

REHABILITATION & REGENERATIVE MEDICINE SECTION

A Virtual Reality Intervention for the Treatment of Phantom Limb Pain: Development and Feasibility Results

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Abstract

Objective. To describe the development of a virtual reality (VR) treatment for phantom limb pain (PLP) and phantom sensations and provide feasibility data from testing the treatment in a population of veterans. Design & Subjects. Fourteen participants completed a baseline visit evaluating their amputation, PLP, and phantom sensations. Subsequently, participants completed a VR treatment modeled after mirror therapy for PLP, navigating in a VR environment with a bicycle pedaler and motion sensor to pair their cadence to a VR avatar. The VR avatar enabled visualization of the participant's intact phantom limb in motion, a hypothesized mechanism of mirror therapy. Setting. Laboratory. Methods. Participants completed pre- and post-treatment measures to evaluate changes in PLP, phantom sensations, and rate helpfulness, realism, immersion, adverse experiences, and treatment satisfaction. Results. Eight of 14 participants (57.1%) reported PLP pre-VR treatment, and 93% (13/14) reported one or more unpleasant phantom sensations. After treatment, 28.6% (4/14) continued to report PLP symptoms (t[13] = 2.7, P = 0.02, d = 0.53) and 28.6% (4/14) reported phantom sensations (t[13] = 4.4, P = 0.001, d = 1.7). Ratings of helpfulness, realism, immersion, and satisfaction were uniformly high to very high. There were no adverse experiences. Four participants completed multiple VR treatments, showing stable improvements in PLP intensity and phantom sensations and high user ratings. Conclusions. This feasibility study of a novel VR intervention for PLP was practical and was associated with significant reductions in PLP intensity and phantom sensations. Our findings support continued research in VRbased treatments in PLP, with a need for direct comparisons between VR and more established PLP treatments.

Key Words: Phantom Limb Pain; Virtual Reality; Chronic Pain; Veterans; Amputee

Virtual reality (VR) technology could provide novel avenues for pain management. Using a variety of hardware and software applications, VR treatments are hypothesized to improve pain through mechanisms such as relaxation, distraction, social connection, and engagement [1]. The flexibility inherent to VR applications (e.g., the ability to design customized VR environments) and the rapidly reducing costs of VR headsets and related hardware enable VR treatments to be increasingly available to address a range of pain conditions [2,3].

A 2018 review of VR treatments for pain-focused on the previous five years of research due to the rapid

evolution of VR technology—identified six studies using VR as a treatment for acute pain (e.g., using VR while completing a painful laboratory task) and nine studies utilizing VR with patients experiencing chronic pain [4]. A separate review in 2017 [5] found eight studies using VR specifically for the treatment of phantom limb pain (PLP) using a broader time frame for identifying articles. Both reviews reported consistent improvements in pain severity resulting from both brief (e.g., single-time use of VR) and repeated VR treatment protocols, along with low rates of adverse effects (e.g., nausea, dizziness), although the strength of these findings was limited by small samples, older VR technologies, and lower-quality study designs [4,5].

Among the applications of VR to chronic pain, PLP-a type of intermittent chronic pain-may be uniquely positioned to benefit, and yet it remains understudied [6]. Like other chronic pain conditions, VR treatments could benefit patients with PLP through general therapeutic mechanisms for pain (e.g., distraction and relaxation) and through PLP-specific neurological mechanisms. Mirror therapy is an established PLP therapy that may promote cortical reorganization by simulating movement of the patient's missing limb, performed using a mirror positioned to help the patient "see" their intact limb in place of the amputated one. This neurological process is hypothesized to reduce pain perception [7]. VR can simulate the same limb illusion as mirror therapy using virtual environments. VR can also incorporate gaming elements into PLP treatment to theoretically increase participants' enjoyment of the experience, potentially improving adherence, and can be configured to multiple kinds of amputations (e.g., upper body, lower body, bilateral amputee populations).

