A Virtual Reality Intervention for Fear of Movement for Veterans with Chronic Pain: Protocol for A Pilot Trial

Christopher A Fowler, PhD*, Lisa M Goff, MSPTa, Kerry E Allen, DPTb, Aaron M Martin, PhDb, Howard Kaplan, MEdc, Kevin E Kip, PhDd, Jennifer L Murphy, PhDb, & Sandra L Winkler, PHD, OTR/La

*Corresponding Author:  Center of Innovation on Disability and Rehabilitation Research, Health Services Research & Development, Department of Veterans Affairs, 8900 Grand Oak Circle, Tampa, FL 33705 E-mail: christopher.fowler3@va.gov, phone 813-558-3904
Abstract

Background: A key concern for people with chronic pain is experiencing increased pain and/or re-injury. Consequently, individuals with chronic pain can develop a maladaptive fear of movement that leads to adverse functional consequences. A primary goal of chronic pain rehabilitation is re-engagement in feared movements through exposure. This is often challenging since safe movement can be uncomfortable. Virtual environments provide a promising opportunity to safely and gradually expose Veterans to movements that are avoided in the real world. The current study will utilize multiple virtual reality (VR) applications (APPs) of varying the intensity levels ranging from passive distraction from pain to active exposure to feared movement. The primary aims of this pilot are to examine VR as an adjunctive nonpharmacological intervention to assist with the adoption and implementation of skills to decrease fear of movement and increase overall functioning among Veterans with chronic pain. The second aim is to validate a hierarchy of VR Apps to assist in gradual exposure to feared movements.

Methods: This study will be conducted in the Chronic Pain Rehabilitation Program (CPRP) at the James A. Haley Veterans Hospital, a unique inpatient program within the VA system. Participants will include up to 20 Veterans who receive a VR intervention as part of their physical therapy. Intake and discharge measures of pain and functional outcomes will be compared to a historical matched control group comprised from Veterans who previously completed the CPRP. A rating form containing qualitative and quantitative experiences will be administered following each VR session to assess feasibility and to validate the hierarchy.

Discussion: This pilot study will inform the feasibility of a multisite randomized controlled trial examining the clinical utility of using VR to reduce fear of movement and increase function.
among Veterans with chronic pain. VR has the advantage of being easily implemented both within VA healthcare settings as well as in Veterans’ own residences, where engagement in ongoing self-management approaches is often most challenging. Presumably, VR that is matched to patient functioning, progresses in intensity, immerses Veterans in the applications, and is perceived positively by Veterans, will result in positive functional outcomes.

Keywords: Chronic Pain, Virtual Reality, Veterans, Rehabilitation, Fear of Movement, Kinesiophobia, Exposure Therapy, Distraction Therapy, Oculus Rift, Hierarchy
Introduction

Pain is among the most costly disorders treated in VA settings [1]. Over five million Veterans were diagnosed with at least one musculoskeletal disorder from 2001-2011, nearly half of whom reported moderate-to-severe pain [2]. While the treatment of pain was established as a VA priority in 1998 [3], in recent years pain management has received more attention due to national concerns regarding opioid overdose and addiction, and high-profile adverse events.

Given these concerns, the Centers for Disease Control and Prevention (CDC) [4] and other national organizations [5] have recommended non-pharmacological approaches as the preferred treatments for chronic pain, defined as pain persisting longer than three months [6]. A key concern for those with chronic pain is experiencing increased pain or injury [7]. As a result, individuals often develop kinesiophobia, a fear of movement that while helpful in acute pain, is maladaptive in chronic pain and leads to adverse functional consequences [7]. Hence, a primary goal of chronic pain rehabilitation is re-engagement in feared movements through exposure; however, this is often challenging since safe movement can be uncomfortable [8].

Virtual Reality

Today’s virtual technologies, such as the technology that will be used for the proposed project, use the computer and wearable devices, specifically, a head-mounted display with built-in sound receivers and head tracking systems and integrated hand and finger-tracking controllers [9]. These devices give the user the illusion of being immersed [10], or present in a non-physical world [11]. Virtual reality (VR) can serve as an adjunctive non-pharmacological intervention to assist with the adoption and implementation of skills to decrease fear of movement and increase overall functioning. Furthermore, the addition of VR to evidence-based treatment modalities can aid in the incorporation of self-management techniques associated with lifestyle changes to
optimize lifelong pain-related outcomes. Presumably, VR that is matched to patient level of functioning, progresses in intensity, immerses Veterans in the applications, and is perceived positively, will result in positive functional outcomes.

