel even worse, bad. So if a person is going through pain, especially if a person is going through pain and they live by themselves, I mean that's a lot to deal with. Then you have nobody there to comfort you. You have nobody there to tell you it's going to get better, whether it's really going to get better or not. Just them telling you that simply could give relief to your mind I mean. (53-year-old African-American female)

Another participant elaborated on how group members might influence each other to improve their level of physical and social activity:

> I think it will alleviate some depression, you know people feel connected to other groups or other people that are like them … You know a lot of people in chronic pain tend to feel very isolated, very lonely … sometimes they don't know how to reach out for help or what help to reach out for. Or they get so used to being in the house, all the activity stops, stop going places, you know. They have to get back to living. I think that's a part of it. Start introducing little things, take a chance, go to a concert. Go hear some live music you know, hey invite some friends over for

> a movie night. I mean just you know, something—there's so many different things. And when you find that you actually living and you're accomplishing things it makes you get out of yourself and you know the depression isn't as bad and you feel connected to people. And of course I feel like it's going to help you deal with your pain. (45-year-old African-American female)

Groups could also be a place where participants encourage each other to push forward and meet their goals:

> I'm going to help you when you fall. I'm going to pick you up when you fall. But we're going to do it again. And we're going to do it again. And we're going to keep on doing it until you know. I got this. Let's go to the next step. (65-year-old White male)

Accountability: Another participant raised the role of accountability to others in the group, and that this might be especially important for those with poor social support:

> When you don't have family or a group like this would become your family a lot of times you—and you're accountable to somebody and it feels like somebody cares like you're doing something good for the benefit of the people whereas if you don't have a family and then you're going through what you're going through … So to have somebody that you always committed to, for different people some people it may not mean that much but to others it may mean more. You don't know what people's family or personal life is like, you know they may not have that particular thing and they may need much more than somebody that does have that support. (Male focus group participant)

Confidentiality concerns: However, some participants did express concerns about group sessions. A few participants noted that not everyone may like participating in group sessions. For example, one participant reflected:

> A group session might not be for everybody, you might have some people that need that one on one. But nobody is going to be 100% satisfied. (Female focus group participant)

Concerns about confidentiality were also identified; this is discussed further in our later discussion of HIV status. For example, one participant commented:

> I'm a people person but … even though everybody is probably there for the same thing but I still ain't comfortable because you know I just keep that part [HIV status] a secret in my life. (43-year-old African-American female)

Incorporating Peer Leadership

Participants voiced the importance of involving a trained staff interventionist in both individual and group sessions. However, there was also a strong desire to involve peer leaders, specifically a person living with HIV and chronic pain who is trained to colead the intervention sessions. Emergent subthemes were coleadership of the intervention by a peer and having sponsors or mentors.

Coleadership by a Peer

Peer involvement was seen as essential to success, with well-trained peers providing a dual perspective. As one participant explained when asked who would lead the intervention sessions:

> It would be two different types of individuals. It would have to be a person that has an educational background, [and] a person that has "experience of it" background. You have to have two perspectives. (48-year-old African-American male)

While knowledge of the intervention content was essential (educational background), being a peer (experience of it) loaned both legitimacy and authenticity to the intervention. Rather than providing a dry, academic presentation, peers were viewed as being in a better position to speak the participants' "language." One participant explained the role of the peer leader as bridging the knowledge or education gap between medical staff and the participant:

> Then as far as getting the leader of the sessions, I think that you do need chronic pain care manager … Whereas the doctor may come in on one level and then your peer can come in and sort of put it into laymen's terms. (Male focus group participant)

The need for the peer component goes beyond simple translation, however. The "experience of it" gives the peer authority that comes from having lived it—an aspect that our participants thought would be essential to the success of any intervention.

> I wouldn't want to hear how to bake a cake from you if you've never baked one … I need somebody who has been dealing with it for a while and is still here. Sometimes my pain gets to the point where you just want to go lay down somewhere and not get up. I need to hear from somebody to tell you … You can make it. (Male focus group participant)

Or, another participant succinctly put it:

> Then it is not just somebody you are all paying to get a check to come in to speak about it. It would be somebody that really knows what they are talking about. (Female focus group participant)

Further, one participant described the special knowledge a peer would possess to play the role of interventionist:

> If you bring somebody in that number one does not know anything about how pain is managed and how pain comes on people who have HIV, I'm not going to be interested because you can't tell me and you haven't gone through what I've gone through, or you were not educated enough to participate enough to be able to tell me anything; so that's what I see. And I'm quite sure any one of us would be able to do something like that because we've been there.

In addition to the legitimacy the intervention derives from peer involvement, participants felt that peers are better positioned to empathize with and understand participants.

> Female focus group participant 1: It would be good because the peer person they probably have some of the same pain and something that you have. They can relate to what you are saying.
>
> Female focus group participant 2: That would help because we know that he or she are on the same level.

As another focus group participant explained:

> To lead the session it should be someone dealing with chronic pain theirselves, who is sympathetic with what we're going through. I can never take the medication the way the doctors prescribe it. I have to take at least double the dose and then suffer the other half of the month in the darkness and under the covers.

> That's just the way it has to be until I get something else happening … And now I'm just addicted to the pain medicine and everything else. But it would be best if they had someone who you know, is dealing with it themselves. (Male focus group participant)

Overall, study participants expressed a strong belief that the intervention should not involve just a group of experts who deliver lectures. While limited "expert" content delivery was acceptable, the clear preference was for a peer, someone who had lived or is living what they live in terms of chronic pain and HIV. They wanted someone who could listen and empathize, but who had been well-trained and educated to provide solutions—solutions that the peers had learned and applied themselves.

Sponsors or Mentors

The need for peer support was a strong theme throughout the interviews and focus groups. Four participants voiced the specific idea of one-on-one peer support; two independently used the word "sponsor" and invoked the analogy to 12-step meetings [40]. For example, one participant talked about the importance of a sponsor in helping them stay on track and for support generally:

> Because you know in AA and NA, they give you sponsors that so they help you stay in the middle of the road, keep you from falling off the, off the wagon. So in the pain situation, I would try to do that same thing. Give it, create it wherein they would have a support system, not just the pain, I mean the medicine, but you also have someone you can talk to as well. (49-year-old African-American male)

The same participant explained in further detail how the sponsor role might work, and how they might help participants implement what is learned during the intervention:

> Well, the sponsor works in that, would work in that situation, say if they were, they were at home. It's evening time and all of a sudden, I have a major migraine headache. I can't stand for the lights to be on. I've got to turn the, unplug the telephone. I can't. So, so therefore, that sponsor, he or she that was at that meeting and someone had talked about that situation at the meeting and talked about what

> they done to make that situation better, then perhaps that sponsor can say, "Hey, remember at the last meeting when John Doe said that he did such and such and such. Why don't you try doing such and such and such? If it worked for John Doe, it might work for you, too." (49-year-old African-American male)

Another participant reinforced the importance of a sponsor in troubleshooting when difficult situations arise:

> Same way like with NA, you have your buddy system set up and you know you collect your phone numbers—when you're in heat—in a hot spot you have somebody you can call, you know? Just to talk or just to get you out of that mental mood that you're in, you know where you can see a light at the end of the tunnel, maybe get something done. (45-year-old African-American female)

Preferences for Intervention Delivery

Participants also provided substantial input on how the intervention should be delivered. Here, we present the two themes that participants expressed most clearly and that would have a significant impact on our intervention design: HIV status of group participants and phone-delivered intervention content.

HIV Status of Group Participants

Participants were asked whether the intervention program should be limited to those living with HIV or if it could be open to anyone living with chronic pain. While several participants voiced that they would feel comfortable participating in a chronic pain intervention with a mixed group of individuals, with and without HIV, others had important reservations about mixed groups.

Most participants were open to participation by anyone with chronic pain.

> It can help anybody, the HIV victims and other patients as well, some of them with obesity probably need help with their chronic pain. So it's for everybody and not just [those living with HIV]. (43-year-old African-American female)

Still, some participants thought that although it might benefit anyone, if the group were mixed, HIV should not be a topic of discussion—the group is about pain only:

> We're going to talk about pain. We're not talking about HIV. We're just talking about pain. So both with or without HIV can be there … the group would decide on what they'll talk about. But if you have someone without HIV in it, we're only going to talk about the pains that you're having. (68-year-old African-American male)

However, other participants noted some reservations about having a group with mixed HIV status. Stigma was discussed as being a particular concern. For example, one participant noted that having an all-HIV+ group might minimize the need to worry about potential stigma from HIV- participants:

> If you got a mixed group, like I said, you're going to always have a person that's negative, uneducated about HIV and just got this just ignorant stigma that if they come in contact with you they're going to catch it … If you're in a group with just your kind [HIV positive] you don't have to worry about it. (54-year-old African-American female)

Another participant noted that HIV stigma might prevent individuals without HIV from learning from their HIV+ peers:

> People with HIV, if it's going to be an all-HIV group then they're going to have a commonness. If it's going to be some people with HIV and some people with not, the people that are uncomfortable with that are not going to be able to receive any good information from that HIV-infected person unless the normal person is not—doesn't have that stigma … I would think it would be better in the beginning maybe to have all the same [status]. (65-year-old White male)

Beyond questions of comfort and commonality, however, there were also concerns about privacy and confidentiality. For example, one participant stated:

> And you've got your confidentiality … even me, myself, I've been diagnosed over 16 years. You still have uneducated people that do not understand that just by sitting by me you will not get HIV. So like I said, it could be okay to have just one or it could be okay to just have it separate because some people just have no other way to put it but are just ignorant. So me personally, I would rather be with my own kind and not have to answer any questions to anybody else … I actually wish they just had a hospital just for people with HIV so every time you go in you

> ain't got to give your diagnosis every time you go in … That's why I said if there was a program it would have to be strictly for just the HIV positive people because like I said a lot of people still are not educated and stigma is alive. It's bad. (54-year-old African-American female)

Phone-Delivered Intervention Content

In individual interviews, lack of transportation was viewed as a major barrier to participation in chronic pain intervention sessions. Therefore, we asked focus group participants the potential role of phone calls in the intervention. In one focus group, a participant echoed our interview findings about using the phone to circumvent common transportation challenges:

> I think some people it would be easier over the phone if they can't get here. It would be—it would be more easier than you might have some that have a disability that makes it really can't come and be interested and it would be more easier on them. And even for those that might not get transportation you know what I'm saying? It would be neat to do it over the phone. (Female focus group participant)

In another focus group, participants spoke positively about participating in a home-based intervention, which might allow people to speak more freely:

> Male focus group participant: I mean sometimes, I would like to sometimes talk to a person on the phone. I am in the comfort of my house. Then come over to their home. We are comfortable enough that we can communicate things.
>
> Female focus group participant: We do not have to talk secretly.
>
> Male focus group participant: Yeah in code.

However, later in the same focus group, participants agreed that phone sessions would be less valuable than group sessions, and should not be used to deliver intervention content. However, phone sessions could be used to check in with participants:

> Moderator: What would be covered over the phone?
>
> Female focus group participant: Appointments.
>
> Female focus group participant: Appointments, who would be able to come. That is it.
>
> Male focus group participant: I mean I think the group is outstanding, but there should still be a liberty there if I want to call you.
>
> Female focus group participant: A phone call every now and then just to check.
>
> Male focus group participant: It should not be like mandatory to say listen, this here, if anybody wants to be on the list, you want to communicate with somebody on the phone, just put it on this list. If you do not, then do not.

Participants in this focus group also expressed concerns about phone confidentiality:

> Male focus group participant: In a group session, you are open and you are discussing everything. On the phone, you do not know what is there.
>
> Female focus group participant: Right.
>
> Female focus group participant: Yeah, that is true.
>
> Male focus group participant: Yeah, that is why it is important to know the person. I mean you do not want to call just anybody. I mean you have got to have that relationship. I am just not going to call just because you are in the group. We may not agree or have the same form of thinking.

Discussion

This study presents formative qualitative work that will guide development of a behavioral intervention for chronic pain tailored to individuals with HIV. While other behavioral interventions for chronic pain have been tested in individuals with HIV [22,41], they have not been developed or tailored specifically for this population, and perhaps as a result, have had limited efficacy and session attendance. To our knowledge, this will be the first chronic pain intervention for this population developed using

formative qualitative investigation to assess patient preferences for intervention structure and delivery. We believe that such formative work will be critical to our intervention's efficacy and effectiveness.

Our results suggest that the intervention should include group sessions; have substantial involvement from peer leaders, potentially including a role for sponsors or mentors; include only individuals with HIV; and avoid delivering content via phone. We believe that these preferences are influenced by the unique psychosocial milieu experienced by HIV-infected individuals with chronic pain; this study provides evidence to support this belief. Our previously published biopsychosocial framework for chronic pain in individuals with HIV [24] can guide our understanding of some of the most important psychological and social factors involved. Specifically, we assert that three psychosocial factors identified in the framework—psychological distress, challenges with close personal relationships, and stigma—are likely to have contributed to our key findings.

In addition to one-on-one sessions to deliver intervention content, participants strongly advocated for a group component. Our biopsychosocial framework highlights the psychological distress caused by stigma and higher rates of psychiatric illness such as depression and anxiety in individuals with both HIV and chronic pain. Additionally, we discuss the importance of close personal relationships in improving HIV outcomes such as antiretroviral adherence and virologic outcomes, and the challenges faced by individuals with chronic pain in having close personal relationships. In this study, participants specifically highlighted the importance of feeling connected to others, less lonely, and less depressed as a rationale for group sessions. Therefore, this psychological

distress and challenges encountered with close personal relationships potentially explain why participants preferred group sessions. It is reassuring that a recent pilot study of a group-based mindfulness intervention for chronic pain in individuals with HIV was found to be feasible and acceptable [42]. Also, our findings underscore the importance of training interventionists to foster an environment of support and respect that would allow participants to realize these benefits.

Participants also expressed a reluctance to use phone sessions to deliver substantive intervention content, and a preference for having HIV-only groups. Stigma and confidentiality concerns were used to justify these preferences. While not universal, we assert that if even a substantial minority of participants expressed these viewpoints, others may be concerned about them, even if to a lesser degree. These issues might prevent the most vulnerable patients from participating in an intervention that involves mixed HIV status groups or attempts to deliver potentially sensitive intervention content over the phone. Therefore, delivering substantive content by phone and conducting mixed groups could represent important barriers to intervention uptake if not considered and incorporated into the intervention. These findings also suggest that content related to HIV stigma and chronic pain stigma should be considered and incorporated.

Additionally, participants' comments on the potential role of phone sessions paint a mixed picture. On the one hand, phone sessions could be a good way to overcome barriers such as transportation or privacy concerns. On the other hand, phone sessions would fail to provide the kind of face-to-face and group interaction that participants seemed to find valuable. Participants suggested that a middle ground would be phone calls used as check-ins or reminders, not necessarily to deliver content.

Peers were frequently mentioned as an important part of the intervention. Two forms of peer involvement were mentioned: 1) co-leadership of the intervention by a peer with a deep understanding of the participants' struggles, and 2) a sponsor or mentor, who could provide support and troubleshoot in times of crisis. There is a strong evidence base for peer interventions for individuals with HIV targeted at a variety of outcomes. In general, peer interventions have shown promise in terms of feasibility and efficacy [43]. Notably, the clinic in which this study was conducted has been the site for prior peer interventions, and participants may have been familiar with this approach. Participants may have stressed the role of a peer for similar reasons that they stressed the role of a group: building close personal relationships with other individuals with chronic pain for support. Peers were also seen as having a first-person viewpoint, meaning that they hold unique expertise and can empathize with participants effectively. Participants' viewpoints on why peer involvement is so important will guide us in selecting and training someone who can optimally meet these needs.

This study has certain limitations. We purposively selected individuals with depression/anxiety and recent substance use, as this represents a population of individuals with HIV and chronic pain; thus we may have under-represented the views of those who do not have these comorbidities. Like other qualitative studies, our study is not designed to be broadly generalizable, but rather to inform the development of an intervention in a specific population. This study was conducted at one comprehensive HIV clinic in a city in the southeastern United States. Due to logistical and financial constraints, it was not possible to conduct a much larger qualitative study at sites across the United States. It is possible that the results obtained would have differed in other settings with better public

transportation (and therefore perhaps less social isolation) or less HIV stigma [44–46]. Once the intervention is developed, we plan to obtain feedback from HIV clinics around the United States that are part of the Center for AIDS Research Network of Integrated Clinical Systems, of which our clinic is the lead site, prior to testing. Finally, we note that this study relied on persons willing and able to appear in person for focus groups and interviews. In this way, it may not capture special concerns or priorities of persons with geographic, time-related, or other contextual barriers to attending in-person programs.

In sum, this study presents formative qualitative work that provides a framework for the structure and delivery of a behavioral intervention for chronic pain in individuals with HIV. We will use these results as the basis for designing our intervention. In addition, we hope that our approach will inform the work of investigators in other disciplines who seek to incorporate formative qualitative work on patient preferences during intervention development.

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INTERVENTION MAPPING TO DEVELOP A SOCIAL COGNITIVE THEORY-BASED INTERVENTION FOR CHRONIC PAIN TAILORED TO INDIVIDUALS WITH HIV

by

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Format adapted for dissertation

Abstract

Chronic pain is an important comorbidity among individuals with HIV. Behavioral interventions are widely regarded as evidence-based, efficacious non-pharmacologic interventions for chronic pain in the general population. An accepted principle in behavioral science is that theory-based, systematically-developed behavioral interventions tailored to the unique needs of a target population are most likely to be efficacious. Our aim was to use Intervention Mapping to systematically develop a Social Cognitive Theory (SCT)-based intervention for chronic pain tailored to individuals with HIV that will improve pain intensity and pain-related functional impairment. Our Intervention Mapping process was informed by qualitative inquiry of 24 patients and seven providers in an HIV primary care clinic. The resulting intervention includes group and one-on-one sessions and peer and staff interventionists. We also developed a conceptual framework that integrates our qualitative findings with SCT-based theoretical constructs. Using this conceptual framework as a guide, our future work will investigate the intervention's impact on chronic pain outcomes, as well as our hypothesized proximal mediators of the intervention's effect.

