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THE USE OF MINDFULNESS MEDITATION TO INCREASE THE EFFICACY OF MIRROR VISUAL FEEDBACK FOR REDUCING PHANTOM LIMB PAIN IN AMPUTEES

A Dissertation Presented to The School of Nursing and Health Professions Clinical Psychology PsyD Program

In Partial Fulfillment of the Requirements for the Degree Doctor of Clinical Psychology

by Nicolas S. Mills, M.A., M.S. San Francisco October 2019

THE UNIVERSITY OF SAN FRANCISCO Dissertation Abstract

The Use of Mindfulness Meditation to Increase the Efficacy of Mirror Visual Feedback for Reducing Phantom Limb Pain in Amputees

Phantom limb pain is a chronic pain condition that negatively impacts the lives of over half of amputees, and results in considerable morbidity. Currently, there is no gold standard for treatment for phantom limb pain. However, a frequently used intervention is the use of mirror visual feedback, in which the amputee watches the reflection of the adjacent non-amputated limb move and exercise. In the last few decades, mindfulnessbased interventions have been increasingly used with individuals living with different types of chronic pain. This study attempts to discover if the addition of a mindfulnessbased intervention, such as guided meditation, will augment the pain-reducing effects that mirror visual feedback has on amputees with phantom limb pain.

Keywords: mindfulness meditation, mirror visual feedback, phantom limb pain

This dissertation, written under the direction of the candidate's dissertation committee and approved by the members of the committee, has been presented to and accepted by the Faculty of the School of Psychology in partial fulfillment of the requirements for the degree of Doctor of Psychology. The content and research methodologies presented in this work represent the work of the candidate alone.

Candidate, Nicolas S. Mills		Date
Dissertation Com	mittee Signatures	
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Date

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I would like to thank my amazing wife Shannon who has been marvelously supportive each step of the way during my process of conducting this study, from her brilliant suggestions to her patience with my struggles. Her making time in our schedule for over a year has allowed this study to materialize. She has inspired the courage it has taken to perform original research and data collection, and her love and support continue to make my life amazing.

I acknowledge my incredible sister Dana and brother-in-law George who have prayed for me, let me do laundry at their house, and given input on the best ways to navigate social media and record my informational videos. My mother's love has replenished my heart, soul, and stomach with her help. Her prayers, encouragement and ideas have proven to be invaluable. My mother, Dana, and George have been vital to me on my bumpy road of life, and have continued their generosity and love during the completion of this dissertation. My father's challenging ethos has kept me sharp, and

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held me to a higher standard of performance throughout the course of academia, and this dissertation continues that ethos.

Dedication

This dissertation is dedicated to all individuals who live with chronic pain. This dissertation is dedicated to all who are at the mercy of the widely varying personalities and motivations of our health professionals, whose ethics and interventions vary greatly from clinician to clinician, despite treating the same diagnosis. This dissertation is dedicated to the individuals who have the daily struggle of surviving relationships with others and themselves while managing their pain, an invisible and oppressive dictator that rarely garners empathy, and often breeds hopelessness. This dissertation is dedicated to the dissolution of boundaries between the fields that explore either the mind or the body. As long as we are territorial with our specialties of psychology, psychiatry, and medicine, as long as we continue to be the proverbial hammers that only consider our patients' symptoms to be familiar nails that we interpret within our own comfortable framework, as long as we direct treatment based on offering interventions that we make a profit from, as long as we practice our specialty of healthcare without considering the meaningful impact of patients' diversity of cultures and experiences that have shaped them, it will be the patient who continues to carry the burden of suffering, of mental and physical pain, with little hope of increasing the quality of their lives within the reductionistic biomedical healthcare systems that we have created.

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Specific Aims

The aim of this study was to determine whether the use of mindfulness meditation (MM), a mindfulness-based intervention for chronic pain, increased the efficacy of mirror visual feedback (MVF) for reducing phantom limb pain. The hypothesis of this dissertation was that those who practice MM in addition to MVF would report a significantly larger decrease in pain than those who only practice MVF. This study sought to rule out the null hypothesis, which is that practicing MM in addition to MVF has no impact on pain reporting of amputees with phantom limb pain.

The concept of a phantom limb is characterized by when a person loses a limb on their body, they may continue to experience sensation in this body part despite it no longer being attached; 85% of amputees report experiencing phantom limb sensations. Unfortunately, up to 90% of these amputees describe these sensations as painful (Melzack, 1990), which is known as phantom limb pain (PLP). There are many different treatments for PLP, but efficacy rates tend to be relatively low (Peterzell, 2016).

The International Association for the Study of Pain (IASP) defines chronic pain as the pain that continues past the expected amount of time for healing, which is typically three to six months post-injury (Apkarian, Baliki, & Geha, 2009). PLP is a specific type of chronic pain (International Association for the Study of Pain, 2011). Psychological diagnoses, like depression, are highly comorbid with phantom limb pain and often assessed in PLP studies (Whyte & Niven, 2001). For example, studies focusing on behavioral health and PLP have indicated that major depression is a significant predictor of and co-morbid with, PLP (Jensen et al., 2002). Further, MM has shown evidence of decreasing depressive symptoms (Turakitwanakan, Pongpaplud, & Kitporntheranunt,

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2017). Thus, it stands to reason that a psychologically impacting, evidence-based practice for chronic pain such as MM might be an effective treatment modality for individuals with the chronic pain condition of PLP.

The use of psychological interventions on the phantom limb pain is not limited to this study. There have been several studies that have addressed the chronic pain condition of PLP through established psychological treatments, such as eye movement desensitization and reprocessing (EMDR) and cognitive behavioral therapy (CBT) (de Roos et al., 2010; Markozannes et al., 2017; Niraj & Niraj, 2014; Spyropoulou et al., 2008).

Research focusing on the impact of MM on mirror visual feedback (MVF) in amputees with PLP is clearly aligned with the Jesuit mission of social justice, as it encourages conceptualizing those suffering from PLP as a combination of both mind and body. This dissertation sought to help those suffering from PLP who had less success with other treatments may have they have tried for their pain, such as MVF alone. The primary outcome measure was changes in experiences of pain (i.e., pain reduction). Thus, the aim of this study was to determine whether psychological interventions such as MVF were more effective for individuals with PLP who utilized the mindfulness-based intervention (MBI) technique of MM.

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Glossary

- CBT Cognitive behavioral therapy
- CNS Central nervous system
- ECT Electroconvulsive therapy
- EMDR Eye movement desensitization and reprocessing
- IASP International Association for the Study of Pain
- IRB Institutional Review Board
- MBI Mindfulness-based interventions
- MM Mindfulness meditation
- MOU Memorandum of understanding
- MVF Mirror visual feedback
- NMDA N-methyl-D-aspartate

PLP - Phantom limb pain

- UCLA University California of Los Angeles
- USF University of San Francisco
- VAS Visual analog scale

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CHAPTER I

Introduction to the Study

Integrated healthcare and behavioral health require consideration of the simultaneous effect of multiple disorders. Specifically, there is much evidence of the relationship that psychological conditions have on the physical disorder of chronic pain (Markozannes et al., 2017). Psychological interventions have a significant role in the management of chronic pain (Garg et al., 2012). For example, interdisciplinary chronic pain programs will sometimes utilize cognitive-behavioral approaches with a patient, helping chronic pain patients increase acceptance of their pain, rather than focus only on relieving the pain itself (Probst et al., 2019). Typically, treatment consists of individual and group therapy, with the CBT component focuing primarily on psychoeducation, the bio-psycho-social pain model, and relaxation training, which often includes MM or other MBI's (Probst et al., 2019). Despite chronic pain being a sensation that is experienced in the body, patient beliefs and expectations regarding pain and its treatment are major determinants of treatment outcomes (Osterweis, Kleinman, & Mechanic, 1987). Thus, it is reasonable to postulate that interventions that modify patient beliefs would impact the efficacy of psychological interventions that treat Phantom Limb Pain (PLP). This study will examine whether mirror visual feedback (MVF) is more effective for individuals with PLP who engage in mindfulness meditation (MM) compared to those who do not engage in MM. It was hypothesized that there would be a greater reduction in pain among individuals engaged in MVF and MM compared to those who engaged in MVF alone.

