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RUNNING HEAD: Internet-based pain self-management for veterans

Internet-based pain self-management for veterans: Feasibility and preliminary efficacy of the Pain EASE program

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ABSTRACT

Objective: To develop and test the feasibility and preliminary efficacy of a cognitive behavioral therapy-based, internet-delivered self-management program for chronic low back pain (cLBP) in veterans.

Methods: Phase I included program development, involving expert panel and participant feedback. Phase II was a single-arm feasibility and preliminary efficacy study of the Pain EASE (i.e., Pain e-health for Activity, Skills, and Education) program. Feasibility (i.e., website use, treatment credibility, satisfaction) was measured using descriptive methods. Mixed models were used to assess mean within-subject changes from baseline to 10 weeks post-baseline in pain interference (primary outcome, West Haven-Yale Multidimensional Pain Inventory, 0-6 scale; WHYMPI), pain intensity, mood, fatigue, sleep, and depression.

Results: Phase I participants (n=15) suggested modifications including style changes, content reduction, additional "Test Your Knowledge" quizzes, and CBT skill practice self-monitoring form revisions for enhanced usability. In Phase II, participants (n=58) were mostly male (93%), white (60%), average age 55 (SD=12), with moderate pain (mean 5.9/10), and 41 (71%) completed the post-baseline assessment. Participants (N=57) logged on 6.1(SD= 8.6) times over 10 weeks and 85% reported being very or moderately satisfied with Pain EASE. Pain interference improved from a mean of 3.8 at baseline to 3.3 at 10 weeks (difference 0.5 (95% CI 0.1 to 0.9), p=0.008). Within-subject improvement also occurred for some secondary outcomes including mood and depression symptoms.

Discussion: Veterans with cLBP may benefit from technology-delivered interventions, which may also reduce pain interference. Overall, veterans found that Pain EASE, an internet-based self-management program, is feasible and satisfactory for cLBP.

INTRODUCTION

Chronic pain affects approximately 20.4% of the US population, and is more prevalent in veterans, whose chronic pain prevalence rates are estimated to be approximately 26% .[1] Compounding the issue of high prevalence rates of chronic pain conditions, veterans are faced with a number of additional challenges for addressing pain. For example, veterans in Veterans Health Administration (VHA) care have higher rates of comorbid medical conditions (e.g., hypertension, type 2 diabetes), and mental health conditions (e.g., post-traumatic stress disorder, depression) that may negatively affect their outcomes.[2, 3]

VHA has long promoted evidence-based non-pharmacological approaches, such as cognitive behavioral therapy (CBT-CP), for the management of chronic pain,[4, 5] and, in response to the opioid epidemic, has further emphasized the use of these approaches. Unfortunately, several barriers to accessing CBT-CP and other evidence-based treatments for chronic pain among veterans include geographic location (many live far from their local VHA medical center), time constraints, caregiver burden, and availability of trained providers and treatments. [6, 7] VHA is addressing some of the barriers to pain care through directives that allow veterans to seek care in their local communities and use of technology (e.g., internet- and smartphone application-based interventions). [8-11] Development and deployment of technology-assisted delivery systems (e.g., telehealth, smartphone applications, interactive voice response, and internet) may not only enhance access to care but also potentially reduce disparities in care among veterans.[12] For example,

data from 29 studies included in a systematic review suggest that patients with chronic pain demonstrate significant improvements following engagement in internet-based self-management pain programs (e.g., CBT or acceptance and commitment-based [ACT] interventions).[13] However, generalizability of these results to veterans is limited, as the studies included had variable data quality and homogeneous participant populations (e.g., predominantly white and female).[13]

Many of the internet-based programs for chronic pain conditions include some clinician involvement and use interventions such as physical activity and discussion groups, rather than CBT. In contrast, some internet-based self-management programs that use CBT techniques have been developed using a self-guided (i.e., no clinician involvement) format. Pooled data for internet-based interventions for anxiety typically find similar results between clinician-guided programs and self-guided programs; however, for programs addressing depression, participants demonstrate slightly better outcomes with clinician involvement, possibly due to greater program adherence in clinician-guided programs. [14] Self-guided programs may provide added benefits of lower operating costs and greater access without the need to rely on a finite number of trained clinicians to facilitate participants' program progress.