Introduction

Chronic pain is defined as pain lasting for more than three months, beyond the period of normal tissue healing.[1] Examples of chronic pain include regional musculoskeletal pain (e.g., low back pain, knee pain), widespread pain including fibromyalgia, headaches, and peripheral neuropathy. Chronic pain is an important public

health problem. Recent studies suggest it occurs in approximately 15% of individuals in the general population [2, 3] and can be associated with significant disability.[4, 5]

Chronic pain is an important comorbidity among individuals with HIV. For reasons that are not fully understood, chronic pain occurs in as many as 30-85% of these patients.[6, 7] In individuals with HIV, chronic pain is associated with up to 10 times greater odds of functional impairment,[8] and can also be associated with suboptimal retention in HIV primary care.[7] The recently-released Department of Health and Human Services National Pain Strategy identified chronic pain in vulnerable populations, including individuals with HIV, as a priority area of investigation.[9]

Management of chronic pain has typically included both pharmacologic and non-pharmacologic therapies. A mainstay of pharmacologic treatment for chronic pain has been long-term opioid therapy. However, in the past few years, the risks of opioids including addiction and overdose have been increasingly recognized.[10] Individuals with HIV are more commonly prescribed opioids than individuals in the general population[11], despite an apparent susceptibility to opioids' mortality risk[12] and drug-drug interactions with antiretrovirals.[13] Therefore, development of non-pharmacologic approaches for individuals with HIV is of particular importance.

Behavioral interventions are widely regarded as evidence-based, efficacious non-pharmacologic interventions for chronic pain in the general population.[9] An accepted principle in behavioral science is that theory-based, systematically-developed behavioral interventions tailored to the unique needs of a target population are more likely to be efficacious.[14] The present study emerged from evidence that such an intervention has not yet been developed for chronic pain in individuals with HIV. Our recent systematic

review of existing chronic pain interventions in individuals with HIV included all interventions for chronic pain, both pharmacologic and non-pharmacologic, that have been tested in individuals with HIV.[15] Eleven interventions met the inclusion criteria, only two of which were behavioral interventions.[16, 17] Neither of these interventions was developed based on a behavior change theory, and neither was tailored to individuals with HIV in a systematic way. Both interventions suffered from poor adherence, reported only small effect sizes, and have not been studied further.

Therefore, our aim was to systematically develop a theory-based intervention for chronic pain tailored to individuals with HIV that will improve key chronic pain outcomes: pain and pain-related functional impairment, including physical and emotional function.[18]

Methods

Intervention Mapping (IM) is a stepwise process for the systematic development and evaluation of a theory- and evidence-based behavioral intervention that is tailored to the target population.[19] Here, we present our approach to the first four steps of IM: 1) needs assessment, 2) identification of behavioral targets and creation of a behavior change matrix using Social Cognitive Theory (SCT), 3) intervention design, and 4) intervention production. Steps 5 and 6, program implementation and evaluation, are the next steps in our research program.

The IM process – especially Steps 2 through 4 – is informed by qualitative inquiry. For this purpose, we recruited 24 patients from a large HIV clinic in the Southeastern US to participate in 12 in-depth individual interviews followed by three

focus groups. The objective was to use patient ideas and preferences to inform our approach to Steps 2 through 4. To analyze our data, we used an independent, thematic approach with three coders (JSM, WA, SRY). Initial discussions led to agreement on key themes and generation of a codebook, which one investigator (SRY) used to code the remaining transcripts. Subsequently, we conducted seven in-depth interviews of HIV clinic providers, including some who hold leadership positions. We recruited providers across disciplines including physicians, nurse practitioners, nurses, and a pharmacist, and approached the data using the same design and analytic techniques.[20] Preliminary results from patient interviews and focus groups have been published previously, and suggested the importance of a group setting, peer interventionists, and groups limited to HIV+ participants.[20] How this work and additional results of these qualitative investigations were integrated into the IM process is detailed here in the description of each IM step.

Intervention Mapping Steps

Step 1: The first step of IM is to conduct a needs assessment of the problem in the target population. The results of this step were described briefly in the introduction and synthesized in a systematic review.[15] We concluded that a behavioral intervention for chronic pain tailored to individuals with HIV is needed.

Step 2: The second step of IM is to create "change objectives." Change objectives are actions aimed at changing key behaviors that influence the desired outcomes. Each change objective will become an intervention session.

We identified key change objectives from the robust literature on evidence-based Pain Self-Management (PSM) interventions.[21-24] PSM interventions draw from cognitive-behavioral therapy, and are manualized interventions designed to reduce pain intensity and pain-related functional impairment in the general population. They can be delivered by a variety of health care professionals (nurses, psychologists, and social workers) trained on the PSM protocol, making them well-suited for diverse settings. PSM interventions provide pain education, and also target patient-centered self-management of key behaviors (e.g., physical activity). These behaviors are each directly targeted by a change objective (e.g. increase physical activity). PSM interventions were named by the National Pain Strategy as evidence-based, scalable approaches to chronic pain management that can be tailored to the needs of specific populations.[9]

We selected a specific PSM intervention as a starting point for our work. This intervention is called Stepped Care for Affective disorders and Musculoskeletal Pain (SCAMP).[25, 26] We chose SCAMP for several reasons. SCAMP was initially developed as a PSM intervention for patients with chronic musculoskeletal pain and depression, a common comorbidity in HIV. SCAMP was also delivered in primary care settings, as we envision for our intervention. Interventionists were nurse care managers, who are more readily available in HIV care settings than psychologists. SCAMP was delivered as a 12-week intervention consisting of one-on-one sessions with a staff interventionist. Each session addressed a unique PSM behavior/change objective (e.g., physical activity, thinking differently about pain, stress management, alternative therapies, talking to your doctor/nurse about pain, utilizing community resources).

As previously described[20], we collected qualitative data (initially interviews, then focus groups) from HIV-infected individuals with chronic pain recruited from an HIV outpatient clinic in the United States. Participants who had at least moderate pain for more than 3 months met eligibility criteria, and we purposively sampled individuals with symptoms of depression or anxiety and current substance. During in-depth individual interviews, we began by asking participants to discuss potential behaviors/change objectives they would like to include in the intervention. Then, they were asked to review the SCAMP manual. Participants were asked to provide feedback regarding the inclusion of each session (behavior/change objective) in the intervention and to suggest new topics.

Next, we completed three focus groups: one of interview participants, and two of new study participants. We conducted a card sort exercise of all potential session topics. Sessions assessed included all SCAMP sessions plus potential session topics that emerged from interview participants (improving mental health, losing weight, sleeping better, taking chronic pain medications, building self-worth, meditation, addressing addiction, improving posture, and distraction). Participants were asked to identify the five most important and three least important sessions, in order. Using a mixture of card sort data, additional qualitative data, and expert opinion, we identified the ten sessions most salient to our intended population.

Step 3: The third step of IM is intervention design. This includes making important choices about the intervention's structure based on prior knowledge of the target population – in this case, our qualitative work. Additionally, a fundamental premise of IM is that all intervention components have theoretical underpinnings.

Therefore, Step 3 also includes systematic integration of theory throughout the intervention.

We selected SCT as it is a widely-cited foundation for chronic pain behavioral interventions.[27] This decision has face validity: SCT is a learning theory, and posits that even in the face of stressors (e.g., pain), people can learn to change their behavior (e.g., engage in regular physical activity) through a variety of methods informed by key theoretically-informed constructs (e.g., self-efficacy, outcome expectations, self-regulation). Table 1 describes key SCT constructs.

How people go about changing their behavior – in other words, the practical application of the theory to address each change objective identified in Step 2 – can be informed by qualitative inquiry. The Results of Step 3 presented below include the theoretical constructs alongside proposed practical applications, and their supporting qualitative results. These practical applications apply across change objectives.

Step 4: The fourth step of IM is intervention production, or the creation of each intervention component. A member of our team (WD) is a pain psychologist and an experienced developer of low-literacy chronic pain intervention manuals. The Principal Investigator (JSM) and WD collaboratively wrote the participant manual. Written materials were based on the SCAMP manual and an evidence-based low-literacy manual (Learning About Managing Pain or LAMP), which WD has delivered in prior studies[28]. With the permission of these manual authors, we used existing passages verbatim when appropriate, given that they are already tested, which serves to strengthen the manual that we produce. However, we created new content when no appropriate content existed. To elicit feedback, we conducted one “pre-testing” focus group of 9

participants during which we presented the overall intervention structure and the manual content. After this focus group, we conducted a final round of revisions.

Conceptual Framework Development

The IM process provided a preliminary understanding of how our intervention may work to improve pain and pain-related functional impairment.[29] This allowed us to develop a SCT-based conceptual framework to pictorially represent our intervention's proposed mechanism (Figure 1).

This study was approved by the Institutional Review Board of the University of Alabama at Birmingham.

Results

Here, we present the results of IM Steps 2-4, which are informed by our qualitative work, and explain how we made key intervention decisions. This process is summarized in Figure 2.

Of the 24 patient participants in interviews and focus groups, most were male (17) and African American (19). Mean age was 48 years (range 33-68), and nearly all (23) participants had an undetectable viral load. Mean pain severity "on average" on the Brief Pain Inventory was 6.6 (SD 3, scale 0-10), and mean interference was 7.2/10 (missing=4). Of seven providers, five were at least 50% devoted to clinical activities, and three held clinic leadership positions.

Step 2: Identifying Change Objectives/Intervention Sessions

Most patient participants believed that pain education should be a required session. Additionally, participants were open to including all other SCAMP sessions. In the card sort exercise, results varied between focus groups, but posture and meditation were always at or near the least preferred. Therefore, these two topics were eliminated. Among the topics that remained, mental health care was incorporated into the pain education session, distraction was incorporated into relaxation skills and stress management, and opioid addiction was incorporated into a chapter on taking opioids (rather than chronic pain medications broadly). We developed the remaining chapters (weight loss, sleep) as they often ranked near the top. In addition to pain education, the final list of the remaining nine change objectives/intervention sessions is included in Figure 2.

Step 3: Design Intervention

Choices regarding intervention structure

Our qualitative work revealed several key patient and provider insights that guided the intervention's design.

a. One-on-one intervention sessions

One theme that emerged was participants' desire to keep the content relevant, and tailored when possible. For example:

> Unidentified male: As long as you are giving people good, heartfelt information, and stuff that they can actually use, they will always come back. If I feel like you are giving me junk, I am not coming back. (Patient)

We agreed with participants (see Step 2 above) that a pain education session should be offered to everyone. This session is essential to understanding subsequent sessions. To meet participants' preference for tailoring, we allowed participants to choose five of the remaining nine behavioral target sessions. To best achieve tailoring, we chose a one-on-one session format for content delivery.

Some participants voiced the importance of certain content being delivered by a clinical expert. For example:

> I want them to be able to tell me…just not tell me…Oh, I'm sorry to hear for your pain. I know that really hurts… I need them to be able to say….Do X, Y, Z and this is what is going to be done for you. I don't think the average person volunteer off the street is going to be able to do that. I think they need to be a trained counselor or whatever. (Patient)

Therefore, we decided that the one-on-one PSM sessions would be delivered by a staff interventionist, who we will call a "pain coach." Due to scalability concerns, we identified staff commonly found in HIV clinics to serve as pain coaches. Rather than selecting a clinical psychologist as is sometimes done in behavioral interventions, we opted for master's level staff (e.g., social worker, health educator, nurse case manager). This is also consistent with SCAMP's approach.

b. Group and peer components

Our previously-published qualitative results found that participants strongly preferred a group component to foster social support for their chronic pain. They also preferred groups that only included HIV+ persons to reduce stigma and protect participant confidentiality about HIV status. Finally, they preferred the involvement of a peer leader to learn how others successfully navigate living with both HIV and chronic

pain.[20] We will call this peer a “pain pal,” a shorthand title suggested by one of our patient participants. To have skill-based content delivered by an “expert,” we decided that the pain pals will facilitate the group sessions together with the pain coaches.

Participant feedback supported SCAMP’s structure of 12 weekly sessions, so we incorporated that into our intervention. To incorporate the group component, we structured our intervention by alternating one-on-one PSM sessions and group sessions, so that participants would receive six of each.

Incorporating Theory

We identified practical applications of each theoretical construct that could be applied broadly, across change objectives. For example, self-monitoring is an important construct that influences self-regulation, a key component of SCT. Our practical application of self-monitoring is for participants to complete “homework and tracking” sections of the manual for each one-on-one session either at home or with the interventionist. This practical application is supported by our qualitative results. Our team employed this process across all SCT constructs, as summarized in Tables 2a-2d.

Step 4: Intervention Production

Manual Creation

Our manual consists of approximately 50% completely new content, and 50% content derived from the two interventions mentioned previously (SCAMP and LAMP). The final version of the manual is written at below a 6th grade level (Flesch-Kinkaid 2.4, Gunning-Fog 5.6) to address health literacy challenges. We produced the manual in

collaboration with a graphic designer, using illustrations to augment the text. Table 3 lists the session topics and their contents.

Pre-testing

The most significant clarification from the pre-testing process was the role of the peer (pain pal). In our prior qualitative work, we identified co-leadership by a peer, and sponsor or mentor as being important. This focus group clarified that rather than having a singular sponsor like in 12-step programs who could be called upon between sessions for help, participants should be encouraged to contact each other and the pain pal.

Conceptual Framework

Based on the work described above, we present an SCT-based conceptual framework for our intervention's mechanisms (Figure 1). We posit that the three intervention components – the group sessions, peer involvement ("pain pal"), and the one-on-one sessions – will influence proximal mediators of the intervention's effect. These proximal mediators are the theoretical constructs discussed here. As our previous work emphasizes the importance of social support for management of chronic pain, it is included as an important proximal mediator. PSM skills are also included, as skill acquisition is an essential part of behavior change. The arrows connecting intervention components with proximal mediators are based on the information described in Tables 2a-2d. For example, social support is derived primarily through group sessions, while self-efficacy includes social modeling by pain pals, self-monitoring in individual

sessions, and feedback during group sessions. These proximal mediators then lead to the adoption of PSM behaviors, which lead to improvements in pain-related outcomes.

Discussion

To our knowledge, this is the first research to systematically develop a theory-based intervention for chronic pain that is tailored to the needs of individuals with HIV. While many interventions report a theoretical basis, IM allowed us to methodically integrate SCT throughout every aspect of this novel intervention. Additionally, our formative qualitative work tailored the intervention to our population's unique needs and preferences. We assert that our rigorous intervention development process maximizes the intervention's likelihood of efficacy, which we will investigate in future studies.

Our previous qualitative work reported patient preferences for group sessions and peer involvement.[20] However, the IM steps used theory to operationalize these intervention components, and helped us understand how their inclusion will influence proximal mediators of the interventions' effect. The resulting conceptual framework will serve as a roadmap for IM Steps 5 and 6. For example, it will help us devise an evaluation plan to assess potential mediators and moderators of the intervention's effects. Once the intervention mechanisms of action are more fully understood, future versions of the intervention may augment or omit certain components in the implementation phase.

Our approach has limitations. Our intervention is tailored to address chronic pain in individuals with HIV, and thus its applicability beyond this population was not addressed. Additionally, we conducted our formative qualitative work at a single HIV clinic in the Deep South. It is possible that additional regional or clinic-specific tailoring

may be necessary during implementation/dissemination. However, we assert that individuals with HIV and HIV treatment settings are more similar than they are different, and that fundamental concerns emergent in our qualitative work and IM exercise are likely to apply broadly.

In sum, we have developed an intervention that has a high likelihood of acceptability and efficacy when tested in future studies. Our formative IM work will serve as a foundation for our future studies that investigate this intervention's efficacy and implementation/dissemination. Additionally, few studies detailing the process of integrating theory into an intervention have been published. We hope that our approach can guide others seeking to use IM to develop behavioral interventions.

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Table 1. Social Cognitive Theory Constructs

Construct	Description
Observational learning	Learning can occur by observing others. People are most likely to pay attention if the information is perceived as valuable and if it is delivered in a way that is understandable.
Self-efficacy	Self-efficacy is the person's belief in their ability to successfully complete the task. The four key ways to develop or increase-self efficacy are mastery experience (prior experience that an individual can draw from), social modeling, improving physical and emotional states, and verbal persuasion.
Outcome expectations	Outcome expectations are the beliefs that something good will come from participating in the intervention; the outcome must be something that is perceived as important. Social outcome expectations are how others evaluate one's behavior, and whether this is viewed as important or not. Self-evaluative outcome expectations are anticipation of how one will feel about themselves if they successfully complete the intervention.
Self-regulation	Self-regulation is the willingness to perform a new behavior now to reach a goal in the future. This is not achieved through sheer willpower or brute force, but rather through gaining skills. There are six ways to achieve self-regulation: self-monitoring (observing or recording one's behavior in a systematic way); goal setting; feedback from others; self-reward; self-instruction (talking oneself through a behavior); and enlistment of social support.