CHAPTER II

The Review of the Literature

Phantom Limb Pain

Phantom limb pain (PLP) is defined "any painful sensation that refers to an absent limb" (Hasanzadeh, Habibi, Soleimani, & Emami, 2013, p. 1). This means that although the person may be without their right arm, they continue to feel pain where the arm once was. The phantom limb experience has been studied for many decades and was first documented by a French military surgeon in 1552 (Ahmed et al., 2017). PLP has been described as pain, such as cramping, or paralysis, that existed before the limb was amputated, and continues to exist due to cortical structures in the brain continuing to "feel" the affected limb is still present (Ramachandran & Rogers-Ramachandran, 1996).

PLP has a complex etiology with related mechanisms in cortical pathways, changes in the central nervous system, and psychological influences. Variables that most saliently impact PLP are still unknown, with hypotheses continually emerging and changing to explain how each variable contributes to PLP (Subedi & Grossberg, 2011). Furthermore, there is no "gold standard' of treatment for PLP due to the complexity of how this diagnosis is impacted by/impacts the mind and body (Le Feuvre & Aldington, 2013). Researchers have explored the nature of PLP, offering a variety of interventions and treatments including biomedical, pharmacological, and psychological interventions (Kiabi et al., 2013). However, the results are mixed in terms of what intervention(s) is/are more effective at decreasing or eliminating PLP (Barbin, Seetha, Casillas, Paysant, & Perennou, 2016; Moura et al., 2012; Thieme, Morkisch, Rietz, Dohle, & Borgetto, 2016).

Existing Treatment for Phantom Limb Pain

The mechanisms involved in PLP that have been suggested have changed through the past from psychogenic theory to the involvement of cortical reorganization in peripheral and central neural changes (Subedi & Grossberg, 2011). Thus, the interventions believed to address these mechanisms have also changed; different interventions are offered to amputees with varying success rates. Treatments for PLP include pharmacological, surgical, and psychological methods that are either used singularly or in combination with other modalities (Subedi & Grossberg, 2011).

Currently, pharmacotherapy is frequently offered for treatment of PLP. Although frequently used in combination with other interventions, prescribed drugs remain the first line of treatment given to patients with PLP (Subedi & Grossberg, 2011). However, it becomes convoluted when trying to measure efficacy rates of prescribed medication, as medicines given for other comorbid diagnoses, such as depression or anxiety, may be also affecting PLP symptoms (Subedi & Grossberg, 2011).

Drugs that are used for the treatment of PLP include opiates, antidepressants, anticonvulsants, sodium channel blockers, beta blockers, N-methyl-D-aspartate (NMDA) receptor antagonists, and Ketamine (Subedi & Grossberg, 2011). Unfortunately, drugs prescribed for the treatment of PLP are typically marginally helpful (Guimmarra & Moseley, 2011).

One type of drug, known as opiates, are typically prescribed for pain, both acute and chronic. However, in the last several decades, research has shown that there is a large distinction between the way acute pain and chronic pain-related diagnoses are treated. We now know that opiates are not only extremely dangerous and costly, but can

even make chronic pain worse (Lee et al., 2011).

Surgical and invasive procedures that are used for the treatment of PLP include nerve blocks, neurectomy, rhizotomy, cordotomy, lobectomy, sympathectomy, central nervous system (CNS) stimulation, transcutaneous nerve stimulation, and electroconvulsive therapy (ECT) (Subedi & Grossberg, 2011). However, noninvasive interventions are preferable to invasive procedures like surgery (McQuaid, 2015).

Psychological interventions that are used for the treatment of PLP include MVF, eye movement desensitization and reprocessing therapy (EMDR), trauma-focused psychotherapy, CBT, and biofeedback (Subedi & Grossberg, 2011). Little research exists on the efficacy and effectiveness of these modalities for the treatment of PLP. The pain experienced by amputees resulting from their phantom limb has been shown to be significantly relieved in studies utilizing trials of psychological interventions without the use of more traditional medical treatments such as pharmacology (Alviar, Hale, & Dungca, 2016). However, some studies emphasize that there is still a need for more empirical evidence regarding the effectiveness of psychological treatments for PLP, and pain management in general (Markozannes et al., 2017).

Mindfulness Meditation as Evidence-Based Practice

The successful management of chronic pain has been significantly impacted by the role of psychologically-based treatments (Garg et al., 2012). An example of a group of non-pharmaceutical and non-surgical interventions that have been used and studied in chronic pain management are Mindfulness-Based Interventions (MBI). MBI typically include practices such as MM, diaphragmatic breathing techniques, and other stress reduction techniques. MBI help lower the perception of pain, increase mobility, improve

functioning and well- being (Majeed, Ali, & Sudak, 2018). Additionally, MM techniques are potentially analgesic interventions (Grant & Rainville, 2009) and have been shown to be effective in pain management treatment plans (Bertisch, Wee, Phillips, & McCarthy, 2009).

Originating from Eastern meditation techniques, mindfulness encourages the individual taking a neutral position of observation on one's own experiences, including pain. It is distinguished by giving one's attention to the present moment, without focusing on the past or the future. This awareness of the present is accompanied by a sense of acceptance, interest, and openness (Hilton et al., 2016).

The effect of MM on chronic pain has been studied since the mid-1980's (Kabat-Zinn, Lipworth, & Burney, 1985) and, presently, continues to be widely studied as a response to the potentially harmful and ineffective interventions being offered in traditional biomedical settings, such as opiates and surgeries (Hilton et al., 2016). Even the use of modern neuroimaging techniques has been employed in studies investigating potential brain mechanisms activated in pain regulation during MM (Zeidan, Grant, Brown, McHaffie, & Coghill, 2012). MM has been selected for this study as there is consistent evidence in support of mindfulness-based interventions (such as MM) in the treatment of several chronic pain conditions (Majeed, Ali, & Sudak, 2018). Further, MM will be used as there are currently no published studies that use only MM for PLP, with or without the use of MVF.

Mirror Visual Feedback/Mirror Box Therapy (MVF)

Traditionally, phantom limb pain has been addressed with pharmacological interventions as a first line of treatment (Alviar, Hale, & Dungca, 2016). However,

effective psychological interventions have also been used for several years, often adjunct to medications (Markozannes et al., 2017). One example of these effective interventions is MVF, also known as "mirror box therapy" (Ramachandran et al., 1992). MVF was created by neuroscientist and researcher V. S. Ramachandran, who has been devoted to exploring the mind's relationship to the body for over 20 years. MVF has been shown to have a medium effect size (average decrease in PLP of 27%) as an intervention for the relief of PLP (Foell et al., 2013). However, like other interventions for PLP, not all amputees respond to MVF treatment. The difference between those who respond well to MVF compared to those who do not is unknown (Foell et al., 2013).

Traditionally, physicians and other prescribing medical clinicians are trained that all pain is essentially the same, and is uniformly treated with opiates (Harden, 2008). In a time when opiates are increasingly contra-indicated for any chronic condition, specifically chronic pain, MVF is an intervention that has few side effects, has no risk of dependency (Rothgangel, et al., 2015), is feasible to implement in-person or via telehealth (Gover-Chamlou, & Tsao, 2015) and is cost-effective (Lamont, Chin, & Kogan, 2011). With this change in zeitgeist of how chronic pain is managed, comes the desire and acceptance of a psychological intervention such as MVF.

Given the advantages of MVF, and yet seeing through the literature the strong connection between psychological composition and efficacy of treatment for PLP, the goal of this dissertation is to explore whether MVF is more effective for individuals with PLP who additionally utilize a psychologically-based treatment approach in combination with MVF.

Despite the mixed results of MVF in terms of pain reduction or elimination in

individuals living with PLP, it remains one of the most well accepted interventions with the least amount of side effects and drawbacks, and targets a complex condition that has historically been difficult to treat (Knotkova et al., 2012).