**Virtual Reality and Pain Management**

Evidence supports the use of VR to attenuate acute and chronic pain; however, the majority of the evidence to date is for treating acute pain or pain persisting less than three months [6]. A rapid evidence assessment of immersive VR for acute pain management (17 studies, 337 patients) found strong evidence for immediate and short-term pain reduction and moderate evidence for short-term effects on physical function [11]. Compared with standard analgesic treatment (i.e. opioids or benzodiazepine) for burn patients, addition of VR distraction resulted in significant reductions in pain intensity (20% reduction), pain unpleasantness (26% reduction), and time spent thinking about pain (37% reduction) [12]. For acute pain, studies suggest that the combination of VR and opioid analgesics may reduce pain-related neural activity, as measured by functional magnetic resonance imaging (fMRI), compared with either treatment condition alone [13]. Not surprisingly, distraction-focused treatments are the most commonly utilized VR interventions for acute pain relief [14]. Still, it has been argued that distraction from pain-related thoughts and emotions promotes avoidance of psychological factors that contribute to the maintenance of chronic pain (e.g., fear of movement) [15]. This can undermine the effectiveness of distraction-only VR therapies among chronic pain populations who have greater need for rehabilitation than immediate relief [15, 16]. To address this consideration, we have conceptualized a two-dimensional hierarchy ranging from ‘passive’ pain distraction to more ‘active’ graded-exposure techniques within the same VR-assisted intervention. The proposed is the first known study that will investigate the use of
Virtual Reality-Assisted Distraction and Exposure Therapy

The current study seeks to extend VR pain research from acute to chronic pain treatment. Distraction and exposure interventions are important components of psychological treatments for improving chronic pain and functional outcomes [8]. Previous VR interventions have focused on both distraction and exposure methods, but not their combination. Discussion of distraction and exposure interventions is important to understanding the rationale of building a two-dimensional hierarchy of degree of movement and intensity of stimulation for people with chronic pain (e.g., sitting passively in a chair experiencing guided meditation to standing and using body movement to participate in virtual activities such as painting). Veterans will validate our proposed VR intensity hierarchy so that once this intervention is implemented at the community level, a guide is available so that Veterans are not over or under exposed.

Distraction therapy is based on the assumption that humans have finite attentional resources; VR distraction consumes some of those resources leaving less cognitive capacity for processing pain and subsequent fear of movement [15, 17]. Distraction methods (guided imagery, relaxation training, pleasant activities, enhanced attention) are components of cognitive-behavioral therapy (CBT) protocols for chronic pain, [16] including the manualized CBT protocol for chronic pain [8] used throughout the VA. VR distraction has also been associated with a reduction in chronic pain in patients with fibromyalgia [18] and neuropathy [19]. Furthermore, a recent controlled trial conducted in an inpatient acute pain care setting demonstrated reduced pain scores among patients playing a ‘medium-intensity’ pain distraction VR applications (APPs) compared to a high-definition nature video [20]. This study primarily
focused on acute pain and only utilized a single APP without varying intensity. The current
intervention period will begin with pleasant, relaxing distraction APPs where no movement is
required. At the beginning of each session, patients will indicate whether they want to progress
to more intense stimulation, i.e., beginning with distraction and progressing to exposure-based
VR experiences, e.g., exposure therapy.

In contrast to distraction therapy, exposure therapy focuses attention on the fearful
stimulus and inducing a feeling of “being there” [21, 22]. To be effective, exposure therapies
should be graded, motivating, and related to real-life functional activities [23, 24]. Virtual
environments provide a cost-effective unique opportunity to match the exposure to the needs of
the patient [15]. Parsons and Trost [15, 23] developed software that allows clinicians to adapt the
content of pre-designed virtual environments to the specific clinical or experimental needs.
Similarly, Springer et al. [25] used avatars performing tasks to create a hierarchy of fearful
stimuli for low back pain patients. Graded stimuli were also used in a study using virtual world
immersion to treat fear of falling [26] where virtual walking difficulty was graded as follows:
Level 1: ground was level with little variation, e.g., walking on a sidewalk; Level 2: a narrow
space for walking, e.g., a corridor, a high step; Level 3: uneven ground scattered with rocks;
Level 4: steep flights of stairs. Significant improvement in fear of falling and anxiety was
reported in the experimental group compared to a (wait listed) control group. VR exposure
therapy has led to improvement in anxiety disorders [27], phantom limb [28] and chronic pain
associated with amputation(s) [28], spinal cord injury related neuropathy [19], and chronic low
back and neck pain [29, 30]. In these studies, participants performed clinically-relevant
movements to complete goal-directed games and activities. Acceptability ratings were high for a
feasibility and safety study of a virtual dodgeball intervention to influence spine flexion for
patients with chronic low back pain and pain-related fear; participants indicated that they would play the virtual game at home if it were available [31]. No virtual game group participants withdrew from the study and no adverse events were reported. These findings paired with the acceptability of VR and lack of adverse events demonstrate promise for using VR as a modality for reducing fear of movement among people with chronic pain conditions.