Table 2. Incorporation of Theoretical Constructs

Construct: Self-regulation		
Six constructs that contribute to self-regulation	**Practical application(s)**	**Supportive qualitative results (quotes)**
Self-monitoring	-Complete "homework and tracking" section of the manual for each one-on-one session either at home or with interventionist	You have two options there. One, an open mind, an open discussion. And the other one is a – give me some – take these with you. Look over and read it. Bring your ideas back to me like homework in that aspect, you know. And we'll discuss this then and we'll say what we're going to talk about. You can take this home with you and you got your time to sit there and go through it. And when we come back and we meet again, we'll discuss these things." (Patient)
Goal-setting	-Set long-term goals (what the participant could achieve if pain was better controlled) during first one-on-one session. -Set specific short term pain-related goals at each one-on-one session. (e.g., take a 15-minute walk this week)	"I will get into saying like right here you got short-term activities and long-term activities. The long – the short term is something like we can come in as we're sitting here. And we'll discuss it right quick. Long term is something like a homework thing. You go home and we write out this thing and we're going to give it a try so when we have our next meeting we'll come back, and see why we came out with it. You tell us how we came out with it, what we did. That would be definitely in my program. That would definitely be with my group." (Patient)
Feedback from others	-Share progress on goals with the group. -Listen to and incorporate feedback received at group and	"[S]ay for instance you come in that day and you have a peer coach that day. You are giving your demonstration. Well, you start to talk. As you begin to talk and go into your demonstration, you begin to explain

	individual sessions. -Brainstorm solutions to pain-related problems in the group.	how this happened and how that unfolded and that unfolded. Then you go into how you remedied it, how you got a remedy for that. Well, you are giving me a whole package, not just what happened, but what was the outcome on what you did to overcome what was happening to you. I do not want to know just that you had these symptoms, but what did you do to relieve these symptoms?" (Patient)
Self-instruction	-Participants will write down how they will achieve their weekly goal; they can refer back to this throughout the week when they get stuck.	"you could do that from the time you wake up till it's time to go to bed what did you do today to reduce your pain or whatever have you? Was your pain able to be reduced? Don't forget to put on there where did you have pain, you know make us up a little notebook or whatever have you. I keep up with stuff like that and I try to write it myself or remember it in my head. And when we come to our sessions you have your notebook right there so you don't have to try to remember and when the question is asked you have the information right there. Also at the bottom you put "My goal is to such and such and such". You might change your goal over the course of three or four weeks, but that's okay you got to let your people know that's okay. You also have to let them know that if they didn't do it, move on to the next day or whatever have you. So being held accountable is going to be easier and getting more results than you just turn us loose and I see you all next week." (Patient)

Enlistment of social support	-Participants will engage in > 80% of group sessions. -Group sessions will offer a chance for follow-up and accountability on individual goals.	"To me it is more like you're dedicated for yourself. I mean you the one in pain, so you make the pledge to yourself and then to your peers because if you see them doing it, you're more apt to do it. If you see it working for them then you'll be more apt to do it, that's the way I see it. It's like a goal or something." (Patient)
Construct: Self-efficacy		
Four constructs that contribute to self-efficacy:	**Practical application(s)**	**Supportive qualitative results (quotes)**
Mastery experience	-Practice each PSM skill (e.g., physical activity, thinking differently) at a frequency determined by the participant -Continue to practice each PSM skill for the duration of the intervention, not just for the week after that skill's session is delivered	"I would go down my list and like I said, teach a person to do [a skill] the day before, not two or three days before. I think it's fresher and on your mind if you do it the night before and it kind of keeps in perspective what's important…And I think that should be a homework assignment like every week from – or at least every day when you come in next week to the session you need to have your five to do lists for five weekdays that you did the night before that day, you know? Be a part of the class. Just to get them started, to teach them thinking about how to do their lists and stuff like that. I think it can be taught. And if they keep it simple for most important to least important hey, three or five things. And then if you get that done, if you want to add something else and you're capable physically of doing something else, hey do it. You know, just a little practice. A little practice." (Patient)
Improving physical or emotional states	Making sure that participants are in the best possible physical and emotional state before every session (e.g., brief deep	"No, um you know there could be different classes. Music was just one of them. I think meditation classes, people need to be taught how to

	breathing or mediation exercise before sessions begin)	meditate appropriately, how to center themselves, how to learn to relax, what helps them relax. Um, you know just learning about um, I guess taking care of the body like mentally and different things you can do to you know slow your blood pressure down, slow your heart rate and things like that. I think a lot of it is going to have to learning to relax. But I think we tend to be so over the top because we're hurting all the time that we can just kind of get lost in the frenzy of it all. So I think a lot of people don't really know how to meditate, how to relax, you know? Even art therapy, you know painting and writing and things like that. I think a lot of that would be beneficial. (Patient)
Verbal persuasion	Cheerleading from peers, staff interventionists, and other intervention participants	**"**For a person, I'd put it like that for a person that if a person tries to lift with weight and he sees a person that they're going to go help them lose weight in a good way, then they'll be motivated to do it. You know, you can encourage that person. (Patient)
Social modeling	Pain pals and group sessions: showing the participant that others like themselves can achieve important pain-related goals	*Because the peer coach, if he or she has experienced some of the things that you are going through, then they can say, "I did this when this happened to me. I experience this when this happened to me. Mentally, I was feeling this way, so I had to do this. Physically, I had to do this because I was feeling this way."* (Patient) *And especially if someone, one of their peers can give them some strategies to – when this happens this is what I do or I've come through it, I struggled just like you did and now I'm on the other side, there's hope. Now I think that can instill hope with*

		them. It can instill like I said a sense of community, I think that's really important so I think these are – this is great patient feedback. (Provider)
Construct: Observational learning		
SCT construct	**Practical application(s)**	**Supportive qualitative results (quotes)**
Observational learning	Pain pals and group sessions: use to allow participants to observe others' successes	*"Because I don't know everything. I know what works for me sometimes but other than that sometimes I sit at home and why is this happening today, why do I feel like this today? What is going on, I did everything I was supposed to do yesterday and it's different. So that's how a session to me should run and it's not just me talking, it's everybody having conversation to help everybody else."* (Patient)
Construct: Outcome Expectations		
SCT construct	**Practical application(s)**	**Supportive qualitative results (quotes)**
Social outcome expectations	Pain pals and group sessions: use to review which session each participant attended, goal-setting, and how they are using the intervention. This will set a social outcome expectation to attend sessions and work on goals.	*Yeah. A pat on the back, even if you have to – realizing that this person you can't do anything to please this person, this, that and the other and nothing is working and that special attention. I do more for people when I get special attention. And I'm serious, we all want to do better, we all want to help but you have to find a way to get to that person and you get to the point where you start to care about people in your group. And so you go home yourself and you put up some stuff and I mean you talked to this person when you all come back to the group and say "Hey I read this, that and the other" and I tried it and it worked. And it might be something that the peer counselor or the care manager didn't see. So everybody has a part.* (Patient) *Me being responsible to my group or whatever have you is – it gives me something to do. It gives me a reason to keep on pushing so I can say this is working.* (Patient)

		When you don't have family or a group like this would become your family a lot of times you – and you're accountable to somebody and it feels like somebody cares like you're doing something good for the benefit of the people whereas if you don't have a family and then you're going through what you're going through and you're likely to drill into another area, just that you know being accountable in a group setting I think it would just make people who don't have that in their life. (Patient)
Self-evaluative outcome expectations	One-on-one sessions: encourage participants to complete goals and think about how they will feel when they do.	*Two is how many floors, how many steps can I go up before I'll be distracted or I continue to do what I got to do? And then see, these are goals that I'm setting in my mind to get away from my pain. And I'm going to go down, I got – we got four flights of steps here. Can I make two? Can I make one flight? Can I make two flights? Okay. This is what I'm doing. But I'm in pain now. But I'm going up and down the steps. And my mind is not on the pain but it's where I'm going.* (Patient)

Table 3. One-on-One Session Topics

Topic	Session contents*
Introduction to your chronic pain	Introductions, pick your sessions, learning more about chronic pain, gate control theory, chronic pain and emotions
Physical activity and your pain	What is physical activity, pros and cons of physical activity, how you spend your days, physical activities you enjoy, pacing
Losing weight to improve your pain	Weight loss and pain, your weight loss picture, how to change how we eat
Stress management and your pain	Introduction to stress, how stress affects you, your experience with stress, stress and pain, managing stress
Relaxation skills to prevent your pain	Relaxation and pain, deep breathing, progressive muscle relaxation, visualization, mindfulness
Sleeping better to help your pain	Importance of sleep, relationship between sleep and pain, things that can hurt sleep, general ways of helping sleep issues
Thinking differently about your pain	Unhelpful thoughts, working to change our unhelpful thoughts
Building self-worth	Unhelpful beliefs, working to change our unhelpful beliefs
Talking with your family and friends about pain	Talking about our pain, ways of talking with others, talking with healthcare providers
Taking opioid pain medications	Your pain medicines, how opioid pain medications work, what the research shows about opioids, taking opioids the way they are prescribed, using strategies besides opioids

*all sessions include goal-setting and homework

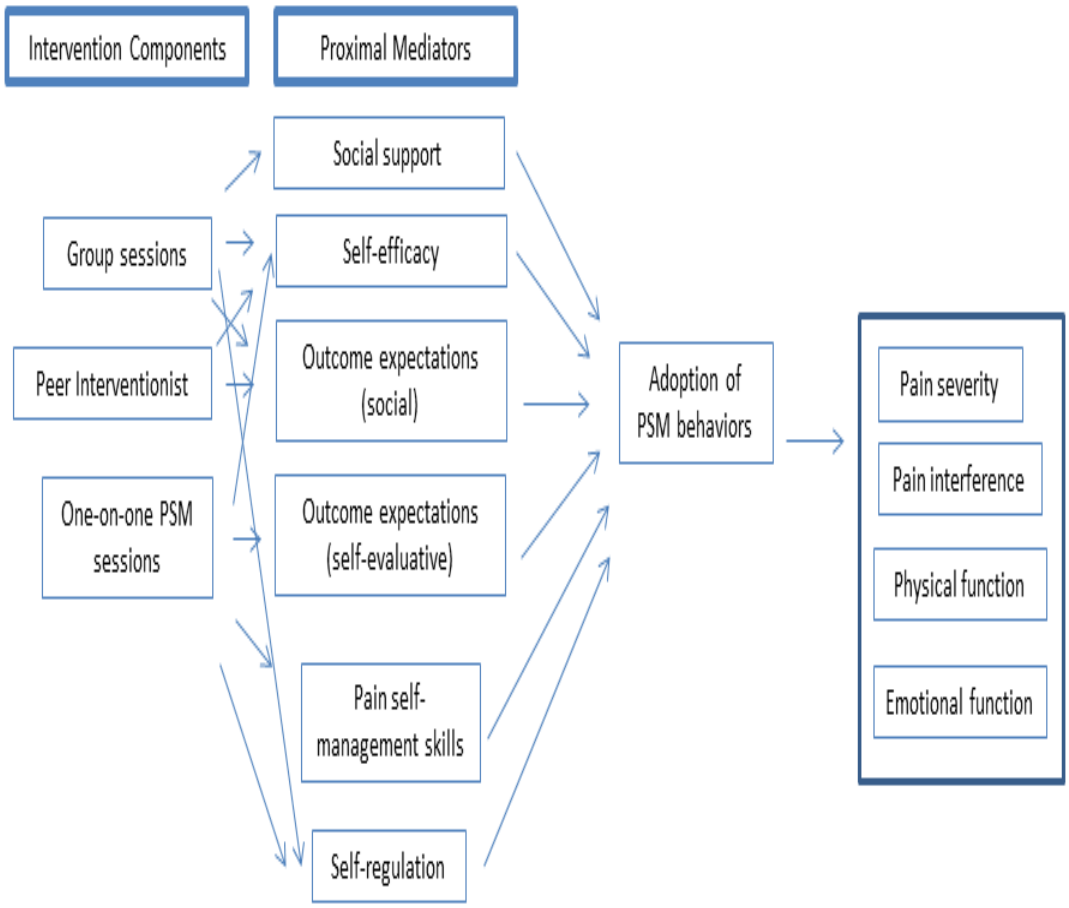
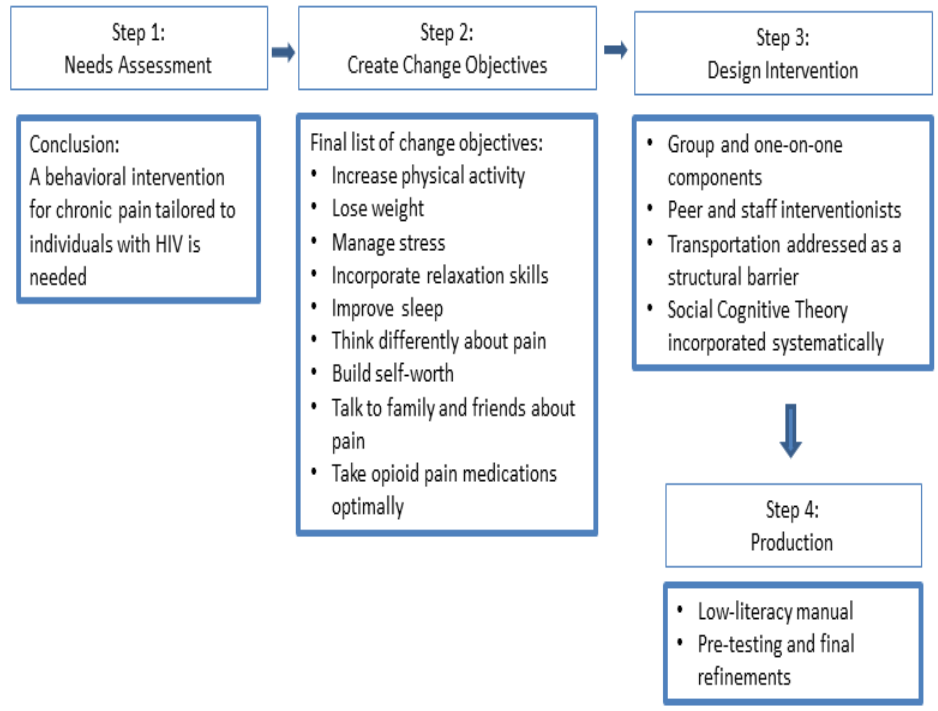


Figure 1. Conceptual Framework for a Pain Self-Management (PSM) Intervention Tailored to Individuals with HIV.



*Steps 5 and 6, Program Implementation and Evaluation, are not shown because they have not yet been completed.

Figure 2. Intervention Mapping Process and Results.

A RANDOMIZED PILOT TRIAL OF A NOVEL BEHAVIORAL INTERVENTION FOR CHRONIC PAIN TAILORED TO INDIVIDUALS WITH HIV

by

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ABSTRACT

Background: Chronic pain is an important and understudied comorbidity in people living with HIV (PLWH). We conducted a pilot trial of Skills TO Manage Pain (STOMP), a recently-developed innovative Social Cognitive Theory-based Pain Self-Management intervention tailored to PLWH.

Setting and participants: Participants were recruited from an HIV primary care clinic. Eligibility criteria included ≥ moderate pain for ≥ three months on the Brief Chronic Pain Questionnaire and a score of ≥ 4 on the 3-item PEG pain severity and interference scale.

Methods: Participants were randomized in a 1:1 fashion to STOMP or a usual care comparison. STOMP is a 12-session intervention with innovative components based on formative qualitative intervention development work: peer co-led group sessions designed to increase participant self-efficacy, and one-on-one pain self-management sessions tailored to PLWH. Outcomes included feasibility (participation), acceptability (qualitative interviews, treatment satisfaction survey), and a pain/function composite (Brief Pain Inventory[BPI]-Total score).

***Results*:** Among 22 participants randomized to STOMP, median session attendance was 9/12 (75%). Of 19 STOMP participants surveyed, 13 reported being "much better" overall since beginning treatment, and 18 reported they would return to the intervention in the future. BPI-total scores decreased by 2 points in the intervention group and 0.9 in the control group (p=0.11).

Conclusions: STOMP is an innovative approach to pain treatment tailored to PLWH. It is feasible, acceptable, and shows preliminary evidence of efficacy and promise for a full-scale trial.

Introduction

Chronic pain, defined as pain lasting for at least three months, is an important comorbidity in people living with HIV (PLWH). Although prevalence estimates vary depending on sampling and measurement methods, as many as 30%-85% of PLWH experience chronic pain.[1-3] Chronic pain in the modern antiretroviral era includes a predominance of musculoskeletal pain,[4,5] is associated with significant functional disability,[6] and in some individuals, suboptimal retention in HIV primary care.[7]

Given the unique biopsychosocial milieu experienced by PLWH[8], interventions for chronic pain should be developed for and tested in this population. However, a recent systematic review found only 11 studies of interventions for chronic pain that have been tested in PLWH.[9] Seven of the interventions tested were pharmacologic, 4 were non-pharmacologic (2 behavioral interventions), and most studies were limited by lack of randomization or short-term follow-up. The 2 behavioral interventions tested both included cognitive behavioral therapy delivered by clinical psychologists, a resource often not available in HIV treatment settings. Both studies were limited by poor session adherence.

Due to the serious risks and modest benefits of medications such as opioids for individuals with chronic pain, the 2016 Department of Health and Human Services National Pain Strategy underscored the urgent importance of developing cost-effective, scalable behavioral interventions, called pain self-management (PSM) interventions, to treat chronic pain.[10] These interventions promote building PSM skills, such as cognitive reframing and increasing physical activity to manage pain, and can be administered as a complement or alternative to pharmacologic approaches. To optimize treatment effects, it

is critical to tailor interventions to the specific needs of the target population, in this case PLWH, and incorporate behavior change theory.[11]

We developed a Social Cognitive Theory (SCT)-based PSM intervention tailored to PLWH called Skills TO Manage Pain (STOMP). Using other PSM intervention manuals as a starting point[12,13], STOMP's development was informed by extensive qualitative inquiry of patients and providers[14], and an intervention mapping technique that integrates qualitative findings and theory into every intervention component.[15] The result is an HIV primary care clinic-based 12-session intervention that includes group, peer, and one-on-one skill building components.