Telepsychology

The American Psychological Association (APA) defines telepsychology (also called "telemental health") as, "the provision of behavioral and/or mental health care services using technological modalities in lieu of, or in addition to, traditional face-toface methods" (APA.org, 2019). Telepsychology has been increasing in use and development since 2003 and has a peer-reviewed scientific journal titled "Telemedicine Journal and E-Health" devoted to reviewing the way telemedicine and telemental health continues to progress. Telemedicine, which includes telemental health, has been used with significant success during the past two decades, and studies have showed that a clinician or researcher can be effective employing psychological interventions for both the mind and the body using this modality (Rothgangel, Braun, Smeets, & Beurskens, 2017). Telemedicine has been shown in studies to significantly improve the access to primary care services for those living with functional limitations (Cho, MacLachlan, Clarke, & Mannan, 2016). A study reviewing the effectiveness of telemental health showed an increase in access to services and consistent effectiveness of use (Hilty, Ferrer, Parish, Johnston, Callahan, & Yellowlees, 2013). A systematic review from 2015 compared patient perceptions between telemental health an in-person psychotherapeutic treatment, and demonstrated that in general, patient satisfaction was comparable between the two (Jenkins-Guarnieri, Pruitt, Luxton, & Johnson, 2015).

Further, telemedicine has been shown to be efficacious in studies addressing

amputees with PLP specifically (Rothgangel, Braun, Smeets, & Beurskens, 2017). Additionally, a case study addressing MVF for amputees with PLP (Gover-Chamlou & Tsao, 2016) showed that due to MVF being a self-administered treatment, the use of telemedicine can be particularly effective in addressing access issues common to amputees that might otherwise prevent them from attending sessions in-person.

CHAPTER III

Methods

This study employed a true experimental research design with assignment of the participants to either the control or experimental group, which are described below.

IRB Approval

The study presented in this dissertation was approved by the University of San Francisco (USF) Institutional Review Board (IRB).

Participant Recruitment

Due to the relatively small number of amputee population available, the recruitment approach for this study was for any amputee with PLP, w/no other specific targeting features. Thus, no detailed demographic information was collected or controlled for, ancillary to the specific inclusion and exclusion criteria. Initial recruiting methods of this study involved contacting clinicians and program directors of various organizations that work with amputees. Unfortunately, this approach failed to yield a sufficient number of participants for this study. The participants of this study were successfully recruited via Facebook.com, an internet social media platform. A Facebook profile page was created for this study, entitled, "Phantom Limb Pain Research" which included information about the study and requesting participation from amputees with PLP. A second, similar internet platform was also created for recruiting participants via USF blog page. After viewing either the Facebook profile or USF blog page, if an amputee decided they wanted to participate, they clicked on a link that brought them to a screening questionnaire (Appendix B) found on Surveymonkey.com to see if they qualified. If the person met all inclusion/exclusion criteria set for eligibility to participate

in this study, they were sent an email with additional information about the study and scheduled the best time and day for them to begin. After scheduling a time and day for the participant to begin the study, they were emailed a copy of the IRB-approved consent form for study participants (Appendix A) to review during their first session.

The number of participants that were able to be recruited was a total of ten amputees; five individuals in the control group, and five in the experimental group, as explained below.

Sample Size

A power analysis was conducted to determine the sample size necessary to achieve a power of .80, this being the commonly used, minimum acceptable level in social sciences. The analysis revealed that for an alpha of .05 and a large effect size, 12 total participants were desirable with half assigned to each group. For a medium effect size, 31 participants would be needed, and for a small effect size, 196 participants will be needed, all to achieve a power of .80 (Cohen, 1992). Although we aimed for as many participants as possible within the time constraints of this study, 12 participants were considered sufficient to achieve the goal of this study, to demonstrate the efficacy of using mindfulness to enhance the effectiveness of MBT, because we expected the effect size to be rather large (Cohen, 1992).

Inclusion Criteria

In order to be eligible to participate in the study, individuals were required to be an amputee according to Mosby's Medical Dictionary (2009) definition of an amputee as a person who has one or more limbs amputated. Additionally, participants were included whether they have experience performing MVF or not in the past, as all participants will

be given an introduction as part of the standardized MVF protocol.

Further inclusion criteria consist of reporting current phantom pain in a missing extremity, being able to meet for daily sessions with the PI five consecutive days in a row and being able to understand and sign the offered consent form.

Exclusion Criteria

Exclusion criteria cover participants who are unable to report pain levels using Visual Analog Scale or perform MVF and/or MM, and those under 18 years of age (minors).

Procedures

All sessions and interventions used in both control group and experimental groups in this study were completely online and employed telepsychology via the programs FaceTime, Zoom, or Google Hangout. Telepsychology was selected as the final recruitment method, as it has been shown to be as effective as other psychological interventions (Hilty, Ferrer, Parish, Johnston, Callahan, & Yellowlees, 2013). Once participants had been recruited, they first began their involvement in the study by meeting with the PI online individually, for approximately one hour. During this first meeting, the goal was to explain the nature of the study, reviewed the consent form, and offer to answer any questions.

Each participant's pain levels were measured over the course of five consecutive days. Further, meeting over five consecutive days reduced the chance of participant attrition dropping out due to life events that may occur during the study. Although there is no one way to perform MVF, research shows that it can take as much practice as is reasonable to allow an amputee to train their mind to respond to the illusion of the

missing limb in the mirror's reflection (McCabe, 2011). During each of these five days, the PI met with the participant online, and asked the participant to report their pain level using the VAS. Next, if a person was assigned to the experimental group, they listened to the mindfulness meditation (MM), then proceeded with MVF. If the participant was assigned to the control group, they did not listen to the MM intervention and proceeded directly to engaging in MVF. Thus, each participant completed the VAS at the beginning and end of each of the five sessions, and each participant completed the protocol of MVF (Appendix J); only the experimental group completed MM.

All participants recruited to this study consisted of amputee patients who experience PLP and receive MVF. Following Consolidated Standards of Reporting Trials (CONSORT) guidelines for reducing bias during the randomization process (consort-statement.org, 2010), the method this study used to generate the random allocation sequence was alternation. The participants were assigned to either the control group (n = 5) or the experimental group (n = 5) depending on when they were recruited. The first recruited participant was assigned to the experimental group, the next recruited participant was assigned to the control group, the next recruited participant was assigned to the experimental group, and so on. Using the process of alternation, the participants in this study were assigned to comparison groups in the trial on the basis of chance, considered to be an adequate method of sequence generation (consort-statement.org, 2010).

Statistical Analysis

This study's statistical design utilized both a paired *t*-test and an unpaired ANOVA of equal groups of amputees with PLP. A paired *t*-test was selected to

determine whether there were statistically significant differences between the same subjects on the multiple data collection periods.

Furthermore, a two-factor ANOVA model with repeated measures on one factor, time, was the first candidate model for this study as each experimental subject's assessment scores was gathered at five similar times across treatment. Factors were treatment and time (repeated); the statistical model can be seen in Appendix F.

Measures

Visual analog scale. Pain levels were determined by using the Visual Analog Scale (VAS) measurement instrument for pain. The VAS is a multi-dimensional measure of pain intensity that is frequently used in clinical research and in clinical settings such as primary care organizations (Dauphin et al., 1999; MacCormack, Horne, & Sheather, 1998). The pain VAS is a single-item scale, is of most value when looking at change within pain scores of individuals, takes less than one minute to complete, and no training is required to determine a score (Hawker, Mian, Kendzerska, & French, 2011). Furthermore, the VAS is available in the public domain and is free and considered "open source."