This report describes the development, feasibility testing, and preliminary effects of a novel VR treatment for PLP, developed for a high-risk veteran population, using state-of-the-art portable VR technologies and customized with three distinct VR environments for a patient-centered treatment approach. Veterans are a population particularly vulnerable to PLP due to their relatively greater exposure to combat-related hazards and to diseases such as diabetes that can result in limb loss and amputations [8,9]. This study was also perhaps the first to target unpleasant phantom sensations (e.g., feeling that the missing limb is in an uncomfortable state or position), which are common among amputees with or without PLP [10]. The aims of the current intervention were 1) to evaluate the feasibility and acceptability of the intervention and 2) to assess the benefits of VR treatment for reducing PLP intensity and phantom sensations, resulting from both initial and repeated use of the VR treatment.

Methods

Participants

We recruited veterans with PLP from the Veterans Affairs San Diego Healthcare System (VASDHS) and

regional areas. Within the VASDHS, we recruited from the primary care and amputee clinics and through communication with providers in these clinics. Inclusion criteria for participation included 1) veterans aged 21-80; 2) possessing an upper or lower extremity amputation with reported PLP for at least six months; 3) PLP intensity >4/10; 4) English-speaking, literate, with stable residence; 5) able to operate a VR headset as evidenced by direct observation; 6) possession of or ability to use a prosthetic limb. Exclusion criteria included 1) major medical illness that could prevent light exercise (e.g., heart failure, severe lung disease); 2) currently active alcohol or substance use disorder as evidenced from medical record; 3) currently active suicidality, homicidality, or unstable psychiatric status in the previous three months as measured by direct observation, patient selfreport, or medical record; 4) moderate or severe cognitive impairment as demonstrated by medical diagnosis or clinical observation. Our objective was to minimize participation barriers for prospective participants to maximize recruitment and permit the results to generalize as widely as possible to patients with PLP. All participants completed written informed consent, and the study was approved by the VASDHS Institutional Review Board.

Study Design

This project was funded by the VA Office of Research and Development as a two-phase study consisting of a) an initial developmental phase tasked with the creation and iterative refinement of an immersive VR treatment for veterans with PLP and 2) a feasibility phase enrolling participants to trial the VR treatment for up to several weeks to provide quantitative feedback concerning the realism, usability, satisfaction, side effects, and effects on PLP and phantom sensations.

Participants completed a baseline visit with the study coordinator to complete informed consent and baseline questionnaires and received training on the setup and use of the VR equipment. Participants had little or no prior experience with VR before the study, although many were familiar with computers and video game technology. The enrollment and baseline visits took place at a designated laboratory space assigned to the study investigators (authors TR and CD). The length of the baseline visits varied from one to two hours due to the different amounts of time needed to complete the VR training and setup, and because some veterans chose to use the VR equipment for different amounts of time.

Participants were asked to bring their prosthesis to the baseline visit, as a prosthesis was necessary to operate the pedaler during the VR treatment. After the baseline visit, participants who wished to continue using the treatment had the option of making return visits to the laboratory or taking the VR equipment home (consisting of an Oculus Rift VR headset, motion sensor, and pedaler) if they had a laptop or home computer where the VR software could be installed. In the second year of the study, portable VR headsets became available (a smartphone with the VR software installed could be connected to these portable headsets, enabling wireless use of the treatment) to participants wishing to use this version outside of the laboratory. Home users were contacted by phone daily or as needed by the study coordinator to track usage and resolve hardware or software problems. Home users completed brief measures after each use to provide data concerning time of use, effects on PLP and phantom sensations, and side effects. Although this protocol resulted in variability in frequency and duration of use of the VR treatment, it permitted the maximum enrollment of veterans and allowed them to participate to the extent that they found beneficial. For the purpose of this feasibility project, we weighted the latter benefits above the methodological limitations.

Virtual Reality Treatment

The developmental phase of the project was conducted through the collaboration of the study investigators and a San Diego-based VR company (Virtual Reality Medical Applications, Inc.) that was registered as a VA vendor and contracted to assist with the VR software development and testing of the VR treatment. The concept of the VR treatment was based upon mirror therapy research (e.g., [11,12]). Patients using mirror therapy perform simple exercises (e.g., clenching the fist from their intact arm) to create the appearance of motion in their missing limb, potentially promoting cortical reorganization [13]. Extending mirror therapy with the use of VR technology involved the development of VR environments where the patient would experience their limbs as intact through the appearance and movement of their VR avatar. We designed VR environments for both upper and lower body amputee populations, with the aim of making them immersive and engaging [14].