Although they have not been directly compared to clinician-guided programs, self-guided internet-based programs for chronic pain demonstrate promising outcomes. In a randomized controlled trial (RCT), Williams et al. tested an internet-based program, *Living Well with Fibromyalgia (now called FibroGuide)*, in which participants (95% female) with fibromyalgia were provided with education and CBT skills for pain management.[6] This program involved no clinician contact between randomization and 6 months following study enrollment. Participants reported improvements in pain, physical functioning, and overall global improvement.[6] Another internet-based pain management program, *Pain COACH*, for hip and knee osteoarthritis also used a self-directed (i.e., non-clinician guided), CBT format.[15] In this RCT, participants, who were also predominantly female, demonstrated improvements in self-efficacy, pain-related functional interference, anxiety, and positive and negative affect. Participants reported high satisfaction with the program, and the trial experienced low attrition.[15] There are fewer studies of technology-based interventions for chronic pain focusing on veterans, who tend to be older males. A pilot study of a self-guided mobile health intervention (i.e., Health *e*Ride) targeting veterans with chronic pain used the transtheoretical model of behavior change to tailor pain self-management to patients. This program, which included cognitive and behavioral skills, found statistically significant reductions in pain and pain impact but included only a 30-day follow-up.[16] Data from prior research of self-guided, CBT-based pain self-management programs delivered via the internet, while promising, are limited, and do not involve veteran samples.

Building on the format and function of the *FibroGuide*, Health *e*Ride, and *Pain COACH* programs, the current study sought to develop and test a pain self-management program that did not require clinician involvement and used a CBT-CP approach developed for veterans in VHA care. The current study employed a two-phase design to (1) develop and refine an internet-based behavioral pain self-management intervention (i.e., the Pain EASE program; [Pain *e*-health for Activity, Skills, and Education]), and (2) test feasibility and

preliminary efficacy of the Pain EASE program in veterans with chronic low back pain (cLBP). Hypotheses included (1) participants would report high levels of credibility, use, and satisfaction with the Pain EASE program, and (2) veterans who participated in Pain EASE would report a clinically meaningful reduction in pain-related functional interference at 10 weeks post-baseline, and improvement on other important problems commonly associated with cLBP.

METHODS

A two-phase design was used to develop and pilot test the program, and to refine the program using feedback from these participants. The refined program was then tested in a single-arm feasibility and preliminary efficacy study. This study was approved by the Institutional Review Board at the VA Connecticut Healthcare System, West Haven, CT. This study was registered at clinicaltrials.gov (registration number NCT01918189).

Description of Pain EASE program

Pain EASE is a self-directed (i.e., does not require clinician involvement), internet-delivered (and device-agnostic, such that it is as readable and usable on a mobile device as it is on a computer) cognitive behavioral therapy-based self-management intervention. It is designed to assist patients in identifying and using relevant pain coping skills to improve functioning and quality of life.

Participants enter the program using a login that enables each user to be recognized by the program, access program features, and save patient-entered data, such as step counts, sleep tracking, and relaxation practice. After they complete the brief version of the Chronic Pain Coping Inventory (CPCI),[17] which measures use of adaptive pain coping skills such as physical activity, pacing, and mental relaxation, a. "Personalized Plan" is generated. The "Personalized Plan" contains suggested coping skills modules based upon low item scores of the CPCI (i.e., infrequently used coping skills), although patients can access all modules. The home page contains a list of all pain coping skills modules, a link to summary information associated with self-monitoring or activities tied to each module (i.e., Tracking Your Progress), links to pain and comorbid conditions resources (e.g., websites and smartphone applications), and a help section for technical challenges.

Pain EASE contains 10 pain coping skill modules, which were slightly modified from those developed and tested in the *COPES* program, a CBT-CP program for veterans with chronic back pain delivered using interactive voice response (IVR) technology.[18, 19] Each module (see Table 1 for a list of modules) adheres to a common structure: (1) brief content presented with graphics and/or audio, (2) an opportunity for self-assessment (i.e., "Test Your Knowledge" quizzes) of the module content followed by automated feedback, and (3) tools for identifying and overcoming barriers to change and module-specific resource materials (e.g., self-monitoring forms and skill-specific information that can be printed and shared with a physician).