The VAS is typically used to measure pain is a straight horizontal line, commonly 100 mm in length (Appendix E). The ends were defined as the limits of the pain being assessed, with at the far left of the line, "0" considered "no pain", and at the far-right end of the line, "100" considered "worst pain imaginable." Essentially, the left end of the line represented the least amount of pain, and the right end of the line represented the most amount of pain. The changes in pain reporting were measured by using a ruler (Streiner & Norman, 1989). The administrator of the VAS determines the score by measuring the

number of millimeters between the "no pain" mark at the far- left end of the line with the patient's indicating line, offering a range of possible scores from 0–100. Thus, the greater the score, the greater the intensity of reported pain. Cut-off points on the pain VAS were: "no pain (0–4 mm), mild pain (5-44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm)" (Jensen, Chen, & Brugger, 2003).

Regarding the validity of the VAS for pain, as there is no gold standard for measuring pain, criterion validity cannot be evaluated (Hawker, Mian, Kendzerska, & French, 2011). In regards to construct validity, "in patients with a variety of rheumatic diseases, the pain VAS has been shown to be highly correlated with a 5-point verbal descriptive scale ('nil,' 'mild,' 'moderate,' 'severe,' and 'very severe') and a numeric rating scale (with response options from 'no pain' to 'unbearable pain'), with correlations ranging from 0.71–0.78 and 0.62–0.91, respectively" (Hawker, Mian, Kendzerska, & French, 2011).

Mindfulness meditation in the experimental condition. The use of mindfulness meditation (MM) in this study involved the participant sitting at their residence on their computer with headphones connected, placing headphones on, and clicking on the link to the UCLA Mindful Awareness Research Center website (https://www.uclahealth.org/marc/body.cfm?id=22&iirf_redirect=1), then clicking "play" on the audio file prompted on the screen. After beginning the audio file, the participant listened to and followed the direction of the person speaking and leading a mindfulness meditation. For example, when the participant was directed to take a deep breath, the participant followed those directions and took a deep breath. Activities that are common in MM include being aware of and controlling breath, noticing sensations in our bodies,

and focusing on imagery. MM sessions can last anywhere from less than one minute to upwards of an hour, depending on what the activity involved might be, and how experienced the individual practicing the MM (Maglione et al., 2016). Participants practiced MM for a total of five sessions, for five consecutive days in a row. Meeting for five days in a row was decided as a reasonable amount of time to ask participants to be part of a study without missing a day, and with the difficulties in recruiting, the PI wanted to ensure the results were valid.

Participants assigned to the experimental group used headphones to listen and participate in a guided meditation followed by a session of MVF. Participants in the control group completed a session of MVF. In both groups, MVF was administered by the investigator who was trained and supervised in the use of MVF.

MVF protocol used in control group. MVF uses the reflection of prescribed movements and activities in a mirror carried out by the intact limb, creating the illusion of both limbs functioning well and without pain (Barbin, Seetha, Casillas, Paysant, & Pérennou, 2016). The specific protocol for MVF that was offered to the participants in both the experimental and control groups followed the protocols that have been established and used with amputee patients during the last two years at Center for Occupational Health in Richmond, CA (Appendix I and Appendix J). These protocols were developed following the guidelines and recommendations put forth by Dr. V. S. Ramachandran, the creator of MVF, and peer-reviewed journal studies that address best practices for clinical applications of MVF (Barbin, Seetha, Casillas, Paysant, & Perennou, 2016).

I administered MVF in this study, and showed the participant how to perform MVF while demonstrating on their own mirror. The participant watched and mimicked what steps and actions the researcher performed, while asking questions. The researcher then explained and led the participant through the appropriate protocol (see Appendix I and Appendix J) to ensure standardization of the MVF.

Evaluation

The results of this study were intended to show that amputees with PLP performing MVF who practice MM were likely to report less pain than amputees with PLP performing MVF without using MM.

The results of this study were disseminated to Dr. Bokarius and his team at Center for Occupational Health in Richmond, CA in order to consider the addition of MM to their existing MVF protocols. The results of this study were disseminated to the amputee groups on Facebook that allowed the PI to recruit participants by posting on their sites. The results of this study were disseminated to all parties who were known to the PI to have a vested interest in amputees and individuals living with PLP. Additionally, I contacted Dr. V. S. Ramachandran to create a discussion about the results of this dissertation's findings. It is hoped that the results of this study stimulate future research around the idea that psychological interventions, such as MM, may have an impact on the success of pain management. It is further hoped that the results of this study will create access to a dialogue with leading investigators in the field of MVF to develop more elaborate studies that follow in this dissertation's footsteps.

CHAPTER IV

Results

Demographics

The participants in this study were recruited using online amputee groups found on Facebook.com. The online nature of these groups made them accessible to amputees nationally, without being restricted to local resources. The demographic information (Table 1) of the participants shows that 50% identified as male (5), and 50% identified as female (5), 90% of participants were lower extremity amputees (9), of which 5 were above the knee amputees ("AKA"), 3 were below the knee amputees ("BKA"), and 2 were Full Arm Amputees. The age range of participant was from individuals in their mid-twenties to those in their late 60's, 10% of participants (1) presented as a person of color, and 90% (9) presented as White.

Table 1.

¥	Ν	Percent
Group		
Experimental	5	50.0
Control	5	50.0
Gender		
Male	5	50.0
Female	5	50.0
Amputee Status		
Extremity Location:		
Lower Extremity Amputees	9	90.0
Upper Extremity Amputees	1	10.00
Amputation Region Specifier:		
Above Knee Amputee (AKA)	5	50.0
Below Knee Amputee (BKA)	4	40.0
Full Arm Amputee	1	10.0
Age Range		
18 - 30	2	20.0
30 - 40	3	30.0
40 - 50	3	30.0

Participant Demographic Information

50 - 60	1	10.0
60 - 70	1	10.0
Race / Ethnicity		
Person of Color	1	10.0
White	9	90.0

Table 2 shows additional descriptive information regarding the participants in the experimental group (N = 5) and those in the control group (N = 5). For all participants in both the experimental group and the control group, the second session produced lower pain rating scores compared to the first session. For Tables below, 1-5 = number of session; A=VAS Pain Rating at beginning of session/pre-intervention; B=VAS Pain Rating at end of session/post-intervention.

Table 2.

Intervention	Session	Minimum	Maximum	Mean	Std. Deviation	Variance
	1A	45.00	95.00	61.60	21.10	445.30
	1 B	42.00	95.00	61.00	21.73	472.00
	2A	36.00	100.00	58.20	25.91	671.20
	2B	25.00	80.00	50.00	22.36	500.00
Control	3A	45.00	90.00	62.60	16.55	273.80
Group	3B	40.00	90.00	57.40	19.07	363.80
(N = 5)	4A	40.00	90.00	61.20	19.37	375.20
	4B	40.00	85.00	57.00	18.57	345.00
	5A	35.00	90.00	58.60	20.12	404.80
	5B	30.00	80.00	51.00	19.03	362.00
	Average	40.50	89.50	57.86	19.43	377.47
	1A	20.00	65.00	46.00	18.51	342.50
	1 B	15.00	55.00	41.00	16.36	267.50
	2A	15.00	62.00	48.00	18.76	352.00
	2B	15.00	60.00	43.60	17.67	312.30
Experimental	3A	20.00	70.00	44.60	19.06	363.30
Group	3B	10.00	65.00	39.00	21.62	467.50
(N = 5)	4A	20.00	60.00	45.60	17.44	304.30
	4B	15.00	50.00	36.00	13.87	192.50
	5A	30.00	70.00	49.00	14.75	217.50
	5B	30.00	62.00	43.60	12.52	156.80
	Average	21.30	61.40	43.64	15.31	234.54

Figure 1 below represents the overall means of VAS pain scores of both the control group ("No Intervention"), and experimental group ("MM"), not individual scores of participants. Session A refers to the VAS pain report of the participant at the beginning of the session, and "Session B" refers to the VAS pain report of the participant at the end of the same session. Thus, Figure 1 shows that in both the experimental group and the control group the second VAS pain score reported at the end of each session was consistently lower than the first VAS pain score reported at the beginning of each session. Additionally, Figure 1 shows that scores for participants in the experiment group were consistently lower than participants in the control group.