STOMP is an innovative approach to pain management in PLWH for several reasons. STOMP is the first behavioral intervention to apply the PSM approach to PLWH. Additionally, STOMP's approach to addressing pain is novel. We are aware of only one other chronic pain intervention that uses peers in a very different way – to deliver one-on-one PSM skill-building content[16]. To our knowledge, STOMP is the first PSM intervention to include peers to share personal experiences and model adaptive PSM behaviors, which we hypothesize will lead to improved self-efficacy. Further, while psychologist-led pain CBT groups are common in clinical practice, they are typically used as an efficient way to deliver content rather than for social support, and have not incorporated peer leaders.

The primary objective of this study was to assess STOMP's feasibility and acceptability, including session adherence and participant experience with the intervention. We also conducted exploratory analyses of the preliminary impact of STOMP on pain-related outcomes.

Methods

We conducted a pilot randomized controlled trial of STOMP compared to usual care (Clinicaltrials.gov: NCT02824562). Our approach to the design and reporting of this pilot trial was informed by Thabane's adaptation of the CONSORT Statement.[17] The study protocol was approved by the University of Alabama at Birmingham's (UAB) Institutional Review Board.

Participants and Setting

PLWH and chronic pain were recruited from the UAB HIV Clinic.[18] This clinic provides comprehensive care, including primary and specialty care, mental health services, case management, and a pharmacy.

Study participants were recruited using fliers, provider referrals, and by querying the clinic's Pain Patient Reported Outcome (PROs). Pain PROs included the two-item Brief Chronic Pain Questionnaire (BCPQ), which asks participants about pain duration and severity,[19,20] and the 3-question PEG, which asks about pain severity and pain-related functional impairment (pain-related interference with general activities and enjoyment of life) on a scale of 0-10.[21]

Potential participants were initially screened by phone using the BCPQ and PEG. Those who met the study's inclusion criteria were invited for an in-person pre-screening visit. At the pre-screening visit, potential participants were again screened using the BCPQ and PEG. We excluded individuals who reported planning surgery or other major treatment during the subsequent few months, extended travel plans, or being unavailable to participate in group sessions on the days/times they were offered. During an initial

assessment, participants were asked about transportation barriers, and transportation vouchers (bus and gas) were provided throughout the intervention as needed.

Enrollment visits for potentially eligible participants were scheduled within approximately two months of the intervention's anticipated start date to ensure that the participant continued to meet inclusion criteria and participant commitment to the study (i.e., a brief run-in period). Participants were consented, enrolled, and completed a battery of questionnaires described below. Then participants were randomized to STOMP vs. usual care. Note that individuals randomized to STOMP also continued to receive usual care, which we assessed systematically in both groups (see Usual Care, below). Randomization was conducted during the enrollment visit in a 1:1 fashion. The study statistician generated a block randomization scheme with block sizes of 2, 4, or 6.

Interventionists

This study used four paid interventionists: two peers with HIV and chronic pain ("pain pals") and two research staff ("pain coaches") to work in pain coach-pain pal pairs. Each pair was responsible for the same 10 participants during the study period and co-led group sessions. Pain coaches also delivered the one-on-one sessions.

The pain pal role was created to be responsive to participants' desire to learn from someone with shared experiences relating to HIV and chronic pain.[14] We also hypothesized that learning by watching a peer model healthy PSM behaviors (a SCT construct) would improve participants' self-efficacy, or confidence in their own abilities. Pain pals were patients identified by clinic leadership as having excellent pain self-management skills and were hired as paid study staff. Participants also saw a role for

learning pain self-management skills from a knowledgeable expert – the pain coach. The pain coaches had master's degrees in health education or social work, and had served as interventionists on prior HIV behavioral trials.

Pain pals and pain coaches received training on chronic pain in HIV and on the study protocol. All attended 2 trainings: 1) a half-day, pain psychology group session delivered by a pain psychologist, and 2) a day-long training workshop with the investigators and staff who developed and tested the pain self-management intervention on which STOMP was structured.[12] Pain coaches initially delivered all one-on-one sessions to their pain pal partner, which served as training for both parties. These sessions were audio-recorded so that the pain coaches could receive individualized feedback. Debriefing sessions with WD and JSM were held weekly throughout the intervention.

STOMP Intervention

STOMP consisted of 12 sessions: six individual and six group sessions alternating weekly for 12 weeks:

- One-on-one sessions: The purpose of the one-on-one sessions was to build pain self-management skills. These sessions were led by the pain coaches. Based on input from our qualitative work, we developed 10 one-on-one sessions; all participants received a pain education session, and were allowed to select 5 of the remaining 9 sessions (physical activity and your pain, losing weight to improve your pain, relaxation skills to prevent your pain, sleeping better to help your pain, thinking differently about your pain, building self-worth, talking with our family and friends about pain, taking opioid pain medications).

- Group sessions: The purpose of the group sessions was to enhance peer support related to chronic pain, an important theme that emerged from our qualitative work.[14] The group sessions were co-led by the pain coach-pain pal pair. Each session included sharing reflections on lessons learned and goals set during one-on-one sessions, and challenges encountered.

Control: Usual Care

The control group received usual care, meaning any other pharmacologic and non-pharmacologic treatments for chronic pain provided by their clinicians and not related to the study. We systematically documented participants' receipt of usual care in both arms, including medications, physical therapy, and clinic visits that could help pain (e.g., pain specialist, psychologist). A usual care control allowed us to estimate retention rates of controls not receiving any active treatment in pain trials, informing the development of an enhanced usual care control in the planned full-scale trial of STOMP.

Sample size

The goal total sample size was 40, with 20 participants per arm, a sample size generally sufficient to investigate feasibility/acceptability.[22]

Feasibility and Acceptability Outcomes

Feasibility outcomes included recruitment, randomization, retention, timely completion of the intervention, and completion of an outcome assessment battery. Acceptability was assessed by semi-structured qualitative interviews at the midpoint and

end of the study, and treatment satisfaction questionnaires. These outcomes are described in more detail in Table 1.

Exploratory assessment of STOMP's efficacy

Outcome assessors were blinded to the intervention condition. Pre and post-intervention study questionnaires were informed by the IMMPACT guidelines on outcomes relevant to pain clinical trials[23], and included SCT constructs hypothesized to be impacted by the intervention:

- Brief Pain Inventory (BPI) total score: A composite measure of pain and function.[24]
- PEG as described above.[21]
- The Pain Self-Efficacy Questionnaire (higher scores indicates better pain self-efficacy, and scores of 40 or more have been associated with better outcomes[25]). Collection of data on other SCT constructs such as self-regulation and outcome expectations was piloted during the study but was not of sufficient quality to merit reporting.
- Tampa Kinesophobia Scale (higher scores indicate greater fear of pain with movement, a maladaptive coping mechanism; mild=23, moderate = 33, severe = 43[26]), and the Pain Catastrophizing Scale (higher scores indicate catastrophizing, clinically relevant catastrophizing = 30 or more[27]).
- Other questionnaires included the PHQ-8 for depressive symptoms (higher scores indicate worse depressive symptoms, a score of 10 or greater is considered moderate depressive symptoms)[28]; the AUDIT-C for alcohol use (used gender-

specific version, ≥ 2 is considered to be at-risk drinking)[29], and the ASSIST for substance use[30].

Analyses

Outcomes were reported as means and standard deviations for continuous variables, and frequencies and percentages for categorical variables. T-tests were used to compare continuous variables and Fisher's exact tests were used to compare percentages. Interviews were analyzed thematically by two independent coders (SRY, JSM). Discrepancies were reconciled, a code book was created, and the lead analyst (SRY) 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.

Results

Participant Flow

Recruitment and enrollment lasted 13 weeks (July-October 2016). The figure details participant flow through the study. Ninety-eight potential participants initiated contact with study staff. Of these 45 participants who completed the enrollment visit, 43 were randomized. One participant was withdrawn because the recruitment goal had been achieved, and one participant was unintentionally not randomized and was placed in the control arm.

Baseline Characteristics

Baseline demographic and clinical characteristics are presented in Table 2. Overall, participants (N = 44) had a median age of 51 years, 25 were female, 38 were black, and 42 were virologically suppressed. Nearly all (42) participants reported that transportation vouchers would help them attend study visits. The most common pain locations were low back, knee, and numbness/tingling in the hands and feet. The mean BPI-total score (0-10) was 7.8 (SD 2.1) in the intervention group and 7.4 (SD 1.6) in the control group. Baseline pain self-efficacy scores were similarly low in both groups, and catastrophizing was similarly high. The majority of participants reported current or prior substance use.

Feasibility

We recruited and randomized 44 participants. The ratio of participants who approached staff to those who were randomized was 98/44=2.1. Of the 22 total participants in the intervention group, the median number of group sessions attended was 3.5 out of 6 (IQR 3-5), the median number of individual sessions attended was 6 out of 6, and the median number of total sessions attended was 9 out of 12 or 75% (IQR 8-11). Seventeen participants (77.3%) completed all 6 one-on-one sessions within the 16-week study period. Reasons for missed sessions included personal or family illness, a conflicting medical appointment, work conflict, voting, and major holidays.

Among the 22 intervention participants, the most commonly selected topics to be discussed during the one-on-one sessions were physical activity (17), relaxation (17), stress (15), sleep (12), weight loss (11), and thinking differently about your pain (10).

Of 44 participants, 36 (82%) completed outcome assessments within one month of completing the intervention (or within one month after the last group session for the control participants). Of the remaining 8, 5 were from the control group and 3 were from the intervention group. Of the 5 control participants who did not complete outcome assessments 1 died, 3 had incorrect phone numbers, and 1 was in jail. Of the 3 intervention participants who did not complete outcome assessments, 2 had incorrect phone numbers and 1 was in jail.

Acceptability

Three major themes emerged from the qualitative interviews: helpfulness of the intervention in reducing pain, behavioral changes as a result of the intervention, and the benefits of the multi-component intervention.

1) Participants indicated that the intervention helped relieve pain. One participant stated: “Sometimes you get where you say, what can they tell me? I’ve been through it all. None of it helped. I really didn’t look for it to help me as much as it has. So, I’m gung ho about trying some more.” (65-year-old African-American Female)
2) Participants described a variety of behavioral changes made as a result of the intervention, including increased physical activity, focusing less on the pain, and thinking differently about pain. One participant noted that the intervention

reduced reliance on pain medications: “It’s benefited me a lot because I don’t have to take pain pills. I’m learning to not take like Tylenols or the Aspirin anymore. I’m learning just to exercise and if I exercise or stretch or cut back on what I eat, I feel better about myself and I love that part.” (32-year-old African-American male)

3) Participants talked about how intervention components - group, peer, and one-on-one skill building sessions – came together to make the intervention work. One participant reflected: “just in having the ability to meet with people, have a support group, meet one on one, gain the tools, different avenues in order to deal with your pain, and have somebody who's willing to listen about your pain. That's the job.” (46-year-old African-American female).

   The support of a peer leader was also important. One participant shared: “They know where you’re coming from and if, at any reason, at any time, you feel like, I’m the worst one, he could tell us things that was like, wow…He could understand where you were coming from…if you’ve never had pain, I ain’t going to say you can’t talk about or teach it or infiltrate it, but it’s nothing like me actually being there.” (65-year-old African-American female)

Seventeen of 19 respondents (89%) to the treatment satisfaction questionnaire reported being very satisfied, 1 moderately satisfied, and 1 neither satisfied nor dissatisfied with the intervention. Thirteen intervention participants reported being “much better” overall since they began treatment, 5 “a little better”, and 1 no change. Almost all (18) participants reported that they would return to the intervention in the future.

Preliminary Efficacy

Table 3 summarizes the changes in outcome measures between the intervention and control group. BPI-total scores decreased on average by 2 points in the intervention group and 0.9 points in the control group (on a scale of 0-10). BPI-total scores decreased by 1 or more in 13 (68%) intervention group participants and 9 (53%) control group participants (p=0.49). Pain catastrophizing decreased on average by 8.6 points in the intervention group and 4 points in the control group (p=0.25). Pain self-efficacy decreased slightly and kinesophobia increased slightly, but neither were statistically significant.

Discussion

For the reasons described above, STOMP represents an important innovation in pain treatment for PLWH. This pilot study was a critical first step in its evaluation. Given the poor session adherence seen in previously published behavioral interventions tested in PLWH, STOMP's feasibility and acceptability was noteworthy. In particular, participants attended 75% of sessions, indicated that it helped improve their pain and function, reported high levels of satisfaction with the intervention. Preliminary findings suggest the intervention's potential impact on pain and pain-related functional impairment.

We believe that the feasibility of this study is generalizable to other study settings. We purposely used staff interventionists with backgrounds often found in HIV clinical care and research settings. Peer interventionists were easily identified and retained for the entire study. The training required was sufficient to ensure fidelity to the study protocol

and carry it out, but not overly onerous. Additionally, the qualitative interviews indicated that the group component is an essential ingredient to the intervention.

We were encouraged by the preliminary impact of our intervention. Although this study was not powered to test efficacy, individuals in the intervention group experienced a 2-point decrease in their BPI-total score, which is considered moderately clinically meaningful.[23] This difference exceeds what has been found in other studies of chronic pain interventions in PLWH.[9] Additionally, this was a 1.1-point greater decrease than the control group, which exceeds the cutoff for the minimum clinically important difference.[31] However, due to the small sample size, these findings are preliminary and a fully powered study is needed before conclusions about efficacy can be confidently drawn. Unlike high dropout rates (>20%) due to lack of effect or adverse seen in studies of opioids,[32] dropout was modest and typically due to extenuating personal circumstances. We were also encouraged by our participants' positive response to the intervention in interviews and on the treatment satisfaction survey; we believe this reflects our systematic intervention development process which included extensive tailoring based on the expressed needs of both participants and clinicians.

In sum, STOMP is feasible and acceptable, and is therefore ready to be tested in a full-scale trial. Positive findings would lead to subsequent dissemination/implementation research on STOMP in HIV treatment settings.

Acknowledgements

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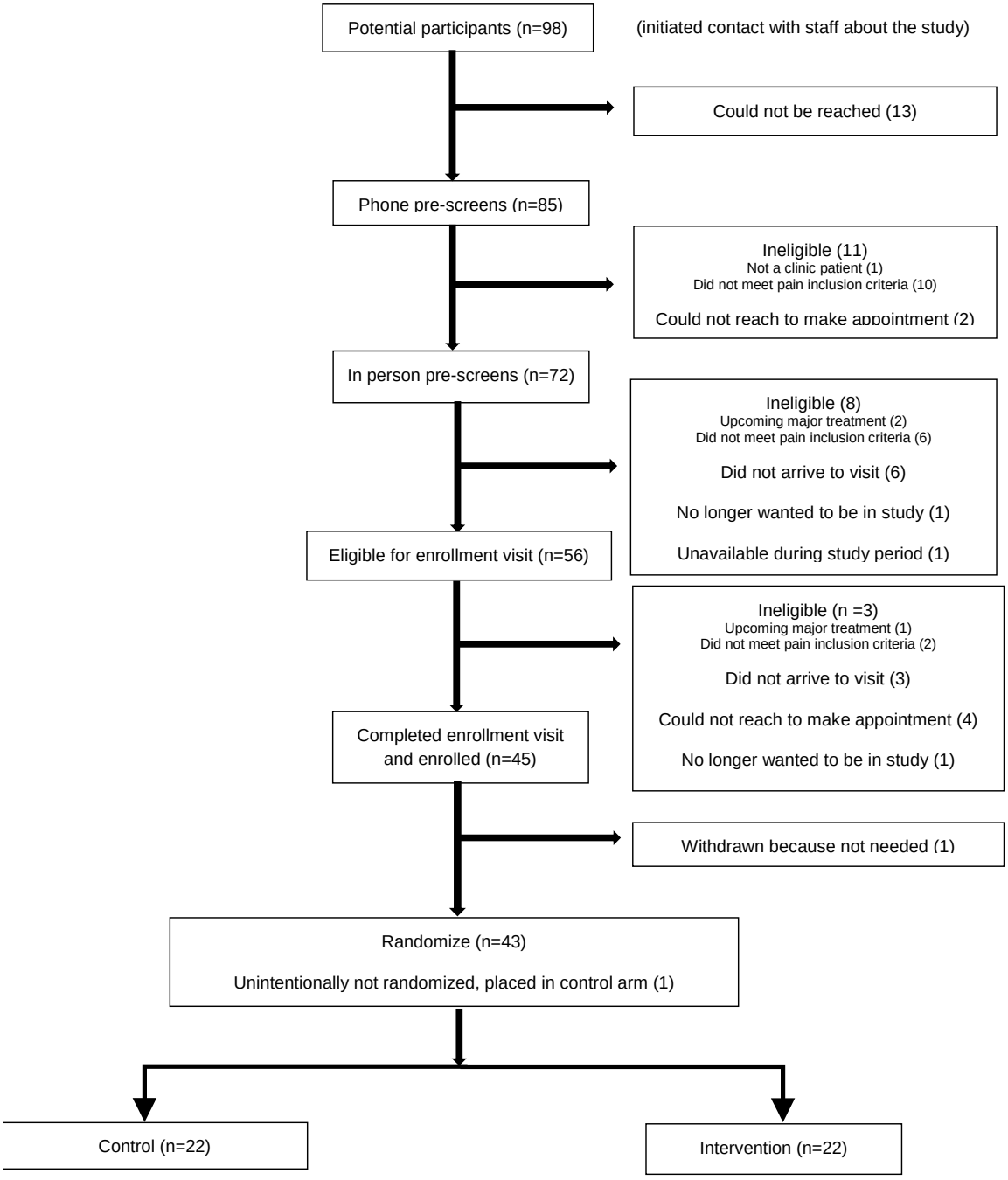

Figure 1. Consort Diagram.