To permit a degree of customization, variability, and patient preference, we developed three distinct VR environments involving the use of a basic bicycle pedaler while wearing the VR headset and a single motion sensor (developed by the VR contractor) attached to the pedal containing the participant's prosthesis. This combination allowed the participant to bicycle on the pedaler at their preferred pace in the VR environment of their choice while wearing the VR headset, with the motion sensor precisely calibrating the cadence of the VR avatar to that of the participant. Brief videos of the equipment and three VR environments are publicly available (https:// www.youtube.com/watch? v=-SydRpqRQIc&feature= youtu.be; a video of the environment we used for participants with upper body amputations is available here: https://www.youtube.com/watch? v=NsyS-LaUmDo).

The VR avatar and bicycle were designed to maximize participants' view of their virtual limbs while navigating in the environments to simulate the mirror therapy

paradigm as closely as possible. For participants with upper body amputations, the pedaler was placed on an adjustable height table in front of them instead of on the floor. To improve usability with a prosthesis, we created a detachable pedal extension that could be placed on either the right or left side as needed for the participant. This pedal extension was 12"×6" in dimension, composed of plastic, and two pounds in weight with a Velcro strap for securing. The pedal extension was designed to create a stable placement for the participant's prosthesis during use (i.e., while wearing the VR headset, participants cannot see their feet, causing their prosthesis to slip from the pedaler easily without a method of securing). Although the study coordinator supervised the participant while using the equipment in the laboratory, once familiar, the participant could easily self-navigate through the VR environments. The functional goal of the development phase was to create VR environments requiring a minimum of equipment and technological skills for use. The developmental phase lasted approximately one year, with weekly team sessions combining the study investigators with the VR developers to test updated versions of the VR software. Figure 1 shows the hardware components of the VR treatment.

Study Outcome Measures

During the baseline visit, participants provided information about demographic characteristics, psychological functioning (depression, post-traumatic stress, quality of life), and PLP and phantom sensations. Specific measures included the following: 1) The Phantom Limb Pain Questionnaire (PLPQ; primary outcome measure [15]) contains 25 items assessing information about the participant's amputation, the presence, characteristics, and intensity of PLP, pain interference, and phantom sensations. Intensity is assessed on a standard 0-10-point Likert scale pain measure. 2) The Trinity Amputation and Prosthetic Experience Scale (TAPES [16]) includes 27 items measuring activity, social functioning, and pain associated with amputation, including PLP. 3) The Short Form-12 (SF-12 [17]) measures physical functioning, general health, vitality, social functioning, and mental health. 4) The Patient Health Questionnaire-9 (PHQ-9 [18]) is a validated, nine-item measure of depression widely used in VA health care settings for assessing depression in veterans. 5) The Post-traumatic stress disorder (PTSD) Checklist-Military version (PCL-M [19]) is a validated, 17-item measure of symptoms common to PTSD. The military version differs from other versions of the PCL in that the items refer specifically to PTSD symptoms related to the participant's military experiences.

Before engaging in the VR treatment during the visit, participants completed questions from the PLPQ concerning PLP intensity and phantom sensations (including options of crushing, tingling, burning, cramping,



Figure 1. Illustration of the virtual reality treatment hardware, consisting of a motion sensor, bicycle pedaler, computer, Oculus headset, and prosthetic pedal.

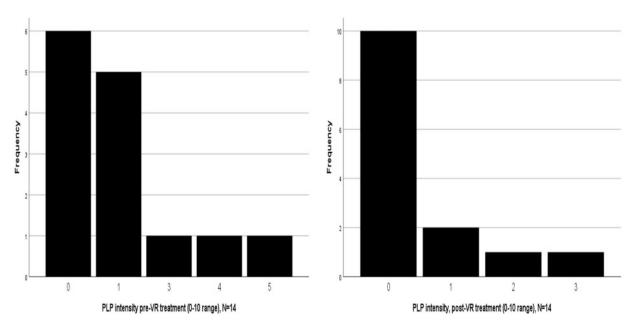


Figure 2. A distribution of phantom limb pain presence and intensity before and after the initial virtual reality treatment.