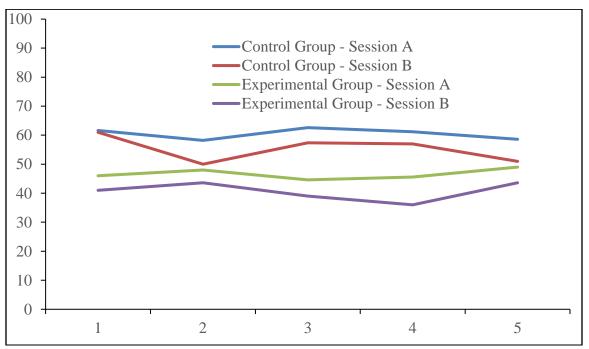


Figure 1. Trend Analysis of Session Scores by Group.

Paired Samples T – Tests were conducted to determine whether statistically significant differences existed between sessions for each participant. This information is consistent with the study's aims, as it may provide additional context for how the null hypothesis is being confirmed or ruled out. The results indicate that for all participants,

VAS pain rating scores in the first session were consistently higher than VAS pain rating scores in the second session. Furthermore, the results show that participants 3 and 5 in the control group showed statistically significant differences between Session 3a (M = 62.60, SD = 16.55) and 3b (M = 57.40, SD = 19.07) (t(4) = 3.55, p = 0.02), and also between Session 5a (M = 58.60, SD = 20.12) and 5b (M = 51.00, SD = 19.03) (t(4) = 3.97, p = 0.02). The results also indicate that of all the participants in the experimental group, participants 3, 4, and 5 showed statistically significant differences between Session 3a (M = 44.60, SD = 19.06) and 3b (M = 39.00, SD = 21.62) (t(4) = 3.31, p = 0.03), Session 4a (M = 45.60, SD = 17.44) and 4b (M = 36.00, SD = 13.87) (t(4) = 4.71, p = 0.01), and Session 5a (M = 49.00, SD = 14.75) and 5b (M = 43.60, SD = 12.52) (t(4) = 3.76, p = 0.02).

Table 3.

Group	Session	Mean	Std. Dev.	Std. Error Mean	95% LCL	95% UCL	df	t
	1A - 1B	0.60	1.34	0.60	-1.07	2.27	4	1.00
	2A - 2B	8.20	7.66	3.43	-1.31	17.71	4	2.39
Control	3A - 3B	5.20	3.27	1.46	1.14	9.26	4	3.55*
	4A - 4B	4.20	4.02	1.80	-0.80	9.20	4	2.33
	5A - 5B	7.60	4.28	1.91	2.29	12.91	4	3.97*
	1A - 1B	5.00	6.12	2.74	-2.60	12.60	4	1.83
Experimental	2A - 2B	4.40	6.27	2.80	-3.38	12.18	4	1.57
	3A - 3B	5.60	3.78	1.69	0.90	10.30	4	3.31*
	4A - 4B	9.60	4.56	2.04	3.94	15.26	4	4.71**
	5A - 5B	5.40	3.21	1.44	1.42	9.38	4	3.76*

Paired	Sam	oles	Т	Test	Results

*p < 0.05

**p < 0.01

Hypothesis

This study hypothesized that amputees with PLP performing MVF who practiced MM were likely to report less pain than amputees with PLP performing MVF without using MM. This study's results showed a trend of amputees with PLP who performed MVF in addition to MM tending to report less pain in each session than amputees with PLP performing MVF without using MM. However, these differences were not statistically significant (Table 4).

For Session 1a, the results indicate there was no statistically significant differences in pain between amputees with PLP performing MVF who practiced MM (M = 46.00, SD = 18.51) and amputees with PLP performing MVF without using MM (M = 61.60, SD = 21.20) (F(1, 8) = 1.55, p = 0.25). For Session 1b, statistically significant differences were not found between amputees with PLP performing MVF who practiced MM (M = 61.00, SD = 21.73) and amputees with PLP performing MVF who using MM (M = 41.00, SD = 16.36) (F(1, 8) = 2.71, p = 0.14).

For Session 2a, the results show there was no statistically significant differences in pain between amputees with PLP performing MVF who practiced MM (M = 58.20, SD = 25.91) and amputees with PLP performing MVF without using MM (M = 48.00, SD = 18.76) (F(1, 8) = 0.51, p = 0.50). For Session 2b, statistically significant differences were not found between amputees with PLP performing MVF who practiced MM (M = 50.00, SD = 22.36) and amputees with PLP performing MVF without using MM (M = 43.60, SD = 17.67) (F(1, 8) = 0.25, p = 0.63).

For Session 3a, the results indicate there was no statistically significant differences between amputees with PLP performing MVF who practiced MM (M =

62.60, SD = 16.55) and amputees with PLP performing MVF without using MM (M = 44.60, SD = 19.06) (F(1, 8) = 2.54, p = 0.15). For Session 3b, statistically significant differences were not found between amputees with PLP performing MVF who practiced MM (M = 57.40, SD = 19.07) and amputees with PLP performing MVF without using MM (M = 39.00, SD = 21.62) (F(1, 8) = 2.04, p = 0.19).

For Session 4a, the results did not show statistically significant differences between amputees with PLP performing MVF who practiced MM (M = 61.20, SD =19.37) and amputees with PLP performing MVF without using MM (M = 45.60, SD =17.44) (F(1, 8) = 1.79, p = 0.22). For Session 4b, the results did not show statistically significant differences between amputees with PLP performing MVF who practiced MM (M = 57.00, SD = 18.57) and amputees with PLP performing MVF without using MM (M =36.00, SD = 13.87) (F(1, 8) = 4.10, p = 0.08).

For Session 5a, the results did not show statistically significant differences between amputees with PLP performing MVF who practiced MM (M = 58.60, SD = 20.12) and amputees with PLP performing MVF without using MM (M = 49.00, SD = 14.75) (F(1, 8) = 0.74, p = 0.42). For Session 5b, the results did not show statistically significant differences between amputees with PLP performing MVF who practiced MM (M = 51.00, SD = 19.03) and amputees with PLP performing MVF without using MM (M = 43.60, SD = 12.52) (F(1, 8) = 0.53, p = 0.49).

For the average, the results did not show statistically significant differences between amputees with PLP performing MVF who practiced MM (M = 57.86, SD =19.43) and amputees with PLP performing MVF without using MM (M = 43.64, SD =15.31) (F(1, 8) = 1.65, p = 0.24).

Table 4.

		Sum of Squares	df	Mean Square	F	р
Session1A	Between Groups	608.40	1	608.40	1.55	0.25
	Within Groups	3151.20	8	393.90		
	Total	3759.60	9			
Session1B	Between Groups	1000.00	1	1000.00	2.71	0.14
	Within Groups	2958.00	8	369.75		
	Total	3958.00	9			
	Between Groups	260.10	1	260.10	0.51	0.50
Session2A	Within Groups	4092.80	8	511.60		
	Total	4352.90	9			
	Between Groups	102.40	1	102.40	0.25	0.63
Session2B	Within Groups	3249.20	8	406.15		
	Total	3351.60	9			
Session3A	Between Groups	810.00	1	810.00	2.54	0.15
	Within Groups	2548.40	8	318.55		
	Total	3358.40	9			
Session3B	Between Groups	846.40	1	846.40	2.04	0.19
	Within Groups	3325.20	8	415.65		
	Total	4171.60	9			
G · 44	Between Groups	608.40	1	608.40	1.79	0.22
Session4A	Within Groups	2718.00	8	339.75		
	Total	3326.40	9			
Session4B	Between Groups	1102.50	1	1102.50	4.10	0.08
	Within Groups	2150.00	8	268.75		
	Total	3252.50	9			
Session5A	Between Groups	230.40	1	230.40	0.74	0.42
	Within Groups	2489.20	8	311.15		
	Total	2719.60	9			
Session5B	Between Groups	136.90	1	136.90	0.53	0.49
	Within Groups	2075.20	8	259.40		
	Total	2212.10	9			

ANOVA Results (N = 10) for Each Session between Interventions

Average	Between Groups	505.52	1	505.52	1.65	0.24
	Within Groups	2448.04	8	306.01		
	Total	2953.57	9			

CHAPTER V

Discussion

The present study aimed to contribute to the existing research on the efficacy of MBI on phantom limb pain. The objective of this study was to discover if MM, a psychological intervention and MBI used for chronic pain, used in addition to the common intervention of MVF, resulted in a significantly lower report of phantom pain than those who only used MVF alone. This dissertation addresses the potential value that offering MM concurrently with MVF has on decreasing PLP. Due to the trend of amputees in the experimental group who practiced MM reporting less pain than amputees in the control group of this study, these results will inform clinicians working with amputees with PLP of the usefulness of MM and may better inform these clinicians on what to offer for decreasing pain levels. Further, this study reflects on the conclusions within the context of the larger scope of not only the effective management of PLP, but also how psychologists can be effective in their role in treating chronic pain and PLP in an integrated health care setting. This is consistent with the existing literature, which shows an increase in utilizing psychologists in pain management programs (Salamon & Cullinan, 2019).