Table 1. Intervention Feasibility and Acceptability Outcomes

Feasibility Outcomes	
Recruitment	Our goal was to be able to recruit all 40 participants using study fliers, referrals from primary care providers, and if needed, a database of individuals from the clinic with chronic pain based on a recent Patient Reported Outcome questionnaire. We determined the approach-to-enroll ratio, which we will use to estimate the number of participants needed to approach for the full-scale trial to achieve our desired sample size.
Randomization	Randomization: Not all pilot trials involve randomization, as the purpose of a pilot trial is to assess feasibility and acceptability rather than to assess the differences in outcomes between the intervention and a control group. However, there is a paucity of chronic pain intervention studies among individuals with HIV, who have an especially high burden of chronic pain. Therefore, we investigated the feasibility and acceptability of randomization to a usual care control among PLWH and chronic pain.
Retention	Given the Center for Disease Control and Prevention's benchmark for behavioral interventions for adherence and retention to HIV treatment and care, our goal was for participants to complete an average of 80% of all study visits. Individuals who missed sessions were called to ask about barriers to attendance.
Completion in allotted time	Group sessions occurred every other week on a fixed schedule. However, one-on-one sessions were scheduled at the participant's convenience. We determined what percentage of participants would be able to complete all one-on-one sessions within the study period (16 weeks).
Outcome assessment completion	Outcome assessments: The full-scale trial will assess distal outcomes including pain and pain-related functional impairment, as well as more proximal outcomes such as SCT constructs (e.g., self-efficacy), and potential confounders of effect (e.g., mood) identified in our previously published conceptual framework. A goal of the present study was to evaluate the feasibility of administering a battery of outcome assessments. Additionally, outcome assessments were conducted immediately following study completion. Our goal was to complete outcome assessments on 80% of individuals randomized to the study within one month of the participant's last session.
Acceptability outcomes	
Participant experience with the study	We conducted qualitative interviews with patient participants at the mid-point and end of the trial. The purpose of these interviews was to assess participants' experience with the study and assess the need for modifications. Participants were asked what they liked and did not like about the intervention, what if anything they noticed changed during the intervention, and what they would change about the intervention in the future.
Participant satisfaction	Participants completed a treatment satisfaction questionnaire after the intervention was completed.

Table 2. STOMP Pilot Trial Baseline Data

	Intervention N=22	**Control N=22**
Age (median, IQR) (EMR)*	51 (48-55)	51 (46-57)
Female gender, n (%) (EMR)	11 (50)	14 (64)
Race, n (%) (EMR)		
White	3 (14)	2 (9)
Black	19 (86)	19 (86)
Other	0 (0)	1 (5)
VL < 200 copies/mL, n (%) (EMR)	21 (95)	21 (95)
CD4+ T cell count (median, IQR) (EMR)	910 (384-1023)	581 (400-714)
Pain location, n (%) (RedCap)**		
Numbness/tingling hands/feet	12 (55)	7 (32)
Headache	5 (23)	5 (23)
Abdominal pain	4 (18)	2 (9)
Low back8	16 (73)	18 (82)
Hip	7 (32)	10 (45)
Shoulder	10 (45)	6 (27)
Knee	12 (55)	13 (59)
Pain everywhere in your body	6 (27)	6 (27)
Transportation: (RedCap)		
Importance on scale 1-10 (median, IQR)	9 (5-10)	6 (3-9)
Assistance would help participant attend sessions	22 (100)	20 (91)
Locations of chronic pain care, n (%) (RedCap)		
Primary care @ HIV clinic	21 (95)	16 (73)
Primary care outside of HIV clinic	0 (0)	2 (9)
Urgent care/sick call	1 (5)	0 (0)
Emergency room	4 (18)	3 (14)
Pain specialist	1 (5)	7 (32)
Other (specify)	UAB ambulatory clinics 1 (5), knee doctor 1 (5)	Orthopedist 1 (5), self-medication 1 (5), spine/arthritis doctor 1 (5)
Current Pain co-interventions, n (%) (Redcap)		
Pain clinic	4 (18)	4 (18)
Seen by a counselor, psychiatrist, or psychologist	12 (55)	13 (59)
Physical therapy	0 (0)	1 (5)
Acupuncture	0 (0)	0 (0)
Massage	0 (0)	1 (5)
Providers seen at UAB (ever) (EMR)		
Addiction individual and/or group session	11 (50)	12(55)
Neurology	3 (14)	3 (14)
Palliative care	6 (27)	12 (55)

Psychiatry	11 (50)	12 (55)
Psychology	10 (45)	11 (50)
Pain Medications (EMR) – opioids, acetaminophen, NSAIDS, muscle relaxants at study start	7 (32)	11 (50)
Opioid pain medications at study start (EMR)	3 (14)	5 (23)
Primary care visit in last 12 weeks (EMR)	15 (68)	17 (77)
Urgent care visit in last 12 weeks (EMR-sick call)	0 (0)	4 (18)
ER visits in the last 12 weeks (EMR)	5 (23)	5 (23)
Medical hospitalizations in the last 12 weeks (EMR)	4 (18)	5 (23)
PEG (0-10), mean SD (RedCap)	8.2 (1.3)	8.0 (1.4)
BPI-Total score (0-10), mean SD (RedCap)	7.1 (2.1)	7.4 (1.6)
Pain self-efficacy questionnaire (0-60), mean SD (RedCap)	32.9 (16.5)	31.6 (19.8)
Tampa Kinesophobia scale (10-40), mean SD (RedCap)	24.2 (5.4)	22.7 (6.5)
Pain catastrophizing scale (0-52), mean SD (RedCap)	30.7 (15.0)	29.2 (16.6)
Currently taking ART	22 (100)	21 (95)
Of those, any ART missed over last 2 weeks Y/N	4 (18)	2 (10)
PHQ-8 (0-24, median, IQR) (RedCap)	8.5 (5.4)	9.3 (6.2)
AUDIT-C ≥ 2 (RedCap)	3 (14)	3 (14)
ASSIST(RedCap): Substance use other than marijuana, non-prescribed opioids		
Current	2 (9)	1 (5)
Prior	14 (64)	18 (82)
Never	6 (27)	3 (14)

*EMR = data pulled from the Electronic Medical Record. **RedCap=patient self-report collected by study staff using RedCap, an online data collection tool programmed for the purposes of this study

Missing values:
Tampa Kineseophobia 5, Pain Catastrophizing 1, PHQ-8 1, AUDIT-C 2

Table 3. Changes in Measures Before and After the Intervention

	Intervention N=19	Control N=17	p-value (between group)*
Mean (SD) (positive is increase, negative is decrease)			
PEG	-1.5 (1.9)	-1.4 (2.3)	0.93
BPI-total	-2.0 (2.1)	-0.9 (1.6)	0.11
Pain self-efficacy questionnaire	4.2 (17.8)	7.4 (15.4)	0.58
Tampa Kinesophobia scale	1.1 (5.4)	-0.2 (2.7)	0.43
Pain catastrophizing scale	-8.6 (11.4)	-4.0 (11.5)	0.25

* t-test; Missing values: Tampa Kineseophobia 3 control 3 intervention, Pain Catastrophizing 1 intervention

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CONCLUSIONS AND FUTURE DIRECTIONS

Summary and Implications of the Three Papers

The three manuscripts presented in this dissertation represent a novel body of work on chronic pain in PLWH. Chronic pain is an important comorbidity in PLWH, and surprisingly, few interventions have been developed to address it. This dissertation fills this gap by presenting the development and pilot testing of a theory based behavioral intervention for chronic pain tailored to PLWH, Skills TO Manage Pain (STOMP). While STOMP is an important product of this work, the three papers presented also contribute significantly to the science surrounding application of behavioral health theory, intervention development methods, and behavioral intervention pilots. Here, the contributions of each paper will be discussed in turn.

Paper 1 is an important example of using qualitative inquiry to inform intervention development. While it is common for investigators to claim use of qualitative results in the intervention development process, and to include qualitative results briefly in pilot trial papers, it is uncommon to see a more detailed reporting. This detailed reporting is important because it provides evidence and a rationale as to why the intervention we ultimately designed incorporating these qualitative findings should work in the target population. We took great care to purposively sample participants with the characteristics of individuals who may benefit most from the intervention – those with symptoms of depression and anxiety, and substance use, in whom behavioral interventions may be particularly challenging. These participants were enthusiastic about

a behavioral intervention, and identified three components -- groups, peers, and one-on-one sessions led by "experts" – that would be critical to an intervention's success, and why. These components also made theoretical sense. For example, participants explained that a group component would be an important way to feel less socially isolated due to their chronic pain. Social isolation was an important component of the social aspect of our recently developed Biopsychosocial Framework for Chronic Pain in HIV which we have developed (32).

The onus was then on our research team to determine how to incorporate these components, as well as a well-established health behavior theory, into the intervention. Just as with qualitative work, it is uncommon for investigators to publish a detailed description of how this qualitative work is merged with theory to develop the intervention. However, without such a description, there is no published record of the intervention's hypothesized mechanism and why the intervention as designed should work. Paper 2, which describes our systematic process of intervention mapping, serves as this record. We hope that Papers 1 and 2 can assist other investigators hoping to conduct and publish this type of rigorous formative work. In addition, it provides a template by which we can investigate the intervention's impact on hypothesized theoretical mediators of the intervention's impact, such as self-efficacy. In short, this paper provides a framework for understanding the underpinnings of the intervention and how it should be evaluated.

Paper 3 is the beginning of that evaluation work. It is a pilot randomized trial of STOMP vs. usual care. The primary purpose of this pilot was to assess feasibility and acceptability. As we discuss at length in the manuscript, the intervention performed well

– participants attended at high levels and felt that the intervention improved their pain and taught them new skills, such as physical activity to improve their pain. We also note preliminary evidence of efficacy, although this pilot trial was not powered to assess the intervention's impact on pain and function. This means there is equipoise for a full-scale efficacy trial of the intervention.

Recommendations for Future Research

While this work is significant, it is only the beginning of a program of research on behavioral interventions for chronic pain in PLWH. The immediate next step is to investigate STOMP's efficacy. We will propose a randomized trial of STOMP plus usual care vs. usual care. Usual care is what we described as co-interventions in Paper 3, and includes routine pharmacologic and non-pharmacologic pain care. Our primary outcome will be a 30% reduction in the Brief Pain Inventory-Total score, a composite of pain and function, which was also measured during the pilot.

Another important near-term goal for our program of research are to understand the intervention's mechanism. Using the theoretical basis for STOMP outlined in Paper 2, we will conduct mediation and moderation analyses of the intervention's theoretical underpinnings (e.g., self-efficacy). This will allow us to make informed decisions about future adaptations or modifications of the intervention. For example, we may choose to augment aspects of the intervention that impact constructs that are important mediators of the intervention's impact, and we would also avoid removing such components. Additionally, we acknowledge that STOMP is a time-intensive intervention, and its ability to be implemented depends to a large extent on its cost-effectiveness. While

conducting the efficacy trial, we will collect detailed data on cost and determine the incremental cost effectiveness ratio and the cost per QALY.

Finally, if the intervention is efficacious, we anticipate conducting implementation and dissemination investigations of STOMP. Examples include comparing the current 12-session STOMP model with a more pared down version (e.g., 6 sessions), using what we learn about the intervention's mechanism as a guide. Additionally, we could also study the implementation of STOMP in varied settings, such as HIV-specific medical homes and Federally Qualified Health Centers, who also care for large numbers of PLWH.

Implications of Findings for Healthcare Providers

STOMP has yet to be tested in an efficacy trial. However, especially given the dearth of available chronic pain interventions in general and in PLWH, there may be practitioners and/or clinics that want to implement STOMP now. If this occurs, it will be important to collect process data on uptake of the intervention, feasibility of incorporation into clinic flow, and other implementation/dissemination outcomes.

Limitations

Our work has limitations. First, the intervention was developed and pilot tested at one clinic – the University of Alabama at Birmingham 1917 HIV Clinic. While it is true that the intervention development and testing process must start somewhere, the intervention's content, feasibility, or acceptability may not be generalizable outside this context. We argue that PLWH who have chronic pain are likely to have more similarities

than differences regardless of their location, but whether this is true is not known. Additionally, the intervention as designed is relatively intensive. We did not conduct "dose-finding" studies to understand the optimal number of sessions, and rather, built STOMP on prior pain self-management interventions of similar length and format. It is possible that a less intensive intervention would be efficacious, and this is something that can be investigated once the efficacy of STOMP itself is proven. Finally, it is possible that the most challenging patients – those with the most substantial physical or emotional impairment from chronic pain or co-occurring conditions – may have chosen not to participate in this study. However, such patients would likely also be too impaired to participate in a behavioral intervention for chronic pain. This is not to say that these patients are beyond help. Rather, other strategies, perhaps involving community outreach to patients whose impairment keeps them from being able to engage in care for chronic pain, are needed to reach this population.

Conclusions

In sum, chronic pain is an important and understudied comorbidity in PLWH. Behavioral interventions for chronic pain in this population are a promising approach. We rigorously developed and pilot tested a theory-based behavioral intervention for chronic pain in PLWH, which we found to be feasible, acceptable, and have preliminary evidence of impact. Future research is needed to assess its efficacy, and if efficacious, move STOMP from evidence into practice.

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APPENDIX A

IRB APPROVALS AND CONSENT FORMS

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on January 24, 2017. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator:	MERLIN, JESSICA S.
Co-Investigator(s):	DAVIES, SUSAN L
Protocol Number:	**X140911002**
Protocol Title:	*Development of a Behavioral Intervention for Chronic Pain in Individuals with HIV*

The IRB reviewed and approved the above named project on 11-7-14. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 11-7-14

Date IRB Approval Issued: 11-7-14

IRB Approval No Longer Valid On: 11-7-15

Marilyn Davis

Member - Institutional Review Board for Human Use (IRB)

Partial HIPAA Waiver Approved?: Yes

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

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irb@uab.edu

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Alabama at Birmingham
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AB 470
1720 2ND AVE S
BIRMINGHAM AL 35294-0104

PI: MERLIN, JESSICA S.
Protocol # X140911002

UAB IRB Approval of
Partial Waiver of HIPAA Authorization
to Use PHI in Screening for Research

☒ **Patient Authorization: Approval of Partial HIPAA Waiver to Use PHI in Screening for Research.** The IRB reviewed the proposed research and granted the request for a "partial HIPAA waiver," to allow the proposed use of protected health information (PHI) in screening for research, based on the following findings:

1. The use/disclosure of PHI to screen candidates for research involves no more than minimal risk to the privacy of individuals
   a. There is an adequate plan to protect the identifiers from improper use and disclosure.
   b. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
   c. The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.
2. The screening cannot practicably be conducted without the waiver or alteration.
3. The screening cannot practicably be conducted without access to and use of the PHI.

—OR—

☐ **Full Review**
The IRB reviewed the proposed research at a **convened meeting** at which a majority of the IRB was present, including one member who is not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities. The partial waiver of authorization for screening was approved by the majority of the IRB members present at the meeting.

_____
Date of Meeting

_____
Signature of Chair, Vice-Chair or Designee

_____
Date

☒ **Expedited Review**
The IRB used an **expedited review procedure** because the research involves no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which use or disclosure is being sought. The review and approval of the partial waiver of authorization for screening was carried out by the Chair of the IRB, or by one of the Vice-Chairs of the IRB as designated by the Chair of the IRB.

11-7-14
Date of Expedited Review

Marilyn Dans
Signature of Chair, Vice-Chair or Designee

11-7-14
Date

Rev. 12/08/2005

Page 1 of 1

Informed Consent

TITLE OF RESEARCH: Development of a Behavioral Intervention for Chronic Pain in Individuals with HIV

IRB PROTOCOL: X140911002

PRINCIPAL INVESTIGATOR: Jessica S. Merlin, MD, MBA

SPONSOR: Palliative Research Enhancement Project (PREP)

Purpose of the research

The purpose of this study is to develop and pilot test a tailored, theory-based intervention for individuals who are living with chronic pain and HIV. Chronic pain is pain lasting longer than 3 months, beyond the period of normal tissue healing, and is common among patients living with HIV. You are being asked to participate in a research study because you are a patient at the 1917 clinic and you experience at least moderate functional impairment from your chronic pain. In this phase of the study we will conduct on-on-one in-depth interviews with patients and health care workers at the clinic to collect information to develop the intervention. This study will enroll approximately 100 participants.

Research studies include only people that choose to participate in them. The purpose of this consent form is to give you the information you will need to help you decide whether or not to participate. Please read this consent form carefully and take your time making your decision.

Explanation of Procedures

If you choose to participate in this study, we will ask you a series of open-ended questions about chronic pain and suggestions for developing a program to help patients who are suffering from chronic pain. Examples of questions that will be asked include: 1) Tell me about your pain?; 2) What things do you do to help treat your pain?; 3) If you were to develop a pain management program targeting patients at the clinic what things would you include?; 4) What if anything would keep you from participating in this intervention? This information will be audio recorded, and transcribed later. All of the information you provide will be kept confidential, and you may refuse to answer any question at any time. The entire interview should take 2 hours to complete.

In addition to participating in the in-depth interview, information from your medical record will also be collected as part of this study. This information includes demographic characteristics (e.g. age, gender, and race), medication adherence, laboratory results (e.g. CD4 cell count and HIV viral load), pain diagnosis and treatment, and physical function.