throbbing, immobile, and "in a fixed position"). After the participants' use of the VR treatment, they again provided information about PLP intensity and phantom sensations. After the VR treatment, participants provided ratings of the "helpfulness of the VR treatment" (from 1 [not helpful] to 7 [very helpful]), "immersion of the VR treatment" (from 1 [not immersive at all] to 6 [completely immersive]), "realism of the VR treatment" (from 1 [not realistic at all] to 9 [completely realistic]), and "satisfaction with the VR treatment" (from 1 [very dissatisfied] to 7 [very satisfied]). The latter items were adapted from sources such as the Presence Questionnaire [20], which was developed to assess participants' experiences with VR environments. Because the items were derived from different sources, however, the Likert scaling differed somewhat across items. The post-treatment measure also included two items about the participants' VR treatment experience, assessing their "positive reactions" (fun, relaxing, challenging, distracting) and "adverse reactions" (dizziness, fatigue, anxiety). Participants completing follow-up VR treatment sessions either in the laboratory or in their home environments completed the pre- and post-treatment measures after each session. The duration of time in the VR environment was also recorded for each treatment session.

Statistical Analyses

Descriptive statistics (means, SDs, frequencies, and percentages) were calculated for demographic, psychological, and PLP and phantom sensation characteristics at baseline. Using standard power calculation metrics (e.g., 80% desired power level, two-sided test, and alpha level set at 0.05), we anticipated a minimum 50% reduction in PLP (e.g., a change from 4/10 to 2/10 in PLP intensity after the VR treatment) and a 1.0 SD in PLP intensity ratings. Based on these calculations, statistical power levels for within-group testing would exceed 90% with a sample size of 15 [21]. Primary analyses for VR-related changes consisted of repeated-measures analysis of variance comparing pre-VR PLP and phantom sensation status with post-treatment status. We calculated effect sizes in the form of Cohen's d values (i.e., group differences/ pooled SD). All statistics were completed using SPSS software (version 25; SPSS.com).

Results

From a total of 27 veterans contacting the study, we enrolled 14 veterans over nine months of recruitment. Among the 13 veterans who were not enrolled, five declined based on location factors (e.g., living too far away to attend) and eight were ineligible (six reported that their pain symptoms were not from PLP, one declined due to family commitments, and one did not respond to contact efforts).

Table 1 summarizes the demographic, psychosocial, and phantom limb characteristics of the sample. Veterans were predominantly male, generally well educated (>75% with at least some college education), and reported low levels of depressive symptoms on the PHQ-9 and low to moderate symptoms on the PCL-M. Most participants rated their health as good to very good (69.2%). All veterans reported that their amputations occurred more than a year ago, with most reporting that their amputations occurred more than five years ago.

Ten of the 14 participants completed the baseline visit and a single treatment session with the VR treatment. Six of the 14 were eligible for subsequent treatments (the others declined based on living too far away for them to make regular return visits or did not have Internet access for home use). Among these six, four participants completed multiple (five, 12, 14, and 28 sessions, respectively) VR treatment sessions either in the laboratory or at home (the other two had medical or living circumstances that prevented follow-up participation).

Table 1. Demographic and baseline status of veteran participants (N = 14)

Variable	Value
Age, y	63.0 (12.6);
	range 37–76
% male	93 (13/14)
% non-Caucasian	36 (5/14)
% married	64 (9/14)
% >high school education	79 (11/14)
% receiving care through VA hospital	79 (11/14)
Baseline PHQ-9*	6.6 (5.4)
Baseline PCL-M*	28.2 (11.2)
Time since amputation	No.
• 1–5 y	5
• 6–10 y	2
• 10+ y	7
Type of amputation	No.
Right leg	3
• Left leg	10
Right arm	1
Average phantom limb pain intensity	5.0 (3.5)
(0–10 scale), past week	
Average length of phantom limb	2.0 (1.4)
pain episodes, min	
Average No. of daily phantom limb pain episodes	2.0 (1.3)
% with phantom sensations	93 (13/14)
% reporting stump pain	57.1
Average stump pain intensity (0–10 scale), past week	2.7 (3.2)
Average length of stump pain episodes,	75/25
% 0–15 min/16–30 min	1 ((5 5)
Average No. of daily stump pain episodes	1.6 (5.5)
Self-rated health	No.
• Very good	2
• Good	8
• Fair	4

PCL-M = PTSD Checklist-Military Version; PHQ-9=Patient Health Questionnaire; VA = Veterans Affairs.