In addition to the modules, participants have the option of using a self-monitoring feature to enter data such as daily pain intensity, sleep quality (i.e., on a scale of 0, "not at all rested" to 10 "extremely rested",

please rate how refreshed or rested you felt after last night's sleep), and number of steps walked, with data entries numerically and graphically displayed (week, month, 6 months). This section also contains monitoring forms commonly used in CBT to guide participants in use of the pain coping skills, such as forms for creating SMART (i.e., Specific, Measurable, Achievable, Relevant, and Time-based) goals, using problem-solving techniques, balancing unhealthy thinking, and tracking relaxation practice. The Tracking Your Progress section has links to other resources (e.g., instructions for pedometer use, downloadable relaxation audio tracks, preparing for a healthcare visit), access to the Test Your Knowledge quizzes, and instructions for how to share self-monitoring information with caregivers and healthcare providers. Finally, the participants using the Pain EASE program can access a Resources section with links to education and skills about chronic pain and comorbid problems (e.g., depression, PTSD, parenting, problem-solving, suicide helpline, smoking cessation, sleep, and weight management) as well as links for free smartphone applications geared toward veterans.

Phase I Development of Pain EASE prototype Methods:

Overview:

Participants with cLBP provided detailed qualitative and quantitative feedback during and after completion of the Pain EASE prototype. Feedback was used to modify and further refine the prototype for inclusion in the trial.

The Pain EASE prototype was developed using an expert panel of clinicians and researchers with expertise in pain management, rehabilitation and health services pain research, conduct of clinical trials of behavioral interventions, and adaptation of therapy materials for technology-based delivery. The prototype website was developed in conjunction with an informatics expert and a graphic/web applications designer incorporating User-Centered Design processes. [20, 21] Once the initial Pain EASE prototype was developed, Phase 1 participants were recruited. This occurred at the end of year 1 of the study.

Participants:

In Phase I, participants with cLBP were recruited via study advertisements placed in clinical areas at one northeastern VA medical center. Participants were screened for (1) presence of chronic (3 months or longer) low back pain, (2) moderate to severe pain intensity (i.e., ≥ 4 on the 11-point pain intensity numeric rating scale [NRS]) in the previous week, (3) interest and readiness to participate in an internet-based pain self-management program (i.e., with the Readiness and Interest Questionnaire. This questionnaire included questions reflecting an indication of “preparation”, “action”, or “maintenance” stage of readiness to change. The brief 5-item staging checklist used a rating of at least 4 or greater on a 0 (not at all interested) to 10 (extremely interested) scale assessing participants’ interest in receiving pain self-management via the Internet, and (4) access to a computer (or tablet, smartphone) and the internet.

Procedures: Participant feedback was solicited regarding the layout of the website, ease of navigation and use, relevance of the materials presented, appeal of the program, understanding of key concepts, appropriateness of the graphics and multimedia interface, problems encountered, amount of material presented, and general likes, dislikes, overall functionality of the program, and recommendations for change.

Qualitative data were collected using a "Think Aloud" process in which the participants provided unstructured verbal feedback while engaged in the computer task. Specifically, during two, 2.5-hour visits participants were asked to comment on usability, design, and navigation of the website while they reviewed each aspect of the program and the content of the skill modules (see above for description). All feedback was audio-recorded, transcribed, coded, and systematically analyzed for emerging themes by two reviewers.

Participants completed an author-created measure (i.e., Post-Intervention Questionnaire; PIQ) containing 12 items with Likert-scale and "Yes/No" responses assessing usability and satisfaction on the same domains described above. Demographic data were collected via electronic health record (EHR) and participant self-report.

Phase I Results: Participants (N=15) were 47% female, 60% White, 27% Black, 13% Hispanic and were an average age of 50.9 years (range 36-60 years old). Average pain duration was 12.3 years (range 0.5-40 years) and average reported pain intensity during the previous week (0-10 where 0=no pain and 10=worst pain imaginable) of 6.9 (range 4-10), which is consistent with moderate pain intensity.

