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Learning to Apply Mindfulness to Pain (LAMP): Design for a Pragmatic Clinical Trial of Two Mindfulness-Based Interventions for Chronic Pain

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Abstract

Background. Mindfulness-based interventions (MBIs) are evidence-based nonpharmacological treatments for treating chronic pain. However, the predominant MBI, mindfulness-based stress reduction, has features that pose significant implementation barriers. **Objectives.** This study will test two approaches to delivering MBIs for improving Veterans' chronic pain and mental health comorbidities. These two approaches address key implementation barriers. **Methods.** We will conduct a four-site, three-arm pragmatic randomized controlled trial, Learning to Apply Mindfulness to Pain (LAMP), to test the effectiveness of two MBIs at improving pain and mental health comorbidities. Mobile+Group LAMP consists of prerecorded modules presented by a mindfulness instructor that are viewed in an online group setting and interspersed with discussions led by a facilitator. Mobile LAMP consists of the same prerecorded modules but does not include a group component. We will test whether either of these MBIs will be more effective than usual care at improving

chronic pain and whether the Mobile+Group LAMP will be more effective than Mobile LAMP at improving chronic pain. Comparisons for the primary hypotheses will be conducted with continuous outcomes (Brief Pain Inventory interference score) repeated at 10 weeks, 6 months, and 12 months. The secondary hypotheses are that Mobile+Group LAMP and Mobile LAMP will be more effective than usual care at improving secondary outcomes (e.g., post-traumatic stress disorder, depression). We will also confirm the comparisons for the primary and secondary hypotheses in gender-specific strata. **Implications**. This trial is expected to result in two approaches for delivering MBIs that will optimize engagement, adherence, and sustainability and be able to reach large numbers of Veterans.

Key Words: mindfulness, veteran, chronic pain

Introduction

Mindfulness-based interventions (MBIs) are an efficacious treatment for improving chronic pain [1–6] and comorbid conditions commonly experienced by Veterans, such as post-traumatic stress disorder (PTSD), sleep disorders, depression, and substance abuse [7, 8]. *Mindfulness* is generally defined as the ability to pay attention to the present moment in a nonjudgmental way. MBIs teach mindfulness skills, which have been shown to improve chronic pain through multiple pathways [3, 9, 10]. MBIs are recommended by the Veterans Health Administration [11], the Army Pain Management Task Force, and the Agency for Healthcare Research and Quality as an evidence-based nonpharmacological treatment for chronic pain [12, 13] and by the American College of Physicians as a first-line treatment for chronic low back pain [6].

Rationale for the Intervention

This research will test two MBIs, which are grounded in mindfulness-based stress reduction but are modified to enhance fidelity, engagement, adherence, and sustainability and to be deliverable to large numbers of Veterans with chronic pain. As others have discussed, mindfulness-based stress reduction has features that pose significant barriers for widespread implementation at the health care system and patient levels [14]. Mindfulness-based stress reduction requires a large commitment of resources from health care systems, as it is comprised of 26 hours of in-person group instruction (eight 2.5-hour in-person sessions and a day-long retreat) and is led by instructors who must complete an extensive training and certification process [15]. Although this training ensures high-quality delivery of essential mindfulness elements, it has led to a paucity of available mindfulness instructors. Both the time required for each course and the lack of certified instructors limit the ability of the U.S. Department of Veterans Affairs (VA) Healthcare Systems to offer MBIs to all Veterans who would benefit from them.

For many patients, the time commitment of mindfulness-based stress reduction, which requires 45 minutes of daily home practice, six days a week, in addition to the 26 hours of instruction, can be impossible or unsustainable and may contribute to the low adherence and high attrition rates reported in many studies [2, 14]. Additionally, access barriers exist for many Veterans who are not able to easily travel to the main Veterans Health Administration (VHA) facilities to attend or who may not be available when sessions are offered [14]. Although the group component is considered an essential part of mindfulness-based stress reduction [16] and can foster feelings of connectedness [17, 18], facilitate the learning process [17], and increase engagement [19], being in mixed-gender groups can be difficult for female Veterans with histories of sexual trauma or assault [14]. This is important because between 15% and 40% of female Veterans have experienced military sexual trauma [20].