**Fear-Avoidance Model for Chronic Pain**

The proposed project is informed by the Fear-Avoidance Theoretical Model [7, 32] that conceptualizes fear as the key emotional component of avoidant behavior patterns: an individual’s fear is based upon the erroneous belief that pain signals physical damage, and thus any activity that exacerbates pain should be avoided [33]. Avoidance promotes a self-perpetuating cycle of physical deconditioning, social withdrawal, and ultimately functional disability [33, 34]. The proposed project is based on the assumption that as patients gradually confront feared activities, e.g., through VR, maladaptive pain beliefs are challenged and fear responses are extinguished [23, 34]. A systematic review found that for patients with low back pain, high fear-avoidance behaviors were associated with more pain/disability than patients with low fear-avoidance behaviors; addressing fear-avoidance behaviors reduced both pain and disability [35]. Hence, fear of pain and its subsequent response may have greater impact on disability than pain itself.

“Fear of movement” is a more specific fear that physical activity will cause (re)injury and can lead patients to avoid movement and become fearful of daily activities [16, 36]. Two studies have investigated the use of VR for patients with chronic pain. One, a feasibility study, suggested that a virtual dodgeball intervention [31] encouraged participants with high fear to alter their tendency to avoid movement and engage in the movement needed to successfully play the game despite possible pain. The second [37] found that integrating virtual walking into physical
therapy resulted in a significant decrease in fear of movement when compared to physical
therapy without virtual walking. The proposed effort is the first known study that will
investigate the use of immersive VR across the distraction to exposure spectrum as an adjunct
strategy for chronic pain management in a sample of US Veterans.

Aims and Objective

The objective of this pilot study is to investigate the feasibility of implementing two VR
modalities within the VA inpatient Chronic Pain Rehabilitation Program (CPRP). The primary
aims are: (1) To validate a hierarchy of VR APPs in terms of movement intensity to guide
recommendations for matching the technology to patient level of functioning; (2) estimate effect
size of the use of VR Apps; and (3) assess feasibility associated with the VR intervention to plan
for a future multi-site trial. Protocol feasibility outcomes will include Veteran recruitment and
retention, VR experiences, and barriers to protocol implementation. Patient-centered outcomes
will examine the impact of VR on fear of movement, pain-related functional outcomes (e.g., pain
catastrophizing), and functional movements (e.g., walking distance).

Methods

Intervention

Veterans will participate in a VR intervention aimed to alleviate fear of movement
associated with chronic pain. The VR intervention will consist of 12 commercially-available
APPs (six per VR modality; two per intensity level) selected by investigators that could
potentially reduce fear of movement. Low intensity APPs require minimal movement (passive).
Moderate intensity APPs include more active activities including exploring virtual environments and
controlling air or watercraft. High intensity APPs will require participants to use greater range of
bodily motion including painting on 3D canvases or rhythm-based activities (similar to the video game ‘Rock Band’) [38]. In order to validate a hierarchy of VR APPs for matching the technology to patient need, comparable APPs were chosen for two VR modalities, Oculus Rift VR [50] and Samsung Oculus Gear VR [51]. The APPs are matched based on two dimensions: Movement Intensity (low, moderate, high), and Veteran Position (seated, standing). Movement intensity includes the level of movement required to meet the demands of the APP. While previous studies have emphasized intensity [20], it is important to consider whether the participant uses the VR technology in a seated vs. a standing position because this may impact the intensity of the required movement. The APPs utilized in this pilot study are presented in Table 1.