Table 2 and Figure 2 describes the results among the 14 participants during their initial use of the VR treatment. Although all participants reported recent PLP episodes averaging $\geq 4/10$ intensity to be eligible for the study, most participants were not experiencing PLP at the specific time of their initial VR treatment, accounting for the low pre-VR treatment means in Table 2 vs Table 1. Nevertheless, the pre- to post-treatment reduction in PLP was statistically significant (t[13] = 2.7, P =0.02, d = 0.53). The reduction in the number of unpleasant phantom sensations experienced from pre- to posttreatment was also significant (t[13] = 4.4, P = 0.001,d = 1.7). Participants reported no adverse events or terminated the treatment due to nausea, dizziness, or anxiety symptoms. In terms of usability, participants rated the treatment highly (>75%) on the dimensions of helpfulness, immersion, realism, and satisfaction.

The bottom section of Table 2 details feasibility and preliminary efficacy results from the four participants who completed multiple VR treatment sessions at home.

Average phantom limb pain intensity, pre/post–VR treatment		1.2 (1.6)/0.5 (0.94)
Average use time (SD)/range, min		12.9 (9.2)/4–35
Unpleasant phantom sensations		
Phantom sensations	No. experiencing before VR use	No. experiencing after VR us
Crushing	2/14	0/14
Tingling	4/14	1/14
Burning	2/14	0/14
Cramping	2/14	0/14
Throbbing	9/14	0/14
Fixed position	3/14	0/14
Average No. of phantom sensations	1.6 (1.3)	0.07 (0.15)
Acceptability ratings		
Helpfulness of VR treatment for PLP ($1 = not$ helpful to $7 = very$ helpful)		5.2 (2.4)
Immersion of VR (1 = not at all to 6 = completely immersive)		5.2 (1.4)
Realism of VR (1 = not at all to 9 = completely realistic)		7.1 (1.8)
Positive reactions		71
• % rating fun		64
% rating relaxing		50
% rating challenging		43
% rating distracting from pain		
Negative reactions		0
% reporting dizziness		0
% reporting fatigue		7
• % reporting anxiety		
Satisfaction with virtual reality treatment $(1 = very dissatisfied)$	· ·	6.4 (1.3)
Phantom limb pain, phantom sensations, and ratings among re	epeat users ($N = 4$; 57 total sessions)	
Average phantom limb pain intensity, pre/post–VR treatment		1.5 (1.9)/0.40 (0.98)
Average use time (SD)/range, min		25.6 (14.4)/4.5-65.3
Unpleasant phantom sensations		
Phantom sensations	No. experiencing before VR use	No. experiencing after VR us
Crushing	10/57	1/57
Tingling	42/57	14/57
Burning	27/57	5/57
Cramping	12/57	2/57
Throbbing	41/57	8/57
Fixed position	4/57	0/57
Average No. of phantom sensations	2.4 (1.4)	0.53 (1.1)
Acceptability ratings		
Helpfulness of VR treatment for PLP ($1 = not$ helpful to $7 = very$ helpful)		6.5 (0.89)
Immersion of VR ($1 = not$ at all to $6 = completely$ immersive)		5.6 (0.60)
Realism of VR ($1 = not$ at all to $9 = completely realistic$)		7.5 (1.5)
Positive reactions		89
% rating fun		68
% rating relaxing		26
% rating challenging		70
% rating distracting from pain		
Negative reactions		5
 % reporting dizziness 		2
% reporting fatigue		9
 % reporting anxiety 		
Satisfaction with virtual reality treatment $(1 = very dissatisfied$	to $7 = $ completely satisfied)	6.5 (0.63)

Table 2. Responses to virtual reality intervention and acceptability ratings from initial trial

PLP = phantom limb pain; VR = virtual reality.