UAB IRB
Date of Approval 11-7-14
Not Valid On 11-7-15

The information that we collect during the interviews will be used to develop the intervention manual. After we have developed this manual we may invite to take part in the pre-testing of the intervention.

Risks and Discomforts

Some of the questions about your experiences living with chronic pain and HIV are sensitive in nature and may potentially cause discomfort. Although we believe that distress is unlikely to occur, you may refuse to answer any question that causes you discomfort. Any unusual distress should be reported to the research staff.

There is also the potential risk of breach of confidentiality associated with your involvement in this study. Every effort will be made to protect your confidentiality. All of the data collected from you will be kept strictly confidential to the extent permitted by law and will be stored on password-protected computers. We will not use personal identifying information such as your name, medical record number, or birth date when reviewing data or publishing results of this study. Instead, we will code the information we collect from you with a unique, unidentifiable subject ID number to help us protect your privacy.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us improve HIV care and clinical outcomes in the future.

Alternatives

You can choose not to participate in the study, and this will not affect your medical care or opportunities for care coordination in any way.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. Research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the Palliative Research Enhancement Project (PREP) for this protocol; and the Office for Human Research Protections (OHRP).

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

Only a code number, not your name, will be used to identify your information on study materials. This will be maintained in a password-protected computer database on a secure server within the 1917 Clinic. Recorded material will not have your name attached to it, just your research code. This digital audio material will be securely uploaded to a secure server. Any paper materials linking your name and code number will be kept in locked filing cabinets in locked offices of study personnel on a need-to-have basis.

Your study materials will be maintained for a period of five years after you finish the study. At that time the research information not already in your medical record will be destroyed.

When we write about results of the study, we will use only numbers and not names or personal facts. No one will be able to link the results back to you. We do this to keep your personal information private.

Refusal or Withdrawal without Penalty

Taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation in Research

You will receive a one-time cash payment of $50 cash for your participation in this study. You will receive this payment at the time you complete the interview.

Questions

If you have any questions, concerns, or complaints about the research or a research- related injury including available treatments, please contact Dr. Jessica Merlin. She will be glad to answer any of your questions. Dr. Merlin may be best reached during normal business hours or after hours by paging her at 205-934-3411 (ask specifically for Dr. Merlin).

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the Institutional Review Board for Human Use (OIRB) at (205) 934-3789 or 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document

Signatures

Your signature below indicates you that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant Date

Signature of Principal Investigator or person obtaining consent Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant Name: _____
Research Protocol: Development of a Behavioral Intervention for Chronic Pain in Individuals with HIV

UAB IRB Protocol Number: X140911002
Principal Investigator: Jessica Merlin, MD, MBA

Sponsor: PREP

What health information do the researchers want to use? All medical information and personal identifiers, including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____
or participant's legally authorized representative: _____ Date: _____
Printed Name of participant's representative: _____
Relationship to the participant: _____

Informed Consent

TITLE OF RESEARCH: **Development of a Behavioral Intervention for Chronic Pain in Individuals with HIV**

IRB PROTOCOL: **X140911002**

PRINCIPAL INVESTIGATOR: **Jessica S. Merlin, MD, MBA**

SPONSOR: **Palliative Research Enhancement Project (PREP)**

Purpose of the research

The purpose of this study is to develop and pilot test a tailored, theory-based intervention for individuals who are living with chronic pain and HIV. Chronic pain is pain lasting longer than 3 months, beyond the period of normal tissue healing, and is common among patients living with HIV. You are being asked to participate in a research study because you have been providing care to patients at the 1917 Clinic for at least 1 year. In this phase of the study we will conduct on-on-one in-depth interviews with patients and health care workers at the clinic to collect information to develop the intervention. This study will enroll approximately 100 participants.

Research studies include only people that choose to participate in them. The purpose of this consent form is to give you the information you will need to help you decide whether or not to participate. Please read this consent form carefully and take your time making your decision.

Explanation of Procedures

If you choose to participate in this study, we will ask you a series of open-ended questions about chronic pain and developing a program to help patients who are suffering from chronic pain. Examples of questions that will be asked include: 1) What things do you believe are helpful for the management of chronic pain among patients at this clinic?; 2) If you were to develop a pain management program targeting patients at the clinic what things would you include?; 3) What if anything would keep patients at the clinic from participating in this intervention? This information will be audio recorded, and transcribed later. All of the information you provide will be kept confidential, and you may refuse to answer any question at any time. The entire interview should take about 1 hour to complete.
In addition to participating in the in-depth interview you will be asked to complete a brief survey about your socio-demographic characteristics and role in the clinic.

The information collected during the interviews will be used to develop the intervention manual. After developing the manual we may invite to take part in the pre-testing of the intervention.

UAB IRB
Date of Approval 11-7-14
Not Valid On 11-7-15

Risks and Discomforts

The main risk associated with taking part in this study is of breach of confidentiality. Every effort will be made to protect your confidentiality. All of the data collected from you will be kept strictly confidential to the extent permitted by law and will be stored on password-protected computers. We will not use personal identifying information such as your name, and age when reviewing data or publishing results of this study. Instead, we will code the information we collect from you with a unique, unidentifiable subject ID number to help us protect your privacy.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us improve HIV care and clinical outcomes in the future.

Alternatives

You can choose not to participate in the study, and this will not affect your medical care or opportunities for care coordination in any way.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. Research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the Palliative Research Enhancement Project (PREP) for this protocol; and the Office for Human Research Protections (OHRP).

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk. Only a code number, not your name, will be used to identify your information on study materials. This will be maintained in a password-protected computer database on a secure server within the 1917 Clinic. Recorded material will not have your name attached to it, just your research code. This digital audio material will be securely uploaded to a secure server. Any paper materials linking your name and code number will be kept in locked filing cabinets in locked offices of study personnel on a need-to-have basis.

Your study materials will be maintained for a period of five years after you finish the study. At that time the research information not already in your medical record will be destroyed.

When we write about results of the study, we will use only numbers and not names or personal facts. No one will be able to link the results back to you. We do this to keep your personal information private.

Refusal or Withdrawal without Penalty

Taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.
If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation in Research

You will receive a one-time gift card valued $15.00 for your participation in this study. You will receive this payment at the time you complete the interview.

Questions

If you have any questions, concerns, or complaints about the research or a research- related injury including available treatments, please contact Dr. Jessica Merlin. She will be glad to answer any of your questions. Dr. Merlin may be best reached during normal business hours or after hours by paging her at 205-934-3411 (ask specifically for Dr. Merlin).
If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the Institutional Review Board for Human Use (OIRB) at (205) 934-3789 or 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates you that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant Date

Signature of Principal Investigator or person obtaining consent Date

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on January 24, 2017. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator:	MERLIN, JESSICA S.
Co-Investigator(s):	GOWER, BARBARA HEATH, SONYA LYNN
Protocol Number:	**X160518004**
Protocol Title:	*A Pilot Study of Inflammation as a Potential Etiology of Chronic Pain in Individuals with HIV*

The IRB reviewed and approved the above named project on 6-10-16. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 6-10-16

Date IRB Approval Issued: 6/13/16

IRB Approval No Longer Valid On: 6-10-17

HIPAA Waiver Approved?: Yes

Marian Dorn

Expedited Reviewer
Member - Institutional Review Board
for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

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THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

PI: MERLIN, JESSICA S.
Protocol # X160518004

UAB IRB Approval of
Waiver of Informed Consent and/or Waiver of Patient Authorization

☐ **Approval of Waiver of Informed Consent to Participate in Research.** The IRB reviewed the proposed research and granted the request for waiver of informed consent to participate in research, based on the following findings:

1. The research involves no more than minimal risk to the subjects.
2. The research cannot practicably be carried out without the waiver.
3. The waiver will not adversely affect the rights and welfare of the subjects.
4. When appropriate, the subjects will be provided with additional pertinent information after participation.

Check one:
- ☐ **and** Waiver of Authorization (below)
- ☑ **or** Waiver of Authorization (below)
- ☐ Waiver of Authorization not applicable

☑ **Approval of Waiver of Patient Authorization to Use PHI in Research.** The IRB reviewed the proposed research and granted the request for waiver of patient authorization to use PHI in research, based on the following findings:

1. The use/disclosure of PHI involves no more than minimal risk to the privacy of individuals
   - i. There is an adequate plan to protect the identifiers from improper use and disclosure.
   - ii. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention that is otherwise required by law.
   - iii. There is an assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.
2. The research cannot practicably be conducted without the waiver or alteration.
3. The research cannot practicably be conducted without access to and use of the PHI.

—OR—

☐ **Full Review**
The IRB reviewed the proposed research at a **convened meeting** at which a majority of the IRB was present, including one member who is not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities. The waiver of authorization was approved by the majority of the IRB members present at the meeting.

Date of Meeting

Signature of Chair, Vice-Chair or Designee

Date

☑ **Expedited Review**
The IRB used an **expedited review procedure** because the research involves no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which use or disclosure is being sought. The review and approval of the waiver of authorization were carried out by the Chair of the IRB, or by one of the Vice-Chairs of the IRB as designated by the Chair of the IRB.

6-10-16
Date of Expedited Review

Signature of Chair, Vice-Chair or Designee

Date 6-10-16

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APPENDIX B

STOMP WORKBOOK

STOMP
SKILLS • TO • MANAGE • PAIN

Taking Opioid Pain Medications

What tool are you adding to your toolbox this week?

What goal are you going to set this week

Homework

Your homework is to meet your goal this week.
How will you do this?

When did you do this?

Week 1	1	2	3	4	5	6	7	8	9	10	11	12
Monday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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Wednesday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How did it go?

TABLE OF CONTENTS

Group Session One: Introduction

This week's goals*[1]

- Get to know each other, including the Pain Pal and the Pain Coach
- Learn about the purpose of this program and why we think it will help
- Learn about the set-up of the group and one-on-one sessions
- Review the program calendar and logistics
- Ground Rules

Tell the group about yourself

- What is your name?
- What do you like to do?

Our experts:

Pain Pal

- An expert in chronic pain from personal experience
- Has received special training in this program
- Is here to lead the group sessions and help participants between sessions if needed

Pain Coach

- Staff with special training in this program and in chronic pain
- Is here to help lead the group session with the Pain Pal, and to lead the one-on-one sessions

Purpose of the program:

- Make your pain better and help you reach your personal goals (things that may be hard to do because of your pain)
- Add to the care your medical team is providing, such as medications, physical therapy, injections or other treatments

How we developed the program:

- Talked to patients at the clinic who have chronic pain
- Met with experts in chronic pain around the US who have run other programs like this

Why are we running this program?*[1]

- Chronic pain is a big problem.
- Most treatments for chronic pain rely on medicine or surgery.
- Many people with chronic pain do not know how pain works in their bodies, and what they can do on their own to help their pain.
- We want to give people with chronic pain the chance to talk to each other.
- Everyone's pain is different. For example, your pain may be in different parts of your body and cause different problems than the person sitting next to you.
- However, we have learned that there are ways to treat pain that help most people, even if their pain isn't exactly the same. That's what we want to share with you.

Talking with our Family and Friends about Pain

What tool are you adding to your toolbox this week?

What goal are you going to set this week

Homework

Your homework is to meet your goal this week.
How will you do this?

When did you do this?

Week 1	1	2	3	4	5	6	7	8	9	10	11	12
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Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How did it go?

Building Self-Worth

What tool are you adding to your toolbox this week?

What goal are you going to set this week

Homework

Your homework is to meet your goal this week.
How will you do this?

When did you do this?

Week 1	1	2	3	4	5	6	7	8	9	10	11	12
Monday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How did it go?

Set up of the sessions

One-on-one sessions

- You pick the sessions you want
- Pain Coach will work through each session with you
- The sessions are all listed in your workbook
- Purpose is to help you find new ways to manage your pain, or to find ways to improve on what you're already doing
- At the back of this book, there is a "Toolbox" and a "Homework" section. This is where you'll be keeping track of the best things you've learned, and how you're doing with your pain. You can share this section with your friends, family, and even your doctor/nurse to show them how well you're doing!

Group sessions:

- Led by Pain Pal like today; Pain Coach will also be there to help
- Talk about how things are going in the one-on-one sessions and what has been helpful
- Learn from each other
- Get input from the Pain Pal

Program Calendar

week one	week two	week three	week four	week five	week six
Group Introduction	One-on-one: Pain Education	Group	One-on-one	Group	One-on-one
week seven	**week eight**	**week nine**	**week ten**	**week 11**	**week 12**
Group	One-on-one	Group	One-on-one	Group	One-on-one

Program Logistics

Our group meetings will always be on ..... (day) at ..... (time) in ..... (location).

One of our staff will call you to set up one-on-one meetings and remind you of group meetings.

Ground Rules[*1]

1. *Confidentiality*
   - What you say is private!
   - We ask **you** not to talk about the people in this group to anyone.
   - Your group **leaders** will not talk about the people in this group to anyone.
   - But if you tell us you are planning to hurt yourself or someone else, we must take steps to keep you or others safe.
2. *Special jobs for group leaders*
   - Give you the latest information on pain.
   - Listen carefully to you.
   - Help you talk to others in your group about your pain.
   - Keep things on time. Keep things moving.

3. *Special jobs for group members*
- Take turns to speak and share experiences.
- Try not to get stuck on one topic.

During group sessions:
- Show up for every group session.
- Be active. Share the wisdom only you can offer!
- Share only what you are comfortable sharing.
- Use what you learn in the group at home.
- Share with the group your thoughts about what you are learning.

During one-on-one sessions:[*2]
- Show up to every session.
- Ask and share anything you want. If time is short, we may ask you to hold your questions for later.
- If it helps you, take notes.
- Make and complete weekly plans.
- Try new things you learn out at home and give them at least a one-week trial.

Between Sessions
- You can talk to each other.
- You can call your Pain Pal or Pain Coach anytime.

Discussion
What makes you excited about this program?
What if anything worries you about this program?
What are you hoping to get out of the program?

1. Adapted with permission from: Eyer,J., Thorn,B.E., Van Dyke, , B. Block, P., DeMonte, C., & DeMonte, W. Learning About Managing Pain Workbook, 2013
2. Adapted with permission from the manual used in: Bair MJ, Ang D, Wu J, Outcalt SD, Sargent C, Kempf C, Froman A, Schmid AA, Damush TM, Yu Z, Davis LW, Kroenke K. Evaluation of Stepped Care for Chronic Pain (ESCAPE) in Veterans of Iraq and Afghanistan Conflicts: A Randomized Trial. *JAMA Internal Medicine* 2015;175(5):682-689.

Thinking Differently About Your Pain

What tool are you adding to your toolbox this week?

What goal are you going to set this week

Homework

Your homework is to meet your goal this week.
How will you do this?

When did you do this?

Week 1	1	2	3	4	5	6	7	8	9	10	11	12
Monday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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Saturday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How did it go?

Sleeping Better to Help Your Pain

What tool are you adding to your toolbox this week?

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What goal are you going to set this week

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Homework

Your homework is to meet your goal this week.
How will you do this?

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When did you do this?

Week 1	1	2	3	4	5	6	7	8	9	10	11	12
Monday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How did it go?

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Group Session Two

Minute of mindfulness

This week's goals:

- Review one key topic about chronic pain.
- Talk about this week's one-on-one session.
- Check in on goals.

Review of Key Chronic Pain Topic

This week's key topic: Gate Control Theory of Pain

Key questions for discussion:

- What questions does the group have about this topic?
- How do you think this topic applies to your life?
- Can anyone share an example of how this topic applies to their life?
- Does anyone have any concerns or doubts about this topic?

Talk about this week's one-on-one session.

- How did it go?
- Which sessions did you pick and why?

Check in on goals

What goals did you set and why?

- Is there anything that you think will make it hard for you to reach your goals? Anything that you think will help? How can the group help?

Relaxation Skills to Help Your Pain

What tool are you adding to your toolbox this week?

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What goal are you going to set this week

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Homework

Your homework is to meet your goal this week.
How will you do this?

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When did you do this?

Week 1	1	2	3	4	5	6	7	8	9	10	11	12
Monday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How did it go?

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Stress Management and Your Pain

What tool are you adding to your toolbox this week?

What goal are you going to set this week

Homework

Your homework is to meet your goal this week.
How will you do this?

When did you do this?

Week 1	1	2	3	4	5	6	7	8	9	10	11	12
Monday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tuesday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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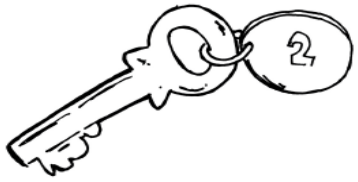
Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How did it go?



Group Session Three

Minute of mindfulness

This week's goals:

- Review one key topic about chronic pain.
- Talk about this week's one-on-one session.
- Check in on goals.

Review of Key Chronic Pain Topic

This week's key topic: .....

Key questions for discussion:

- What questions does the group have about this topic?
- How do you think this topic applies to your life?
  - Can anyone share an example of how this topic applies to their life?
- Does anyone have any concerns or doubts about this topic?

Talk about this week's one-on-one session.

- How did it go?
- How do you think you will apply what you learned?
- What do you think the group should know about what you learned in your session?

Check in on goals

How are you doing with your goals?

- Is there anything that you think will make it hard for you to reach your goals? Anything that you think will help? How can the group help?

How did it go?

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Losing Weight to Improve Your Pain

What tool are you adding to your toolbox this week?

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What goal are you going to set this week

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Homework

Your homework is to meet your goal this week. How will you do this?

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When did you do this?

Week 1	1	2	3	4	5	6	7	8	9	10	11	12
Monday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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Saturday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How did it go?

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Toolbox and Homework

Introduction to Your Chronic Pain

What tool are you adding to your toolbox this week?
Write down your key take-away from what you learned today.