Table 1

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<tr>
<th>Intensity</th>
<th>VR Platform</th>
<th>Oculus Rift</th>
<th>Samsung Oculus Gear VR</th>
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<td>2.) Rest VR: Rest &amp; Meditate [45]</td>
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<td>4.) The Grand Canyon VR Experience [42]</td>
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<td>6.) The Show Must Go On [44]</td>
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As mentioned above, the intervention will be delivered via using two VR devices: Oculus Rift VR [50] and Samsung Oculus Gear VR headset [51]. Oculus Rift is a commercially available VR head-mounted display (HMD) with two hand-operated controllers which can be used with commercial computers with appropriate processing and graphics capabilities [9, 50].
The HMD detects head movement and the controllers detect movements for each hand via 3-D inertial sensor technology [9]. While the Oculus Rift was initially designed as a gaming platform, several case and pilot studies have examined its feasibility for research and treatment of acute and chronic pain, psychological, and movement-based disorders [52-55]. The Samsung Oculus Gear VR headset is another commercially available unit designed for use with the Samsung Galaxy Series smartphones (i.e., series S6 to S8). The headset projects VR images which in addition to sound are provided by the smartphone. The Samsung Oculus Gear VR headset has also been utilized in previous research for acute pain management among hospitalized patients [20]. The Samsung Oculus Gear VR offers advantages over higher-end HMD units such as Oculus Rift including reduced cost and greater mobility because the headset is not tethered to a computer. However, the Samsung Oculus Gear VR headset has less powerful and complex graphical capabilities when compared to the Oculus Rift HMD. Both the Oculus Rift (MSRP $399.99) and Samsung Oculus Gear VR (MSRP $129.99) are relatively inexpensive compared to previous VR HMD’s which cost in the thousands of dollars [9]. Figure 1 presents photos of research team members using the Oculus Rift and Samsung Oculus Gear VR (used with written permission).
Study Setting

The CPRP at the James A. Haley Veterans Hospital is a 19-day residential chronic pain treatment program. The interdisciplinary treatment provided in the CPRP utilizes a cognitive-behavioral treatment approach that targets the physical and psychological impact of chronic pain. This intensive inpatient setting provides 6-8 hours of supervised therapeutic programming daily in addition to 2-3 hours of independent, goal-directed therapy assignments (e.g., practicing relaxation techniques, walking and exercise program participation). Treatment modalities provided in the CPRP include graduated physical therapy, aquatic therapy, occupational therapy, paced walking program, relaxation training, individual psychotherapy, group psychoeducation, and family interventions. Weekend treatment activities include social and recreational activities as well as walking, exercise, and relaxation sessions twice per day. For a more detailed review...
of the program, see Murphy et al [56, 57]. This inpatient environment was chosen in part to reduce risk for adverse outcomes associated with VR use in this population (e.g., balance issues).

**Participants and Recruitment**

During admission to the CPRP, the clinical staff will explain the study to potential participants. Veterans are admitted to and discharged from the CPRP on a weekly basis. Each week four Veterans graduate from the program and are subsequently discharged from CPRP care. Concurrently, up to four new Veterans are admitted into the CPRP weekly. Typical CPRP enrollment includes 12 Veterans at a given time. For the pilot study, all Veterans ($N \leq 20$) enrolled in the CPRP over the 3-week data collection period will be recruited. Interested individuals will be consented in-person by the research staff. A historically-matched control group will comprise up to 20 Veterans that previously completed the CPRP. This data will be pulled from the VA electronic medical record.

The CPRP is the sole inpatient chronic pain program within the VA system, and its attendees are Veterans referred system wide. Demographic characteristics from two previous studies examining a cohort of Veterans ($N=705$) admitted to the CPRP from August 2006 through April 2011 indicated that CPRP attendees were typically around 50 years old, have an average pain duration of roughly 13 years, primarily experience back pain ($>50\%$), are prominently male ($>75\%$), Caucasian ($>60\%$), on disability or retired ($>70\%$), slightly more likely to be married ($\geq 55\%$), less likely to be prescribed opioids daily ($\leq 40\%$), and experience ‘moderate’ relief from opioid therapy [56, 57]. Furthermore, 105 Veterans (roughly 15%) did not complete the CPRP over this period secondary to early discharge for non-compliance ($N=78$) and medical or family emergencies ($N=27$). Consistent with the VA mission to reduce high-dose opioid use, all new
CPRP attendees must agree to begin an opioid taper upon admission to the program when applicable.

**Confidentiality**

Several steps will be taken to secure participant confidentiality. First, any contact information from interested Veterans will be sent from CPRP staff to the research team via VA-encrypted e-mail. Second, electronic data files will be saved only on a secured VA server behind the VA firewall. Third, informed consents will be stored in locked filing cabinets in the project manager’s office. Finally, all raw data will be stored separately in a locked filing cabinet in the principal investigators office.

**Design**

This pilot study will utilize a pretest-posttest quasi-experimental design with a matched historical control group. The VR intervention will be implemented as a standard part of CPRP physical therapy (PT) sessions. For each PT session, participants will be assigned to use one of two VR modalities (Oculus Rift, Gear VR). VR assignments will be balanced secondary to equipment availability. Specifically, participants will participate in two sessions of Gear VR for each session of Oculus Rift use. The historical matched control group will consist of Veterans who have completed the JAHVH inpatient chronic pain program prior to the pilot trial. The match will be based on similarities in age, gender, and baseline fear of movement with the intervention group. We selected the historical control design rather than randomization because the duration of the inpatient program is only 19 days, patients are admitted on a rolling basis, and it is not feasible or ethical to deny half of the patients this treatment opportunity.