The results indicate that the participants in the experimental group of this study who used the addition of MM to an MVF protocol did not report significantly lower pain levels than those participants in the control group who used MVF on its own. The amputees in the experimental group of this study who received both MM and MVF did consistently report lower pain levels than the control group, however the difference in pain reporting was not enough to be statistically significant. This finding is supported in

the literature in that studies offering MBI and MM as interventions for painful conditions are commonly effective in improving pain, depressive symptoms, and quality of life of individuals with chronic pain (Hilton et al., 2017). Additionally, an unintended finding of this study was the consistent, anecdotal report from participants of the anxiety that accompanied having to be reminded of and having to come to terms with the loss of their limb in which they have been experiencing phantom pain. This finding is particularly interesting, as undesirable side-effects are not routinely reported in the literature (Barbin, Seetha, Casillas, Paysant, & Pérennou, 2016).

Implications

The results of this study indicate that the participants who used MM in addition to MVF did not meet the criteria for showing statistical significance for decreasing reported pain levels in amputees with PLP. However, this study found a trend for those in the experimental group reporting less pain compared to the control group. However, the trend did not reach statistical significance.

The literature supports that MBIs, and specifically MM, has been shown to reduce pain reporting in individuals with chronic pain conditions, including PLP (Bertisch, Wee, Phillips, & McCarthy, 2009; Hilton, Hempel, Ewing, Apaydin, Xenakis, Newberry, Maglione, 2017; Kabat-Zinn, Lipworth, & Burney, 1985; Majeed, Ali, & Sudak, 2018).

Although not ideal, the results of this study may still be viewed as favorable, and hopefully inspiring to other researchers to create additional studies that measure the potential impact of MM on PLP levels.

Limitations

The current study is not without limitations. A limitation of this study was the relatively attenuated number of participants (N). Difficulty in recruiting amputees for this study was predicted, as amputees represent only 0.6% of the US population (advancedamputees.com, 2012). A larger sample would have given this pilot study more statistical power and generalizability, and the study's sample was likely too small to detect significant changes in pain levels with the addition of MM to MVF.

Recruiting time for the current study's participants took approximately 12 months, during which time 55 amputees responded to an online questionnaire screen to determine appropriateness of each participant. Of these 55 individuals who submitted a questionnaire, only a total of 10 participants completed the study. Additionally, recruitment issues for this relatively small population of amputees who experience PLP was furthered by the nature of the dissertation format (e.g., no grant funding, unable to devote multiple years to recruitment). Despite the relatively low number of participants in this study, the results still supported the study's initial hypothesis of the experimental group reporting less pain than the control group. The data analysis suggests a trend in those in the experimental condition reporting less pain relative to controls, (i.e., "treatment as usual"), however, the trend did not reach statistical significance.

Despite the frequent comorbidity of chronic pain with psychiatric symptoms and disorders, this study chose not to include a screen for depression, anxiety, or other symptoms commonly associated with chronic pain syndromes (Mckechnie & John, 2014). This decision was made due to the restricting nature of the dissertation process, such as length of time for recruitment, data analysis, and no grant funding.

Further, a consequence of this study's relatively small sample is an increased chance of not achieving significance (type II error). Running multiple tests on this study's small sample does not overcome this problem as long as a proper Bonferroni correction is made for multiple testing I did find a discernible trend, suggesting that future studies with larger sample sizes should be done to determine if the contribution of MM to pain reduction is statistically significant. It is hoped that future studies with larger sample sizes may show statistical significance, as this pilot study was unable to.

A significant limitation in this study that I had was no way of controlling what activities the participants engaged in between each session that may have impacted their pain level reporting. For example, if a participant engaged in strenuous aerobic exercise before one of their MVF sessions, the subsequent increase in circulation or rise in dopamine levels may have impacted how they reported the pain they experienced. Another example may be if a participant received bad news before an MVF session, they may be likely to report higher pain levels due to negative emotions influencing how they report their entirely subjective experience of pain (Melzack, 1973). This limitation was the result of this study's methodology, which did not require participants to report their activities between sessions. This study attempted to control for this limitation by the methodological approach of randomization. Future research would better assess what may be impacting amputees' pain reporting by participants maintaining a log of daily activities, disclosed each day to the researchers.

Another limitation in this study is that its methodology was restricted to the guidelines of a quantitative study, and qualitative information was not collected. This study would have benefited from the acquisition and incorporation of qualitative

information in addition to quantitative, as using a more wholistic view of each participant could provide additional factors which may have impacted pain level reporting. For example, knowledge of medical records, medications currently prescribed, and active DSM-5 diagnoses would all provide a clearer understanding of each amputee's context. The participant's circumstances would be helpful to know, as this information may be relevant to why an amputee reports particularly high or low on any pain level measure, which is inherently subjective (Hawker, Mian, Kendzerska, & French, 2011). This information would have been helpful in this study as steps would have been created within the methodology to attempt to control for different relevant circumstances and events which may have impacted pain reporting. Similar studies may consider using a mixed methods approach to include relevant contextual information about each participant.

An additional limitation of this study was the face validity of the pre- and postintervention pain reporting using the VAS measure. During the explanation of the study to each participant at the beginning of the first session, it was made clear to each person that I was investigating if the discussed interventions (MVF for the control group, and MM in addition to MVF for the experimental group) were going to lower their pain. The expectation for reporting an improvement in pain levels was always clear at the end of each session, when the participant was asked for their post-intervention pain level VAS number (0-100). Due to the transparency of what was being studied, and the VAS measure being entirely subjective, the risk of the participant reporting a lower pain level in order to appease the researcher was entirely possible, if not likely. This limitation in turn may be related to a similar threat to external validity, which are Hawthorne effects,

as I worked to form a positive relationship with each participant. This relationship was sought in order to help prevent attrition and increase honest reporting, and it is possible that a participant may have "faked good" by reporting less pain in order to appease me.

Suggestions for Future Research

In order to address the limitation of the transparency of what was being studied and possible Hawthorne effects (Goodwin, Stange, Zyzanski, Crabtree, Borawski, & Flocke, 2017) including participants "faking good," future researchers may consider different ways of approaching how pain reporting is executed. For example, a future study may capture more accurate pain reporting and decrease the likelihood of the participant wanting to satisfy the researcher, if perhaps the second data point was not collected at all. This approach would direct the researcher to ask for the participant's pain level only once each meeting, preferably at the beginning of the session. Asking for a pain report at the beginning of the session would remove the immediate expectation of reporting on the efficacy of the intervention and would allow the participant to report their pain levels gradually over multiple sessions. Additionally, perhaps have a different researcher administer/collect the data.

The relatively small number of participants in this study stands as one of its most salient limitations. Conversely, it is encouraging that the intervention of MM appeared to make a desirable difference in pain reporting, and likely with the most minimum use of MM as an intervention. This implies that perhaps more studies need to be created while attending to the limitations that this and other similar studies may have neglected to address. Future research that keeps all details the same as this study, but simply increases the number of participants, would be likely to show statistically significant results.