In the past decade, MBIs developed to address barriers associated with standard mindfulness-based stress reduction have been shown to be effective at improving chronic pain and comorbid mental health conditions [3, 21–24]. Adaptations include reduced in-class and home practice requirements, alternative modes of delivery (e.g., asynchronous, online, mobile), and elimination of the group component. A meta-analysis of 15 randomized controlled trials of online MBIs concluded that they have a small but significantly beneficial effect on depression, anxiety, and well-being and a larger effect on stress [23].

With the proliferation of smartphones and mobile health (mHealth) applications (apps), there has been growing interest in developing and testing mobile applications to deliver nonpharmacological pain treatment [25]. Mobile health self-management nonpharmacological pain treatments can address system-level barriers associated with the current referral process, including limited access through failure of providers to offer nonpharmacological pain treatment modalities to patients [26]. Mobile health MBIs may also be a good alternative for women Veterans who prefer to receive care outside VA because of military sexual trauma and other types of sexual harassment (including at the VA) [27, 28] and for rural Veterans who experience barriers to accessing VA services.

Methods

Primary Hypotheses

The primary hypotheses are that MBIs (Mobile+Group LAMP [Learning to Apply Mindfulness to Pain] and

Mobile LAMP; described below) will be more effective than usual care at improving chronic pain and that Mobile+Group LAMP will be more effective than Mobile LAMP at improving chronic pain. These hypotheses will be tested with continuous outcomes (Brief Pain Inventory [BPI] interference score) repeated at 10 weeks, 6 months, and 12 months. The secondary hypotheses are that both the Mobile+Group and Mobile LAMP interventions will be more effective than usual care at improving secondary outcomes (e.g., PTSD, depression). We will also confirm comparisons for the primary and secondary hypotheses in gender-specific strata, based on self-identified gender from the baseline survey.

Overall Design

We are conducting a four-site, three-arm randomized controlled trial (N = 750; Mobile+Group LAMP, Mobile LAMP, and usual care) to test intervention effectiveness and address key implementation questions. Our design was guided by the PRECIS (PRagmatic Explanatory Continuum Indicator Summary) tool [29] and maximizes pragmatism, while including several explanatory elements to ensure internal validity. As can be seen in Figure 1, pragmatic design features include those related to: 1) recruitment and 2) setting (participants recruited from and the study conducted in real-world clinical settings); 3) primary outcome (improvement in functioning, which is highly relevant to patients with chronic pain) [30]; 4) primary analysis (intention-to-treat); and 5) eligibility (broad inclusion and narrow exclusion criteria, which are those that would be required if this was implemented in a nonclinical setting, with the exception of the requirement of completing a baseline survey). Additionally, 6) we do not attempt to control for nonspecific effects because of differences in time and attention of the interventions, and 7) we use "usual care" as a comparator. More explanatory elements include those related to: 1) organization (we are using interventionists employed by the study; however, the intervention is designed so a variety of VHA staff could administer it); b) flexibility in delivery (facilitators will be delivering a manualized intervention); c) adherence (we will use engagement strategies such as email and text reminders to increase intervention participation); and d) follow-up (we will use extensive measures to obtain follow-up data from participants at 10-week, 6-month, and 12-month time points to ensure high internal validity).

Study Population

Participants must be from one of the participating sites: the Minneapolis, Durham, Indianapolis, and Greater Los Angeles Veterans Affairs Healthcare Systems. They must have documented in their VA electronic health record receipt of qualifying pain diagnoses within the same pain category on at least two occasions, at least 90 days apart, during the previous 2 years. Pain categories were defined according to the *International Classification of Diseases, 10th Revision* (ICD-10) (see Supplementary Data for full description). Participants must report a pain duration of ≥6 months (pain chronicity threshold) and a pain severity score of ≥4 on the 0–10 Numeric Rating Scale (pain severity threshold) [31]. Patients must have access to a smartphone that meets the requirements of the mobile app software, be willing and able to download the mobile app on their phone, and have wireless or cellular internet access on a daily basis (e.g., at home). Participants must be willing to meet remotely online on the dates and at the times that Mobile+Group LAMP sessions are held and must be willing to attend all sessions of the arm to which they are randomized. We will exclude patients who have diagnoses of schizophrenia, bipolar disorder, or other psychosis within the prior 18 months in their electronic health records; have active psychotic symptoms, suicidality, severe depression, and/or active manic episode or poorly controlled bipolar disorder (assessed by chart review); are currently enrolled in a research study for their pain; or are enrolled in mindfulness-based stress reduction.