**Measures**
Measures of feasibility, functional outcomes, and chronic pain were chosen for the pilot study. Functional and pain measures were chosen based on their psychometric properties and relevance to chronic pain populations. All pain and functional measures are available in the public domain. The daily rating form (see below) is available from the authors upon request.

**Feasibility Measures**

1.) **Daily Rating Form**

Each day following VR use, participants will complete a daily rating form. The daily rating form will ask participants questions regarding their VR experiences including a single-item assessing ‘Cybersickness’ [58], their level of ‘Immersion’ in the VR experience [59], and the length of their VR experience. Participants will also be given the opportunity to provide any additional information about their VR utilization experience via three open-ended question, i.e., likes, dislikes, symptoms, and additional comments. This information will be utilized to gain a better understanding of potential barriers and facilitators of using VR within this population as well as the establishment of the APP hierarchy. The research team will use the daily rating form to record which VR modality and APPs the Veteran selects during their VR session, whether they participate in a seated or standing position, and additional information regarding implementation and feasibility.

**Functional Outcome Measures**

1.) **2-Minute Walk Test**

The 2-Minute Walk Test (2MWT) [60] is a measure of how far participants can walk during a 2-minute interval. The 2MWT is administered in an area free of obstacles. Participants will be instructed to walk as far as possible during the timed period. A measuring wheel will be utilized to assess total meters walked. Walking tests have demonstrated good test-retest
reliability ($ICC=.87$) and convergent validity with other gait measures among people with chronic pain [61].

2.) **Five Time Sit to Stand Test**

The Five Time Sit to Stand Test (FTSST) [62] has been utilized to quantify change in multiple factors including disability [63] and functional deficits in activities in daily living (ADLs) [64]. This task will instruct participants to cross their arms at their chest, stand from a seated position (44 cm chair), and sit back down as quickly as possible for five repetitions without using their arms. The clinician will record the time in seconds the participant requires to complete this task. Improvements in FTSST times have been demonstrated at post-treatment, six-month, and 12-month follow-ups among persons with chronic low back pain following PT and graded exposure therapies [65].

3.) **Fear of Daily Activities Questionnaire**

The Fear of Daily Activities Questionnaire (FDAQ) [66] is a self-report measure designed to assess specific feared activities for people with chronic pain. It was developed to adequately assess hypotheses consistent with the Fear-Avoidance Model for chronic pain [66]. All 10-items are measured using a 100-point numeric rating scale ranging from 0 (*no fear*) to 100 (*maximal fear*). The FDAQ can be averaged and utilized as a full-scale with items reflecting upright and seated posture as well as spinal movement. The full-scale FDAQ has demonstrated good internal (Cronbach’s $\alpha=.91$) and test-retest reliability ($ICC=.90$) as well as strong concurrent validity with disability ($r=.70$) and moderate concurrent validity at baseline with other pain measures to be used in this study, e.g., Pain Catastrophizing Scale ($r=.52$) and the Numeric Rating Scales ($r=.34$) [66, 67]. The FDAQ has shown also shown concurrent validity.
366and sensitivity to change with reductions in disability ($r=.49$) and pain catastrophizing ($r=.35$) at
367four-week follow-up following graded-exposure physical therapy [66, 67].

3684. Patient Specific Functional Scale

369The Patient Specific Function Scale (PSFS) [68] can be tailored to the individual’s health-related functioning. Participants are asked to self-select three-to-five activities that cause great difficulty or they can no longer engage in secondary to a specific health condition. They are then asked to rate the difficulty of these activities on an 11-point scale anchored by 0 (unable to perform) and 10 (able to perform at prior level). A score is obtained by averaging activities. For interpretation consistency, the PSFS will be reverse-scored so that higher scores indicate worse outcomes. The PSFS has demonstrated good test-test reliability ($ICC=.82$) and sensitivity to change among people with chronic neck pain [69]. Furthermore, the PSFS has shown good test-retest reliability among people with acute low back pain ($ICC=.91-.97$) [70]. This scale has also demonstrated convergent validity with disability ($r=.55-.74$) and health-related quality of life role functioning ($r=.44$), physical functioning ($r=.30$), and bodily pain ($r=.34$) [70].