Qualitative feedback focused on themes consistent with minor style changes (e.g., color changes, images), reduction of content for some modules, addition of "Test Your Knowledge" quiz for all modules, minor functional changes (e.g., addition of links for forms, links to the dashboard), and restyling the tracking forms for enhanced usability. Quantitative feedback for the PIQ is summarized in Table 2. The results of the Think Aloud interviews and PIQ were shared with members of the expert panel and were used to inform modification of the Pain EASE program, which was then examined in the Phase II feasibility trial. Phase II Feasibility and Preliminary Efficacy Trial Methods:

Phase II was a single-arm trial designed to test feasibility (usability and satisfaction) and preliminary efficacy of the modified Pain EASE program conducted at the end of year 2. Participants were provided access to the Pain EASE program for 10 weeks in conjunction with usual care for their pain condition(s). After analyzing qualitative data from Phase I, modifications to the Pain EASE prototype were completed and the prototype was tested. Following confirmation that the Pain EASE program was functional, Phase II participants were recruited (i.e., at the end of year 2).

Participants:

Participants with moderate-to-severe chronic low back pain were recruited via study advertisements posted in clinical care areas as well as a staffed education outreach table that provided general patient education about chronic pain and information about relevant studies. Interested participants were screened for eligibility in person or via telephone. Eligibility criteria were the following: (1) an International Classification of Diseases (ICD)-9 diagnosis consistent with low back pain in the electronic health record; (2) presence of moderate pain (i.e., NRS pain intensity scores of ≥ 4) for a period of ≥ 3 months; (3) absence of any life threatening or acute medical conditions (e.g., severe COPD, lower limb amputation, terminal cancer) or serious psychiatric condition (e.g., active substance abuse, psychosis or suicidality) that could impair participation; (4) absence of planned surgical interventions for pain during forecasted study participation; (5)

availability of a computer/tablet/smartphone with internet access in the participant's residence; (6) indication of "preparation", "action", or "maintenance" stage of readiness to change on a brief five-item staging checklist; and (7) a rating of at least 4 or greater on a 0 (not at all interested) to 10 (extremely interested) rating scale assessing participants' interest in receiving pain self-management via the Internet based on the stages of change model.

Procedures:

Following screening, eligible and interested participants were scheduled for an in-person appointment to obtain written informed consent and to collect baseline assessment data. After baseline data collection, participants were provided instructions for accessing the Pain EASE program as well as a user ID and temporary password that they were automatically prompted to change at initial login. Participants were also provided with a pedometer to facilitate the exercise/walking module in the program and informed that a member of the study staff would contact them weekly (weeks 1-10 post-baseline) for a brief, 5 to 10-minute phone call. During the call, the staff member ensured there were no difficulties with accessing the website, collected participant reports of which skill module(s) they accessed during the previous week, assessed self-reported behavioral goal adherence ratings for the previous week's skill practice (i.e., using a 0-10 Likert scale, where 0 indicates no adherence to completing the goal and 10 indicates complete adherence), and collected daily pedometer step count data. All participants continued to receive usual pain care directed by their medical provider. Participants were contacted to schedule a post-baseline assessment visit after 10 weeks of access to the program.

Feasibility and Preliminary Efficacy Outcome Variables and Measures:

The current study used guidelines from the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) for the assessment of multiple dimensions of the pain experience in all pain treatment trials,[22] including the use of Intent-to-Treat analyses, assessment of treatment credibility, monitoring of subject attrition, and monitoring of adherence.[23] All measures (with the exception of the author-created PIQ, which was not tested) demonstrate adequate reliability and validity.

Feasibility measures

Module completion: The website tracked which modules were accessed, time spent at each login, and number of times each participant accessed (i.e., program logins) the program. Consecutive login attempts less than two minutes apart were not counted as this likely represented a forgotten or changed password. Mean number of modules accessed was calculated. *Treatment credibility:* At post-baseline, participants' judgments of treatment credibility was assessed using an adapted version of a questionnaire created by Borkovec and Nau.[24] *Patient satisfaction* was assessed by the Pain Treatment Satisfaction Scale which is a 5-item satisfaction survey designed to assess patient satisfaction with 5 domains of pain care.[25] *Program-specific feedback* was examined using the Post-intervention Questionnaire (PIQ; described above) at post-treatment. Treatment credibility, patient satisfaction, and program-specific feedback were collected in-person or via

mailed questionnaires (i.e., if the participant could not travel to the VA medical center) approximately 10 weeks post-baseline assessment.