Screening, Recruitment, and Randomization Procedures

We aim to recruit 750 participants from the four participating sites by using a proactive recruitment strategy. The study programmer will identify patients by searching the electronic health record using algorithms derived from ICD-10 codes, described above. The study programmer will then assign these patients a Study ID and create a crosswalk so that identifiable data is kept behind the VA firewall. Introductory letters will be mailed to these patients, with follow-up postcards sent to nonresponders. These introductory letters will include instructions for accessing the study website (along with a phone number to call for help), an opt-out option, information about monetary incentives ($25 per survey for a possible total of $100), an information sheet, and a general introductory brochure. Participants will access the website by using a unique identifier (Qualtrics FedRAMP ID) with either a secure, shortened URL or a QR code that can be scanned. The shortened URL and QR code will be available in the introductory letter and follow-up postcard. Participants who log into the study website will then be directed to the study screener. If participants screen as eligible, they will then complete the Qualtrics FedRAMP baseline survey. Completion of the screener, baseline survey, chart review, and brief phone call to verify availability, commitment, and necessary technology will result in randomization to one of the three study arms, Mobile+Group LAMP, Mobile LAMP, or usual care (1:1:1), with 250 participants in each arm.

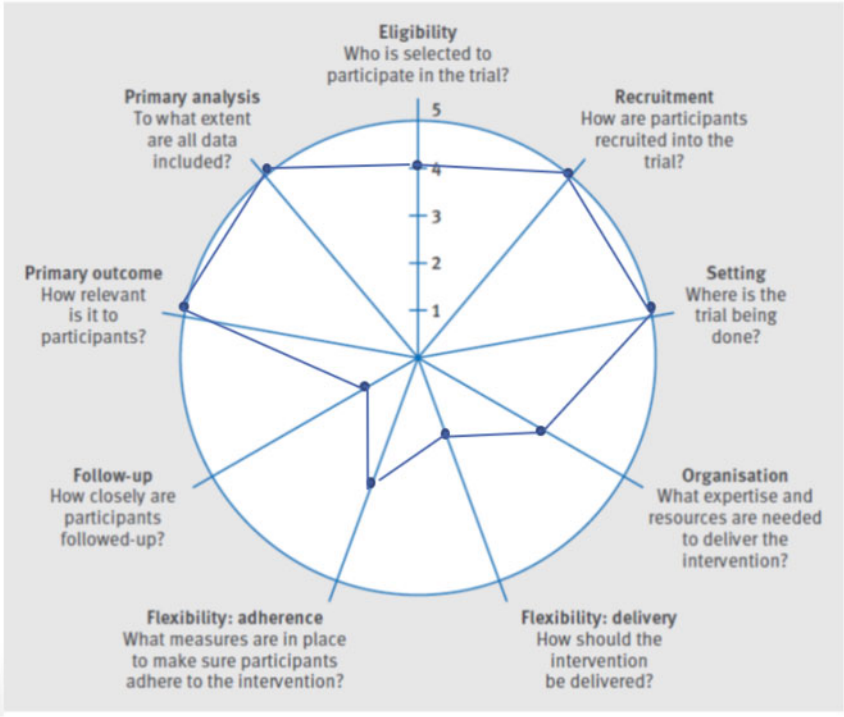

Figure 1. The PRagmatic-explanatory continuum indicator summary 2 (PRECIS-2) wheel. Adapted by permission from BMJ Publishing Group Limited. [The PRECIS-2 tool: designing trials that are fit for purpose, Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. BMJ 2015;350:h2147]

Blinding

Blinding of participants is not feasible. To minimize potential bias and enhance study rigor, 1) all study personnel involved in screening and enrollment will be masked to upcoming computer-generated randomization assignments; and 2) study personnel involved in outcome assessment will not be involved in intervention delivery and will be trained in ensuring unbiased data collection.

Baseline and Follow-Up Procedures

Baseline data are required for inclusion in the study. Patient-reported primary and secondary outcome data will be collected at 10 weeks, 6 months, and 12 months. We will use online collection, with mail and phone follow-up.

The primary outcome is the BPI interference score over the 12-month follow-up period, assessed at 10 weeks, 6 months, and 12 months, to capture short-term, mid-term, and long-term effects. Secondary outcomes include Patient-Reported Outcomes Measurement Information System (PROMIS)-29 Profile v.2.0 measures of physical function, anxiety, fatigue, sleep disturbance, participation in social roles and activities, depression (assessed by the Patient Health Questionnaire depression scale [PHQ8]), PTSD (assessed by the Post Traumatic Stress Disorder Checklist for Diagnostic and Statistical Manual of Mental Disorders - 5 [PCL5]), and patient ratings of global improvement of pain. These outcomes will be assessed at baseline, 10 weeks, 6 months, and 12 months, except for the global improvement of pain change score, which will not be assessed at baseline. See Supplementary Data for a complete list of survey measures. We will use electronic medical data from VA health care records to assess other measures of chronic pain burden, including changes in analgesic use and health care utilization.