These participants completed a total of 57 treatment sessions, completing pre- and post-treatment ratings of PLP, phantom sensations, and user feedback each session. Trends from these repeat VR sessions were very similar to the statistics from the larger group of initial users, with evidence of consistent decreases in PLP and phantom sensations and favorable user ratings.

In 44% (25/57) of the repeat VR sessions, participants rated their phantom limb pain >0 before VR use

(i.e., participants were experiencing PLP at the time of use) vs 18% after using the VR treatment. Average preto post-treatment PLPQ scores for these sessions were 3.2 (1.6) and 0.88 (0.13), respectively. Examining within-person trends among the repeat VR users, usability ratings on the dimensions of helpfulness, immersion, realism, and satisfaction remained stable across subsequent sessions. Similarly, usage time remained stable for each participant, with one

participant routinely using the VR treatment for 40–60 minutes per session.

Conclusions

This report described the results of a two-phase feasibility study designed to a) develop a customized VR treatment for PLP and b) test the intervention, including the feasibility, acceptability, and effects of the treatment on PLP and phantom sensations. Use of the VR treatment was associated with statistically significant reductions in PLP intensity and phantom sensations. These benefits were present among both initial and repeat users of the treatment. Participants similarly rated the VR treatment high on the dimensions of immersion, realism, helpfulness, satisfaction, and fun.

One of the factors that inspired the current project was our own prior experience with mirror therapy for PLP [22]. In this previous randomized controlled trial, mirror therapy was effective for PLP reduction, but no more effective than a control psychotherapy condition. Further, we observed frequent difficulties for participants traveling to the hospital for treatment sessions, struggles adhering to the mirror therapy exercises, and practical barriers to having the mirror accessible for use during PLP episodes. This experience motivated us to consider VR technology as a means of making the treatment more portable, enjoyable, and usable in natural living environments [23].

As noted in the introduction, research investigating the effects of VR treatments for phantom limb pain remains limited in volume and quality. The 2017 review of VR and augmented reality treatments for PLP [5], for example, identified just eight total studies, six of which provided quantitative results from small samples and all of which were rated as being of low methodological quality. Probably the highest-quality study in the field to date was published in 2016 [6], consisting of a single-group design with 14 upper body amputee participants with PLP who completed 12 sessions of a treatment using VR technology to simulate the motion of their missing limb through their avatar in a racing game.

There are multiple factors contributing to the paucity of quality VR for PLP research. VR technology has, until recently, been financially costly and required technical skills rarely possessed by pain researchers. As such, successful VR studies—like the present study—often necessitate collaborations between researchers and VR specialists. For the current study, the technical assistance of the VR contractor was essential to the success of our project. The VR team members completed the lengthy and iterative programming process for the VR software, designed motion sensors for the pedaler, and contributed many design improvements from participant feedback that would have been difficult to generate without their expertise. Notably, VR technology changed measurably over our study. For example, at study onset, our VR headsets required direct HDMI connections with a gaming computer to operate. Within two years, however, inexpensive and wireless VR headsets were available that operated by inserting a smartphone, bypassing the need for a computer. As our study completed, VR headsets were appearing in the marketplace as standalone hardware requiring neither computer nor smartphone support. This remarkable pace of technology change is expected to continue, requiring that researchers using VR stay abreast of field advancements to conduct research that has ecological validity.

A second challenge for PLP researchers is that VR studies targeting PLP differ in important ways from VR interventions used for non-PLP forms of chronic pain. VR for PLP interventions typically involve a physically active component where the participant is engaging in a VR environment with their avatar to create an illusion that their missing limb is intact and in motion. Based on mirror therapy theory, this illusion of movementwhether created by a standard mirror or by a VR environment-may be essential for the treatment to be effective (e.g., [11]). VR for other types of chronic pain, in contrast, is often passive, with the objective of creating distraction or relaxation [1,4]. This difference is important because it may require more development resources to create the moving, interactive environments necessary for PLP-specific VR treatments.