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Physical Activity and Your Pain

What tool are you adding to your toolbox this week?

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What goal are you going to set this week

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Homework

Your homework is to meet your goal this week. How will you do this?

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When did you do this?

Week 1	1	2	3	4	5	6	7	8	9	10	11	12
Monday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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Saturday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Group Session Four

Minute of mindfulness

This week's goals:

- Review one key topic about chronic pain.
- Talk about this week's one-on-one session.
- Check in on goals.

Review of Key Chronic Pain Topic

This week's key topic: .....

Key questions for discussion:

- What questions does the group have about this topic?
- How do you think this topic applies to your life?
  - Can anyone share an example of how this topic applies to their life?
- Does anyone have any concerns or doubts about this topic?

Talk about this week's one-on-one session.

- How did it go?
- How do you think you will apply what you learned?
- What do you think the group should know about what you learned in your session?

Check in on goals

How are you doing with your goals?

- Is there anything that you think will make it hard for you to reach your goals? Anything that you think will help? How can the group help?

Other tips:

- Tell your doctor or nurse about all of your other medicines (including over-the-counter medicines and herbs)
- Only get opioid medicines from one doctor or nurse so that they don't accidentally prescribe you the wrong amount.
- Use one pharmacy to avoid problems or mix-ups.
- Take the medicines the way your doctor or nurse prescribes them

Using what you've learned in this program

When things get tough:

What else can she do instead?

1. .....
2. .....
3. .....
4. .....

Toolbox and Homework
Go to your toolbox and homework – p. 63

Group Session Five

Minute of mindfulness

This week's goals:

- Review one key topic about chronic pain.
- Talk about this week's one-on-one session.
- Check in on goals.

Review of Key Chronic Pain Topic

This week's key topic: .....

Key questions for discussion:

- What questions does the group have about this topic?
- How do you think this topic applies to your life?
  - Can anyone share an example of how this topic applies to their life?
- Does anyone have any concerns or doubts about this topic?

Talk about this week's one-on-one session.

- How did it go?
- How do you think you will apply what you learned?
- What do you think the group should know about what you learned in your session?

Check in on goals

How are you doing with your goals?

- Is there anything that you think will make it hard for you to reach your goals? Anything that you think will help? How can the group help?

It's a good idea to take opioids the way your doctor or nurse prescribes them. For example:

- If we take our medicines regularly, they can help us the same amount during the whole day.
- If we take our medicine early, then it will run out of our bodies at some point (maybe while we are trying to sleep)
- We may run out of our medicines before we can refill them and have several days where our body feels worse
- We may take too much too early and accidentally overdose.

There are medicines and treatments besides opioids for pain

Your doctor or nurse might prescribe other medications or treatments for your pain. Can you think of any?

1. ....
2. ....
3. ....

This is because as we learned, opioid pain medicines don't take pain away! Other treatments may also help block the pain signal in different ways. For example:

- some depression medications block pain signals like opioids do; they also improve your mood, which closes the gate
- medicines like gabapentin (Neurontin) or pregabalin (Lyrica) help relieve nerve pain
- other treatments like physical therapy and counseling close the gate

Which medicine or treatment above has helped, if any?

.....

What can we do to take opioids in the best possible way, so that they help the most and are as safe as possible?

Staying safe

Here are some tips to stay safe:

- How do you know how many pills to take every day? [always the way the doctor or nurse says]
- What about drinking alcohol? [best to avoid]
- What about non-prescription drugs (heroin, cocaine, meth)? [best to avoid]

But with long-term pain, things are different.

In our first session, we talked about how long-term pain is not just about worn out or hurt body parts.

In long-term pain, the opioids may sometimes block the pain signal in the spinal cord. But, sometimes they do other things that we don't want them to do.

For example:

- If we take them for a long time our bodies can adjust and the gate will open wider, allowing MORE pain to get through.
- Opioid "receptors" do more than just deal with pain; they are also receptors for mood, pleasure, and addiction.

This is why sometimes:

- Opioids help with pain, but they don't take it away
- Opioids can cause other problems with our mood or addiction

What the research shows about opioids

In the last few years, we've learned a lot about opioids. We've learned:

- Many people with long-term pain take opioids.
- Opioids do not take peoples' pain away.
- Opioids have risks we never knew about before. Even if you haven't had one of these things happen to you, it's good to know about them. They can happen at any dose.
  - "Overdose" (dying from the pain medicine)
  - Increased pain ("hyperalgesia")
  - Depression, anxiety
  - Addiction (to the opioid, to other things)

There are some things that increase the risk of serious problems:

- Taking opioids with some other medicines (like some anxiety or sleep medicines)
- High doses of opioids

Opioids can be tricky

Because opioids don't always work as well as you want them to, it might seem like you should take more. But, more is not always better.

There are many times in life when more is not better:

With opioids, taking more than prescribed can increase your risk of the problems we talked about before.

Group Session Six

Minute of mindfulness

This week's goals:

- Talk about this week's one-on-one session.
- Check in on goals.
- Life-long pain skills.

Talk about this week's one-on-one session.

- How did it go?
- How do you think you will apply what you learned?
- What do you think the group should know about what you learned in your session?

Check in on goals

How are you doing with your goals?

- Is there anything that you think will make it hard for you to reach your goals? Anything that you think will help? How can the group help?

Life-long pain skills

- What have you learned in this program that will help you take care of your pain?
- In chronic pain, "flare-ups" can happen. Some days are better, some days are worse. How will you deal with those bad days?

Taking Opioid Pain Medications

Weekly check-in:

- What questions do you have about the things you've learned so far?
- How are you using what's in your Toolbox to meet your goals?

In this session we will:

- Learn about opioid pain medications
- Come up with ways to take the medications so they will help you the most
- Decide which of these ways you want to try

Your pain medicines

Which medicines do you take for pain?

How long have you been on these medicines (or medicines like them)?

....

....

....

Today, we are going to focus on opioid pain medicines.

Why did you pick this section?

There are many reasons why people pick this section. Did you pick this section because:

1. You want to learn more about opioids
2. You feel like the medicines aren't working as well as you hoped they would
3. You want more medicine but your doctor or nurse said "no"
4. You've had other problems with your medicines (running out early, stolen medicine, side effects)
5. You think you may be addicted to the medicine
6. Another reason?

How do opioid pain medicines work?

Opioid medicines work by attaching to an opioid "receptor." In short-term pain, like pain caused by broken bones or after a surgery, opioids block the pain signal in your spinal cord.

Introduction to your chronic pain

In this session you will:

- Help your Pain Coach learn more about you and your chronic pain.
- Pick 5 sessions you will work on with the Pain Coach during the program.
- Learn some things about chronic pain that will help you with this program.

Introductions

Tell us more about you:

- How do you spend your days?
- What are your favorite ways to spend your time?
- From who or what do you get support?

Tell us more about your pain:

- Where do you have pain?
- How long have you had it?
- How does it affect your ability to do the things you like and need to do?
- What types of medications or other treatments do you use for your pain?

About the Pain Coach:

name ..... phone number .....

When to call the Pain Coach:

1. .....
2. .....
3. .....

The goal of this program is to help improve your pain so that you can do more of the things you want and need to do. Name three things you would like to do when your pain is better.

1. .....
2. .....
3. .....

We've told you a little bit about this program. What are three things that you think would make you want to complete the program?

1. .....
2. .....
3. .....

What are three things that might make it hard for you to complete the program?

1. .....
2. .....
3. .....

How to Stand Tall*[1]

- Say "No" when others ask you to do something you don't want to do.
  - It is not rude to protect your time and body.
- Plan what you want to say ahead of time.
- Use "I" statements
  - Tell the other person the problem simply.
  - Tell the other person what it is like for you when that problem happens.
  - Tell the other person what you want to change.
  - Say how this change will be better for you both.

  Come up with examples.

What are some situations where you can practice standing tall?

.....
.....
.....

Talking with Healthcare Providers

What can we do to make it easier to talk with our healthcare workers?

.....
.....
.....

Some ideas:

- Think ahead about what you want to get out of the visit
- Write down questions before your appointment
- Ask questions if you don't understand or don't agree
  - If you're having side effects, ask about other options you have

1. Used with permission from: Eyer,J., Thorn,B.E.,Van Dyke, , B. Block, P., DeMonte, C., & DeMonte, W. Learning About Managing Pain Workbook, 2013.

Talking with our Families, Friends, and Health Care Providers about Pain

Weekly check-in

- What questions do you have about the things you've learned so far?
- How are you using what's in your Toolbox to meet your goals?

In this session we will:

- Learn about types of communication with other people.
- Learn how to communicate better with others.

Talking about our Pain

Who do you talk with about your pain?

How has your pain changed the way you talk with others?

Ways of talking with others[*1]

There are 3 major ways of talking with other people.

Attack – We talk without showing respect for others.
"You are always messing the laundry up!"

Can you think of another example?

Retreat – We hold back how we really feel and don't share what we need.
"That sounds like a great idea" (Even if you do not agree)

Can you think of another example?

Stand Tall – We share our feelings and needs in a way that shows respect for others.
"I can see you are excited to go out, but I am tired today. Maybe we can go tomorrow?"

Can you think of another example?

Pick your sessions

Which 5 sessions would you like to pick to help you meet your goals?

- Physical activity and your pain ☐
- Losing weight to improve your pain ☐
- Stress Management and your pain ☐
- Relaxation skills for your pain ☐
- Sleeping better to help your pain ☐
- Thinking differently about your pain ☐
- Building self-worth ☐
- Talking with our family and friends about pain ☐
- Taking opiod pain medications ☐

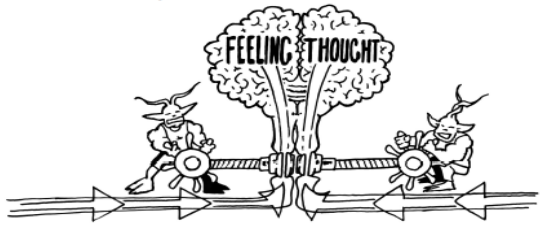
Learning more about chronic pain

Many people with chronic pain have not had a chance to talk to their doctor or nurse about what causes chronic pain, and what they can do about it. Many doctors and nurses want to help, but don't know much about chronic pain. You may know some of what we are going to tell you, and some of it may be new information.

A few important facts:

- We wish we had a pill or treatment to take your pain away.
- Your pain isn't your fault.
- We are here to help.
- We have faith in you, that you can use what you learn in this program to put the pain in the background of your life and do the things you want and need to do.
- Lots of things can make pain worse: trouble sleeping, depression, anxiety, stress, using drugs that aren't prescribed, lack of physical activity.
- Medications can be a part of someone's pain treatment plan, but there are lots of other things besides medications that can help too. Some of them are tools that address things that make pain worse. Many of them are covered in this program.

Gate Control Theory[*1]



- "Pain is in the Brain" — there is a lot of research that supports this idea.
- Your body sends signals to the brain.
- The brain reads these signals and makes you feel pain.
- BUT, it is not a one-way road!
- The brain can send signals back to your body.
- These brain signals open or close a gate that can make more pain or less pain in the body.
- It is actually a two-way street!

What make your pain worse?

What makes your pain better?

Close the Gate to Pain Signals[*1]

- An open gate – **more** pain signals to the brain!
  - Things that open the gate:
    - No physical activity (Sitting, not doing much)
    - Depression, anger, fear
    - Unhelpful thoughts
    - Even pain medicine opens the gate sometimes
      - When you take it for a long time **or**
      - When you take more than the doctor prescribes
- A closed gate – fewer pain signals to the brain!
  - Things that close the gate:
    - Being active without overdoing it
    - Pacing your activities
    - Feeling positive
    - Thinking positive (having hope!)
    - Pain medicine (sometimes)
      - When you take it for a short time and
      - When you use it the way the doctor says to

- These beliefs can also hurt us.
  - They can stop us from doing things to help ourselves
  - If "I am broken" is true then I should not be active.

How do your beliefs help you?

.....

.....

How do your beliefs hurt you?

.....

.....

Second, we can check to see if the belief is always true.

- We can look for any proof that our belief is not always true.
  - If I took the garbage out last week, then "I am broken" is not always true

What proof can you think of that your belief is not always true?

.....

.....

Third, we can try acting like the belief is not true.

- Ask yourself, what would you be doing differently if your belief was NOT true?
  - If "I am broken" were not true, I would wash the dishes and call my friends.
- Next try doing those activities even if it feels "fake" at first.
  - I will call my friends and wash half the dishes tonight.
- If we can do these activities we can start to prove to ourselves that our belief is not always true.

What would you do differently if your belief was NOT true?

.....

.....

.....

.....

Which of these things can I try this week?

.....

Finally, we can use positive statements to help remind us throughout the day.

- Find a phrase or statement that you find meaningful.
  - Some examples are "I am able to make it through the day," "I am well today," or "I am here for a reason: ......"
- Write this down on a small card or piece of paper.
- Place this card in your wallet or purse. Or you can place it anywhere that you'll see it every day. On a mirror or the dashboard of your car.

Chronic Pain and Emotions

Chronic pain can change the way you feel, which can cause other problems. Here are some ideas about how that might happen:

Scared/Worried

- Sometimes people with chronic pain become scared that they will injure themselves.
- Being scared of hurting can cause people to stop being physically active.

Sadness

- Sometimes people with chronic pain become sad about things they miss doing.
- Being sad can cause people to stop trying activities they used to enjoy.

Anger

- Sometimes people get angry about not being able to do things they think that they should be able to do.
- If we get too angry we might yell at the people around us.

Which of these emotions, if any, have you felt because of your pain?

.....

Short-Term Pain[*1]

- Something happened that caused the pain directly, like a fall or an accident.
- The pain happens at the place where the injury is. It hurts when you press on the injury. It hurts when you move the injured place on the body.
- The pain can be really bad, medium, mild or none at all.
- The pain goes away as the body heals. Cuts go away in 2 to 3 weeks. Broken bones heal in 3 to 4 months.

Chronic Pain[*1]

- Some people with chronic pain started out with short-term pain. They had an injury (like a broken back or other spine problem). Their injury was fixed but the pain stayed. Why?

  - Scar tissue from the injury or surgery may have formed
  - Arthritis may have come on
  - The brain may have changed and become more alert to smaller pain signals
- Chronic pain may come from an unknown cause.
- Chronic pain is not always a sign that there is an injury going on in your body.
- Chronic pain may be very bad, medium, or mild, and can change back and forth over time.
- Chronic pain is long term.
- Common medical treatments such as medicine and surgery do not always work well for pain.
- Pain "flare-ups" are a part of chronic pain. Some days your pain is better, some days your pain is worse. The things you learn in this program will help you deal with the bad days.

Homework

Every week you will be asked to do some homework.

Toolbox and Homework

Go to your toolbox – p. 55

1. Used with permission from: Eyer,J., Thorn,B.E.,Van Dyke, , B. Block, P., DeMonte, C., & DeMonte, W. Learning About Managing Pain Workbook, 2013.
2. Adapted with permission from the manual used in: Bair MJ, Ang D, Wu J, Outcalt SD, Sargent C, Kempf C, Froman A, Schmid AA, Damush TM, Yu Z, Davis LW, Kroenke K. Evaluation of Stepped Care for Chronic Pain (ESCAPE) in Veterans of Iraq and Afghanistan Conflicts: A Randomized Trial. *JAMA Internal Medicine* 2015;175(5):682-689.

Building Self-worth

Weekly check-in

- What questions do you have about the things you've learned so far?
- How are you using what's in your Toolbox to meet your goals?

In this session we will:

- Learn about how to build your self-worth.
- Figure out what unhelpful beliefs you are having.

Unhelpful Beliefs

- How we feel about ourselves usually depends on some deep beliefs we have about ourselves.
- Sometimes our deep beliefs about ourselves can be helpful.

What are some helpful beliefs you have that help you feel better?

.....

.....

Here are some other examples:

- Believing "I am capable" helps us feel better.
- But, sometimes our beliefs make us feel worse.
- These unhelpful beliefs can become stronger when we are stressed.

What are some unhelpful beliefs you've had before?

.....

.....

- Sometimes these beliefs are related to our pain.

What unhelpful beliefs have you had about your pain?

.....

.....

Here are some other examples:

- Believing "I am broken," can make us feel like we are worthless.
- Thinking "I did something wrong and I deserve this" can make us feel like the pain is your fault.

Working to change our unhelpful beliefs

There are three main ways we can work to change our unhelpful beliefs.

First, ask how is this Belief working for me and how is it working against me?

- These beliefs help us in some ways.
  - They can give us an excuse during stressful times.
  - If "I am broken" is true then I do not need to help my neighbor move.

Physical Activity and Your Pain

Weekly check-in

- What questions do you have about the things you've learned so far?
- How are you using what's in your Toolbox to meet your goals?

In this session we will:

- Learn about physical activity and how it relates to pain
- Think about your goals for physical activity, and decide how you will achieve these goals

What is physical activity?

According to the Centers for Disease Control, physical activity is "anything that gets your body moving."

Lots of things are physical activity. What are some examples?

1. .....
2. .....
3. .....

Here are some examples we thought of:*[1]

- Walking
- Doing chores
- Riding a bike
- Dancing
- Running
- Gardening
- Playing Sports
- Carrying Groceries
- Volunteering doing something you enjoy / helping others
- Washing your car
- Taking care of animals
- Exercises that use your body's weight (sit-ups, push-ups)

It's ok to do any of these for 10 minutes at a time! Doesn't need to be long!

Example 1

- Step one. My thought: "If I exercise, I'm going to hurt myself."
  - Main emotion: Fear
- Step two. Evidence:
  - True: I feel sore when I exercise.
  - Not True: Feeling sore is not the same thing as hurting myself.
- Step three. New thought: "If I go for a walk, I may feel sore later, but it will help me get stronger and manage my pain."
  - Emotion: I feel a little less afraid.