Preliminary efficacy measures

Pain Interference: The 9-item Interference subscale of the West Haven-Yale Multidimensional Pain Inventory (WHYMPI)-Interference scale assesses pain-related interference.[26] A reduction in WHYMPI-Interference Scale scores of 0.6 or greater has been identified as an indicator of meaningful improvement in physical functioning.[22] *Pain intensity:* Participants were asked, "Please rate your pain by indicating the number that best describes your average pain over the past week on a 0 (no pain) to 10 (pain as bad as you can imagine) scale". [27] *Emotional functioning:* The 65-item Profile of Mood States (POMS) is a multidimensional measure of emotional functioning designed to assess six dimensions of mood.[28] Depressive symptom severity was assessed using the 21-item Beck Depression Inventory (BDI).[29, 30] *Fatigue* was assessed using the Multidimensional Fatigue Inventory (MFI), which can be scored to produce 5 dimensions: general fatigue, physical fatigue, mental fatigue, reduced motivation, and reduced activity.[31] *Sleep Problems* were assessed using the MOS Sleep Scale. The MOS is segregated into subscales addressing seven sleep domains (i.e. sleep disturbance, snoring, awaken short of breath or with headache, adequacy of sleep, somnolence, a problems index 1 and a problems index 2). An additional single item assesses quantity of sleep.[32] All preliminary efficacy measures were collected via questionnaires that participants completed in-person at baseline and in-person or via mailed questionnaires (i.e., if the participant could not travel to the VA medical center) approximately 10 weeks post-baseline assessment.

Demographic and pain-relevant variables

Participants' age, sex, and racial/ethnic background were assessed at baseline. Pain duration and medication use were collected via participant interview and EHR review. Medications were coded into the following categories: non-steroidal anti-inflammatory drugs (NSAIDs), opioid analgesics, and anti-epileptics, muscle relaxants, acetaminophen, SSRIs, and SNRIs using a recording sheet used in our prior studies.

Sample Size:

While the primary purpose of this study was to determine feasibility and acceptability, sample size was calculated to estimate preliminary efficacy. Sample size calculation was based on a study design with one treatment condition and a primary hypothesis assessing a single primary outcome (i.e., WHYMPI-Interference Scale). A sample size of N=44 provided 90% power to detect a 0.6 point reduction in interference from baseline to follow-up, assuming a standard deviation of paired differences of 1.2, with a two-sided paired t-test at a significance level (alpha) of 0.05. A target sample size of N=55 patients was selected to account for 20% attrition at follow-up.

Statistical Analyses:

Descriptive statistics were used to examine demographic variables (i.e., age, race/ethnicity, sex), clinical characteristics (i.e., pain intensity, pain duration, medication use), and to analyze feasibility data such

as skill module use, number of logins, treatment credibility at post-assessment, patient satisfaction, and the PIQ results for usability, navigation, and satisfaction.

Mixed models (using an unstructured correlation structure) regression over the baseline and 10-week post-baseline follow-up assessments were used to examine within-subject change in outcome measures for preliminary efficacy variables. Mixed models can accommodate partially missing data so that all subjects with at least one of the two measurements (baseline and follow-up) available can be included in the analysis. The only predictor in the mixed models was time, a within-subject categorical variable with two levels: baseline and follow-up. Mixed models give valid results under the assumption that the missingness is at random (that is, missingness does not depend on unobserved data). In other words, the mixed model assumes that the outcomes of those with missing follow-up are similar to the outcomes of those with available follow-up with the same baseline. Following intent-to-treat principles, mixed models included all 58 participants with baseline data (whether or not they completed the follow-up).

As a sensitivity analysis, we performed a multiple imputation analysis using 100 imputed datasets generated by the Multivariate Imputation by Chain Equations (MICE) method. The following variables were included in the imputation model: sex, age, race (white vs. not), pain duration, number of modules completed, baseline pain intensity, baseline BDI-I depression, baseline interference and interference at follow-up. Due to our low sample size, it was not possible to include all available variables in the imputation model. For the primary analysis, the estimated decrease in interference (10 week minus baseline) was -0.6 (95% -0.9 to -0.2, p=0.003), a result that is very similar to the result obtained from the mixed model in Table 4.