380Pain Measures

3811. Pain Outcomes Questionnaire-VA

382The Intake and Discharge Questionnaires from the Pain Outcomes Questionnaire-VA (POQ-VA) [71] will be utilized to assess pain-related treatment outcomes. This comprehensive multidimensional instrument was developed and validated specifically for Veteran populations. The Intake Questionnaire contains: 19 ‘primary items’ that measure pain treatment outcomes across six prominent pain-related domains including pain intensity, pain-related fear (e.g., kinesiophobia), interference with mobility, interference with ADLs, vitality (e.g., strength, endurance), and negative affect (e.g., depression, anxiety). Additional items will be used to
assess demographic and personal information including pain history (e.g., duration, locations), disability status (e.g., VA service connection), employment status, opioid use (e.g., association with pain relief), and pain-related medical utilization over the previous 3 months. Scale items including pain treatment domains are measured on 11-point rating scales (0 to 10) grounded with higher scores indicating better outcomes. The Discharge Questionnaire contains the same 19 primary items from intake, a 5-item pain treatment satisfaction scale, and 3-items regarding medication use. The vitality, negative affect, and interference with mobility and ADL pain treatment outcome scales have demonstrated acceptable reliability (Cronbach’s α=.78-.90), but not pain-related fear (Cronbach’s α=.59) [71]. These scales have also demonstrated good generalizability, discriminant and concurrent validity, and sensitivity to change [71, 72]. The 19 ‘primary items’ will be used to assess change in this study.

2.) Pain Catastrophizing Scale

The 13-item Pain Catastrophizing Scale (PCS) [73] will be used to measure maladaptive and exaggerated negative beliefs “toward actual or anticipated experiences” of pain (p. 602) [74]. The PCS has demonstrated utility as both a full-scale score as well as a three-factor structure with sub-scales measuring cognitive ‘Rumination’ on pain symptoms (“I keep thinking about how much it hurts”), ‘Magnification’ of pain symptoms (“I become afraid that the pain will get worse”), and ‘Helplessness’ (“There is nothing I can do to reduce the intensity of the pain”) [73, 75, 76]. All items are measured on a 5-point Likert-type scale anchored by 0 (Not at All) and 4 (All the Time) with higher scores indicating greater levels of catastrophizing. The PCS scales have demonstrated acceptable internal consistency (Cronbach’s α=.64-.93) and test-retest reliability (ICC=.75) [76]. The full-scale score has demonstrated criterion validity in
differentiating between chronic pain outpatient and community adult samples [77]. The PCS sub-scales will be examined in the current study.

**Procedures**

The initial cohort of Veterans (N=8) will be informed about the study by the clinical staff the week prior to the beginning of data collection. A member of the research team will be present to answer any questions and to consent interested participants individually. As new Veterans are admitted to the CPRP, licensed clinical psychologists will inform prospective participants (N=12) about the study and provide them with a flyer during their initial CPRP orientation. The clinical staff will then send a VA encrypted e-mail containing the contact information of any interested Veterans to the study coordinator. The research team will then reach out to potential participants through their preferred contact method or in-person to further discuss the study and answer any additional questions. Informed consent will be obtained from interested participants by one of the three members of the research team: a licensed physical therapist, a licensed occupational therapist, or a clinical psychology post-doctoral fellow. Participants will be explicitly informed that they can leave the study at any time without penalty. Furthermore, they will be informed that they can participate in VR as part of their PT even if they choose not to consent for participation in the study.

The VR intervention will take place in the CPRP gym as part of daily PT sessions. The CPRP provides two daily group sessions of PT, each session containing up to six Veterans. Within each of these PT sessions, participants will be separated into one of two groups each containing three participants. As previously mentioned, participants in each of the 2 daily PT sessions will be randomized into two separate groups. One group will receive the VR intervention for the first 20-minutes of therapy with the other group receiving standard PT.
During VR sessions, one participant will use the Oculus Rift and select which APP they would prefer to participate in during the session. Similarly, two participants will select APPs using Samsung Oculus Gear VR. The Veteran will choose whether to sit or stand during their VR participation. After the 20-minute VR sessions, the groups will switch treatment modalities (VR to PT and vice versa). Across the study, all participants will receive the opportunity to utilize both the Oculus Rift and the Gear VR modalities. Each day participants will be administered the daily rating form to collect data following their VR experience (See Table 2). Engagement between participants and the research team during VR sessions will help ensure adherence to the intervention protocol. Pain and functional outcome measures will be administered by the CPRP staff at admission and discharge to assess treatment progress. These measures along with participant demographic information will be retrieved from the VA electronic medical record by the research team.
Table 2

Study Schedule.

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<tr>
<th>CPRP Timeline</th>
<th>Admission</th>
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</table>

Note. VR session timeline only applicable to treatment group. Intake and discharge measurement points apply to the VR and historical control groups.