Description of Study Interventions

We will test two adaptations of standard mindfulness-based stress reduction, Mobile+Group LAMP and Mobile LAMP, aimed at decreasing system-level and Veteran-level barriers to use. The usual care arm will not have access to the MBI training with either the app or the group. After the entire follow-up period is complete, participants in the usual care arm will be given access to MBI training on the app.

The Mobile+Group LAMP intervention was based on a similar study by two of the present study's co-investigators (RE and AH; NIH #1R21AT009110-01A1; principal investigator RE) and has been pilot-tested with 26 Veterans. Mobile+Group LAMP consists of online training modules, delivered by a trained mindfulness instructor, which were designed to be viewed in person, on a large screen, and in group settings and to be interspersed with reflections and group discussions. A trained facilitator, who is not required to be an expert in mindfulness, leads the group. Because of the COVID-19 (coronavirus disease 2019) pandemic, we modified the

Mobile+Group intervention so that group sessions will now be held remotely through the use of videoconferencing software rather than in person.

Mobile LAMP consists of the same training modules delivered on an app (and available online), with no group interaction. Inclusion of this condition will allow us to rigorously test the addition of the group component of the intervention. This is important because there is little research designed to rigorously test the added benefit of groups relative to their costs [14]. Mobile LAMP requires fewer VHA resources and reduces barriers associated with the group format. However, Mobile+Group LAMP affords benefits related to having a facilitated group (e.g., accountability, support, motivation), which may increase participation and engagement and improve outcomes [19].

Both MBIs address the goals of scalability (availability of qualified instructors, uneven quality of instructors, consistency) and Veteran-centeredness (reduced class time and practice demands, more effective communication about how the MBI will address outcomes of concern to Veterans). Both MBIs are shorter than standard mindfulness-based stress reduction programs. Mobile+Group LAMP consists of eight 1.5-hour sessions, and Mobile LAMP consists of eight 45-minute sessions. Both conditions are preceded by a technical session of 30 to 45 minutes (delivered in the group setting for Mobile+Group LAMP and as part of a one-on-one introductory phone call with a facilitator for participants in the Mobile LAMP condition). Participants in the Mobile LAMP condition will also receive a second check-in (by phone) between weeks 3 and 4 to provide reminders and address questions and challenges to engagement, as well as a "wrap-up" call in the final week; we added these individual calls to improve engagement on the basis of the results of our pilot study. Participants in both groups are encouraged to engage in daily practice activities that fit their preferences and their abilities. These include small "in-the-moment" mindfulness practices (1–2 minutes), meditations (5–10 minutes), and mindful movement (5–10 minutes). Participants will be considered to have completed the intervention if they participated in five of the eight sessions, assessed by survey self-report, which will be validated by attendance records and app usage data.

Important advances in behavioral health have provided theoretical and evidence-based models to strengthen and optimize interventions, including MBIs, to improve fidelity, reduce attrition, improve engagement, and help intervention participants achieve their desired outcomes. Using the Behavior Change Wheel Model [32], which synthesizes 19 behavior change frameworks and maps intervention elements with participant needs and desired outcomes, LAMP incorporates specific behavioral change strategies that are not part of standard mindfulness-based stress reduction. These "motivational affordances" in online self-management interventions have been shown to contribute to adherence [33]. For example, LAMP educational modules help Veterans understand how mindfulness practices are expected to lead to desired outcomes (e.g., reduction in pain interference, improvements in fatigue). This is important, as research has shown that lack of communication before and during the course of the program about how the MBI will address outcomes of concern to Veterans is a barrier to enrollment and adherence [14]. Examples of other behavioral change strategies built into the LAMP interventions include behavioral goal setting and monitoring, practice and rehearsal, problem-solving, and verbal persuasion. LAMP also takes advantage of the fact that the majority of individuals have their mobile devices with them for much of the day and check them frequently [34]. This allows for "real-time engagement" [34], in which individuals can use Mobile LAMP when they experience cues that trigger maladaptive pain- and stress-related behaviors, in order to engage in adaptive behaviors.