Future researchers might consider using additional sessions beyond the five that were included in this study, thus increasing the frequency and perhaps efficacy of the MM intervention itself. Meeting with participants for only five sessions may not have produced an adequate representation of the impact of MM. Future research would better assess the impact of MM by providing additional sessions with each participant. Additionally, meeting with each participant for a total of five sessions may have warranted a meaningful intervention for the purpose of this study, but may have underestimated the potential of MM as a useful intervention over longer periods of time.

Further, researchers creating a similar future study would more accurately evaluate the intervention if the study first established a minimum proficiency of MM. This proficiency would provide consistency of measurable impact of MM and would therefore be a better test of the intervention. Without any standardized training, the participants utilized merely an elementary use of MM, as mindfulness meditation training typically involves a "practice", analogous to yoga and traditional meditations (Basso, McHale, Ende, Oberlin, & Suzuki, 2019). Thus, future research could more accurately assess the impact of MM if a determined amount of time was dedicated to the participants training and practicing MM in order to first "build" the study's intervention.

Additionally, future researchers would be able to more effectively generalize their results by including a more diverse sample of participants, ideally those who would include a large variety of different experiences in their lives. In order to create a reasonably generalizable study that explores pain reporting, researchers need to include participants from as many different cultures (e.g., racial, ethnic, religious) and contexts (e.g., socioeconomic status, lost limb in a variety of different ways) as possible. As far

back as the 1970's, studies have explored how these kinds of variables can and do impact pain level reporting (Melzack, 1973), and thus to create a study that is useful to the public, the more different the sample population, the stronger the study's external validity would be.

This study's research question of whether a psychological intervention (MM) would impact the efficacy of MVF, suggests that the psychological well-being of an amputee may impact their ability to benefit from MVF. Future studies may show that the mental health of participants is indeed a relevant variable to consider when studying PLP. If amputee study participants have better outcomes from MVF when their minds are experiencing less psychological symptoms, then it may also imply that when an amputee is experiencing psychological symptoms (e.g., anxiety, depression), interventions such as MVF may be less effective. Further, this view suggests a need for a psychological assessment of amputees prior to the administration of MVF, and perhaps the development of a screen to detect salient psychological symptoms of amputees before using MVF specifically.

A mixed method approach may be useful in similar future studies, as it would allow exploration of each participant's individual context, which in turn impacts the way they report their pain. By using one of the many brief survey questionnaires that investigate the subjective nature of a person's pain, much context could be gained from which to help make sense of why a person would report a higher or lower pain rating. For example, administering the Pain Catastrophizing Scale (PCS) to participants before beginning their participation in a study would give the researchers a general idea of how they feel about their pain, and how much higher level of pain they would report on due to

their degree of pain catastrophizing (Osman, Barrios, Kopper, Hauptmann, Jones, & O'Neill, 1995).

In conclusion, this study did not produce statistically significant results that allowed the ruling out of the study's null hypothesis. However, despite not achieving statistical significance, the results point towards supporting the hypothesis that the addition of MM to MVF would result in lower pain reporting by amputees with PLP than using MVF alone. It is hoped that future researchers will be encouraged to continue this line of research, as it appears likely that by changing only a minimal amount of this study's parameters, they would likely demonstrate statistical significance in their findings.

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Appendix A

Consent Form for Study Participants

University of San Francisco Consent to Participate in a Research Study

Below is a description of the research procedures and an explanation of your rights as a research participant. You should read this information carefully. If you agree to participate, you will sign in the space provided to indicate that you have read and understand the information on this consent form. You are entitled to and will receive a copy of this form.

You have been asked to participate in a research study conducted by Nicolas Mills, a graduate student in the Department of Clinical Psychology at the University of San Francisco. The faculty supervisor for this study is Doctor William Bosl, an instructor in the Department of Clinical Psychology at the University of San Francisco.

WHAT THE STUDY IS ABOUT:

The purpose of this research study is to determine whether or not the addition of mindfulness techniques helps the outcomes of mirror box therapy for people experiencing phantom limb pain.

WHAT WE WILL ASK YOU TO DO:

During this study, the following will happen: At the beginning of each session you will be asked to report your pain level on the Visual Analog Scale (VAS) which will be provided by Nicolas Mills. You may then listen to a 5-minute recording of a "mindfulness meditation" and be asked to follow along while you listen. This may involve you sitting at a desk with headphones connected to a laptop computer connected to the internet, which will play the meditation after clicking on a link which will already be on the screen waiting for you. This may involve relaxing and focusing on your breathing. You will then be asked to learn how to use a version of mirror box therapy to address your phantom pain. This will involve you looking at and doing small movements with the remaining limb adjacent to the one that was amputated. You will then do mirror box therapy with Nicolas Mills for approximately 50 minutes, for a total of approximately 60 minutes each session. Using the VAS, you will be asked for information about your pain level at the end of each session.

DURATION AND LOCATION OF THE STUDY:

Your participation in this study will involve your attendance at a total of 5 sessions of meeting with Nicolas Mills over the course of 1 week, completing 1 session per day for 5 consecutive days. Each session will be approximately 60 minutes long. The study will take place online via Skype/FaceTime.

POTENTIAL RISKS AND DISCOMFORTS:

Side effects of mirror box therapy are not systematically reported, and research has shown that potential for side-effects are extremely low. Although mirror box therapy is considered extremely safe and reported side-effects are extremely rare, the research procedures described above may involve the following risks and/or discomforts: dizziness, confusion, and possibly increasing depressed feelings about having lost part of

your body from seeing the reflection of your corresponding limb that is still intact. If you wish, you may choose to withdraw your consent and discontinue your participation at any time during the study without penalty. In the very unlikely event of a participant experiencing acute distress, they will be immediately referred to emergency psychiatric services locally.

BENEFITS:

The possible benefits to you of participating in this study are the decrease or loss of phantom pain and/or phantom sensation in your amputated limb.

PRIVACY/CONFIDENTIALITY:

Because no information will be recorded to uniquely identify you (such as your name), the data you provide will be anonymous.

COMPENSATION/PAYMENT FOR PARTICIPATION:

There is no payment or other form of compensation for your participation in this study.

VOLUNTARY NATURE OF THE STUDY:

Your participation is voluntary and you may refuse to participate without penalty or loss. Furthermore, you may skip any questions or tasks that make you uncomfortable and may discontinue your participation at any time without penalty.

OFFER TO ANSWER QUESTIONS:

Please ask any questions you have now. If you have questions later, you should contact the principal investigator: Nicolas Mills at nmsills@usfca.edu. If you have questions or concerns about your rights as a participant in this study, you may contact the University of San Francisco Institutional Review Board at IRBPHS@usfca.edu.

I HAVE READ THE ABOVE INFORMATION. ANY QUESTIONS I HAVE ASKED HAVE BEEN ANSWERED. I AGREE TO PARTICIPATE IN THIS RESEARCH PROJECT AND I WILL RECEIVE A COPY OF THIS CONSENT FORM.

- 1. Do you agree to the above terms? By clicking Yes, you consent to participating in this research study.
- 2. Please enter your first and last name as your electronic signature:
- 3. Please enter today's date:

Appendix B

Participant Questionnaire Screen

Phantom Pain Online Study Screen	
	-
Please answer a few questions to see if you're right for this study. All info is kept confidential.	
* 1. Are you over 18 years old?	
○ Yes	
○ No	
* 2. Are you an amputee?	
) Yes	
○ No	
\sim	
* 3. Do you experience pain where your amputated body part used to be (known as "phantom pain")?	
⊖ Yes	
O No	
* 4. Do you have home internet access on a computer or laptop with the program FaceTime or Skype?	
⊖ Yes	
* 5. This study requires you (participants) to select 5 consecutive daysof your choice to meet for 1 hou	ur a
day.	
Example: Mon 4/1 - Fri 4/5 at 1pm	
Is there a time would you be able to meet with a researcher on FaceTime or Skype fo f hour a day	
for 5 days in a row?	
⊖ Yes	
No	
* 6. What is your first and last name?	