Phase II Results:

Figure 1 represents a flowchart of participant recruitment, enrollment, and engagement. Eighty-four veterans were screened for eligibility. Of those, 59 participants were enrolled, and 58 participants completed baseline assessments, 41 (71%) of whom were also assessed at post-treatment. Attrition at post-baseline was 29%. Supplemental Table 1 presents a comparison of those with missing follow-up versus those with available follow-up in terms of baseline characteristics. There was no statistically significant difference between the two groups.

Enrolled participants (N=59) were 93% male, with a mean (Standard Deviation (SD)) age of 55(12) years (age ranged from 29-77 years), and predominantly white (White: 59.3%, Black: 32.2%, Hispanic: 1.7%, Mixed Race: 1.7% Unknown 5.1%). They had a mean pain intensity NRS score at baseline of 5.9/10, which reflects a moderate level of pain, and a reported pain duration of 12.7 years (SD 12.1 years; range 0.67-47.0 years). Participants' pain medication use at baseline was as follows: NSAID 29.3%, antiepileptic 17.2%, opioid 15.5%, partial opioid agonist 10.3%, muscle relaxant 6.8%, acetaminophen 3.4%, SSRI 1.7%, SNRI 0.00%, other 1.7%, and 41.4% of participants were not prescribed a medication for pain by VHA providers at baseline assessment per self-report and EHR review.

Participants who logged into the program at least at once (N=57) accessed the program an average of 6.1 (SD= 8.6) times over the 10-week access period. Of those who accessed skill modules (N=51), the

average number of modules accessed was 3.8 (SD=3.5). Five participants accessed all 10 modules. Participants with missing data at follow-up completed fewer modules than those with available data (median 1 vs. 3, p<.001). Participants who completed the post-baseline assessment (N=41) accessed the program an average of 7.8 (SD= 9.7) times over the 10-week access period, slightly more frequently than those who did not complete the post-baseline assessment. Using login and logout date and time data (N=49), the average time spent using the program after login was 17.4 minutes. Table 3 presents participants' responses to treatment credibility, treatment satisfaction, and the PIQ items. On the PIQ, participants rated the eight items reflecting program components as a 7/10 or higher and they were slightly more likely to prefer receiving the intervention via the internet than in person (5.9/10). Overall, 85% (34/40) of participants reported they were very or moderately satisfied with the Pain EASE program. Participants, on average, found the treatment to be credible (mean ratings on Treatment Credibility items ranged from 7.1 to 8.8/10).

Preliminary efficacy results are presented in Table 4. All N=58 subjects with baseline data were included in the mixed model analyses. Overall, results demonstrated that pain-related interference (measured by the WHYMPI) decreased from a mean of 3.8 at baseline to 3.33 at the 10-week follow-up, for a difference of 0.5 points (95% CI 0.15 to 0.92, p=0.008), with a medium effect size, *d*= -0.4. Additional statistically-significant changes are indicated in Table 4, largely reflecting improvements in mood and depression symptoms. The proportions of participants improving by ≥ 30% and 50% on measures of pain-related interference and pain intensity were calculated. In terms of interference, 26.8% (11/41) improved by at least 30% from baseline and 14.6% (6/41) improved by at least 50%. In terms of pain intensity, 19.5% (8/41) improved by at least 30% from baseline and 4.9% (2/41) improved by at least 50%. The sensitivity analysis to missing data (multiple imputation) indicated that, for the primary analysis, the estimated decrease in interference (10 week minus baseline) was -0.6 (95% -0.9 to -0.2, p=0.003), a result that is very similar to the result obtained from the mixed model in Table 4.

DISCUSSION

Pain EASE, a self-guided, CBT-based, self-management program delivered via the internet was developed for use in veterans with cLBP. The first phase of this 2-phase, mixed methods study collected qualitative feedback about a prototype of the Pain EASE program from participants with cLBP to facilitate patient-centered modifications to the program. Phase I participants suggested website style changes, content reduction, the addition of "Test Your Knowledge" quizzes, and CBT skill practice self-monitoring form revisions, all of which were completed prior to the start of Phase II to enhance usability of the program.