Sample Size Determination

Our power calculation uses the BPI interference score as the primary outcome measure. For our primary analysis, we estimate up to 20% attrition, so up to 750 people will need to be randomized to obtain a sample of 600 people with complete data. Two hundred participants in each of the three arms will yield 80% power to reject the null hypothesis of equal means if any of the three arms differ from each other by an effect size of 0.33 or greater. This is based on an alpha level of 0.0167 (Bonferroni correction of two-sided alpha = 0.05/3) for each of the three comparisons (Mobile+Group LAMP vs usual care, Mobile LAMP vs usual care, and Mobile+Group LAMP vs Mobile LAMP). With the same assumptions, there will be 90% power to detect differences of 0.38 or greater. Analyses that are stratified by gender will have 80% power to detect differences of 0.50 accounting for treatment arm and gender (this includes Bonferroni correction to incorporate the six comparisons).

We estimate that we may need to screen up to 30,000 patients (23,000 male and 7,000 female) to reach our recruitment goals. On the basis of our pilot, we estimate a randomization rate of 2.5%, with women responding at up to three times the rate of men (an approximately 4.5% response rate for women and almost 2% for men). Ultimately, this would yield a randomized N = 750 with retention of 600 or more participants (approximately 100 men and 100 women in each of the three intervention arms) at 10 weeks, 6 months, and 12 months.

Analytic Methods

We will use an intention-to-treat approach. Preliminary descriptive analyses will summarize the distributions of the baseline measures across treatment arms overall and by gender and will similarly assess the outcome distributions across assessment time points. We will summarize

the completeness of the self-reported outcome assessments and examine associations between completeness and baseline measures, as well as the association with secondary outcome assessments that are collected from the electronic medical record (e.g., medications, health care utilization related to pain treatment). Initial analyses will use all available follow-up data, and subsequent sensitivity analyses will examine the potential effect of response bias. For analyses of the primary outcome, all repeated measurements of the BPI interference score will be fitted in a mixed model for repeated measures as a function of the group assignment, while controlling for time points and baseline values of the outcome as fixed effects, with participants as random effects. Between-group differences over the entire follow-up period will be the primary test of treatment group differences (this will be done for all three comparisons of the Mobile LAMP, Mobile+Group LAMP, and usual care arms). Between-group differences will be estimated for each of the time points (i.e., 10 weeks, 6 months, and 12 months). The secondary outcomes (pain intensity, physical function, anxiety, fatigue, sleep disturbance, participation in social roles and activities, depression, patient ratings of improvement of pain, and PTSD) will be similarly analyzed by using the same linear mixed-effect models for normal continuous measures and appropriate generalized linear mixed effect models for non-normal measures.

Additional exploratory analyses will involve the assessment of the extent to which amount of mindfulness practice, pain acceptance, pain-related fear avoidance, pain management self-efficacy, mindfulness skills, and perceived stress mediate the effects of the intervention, and these analyses will use the bootstrap approach to obtain confidence intervals. Similar to the methods described above for the primary analyses, weighted selection model analyses will examine the sensitivity of the initial results to response biases. To do this, we will fit a series of weighted selection model analyses. Each analysis will use an expectation-maximization algorithm to estimate weights to assign to potential values of the missing outcomes for use in the regression model. Models will be varied to use different combinations of variables (intervention, observation and value of the outcome at various assessments, and baseline covariates, together with pain measurements and utilization of services over the follow-up period) as predictors to consider different potential missing-at-random and missing-not-at-random mechanisms that could be generating the missing data.

Given the aforementioned potential for women and men to respond differently to group-based interventions, we will also examine interactions between treatment and gender. However, tests for interaction tend to be underpowered. As a result, gender-stratified results will be presented in secondary analyses even if statistical evidence of interaction is not found.

Implementation and Dissemination Activities

Implementation data will be collected and described, guided by the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [35]. We will conduct interviews to understand the barriers perceived by patients, staff, and health system leaders and will collect quantitative data to assess intervention application and adherence and to inform cost estimates.

If the LAMP intervention is effective, implementation will be informed by data gathered through our RE-AIM analyses, ongoing discussions with our Veteran and stakeholder panels, and input from our operational partners, which include the VA Office of Patient-Centered Care and Cultural Transformation and the VHA National Pain Management Program Office. We will identify adaptations from the research protocol (including information, tools, and support) that are needed to translate and maintain the intervention in routine clinical practice. We will create an implementation toolkit and replication manual, which will incorporate lessons learned through the RE-AIM analysis. We will work with our Veteran and stakeholder engagement groups to disseminate our research beyond academic journals, to reach Veterans and family members, clinicians, administrators, and policy makers.