Example 2

- Step one. My thought: "I'm always going to hurt like this."
  - Main emotion: Anger
- Step two. Evidence:
  - True: I have had this chronic pain for years.
  - Not True: I'm learning ways to manage my pain better.
- Step three. New thought: "I may hurt some, but I'll have good days and bad days, and I know how to help myself cope better."
  - Emotion: I feel a little less angry.

Look out for Red Flag Words

- Red Flag Words are words that tell an "extreme."
- Words like always, never, every, no one, and all the time are Red Flag Words.
- Change the Red Flag Word to change these thoughts to something less extreme. Using "Some" or "sometimes" usually works.

Which of these two ways to work on unhelpful thoughts (Looking out for Red Flag Words and Challenging Unhelpful Thoughts), if either, do you think you can change this week?

1. Used with permission from: Eyer, J., Thorn, B.E., Van Dyke, , B. Block, P., DeMonte, C., & DeMonte, W. Learning About Managing Pain Workbook, 2013.

How have your thoughts made you feel?

How have they changed what you do?

- When we are stressed we can think of the worst possibility. This is called Catastrophizing.
- Sometimes we have unhelpful thoughts about our pain. Usually, our unhelpful thoughts lead to more unhelpful thoughts. These unhelpful thoughts can make us feel bad and change what we do.

What unhelpful thoughts have you had about your pain?

Here are some other examples:

- Thinking "I want to cut my ..... off," or "I can't get through the pain" can make it harder to take care of yourself.

How have your thoughts about pain made you feel?

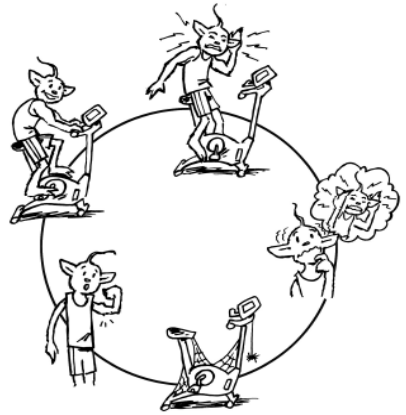
How have they changed what you do?

Working to change our Unhelpful Thoughts[*1]

There are two main ways we can work to change our unhelpful thoughts.

- Challenge unhelpful thoughts
  - Step one: First, figure out what unhelpful thoughts you are having and what emotion you are feeling.
  - Step two: Act like a jury for your thoughts
    - Ask yourself, "What is the evidence that this is true?"
    - Then ask yourself, "What is the evidence that it is not true?"
    - So, what do you decide?
  - Step three: Come up with a new thought that is more helpful than the original. Usually, these thoughts are more real and positive.
    - Example: "No one loves me!"
    - Corrected: "Some people may not like me, but some people love me."
    - Example: "I always screw everything up!"
    - Corrected: "I sometimes screw some things up."

Why does physical activity matter when it comes to pain?[*2]



- When we are in pain, we may be afraid of causing more pain from physical activity.
- It is natural to withdraw and become less active because of a new injury. This allows time for healing.
- When pain is chronic, a lack of physical activity makes our pain worse.

Can you think of some pros and cons of physical activity?

Pros:
1. .....
2. .....
3. .....

Cons:
1. .....
2. .....
3. .....

Here are some we thought of:

Pros of Physical Activity[*2]

- Helps make muscles strong.
- Strong muscles are like our shield and protect us
  - By holding our bones in place
  - By keeping us stable and balanced
  - Weak muscles mean more pain because the muscles cannot support the bones.

- Improves mood (closes gate)
- Improves sleep
- Helps to lose weight or keep weight healthy
- Helps with other medical problems
- May help distract from pain (closes gate)
- May give a sense of satisfaction and this can reduce the feeling of being overwhelmed by pain.
- Lack of physical activity may increase boredom, depression, and low self-esteem. Boredom, depression, and low self-esteem increase pain.

Cons of Physical Activity[*2]

- Can cause some soreness, especially at first
- If you overdo exercise, it can cause pain
- Can get you sweaty
- Can be hard to find the time

Question: how do you spend your days?

1. .....
2. .....
3. .....

If pain isn't a problem: What physical activities, if any, do you enjoy most?

1. .....
2. .....
3. .....

What physical activities, if any, do you do on a regular basis (weekly or more)?

1. .....
2. .....
3. .....

Goals

Are you open to setting goals for your physical activity?

If yes: (and pick things you enjoy!)

1. .....
2. .....
3. .....

How can you reach these goals?

1. .....
2. .....
3. .....

Thinking Differently about Your Pain

Weekly check-in

- What questions do you have about the things you've learned so far?
- How are you using what's in your Toolbox to meet your goals?

In this session we will:

- Learn about helpful and unhelpful thoughts we can have about pain.
- Figure out what unhelpful thoughts you are having about your pain, and decide whether and how to make changes to work on these thoughts.

Unhelpful Thoughts

- We have lots of thoughts throughout the day and they affect the way we feel and how we act!
- Sometimes our thoughts can help us feel better.

What are some helpful thoughts you've had before that help you feel better?

.....

.....

Here are some other examples:

- Thinking "I am ....." or thinking about things that you are looking forward to doing helps us feel better.
- But, sometimes our thoughts make us feel bad. These unhelpful thoughts happen more often when we are stressed.

What are some unhelpful thoughts you've had before?

.....

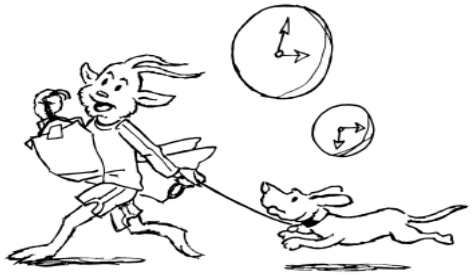
.....

- Unhelpful thoughts can make us feel bad, and do things we don't want to do..

Here are some tips to help you reach these goals:

Pacing

People with chronic pain have good days and bad days. On good days we might try to do too much in order to finish tasks that we did not do on other days. If we do too much, then we will have more pain later.



Pacing can help

1. Pick an activity that you overdo.
2. Pick a short amount of time to do the activity. (For example, 20 minutes)
3. When time is up, rest for a set amount of time. (For example, 5 minutes)
4. Most importantly, stick to the times you picked! Even if you feel like you can do more.

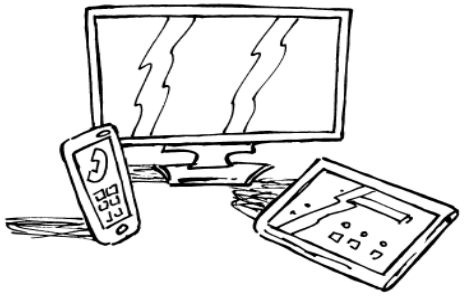
Sticking to a timer like this, will prevent us from overdoing or resting too much.

Toolbox and Homework
Go to your toolbox and homework – p. 55

1. Adapted from: http://www.cdc.gov/nccdphp/dnpa/physical/pdf/PA_Intensity_table_2_1.pdf
2. Used with permission from: Eyer,J., Thorn,B.E.,Van Dyke, , B. Block, P., DeMonte, C., & DeMonte, W. Learning About Managing Pain Workbook, 2013.

General ways of helping sleep issues*[1]

- Try to get up and go to bed at the same time every day.
- Try to stay up all day instead of taking naps
- Remove light from the bedroom (TVs, Phones, Tablets)
- Caffeine: what do like to drink?
  - Avoiding caffeine after noon can help sleep issues.
- Alcohol: how much do you drink?
  - Drinking alcohol can make you tired, but the sleep is not as restful for your body. Avoiding alcohol can make sleeping easier.
- Exercise during the day can make it easier to sleep at night.
- Changing your current medications, if they are causing the problem, can help with sleep issues.
- Sometimes, other medical treatments can help with sleep. For example, if you have "sleep apnea," getting this treated can help a lot with sleep. Sometimes medications prescribed by your doctor can help with sleep.



Which of these, if any, do you think you can change this week?

Toolbox and Homework
Go to your toolbox and homework – p. 59

1. Adapted with permission from the manual used in: Bair MJ, Ang D, Wu J, Outcalt SD, Sargent C, Kempf C, Froman A, Schmid AA, Damush TM, Yu Z, Davis LW, Kroenke K. Evaluation of Stepped Care for Chronic Pain (ESCAPE) in Veterans of Iraq and Afghanistan Conflicts: A Randomized Trial. *JAMA Internal Medicine* 2015;175(5):682-689.

Sleeping Better to Help Your Pain

Weekly check-in

- What questions do you have about the things you've learned so far?
- How are you using what's in your Toolbox to meet your goals?

In this session we will:

- Learn about what makes it easier and harder for us to sleep well.
- Figure out which of these things, if any, apply to you, and decide whether to make changes that could help your sleep.

Sleep is Important

Pain can make it harder to sleep, and sleep can make pain harder to deal with.

Good sleep helps us:

- Think clearer.
- Be happier or calmer.
- Heal our bodies.
- Have more energy.
- Deal with our pain better.

In what ways could your sleep be better?

What types of things do you do to make your sleep better?

Relationship between sleep and pain

- Poor sleep can make pain worse the next day by opening the gate and letting in more pain signals.
- When we have flare ups it can make it harder to fall asleep or wake up.
- Being tired makes it harder to take care of ourselves and do the activities that help manage our pain.

Things that can hurt sleep

- Napping during the day.
- Bright lights in the bedroom.
- Noisy bedrooms. (TV, Music, etc)
- Staying in bed if you are not tired. (Get up and do something that is not too exciting).
- Different medications can cause sleep problems. It is important to check the side-effects and talk to your doctor.

Which of these, if any, do you do?

Losing Weight to Improve your Pain

Weekly check-in

- What questions do you have about the things you've learned so far?
- How are you using what's in your Toolbox to meet your goals?

In this session we will:

- Learn about your weight loss picture and how it relates to your pain
- Come up with changes you could make to help you lose weight
- Decide which changes, if any, you will make

Weight loss on pain

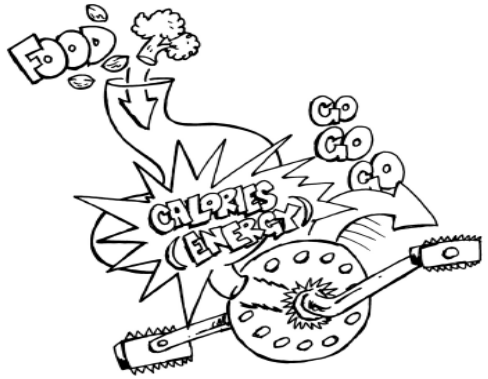
Extra weight puts stress on your body, like carrying around a heavy backpack that you cannot take off.

This can make your pain worse; losing weight can make pain better. Losing weight also makes it easier to be active, which can help make your pain better.

Your weight loss picture

You may have heard lots of different things about what might help you lose weight. This can get confusing, and it may be hard to know what YOU can do.

We can come up with a weight loss picture just for you.



Let's keep it simple. "Calories" come from food, and give us energy.

Whether our weight goes up, down, or stays the same has to do with how many calories come into our bodies and how many calories go out.

Losing Weight to Improve Your Pain

In:

Food and drinks

What do you typically like to eat and drink?

Breakfast .....
Lunch .....
Dinner .....
Snack .....

Out:

Physical activity

What do you do in a day?

.....
.....
.....

Resting

We gain weight when we take in more calories than go out. If we want to lose weight, we have to make more calories go out than we take in.

Chronic pain can sometimes make peoples' weight loss pictures go way out of balance. How does chronic pain affect your weight loss picture?

1. .....
2. .....
3. .....

Here are some examples of how chronic pain might affect your weight loss picture:

- makes us less likely to be active
- makes us more likely to snack when we don't mean to:
  - we might wake up at night with pain and snack
  - we might snack to take our minds off our pain

Special Place (Visualization)

1. One way to distract ourselves from our current situation is to practice going to our special place in our mind.
2. Pick a place that is safe and calming for you. It can be real or imaginary. Some people like a private island.
3. Imagine what you will notice with each of your senses. (See, Hear, Touch, Smell, Taste.)
4. Practice using each of your senses to make your special place seem real.

How was that for you?

Mindfulness

Our attention is like a spotlight. Sometimes our pain can demand that spotlight and we forget to pay attention to other things that are happening around us. Also, we can get caught up thinking about the future or past.

Practice mindfulness meditation by focusing on your breathing. Your breathing is always happening in the present moment. Eventually, you can practice paying attention to what thoughts are in your head. Just notice where your attention goes without being judgmental towards it.

Practice

How was that for you?

Which of these relaxation techniques (Deep Breathing, Progressive Muscle Relaxation, Visualization, or Mindfulness) do you think you can practice this week?

Toolbox and Homework
Go to your toolbox and homework – p. 58

How to change how we eat

Here are two of the best ways to change how we eat:

- We can track what we eat. If we write down everything that we eat, usually we will start to change how we eat. At least you will know what foods you can cut back on.

Be specific!

NOT: "Chicken Dinner"

YES: "2 chicken breasts, 1 scoop mashed potatoes, 1 soda"

- Slow down how we eat. One way is called Mindful Eating. This means slowing down and paying attention to our food. This helps us notice when we are full sooner.

1. Take a bite like you normally would.
2. How long did that take?
3. Pick up another bite, but don't eat it.
4. Notice the color, texture, smell, and shape.
5. Now put it in your mouth but do not swallow or chew
6. Notice the feel and flavor.
7. Now chew slowly.
8. Swallow

How was that different than eating normally?

Toolbox and Homework
Go to your toolbox and homework – p. 56

Relaxation Skills to Help Your Pain

Weekly check-in

- What questions do you have about the things you've learned so far?
- How are you using what's in your Toolbox to meet your goals?

In this session we will:

- Learn about the relaxation response and how it helps reduce pain.
- Try several types of relaxation and pick one to practice at home.

Relaxation and Pain

- We usually tense our muscles when we are stressed. Sometimes this can increase our pain. If we can relax our muscles we can reduce our pain.
- These techniques can also help distract us from our pain.
- We can train our attention so that we do not focus as much on our pain.

Deep Breathing

Breathing with our belly is easier for our body. Since it takes less work it is more calming. Also, breathing slower helps calm us down.

To practice breathing with your belly put one hand on your belly and one hand on your chest. Try only moving the hand on your belly when you breathe.

To practice breathing slower, try breathing in to the count of 4 and out to the count of 6. About 10 seconds for a full breath.

Now practice this new way of breathing for 2 minutes.

How was that for you?

Progressive Muscle Relaxation

An easy way to practice relaxing your muscles is to tighten them first. It makes it easier to practice relaxing them and noticing what it feels like to let go of tension.

Practice Progressive Muscle Relaxation

· Feel free to not tense any areas that are already painful. Just observe them.

How was that for you?

Stress Management and Your Pain

Weekly check-in

- What questions do you have about the things you've learned so far?
- How are you using what's in your Toolbox to meet your goals?

In this session we will:

- Learn about stress and how it affects us
- Learn about how stress and pain are related
- Learn how to manage your stress to manage your pain
- Figure out which of these things would work best for you, and decide whether to make changes that could reduce your stress and help your pain.

Introduction to Stress*[1]

What makes you stressed?

What happens to you when you are stressed?

What is stress?

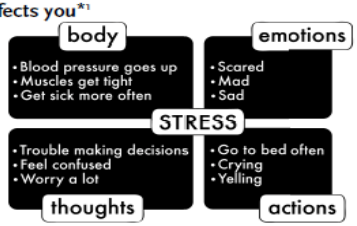
Stress is a response to problems in life. Stress can come from good problems or bad problems.

Good problems like children or grandchildren, or planning for a family or holiday gathering.

Bad problems like bills or pain.

When we have stress, it affects us in lots of ways. That's called the "stress response."

How stress affects you*[1]



Your experience with stress

- Think about a stressful experience you have had. What have you done to get past it?

Stress and Pain

How does stress make our pain worse?

Stress makes us tighten our muscles.

Stress opens the gate wider letting in more pain signals.

When you're stressed what do you notice about your pain?

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Managing Stress[*2]

Is there anything from your past experience you can use to help you with your pain?

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Here are a few MORE ideas for managing your stress:

- Relaxation Techniques
  - Breathing with your belly instead of your chest is easier for your body.
  - Taking slow breaths with your belly can help relax your muscles.

- Self-care (taking time for yourself, instead of for others)
  - Do you feel like you are asked to do too much?
  - Practice saying "No" to others requests. It is not selfish.
  - Practice standing up for yourself. Explain politely that you cannot do too much today.
  - Can you give an example of how this applies to you?

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- Enjoyable Activities

  - We usually stop doing things we enjoy when we have pain.
  - What have you stopped doing that you enjoyed because of pain?

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We can sometimes make changes to these activities so we can still do them, or something similar. What could you do instead of ..... ?

- Good sleep (see chapter)

- Thinking differently about your pain (see chapter)

1. Used with permission from: Eyer,J., Thorn,B.E.,Van Dyke, , B. Block, P., DeMonte, C., & DeMonte, W. Learning About Managing Pain Workbook, 2013
2. Adapted with permission from the manual used in: Bair MJ, Ang D, Wu J, Outcalt SD, Sargent C, Kempf C, Froman A, Schmid AA, Damush TM, Yu Z, Davis LW, Kroenke K. Evaluation of Stepped Care for Chronic Pain (ESCAPE) in Veterans of Iraq and Afghanistan Conflicts: A Randomized Trial. *JAMA Internal Medicine* 2015;175(5):682-689.