Appendix C

Visual Analogue Scale for Pain

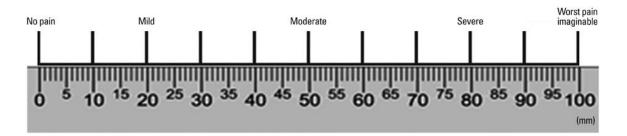


Fig. 1. Visual analog scale ranged from 0 mm (no pain) to 100 mm (worst pain imaginable).

Appendix D

Intervention Timeline

Table A1	
Intervention	Timeline

Day 1

Participant meets with PI online at agreed upon time. PI reviews and offers consent form for participation in study PI gives Measurement 1 PI offers MM and/or MVF with participant PI gives Measurement 2

Day 2 Participant meets with PI online at agreed upon time. PI gives Measurement 3 PI offers MM and/or MVF with participant PI gives Measurement 4

Day 3 Participant meets with PI online at agreed upon time. PI gives Measurement 5 PI offers MM and/or MVF with participant PI gives Measurement 6

Day 4 Participant meets with PI online at agreed upon time. PI gives Measurement 7 PI offers MM and/or MVF with participant PI gives Measurement 8

Day 5 Participant meets with PI online at agreed upon time. PI gives Measurement 9 PI offers MM and/or MVF with participant PI gives Measurement 10 Appendix E

Repeated Measures ANOVA

Repeated Measures ANOVA

The model will be:

$$Y_{ijk} = \mu + \tau_i + d_{ik} + \beta_j + \tau\beta_{ij} + \epsilon_{ijk}$$

with i = 1, 2 (1 = treatment group, 2 = control group); j = 1, ..., 4 (4 different times of

assessment scores); k = 1, ..., 5 ([assuming] 8 subjects in each group);

where:

 Y_{iik} is the assessment score of k^{th} subject in i^{th} treatment group at j^{th} time;

 μ is the overall mean, an unknown constant;

 τ_i is the *i*th treatment effect;

 β_i is the *j*th time effect;

 d_{ik} is the random error attributable to each subject within each group;

 $\tau \beta_{ii}$ is the treatment-time interaction effect; and

 ϵ_{ijk} is the experimental random error.

Assumptions:

- d_{ik} 's are independent and normally distributed ~N(0, σ^2).
- ϵ_{iik} 's are independent and normally distributed ~N(0, σ^2).
- d_{ik} and ϵ_{ijk} are independently distributed.
- Huynh– Feldt condition is valid. [meaning: the variances of the differences between *any* pair of assessment scores of the same subject must be equal].

Null Hypotheses to be tested:

- $H_0: \Theta_{TB} = 0$
 - \succ F = MS_{Trt*Time}/MSError
- $H_0: \Theta_B = 0$

- \succ F = MS_{Time}/MSError
- $H_0: \Theta_T = 0$
 - \succ F = MS_{Trt}/MSError

Appendix F

Mindfulness Mediation Script

Breathing Meditation (5:31)

Find a relaxed, comfortable position Seated on a chair or on the floor, on a cushion Keep your back upright, but not too tight Hands resting wherever they're comfortable Tongue on the roof of your mouth or wherever it's comfortable. And you can notice your body From the inside Noticing the shape of your body, the weight, touch And let yourself relax And become curious about your body Seated here The sensations of your body The touch The connection with the floor The chair Relax any areas of tightness or tension Just breathe Soften And now begin to tune into your breath In your body Feeling the natural flow of breath Don't need to do anything to your breath Not long not short just natural And notice where you feel your breath in your body It might be in your abdomen It may be in your chest or throat Or in your nostrils See if you can feel the sensations of breath One breath at a time When one breath ends, the next breath begins Now as you do this you might notice that your mind might start to wander You might start thinking about other things If this happens this is not a problem It's very natural Just notice that your mind has wandered You can say "thinking" or "wandering" in your head softly And then gently redirect your attention right back to the breathing So we'll stay with this for some time in silence Just a short time Noticing our breath From time to time getting lost in thought and returning to our breath See if you can be really kind to yourself in the process And once again you can notice your body, your whole body, seated here Let yourself relax even more deeply

And then offer yourself some appreciation For doing this practice today Whatever that means to you Finding a sense of ease and wellbeing for yourself and this day [bell rings]

(UCLA Mindful Awareness Research Center, http://marc.ucla.edu/mindful-meditations)

Appendix G

Permission Email

Yes you are welcome to use it. Just credit and link us appropriately and send me the results!

Best, Diana

Diana Winston Director of Mindfulness Education UCLA's Mindful Awareness Research Center <u>www.marc.ucla.edu</u>

From: Nicolas Mills <<u>nsmills@dons.usfca.edu</u>> Sent: Saturday, April 28, 2018 1:30:21 PM To: Winston, Diana Subject: Request permission for dissertation study

Dear Ms. Winston,

My name is Nicolas Mills, I am a graduate student in the clinical psychology department at University of San Francisco working on my dissertation. I wanted to politely and humbly ask your permission to please use your "Breathing Meditation" on the UCLA MARC website (<u>http://marc.ucla.edu/mindful-meditations</u>) as an intervention in my study.

My dissertation addresses an underserved population by examining the use of guided meditation as a way to increase the efficacy of mirror box therapy for reducing phantom limb pain in amputees. Both my experimental and control group will receive a mirror box therapy protocol, but my intervention group will listen to your guided meditation immediately proceeding the mirror box therapy. My study will likely have an N of approximately 10, as recruiting participants with this condition is very difficult. I will be under the guidance of my dissertation chair Dr. William Bosl, MS, PhD, PhD at USF, and my study will be pending our IRB board's approval for all ethical and legal considerations.

I propose my dissertation on May 22nd, and, at your convenience, would love to have your permission to use your wonderful guided meditation in my study. I can send any drafts and/or final copies at any time per your request.

Thank you very much for your consideration, and please let me know if I can answer any questions at all.

Best regards,

Nicolas

Appendix H

Mirror Visual Feedback Protocol for Upper Extremity

MVF Protocol (Upper Extremity)

If scarring on arm/wrist, ask amputee to wear long sleeves during treatment Does participant practice mindfulness meditation technique before activities?

- YES____
- NO_____

Clinician: "Please look at your hand's reflection in the mirror while doing these activities. Although your amputated hand remains still inside the mirror box, try to imagine your missing limb is actually moving during these activities, that what you see is actually happening. Please try it with me."

Make sure patient moves stump hand/fingers inside box during activities, uses both hands simultaneously

Check off Activity + # / Length of time :

- Slow waving 5 minutes
- Make fist/open hand 5 minutes
- Touching tips of fingers to thumb 5 minutes
- Drawing on Post-It note:
 - o 10 vertical lines X 10 horizontal lines
- Finger lift/drop 5 minutes
- Placing paperclips into box

Notes:_____

Appendix I

Mirror Visual Feedback Protocol for Lower Extremity

MVF Protocol (Lower Extremity)

If any scarring on foot/ankle/leg, ask amputee to wear long sleeves during treatment Does participant practice mindfulness meditation technique before activities?

- YES____
- NO_____

Clinician: "Please look at your leg's reflection in the mirror while doing these activities. Although your amputated leg remains still inside the mirror box, try to imagine your missing limb is actually moving during these activities, that what you see is actually happening. This will take some practice, but is very important. Please try it with me."

Make sure patient moves stump leg/foot inside box during activities, uses both legs/feet simultaneously

Check off Activity + # / Length of time :

- o Flexing/relaxing quadriceps (foot stays on ground) 5 minutes
- Pointing toes away from head, then towards 5 minutes
- Rolling foot/ankle in circles clockwise/counterclockwise 2.5 mins/2.5 mins

- Curling toes and relaxing toes 5 minutes
- "Waving" foot left and right (don't bend knee or ankle) 5 minutes
- Rubbing knee 5 minutes

Notes:_____