Discussion

The proposed project uses several novel approaches to advance nonpharmacological research for chronic pain. Many of these approaches were designed to address key barriers hindering the impact of evidence-based nonpharmacological interventions for chronic pain [36]. Our trial is the first to test scalable MBIs specifically for treating chronic pain in the VHA context and is designed to increase reach and ultimately impact. This will enable the VHA to offer nonpharmacological pain management strategies to more Veterans who could benefit. Both interventions will include components aimed at increasing treatment effectiveness by reducing attrition and improving engagement, practice, and sustainability. Moreover, these strategies were informed by feedback from Veterans with chronic pain. This is expected to increase adherence and facilitate the use of mindfulness strategies in daily life after the intervention, leading to greater enactment of adaptive vs maladaptive pain- and stress-related responses and behaviors. The use of prerecorded modules presented by an experienced mindfulness instructor addresses barriers related to fidelity of intervention delivery and barriers related to the availability and cost of mindfulness instructors. Our project also addresses barriers to MBIs that are specific to women Veterans, a priority population that is at elevated risk of chronic pain and mental health comorbidities. The study is the first to assess the added benefits of the group component of MBIs for chronic pain, which is an important

issue to address given the costs associated with groups (e.g., VHA resources, additional burden on participants related to scheduling, barriers to enrollment for patients who do not want to be part of a group). The use of scalable MBIs enables us and other researchers to efficiently conduct multisite randomized controlled trials, which have myriad methodological benefits over single-site trials (e.g., greater external validity, greater statistical power, and rapid recruitment) [37].

Our design was influenced by input from the Pain Management Collaboratory Coordinating Center (PMC3). This input led us to modify our inclusion/exclusion criteria, the primary outcome, and the primary sample. Originally, the study was designed to have co-primary outcomes based on BPI and the Roland Morris Disability scores, and these scales were going to be analyzed primarily as a responder analysis with a dichotomous outcome about whether or not the participant's score dropped by 30% or more. After discussion with the PMC3, the co-primary outcome was dropped in favor of a single primary BPI outcome, and this outcome was changed to an assessment of continuous change in the BPI interference score over the 12-month follow-up period with repeated measures. Additionally, with feedback from the PMC3, the primary comparisons are proposed for the entire sample of men and women, and the gender-specific results are secondary.

We also made two changes, with input from the PMC3, in response to the COVID-19 pandemic. First, we will now include in our baseline survey the Pain Management Collaboratory Coronavirus Pandemic (COVID-19) Measures, which comprise seven items assessing the potential impacts of the coronavirus pandemic. Second, we are now delivering the Mobile+Group LAMP condition remotely. We are modifying our facilitator training protocol and intervention materials to address this change and are incorporating barriers and facilitators documented by co-investigators RE and AH, based on a rapid assessment conducted during the transition from in-person to remote delivery of a similar intervention in another study (NIH #1R21AT009110-01A1; principal investigator RE). Although we did not anticipate delivering the group intervention remotely, this approach is aligned with the VHA's expansion of remote services and addresses recommendations of telehealth MBIs as a way to improve accessibility for Veterans [14]. The intervention's rapid response to factors related to the COVID-19 pandemic demonstrates its ability to effectively adapt to unexpected changes in contextual factors that may occur during the course of the study and in real-world clinical settings.

Conclusion

Our trial is the first to test cost-effective, scalable MBIs specifically for treating chronic pain in VA health-delivery organizations and is designed to increase reach and ultimately impact. This will enable the VA to offer nonpharmacological pain management strategies to more Veterans who could benefit. Moreover, if effective, Mobile LAMP would be accessible to Veterans who find it difficult to access nonpharmacological treatment for pain. The use of prerecorded modules presented by an experienced mindfulness instructor addresses barriers related to fidelity of intervention delivery. Our project addresses barriers to MBIs that are specific to women Veterans, a priority population that is at elevated risk for chronic pain and mental health comorbidities, and is the first study that will be statistically powered to examine the effects of MBIs on women with chronic pain. This intervention could also be adapted for active military members and the civilian population.

Supplementary Data

Supplementary Data may be found online at http://painmedicine.oxfordjournals.org.

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