Members of the research staff will be trained in the administration of these VR modalities by the PI prior to data collection. In the current study, Veterans using the Oculus Rift will be supervised by the PI, a clinical psychology postdoctoral fellow, while Veterans using the Samsung Oculus Gear VR will be supervised by a licensed physical therapist, occupational therapist, or a pre-medical student research assistant. A customizable user manual for Oculus Rift and Samsung Oculus Gear VR was developed for this study to assist in training the research team and to use with the study protocol (available upon request).

The annual internal audit completed by the research compliance office at the James A. Haley Veterans Hospital will serve the purpose of examining ethical compliance. Any adverse events will be reported to clinical staff, the research service at the James A. Haley Veterans Hospital...
Hospital, and the University of South Florida IRB. Any protocol changes will be discussed in
research team meetings and cleared with the IRB and research service.

Analytic Plan for Quantitative Data

The methods described below refer to quantitative assessment of the study specific aims. For all aims, baseline demographic, pain and function characteristics will be described by use of means and standard deviations for continuous variables and percentages for categorical variables. For the questionnaire measures, distributions of scores will be examined for skewness to determine whether transformations or use of non-parametric methods are required. Multiple steps will be taken to handle missing data. Patterns of missing items from questionnaires will be examined using Little’s Missing Completely at Random Test [78]. If data are shown to be missing completely at random, missing data will be estimated using the multiple imputation method with demographic information as well as participant scores on baseline pain and functional measures as predictors of missing items [79]. No attempts will be made to impute entire missing scales.

Aim 1

Validate a hierarchy of VR APPs in terms of movement intensity to guide recommendations for matching the technology to patient level of functioning. Distributions of the preferred level of VR intensity (range of 1-6) will be calculated and plotted across all sessions and over the course of the program to examine potential change in intensity preference. For assessment of intensity of change over time, repeated-measures (per session) linear mixed models will be fit to examine within-subject change over time, as well as if there exists covariate x time interaction for key variables. Specifically, aim #1 will match intervention and control subjects on age, gender, and baseline fear of movement scores. Thus, in the linear mixed
models, we will examine whether there emerges a different rate of change in intensity preference by baseline level of fear of movement. These analyses are designed to quantify the distribution of patient “start points” for their preferred level of intensity, followed by likely progression to different levels of intensity.

Aim 2

Estimate effect size associated with the VR intervention to plan for a future multi-site trial. Analysis of covariance (ANCOVA) will be used to compare change in outcome scores between the historical control group and VR intervention group. Whereas, by design, the groups will be matched on age, gender, and baseline fear of movement scores, this design is non-randomized and yields the potential for confounding. Therefore, non-matched baseline characteristics will be compared between the two groups by use of student t-tests or Wilcoxon rank sum tests (if any skewed variables) for continuous variables and chi-square tests for categorical variables. The ANCOVA models will adjust for potential confounding variables, as well as baseline value of the outcome of interest. Separate models will be fit for scores on the primary outcome (fear of movement) as well as the secondary outcomes of mobility, pain catastrophizing, and function. For each model, standardized effect size calculations will be made along with 95% confidence intervals to provide insight into the likely magnitude of effect associated with the VR intervention. Due to the preliminary nature of this work, no formal corrections will be made for multiple comparisons (outcome variables) [80].

Analytic Plan for Qualitative Data

Veteran feedback and responses to questions on the daily rating form will be transcribed word-by-word and analyzed using Microsoft (MS) Word following the Interpretative Phenomenological Analysis procedure described by Pietkiewicz & Smith [81]. First, the text
will be read several times. Second, exploratory commenting will be performed line-by-line to
describe the content, use of language, and conceptual coding using gerunds [81]. Third,
chronologically ordered emergent themes will be developed: a MS Word document will be
created for each emergent theme contained within the associated transcript extracts. Finally,
super-ordinate themes will be identified by searching for patterns and connections between the
emerging themes.

Results

The VR intervention in the CPRP was recently completed. The second phase, of the
study will involving pulling Veteran intake and discharge data for pain and functional measures
from the electronic medical record. This final phase will include identification of the
historically-matched control group from the electronic medical record. The results of this study
will be used to inform a future multi-site randomized controlled trial (RCT). Findings from this
study will be published in a peer-reviewed journal and presented at a national VR conference.

Discussion

Several pilot studies have demonstrated the efficacy of using VR interventions as a means
of pain distraction for people with acute [11-13, 20] and to a lesser extent chronic pain [17-19].
Similarly, the available evidence suggests that graded exposure to feared movements via VR
interventions can improve function among people with chronic pain conditions [28-31].