Perhaps the chief barrier to high-quality VR treatment studies for PLP, however, originates from the characteristics of PLP rather than from the above technical challenges. Unlike common sources of chronic pain such as low back pain, that often varies only in intensity, PLP is an intermittent and often unpredictable pain condition that varies markedly in frequency and intensity among amputees [24]. Although some studies indicate that the prevalence of PLP among amputees is as high as 80%, in practice, the rates of frequent and disabling PLP vary [25]. For patients experiencing PLP symptoms that may occur a few times or for a few minutes per week, a VR treatment must be portable and easy to initiate in order to address the pain in real time. Our patients (Table 2) averaged just two episodes of PLP per day despite being a veteran sample with significant disabilities. The intermittent nature of PLP makes it difficult to measure the impact of treatment in a controlled laboratory setting. For our participants using the VR treatment in their home environments, we encouraged them to use the treatment regularly, but particularly when they experienced an increase in PLP symptoms or unpleasant phantom sensations.

Two of the important novel features of this project were a) the expanded focus on phantom sensations in addition to PLP [26] and b) the development of a VR treatment that functioned as a recreational form of physical activity that may promote adherence, longer-term use, and improvements in cardiovascular health, which is often compromised in patients with PLP. Whereas PLP symptoms are generally intermittent, many patients describe chronic unpleasant phantom sensations [10]. These sensations frequently include uncomfortable but not necessarily painful features such as tingling, cramping, throbbing, and immobility; >90% of our participants reported one or more of these sensations. During initial laboratory testing, we found that participants averaged 1.6 phantom sensations before VR treatment use, even though only half reported PLP at the time. Home and repeat VR treatment users reported an even higher average (2.8) of phantom sensations before beginning their VR treatment sessions. Both initial and repeat users reported reductions >75% in these unpleasant sensations after VR treatment use. Because of their frequent experience, VR treatments that can also reduce phantom sensations in addition to PLP intensity may be particularly valuable for improving patients' quality of life. We believe the enjoyment factor of the exercise component of VR treatment is also critical for maximizing treatment benefits. With a majority of amputations in veteran populations resulting from advanced diabetes, finding sustainable ways to promote exercise with these patients can potentially have health benefits beyond their PLP symptoms.

Limitations

There are several important limitations to consider in interpreting this work. Unfortunately, the limited number of eligible veterans, combined with participants often reporting that they had previously tried mirror therapy, made our original plans to randomize participants to our VR treatment or standard mirror therapy untenable. A direct comparison between VR and standard mirror therapy remains a valuable scientific goal for the future to provide a clearer interpretation of the unique benefits attributable to the VR format. Second, we struggled recruiting adequate numbers of ethnic minority and female populations. The primary barrier to additional recruitment was an absence of regular PLP among veteran amputees. Due to the feasibility design of this study, our protocol did not include a follow-up period to evaluate the durability of the treatment effects in a standardized manner. We relied primarily on medical records for identifying exclusion factors rather than medical tests or diagnostic interviews, although medical records can be unreliable sources of information regarding factors such as substance abuse and psychiatric disorders. Our hospital sample often had significant cardiovascular disease and other medical comorbidities, making the sample possibly difficult to generalize to healthier patient populations. Because we used items from different VR questionnaires for treatment ratings, this resulted in different Likert scale formats, which should be standardized in future research.

Although we developed a parallel VR treatment for upper body amputees, just one participant was eligible

for this treatment version (this participant used the VR treatment four times with favorable results), leaving us without sufficient data for evaluation. Additional research will be necessary to properly validate the upper body treatment. For this study, we recruited only participants with a single missing upper or lower body limb. In theory, our VR treatment could be used by participants with bilateral amputations by placing pedaler extensions on both sides of the pedaler for secure movement, but we did not test this option due to a lack of bilateral amputee participants.

Conclusions

In this development and feasibility study, we created a VR treatment for PLP that was highly rated by participants in terms of usability, improving PLP intensity, and reducing unpleasant phantom sensations. With VR hardware and software technologies rapidly growing in quality in recent years while decreasing in cost, VR is an increasingly viable treatment approach for PLP. Although there are important methodological limitations to this preliminary study, the findings are supportive of future research to more definitely evaluate the shorterand longer-term benefits for PLP and phantom sensations resulting from VR treatments.

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