However, there is a lack of sufficient evidence from studies examining multiple VR APPS or
varying simulation intensity levels, both of which have been identified as important directions
for future VR research [20]. Furthermore, no studies have examined distraction and exposure
methods as part of a two-dimensional VR hierarchy. The current study addresses these gaps in
the literature by utilizing multiple VR APPs of varying the intensity levels that range from
passive distraction from pain to active exposure to movement. Moreover, this pilot study will inform the feasibility of a multi-site RCT examining the clinical utility of using VR to reduce fear of movement and increase function among Veterans with chronic pain. VR therapies are projected to have a $3.9 billion-dollar market size by 2023 [82], yet despite this tremendous public health burden, published research to date has not extended beyond pilot trials and case studies. Given the lack of largescale RCT’s examining the clinical effectiveness of VR, evidence from this pilot trial presents a key step to inform a larger multi-site trial.

Examining the feasibility of this intervention and validating this VR hierarchy will also be beneficial for Veterans, clinicians, and policy makers. Per the 2016 National Pain Strategy [83], the federal government’s first coordinated plan strives to reduce the burden of chronic pain in the United States, variations in clinical practice and inadequate tailoring of pain therapies, as well as a reliance on relatively ineffective high-risk treatments, all of which contribute to the poor quality of care for people with pain. If the aims of this research are achieved, VR will be used in combination with established pain management strategies to decrease pain and opioid use. VR has the advantage of being easily implemented both within VA healthcare settings as well as in Veterans’ own residences, where engagement in ongoing self-management approaches is often most challenging.

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Conflicts of Interests
The authors have no competing interests to declare.

Ethics Approval and Consent to Participate
This trial was approved by the University of South Florida IRB (Protocol 00031503) and the James A. Haley VA Hospital R&D Committee.

Availability of Data and Materials
Once completed, the final de-identified datasets from this study (qualitative and quantitative) and the VR user manual will be made available by the corresponding author upon reasonable request.

Abbreviations
2MWT: 2-Minute Walking Test
ADL: Activities of Daily Living
CBT: Cognitive-Behavioral Therapy
CPRP: Chronic Pain Rehabilitation Program
FDAQ: Fear of Daily Activities Questionnaire
FTSST: Five Time Sit to Stand Test
HMD: Head-Mounted Display
PCS: Pain Catastrophizing Scale
POQ-VA: Pain Outcomes Questionnaire-VA
PSFS: Patient Specific Functional Scale
PT: Physical Therapy
VR: Virtual Reality
References


http://www.webcitation.org/706lYMMf8

https://www.multiverseinc.com/dreamflight. Archived at:
http://www.webcitation.org/706j5s5U


http://www.webcitation.org/706lzsBCR

Oculus VR. 2016. Oculus Rift (Virtual Reality Head-Mounted Device).

Samsung, Oculus VR. 2015. Samsung Oculus Gear VR (Virtual Reality Head-Mounted
http://www.webcitation.org/706J6M3PU

Czub M, Piskorz J. Body movement reduces pain intensity in virtual reality–based

of articulated arm mounted Oculus Rift virtual reality goggles for adjunctive pain control
during occupational therapy in pediatric burn patients. Cyberpsychol, Behav, and Soc
Netw, 2014 Jun;17(6):397-401. PMID: 24892204

Jin W, Choo A, Gromala D, Shaw C, Squire P. A virtual reality game for chronic pain
management: A randomized, controlled clinical study. In: Westwood JD, Westwood SW,

Xu X, Chen KB, Lin JH, Radwin RG. The accuracy of the Oculus Rift virtual reality
head-mounted display during cervical spine mobility measurement. J Biomech, 2015
Jan;48(4):721-4. PMID: 25636855

Murphy JL, Clark ME, Banou E. Opioid cessation and multidimensional outcomes after
2275103

Murphy JL, Phillips KM, Rafie S. Sex differences between Veterans participating in
interdisciplinary chronic pain rehabilitation. JRRD, 2016 Jan;53(1):83-94. PMID:
27005932

Davis S, Nesbitt K, Nalivaiko E, editors. A systematic review of cybersickness.
Proceedings of the 34th Conference on Interactive Entertainment; 2014 Dec 2-3:

Bouchard S, Robillard G, St-Jacques J, Dumoulin S, Patry JM, Renaud P. Reliability and
validity of a single-item measure of presence in VR. Proceedings of the 3rd IEEE
International workshop on haptic virtual environments and their applications; 2004 Oct 2-
Ottawa, Ontario, Canada. HAVE; 2004.

Butland RJ, Pang J, Gross ER, Woodcock AA, Geddes DM. Two-, six-, and 12-minute

characteristics and clinical usefulness of physical performance tests in patients with low