Results of Phase II, the feasibility and preliminary efficacy trial, support the feasibility of the Pain EASE program for veterans with cLBP. The majority of participants expressed satisfaction with the program, found the treatment to be credible, and engaged with the program, despite the absence of clinician guidance. Closer examination of the feasibility data suggests some potential challenges, including that 22% of participants screened for study enrollment ultimately were not interested in participating. This may not be specific to

recruiting for the Pain EASE trial but also reflect overall challenges in recruiting veterans for nonpharmacological treatments for pain, which has been examined and reported previously. [33] In addition, on a measure of treatment satisfaction, only 40% of Phase II participants reported most or all of their needs were met by the Pain EASE program. While that item is non-specific, there may be aspects of the chronic pain experience that Pain EASE does not address that are important to these participants. Future studies may consider gathering additional qualitative data from participants to further modify the program.

Data reflecting website use provided additional feasibility information. On average, participants logged on to the website approximately 6 times in 10 weeks, suggesting they may not have used the program each week. Although participants' access to Pain EASE modules was not restricted, participants accessed less than 4 of the 10 modules, on average. This may reflect viewing only those modules suggested by the personalized plan, or perhaps participants chose modules of greatest interest based on the name of the skill presented in a given module. The modules are relatively brief, in terms of content, reflecting both feedback from Phase I participants about amount of content and desire to keep written content brief for ease of viewing via smartphone. Given that participants logged onto the website an average of 17 minutes at each use, it is possible that they accessed more than one (or several) modules at each logon, as they were not restricted to certain modules or a certain number of modules in any given week of the program. In addition, the average number of skill modules completed is consistent with a "dose" of CBT, (i.e., 3 sessions, as defined in other trials by this group using the same CBT content). [18, 19, 34, 35]

Engaging participants in the program is an important task. It is likely beneficial that the Pain EASE program is device-agnostic (i.e., as readable and usable on a mobile device as it is on a computer), providing flexibility for using the program without requiring a desktop or laptop computer. Future studies may also consider whether providing clinical support for Pain EASE would improve engagement and outcomes. Perhaps intermittent "check-ins" with a clinician, or as some studies have used, clinician-guided goal-setting may help improve adherence to pain coping skills presented and could improve outcomes. One group examined different levels of clinician contact (i.e., support) along with engagement in the *Pain Course*, a CBT-oriented, internet-delivered pain intervention and found similar clinically-important improvements and satisfaction and adherence across regular clinician contact, optional clinician contact, and no contact conditions.[36] These improvements in disability, pain intensity, and mood symptoms remained across conditions at 12 and 24-month follow-up assessments.[37] Although study staff in the current study contacted participants weekly to collect data, they were not clinicians and were instructed to ask structured data-gathering questions, rather than providing support or assistance with behavior change; however, even this brief contact may have promoted more consistent engagement among participants. Interestingly, when asked whether they preferred in-person pain management treatment compared with technology-delivered treatment, participants were almost evenly divided. These preferences could also be further explored in future studies, as could an in-person treatment comparison condition, as relatively fewer internet-based pain management programs used this as a comparison.[13]

Preliminary efficacy results are also promising. Following 10 weeks of self-directed access to the Pain EASE program, participants demonstrated a significant reduction in pain interference as measured by the WHYMPI. While this reduction of 0.5 points (95% CI 0.2, 0.9) was statistically significant, the current study design examined preliminary efficacy in a small sample without a comparison condition and is therefore limited in ability to draw definitive conclusions about the effect of the intervention. Because chronic pain and depression are frequently comorbid conditions, depression and overall mood symptoms were also assessed, showing improvement in two measures of depression, as well as a measure of tension. This is consistent with findings of other internet-based interventions for chronic pain. For example, Ferwerda and colleagues examined a clinician-guided cognitive-behavioral therapy-based internet-delivered program for participants with rheumatoid arthritis. Participants who received the intervention achieved significant improvements in depressed mood and other mood symptoms compared to control condition participants, over a one-year follow-up period.[38] Interestingly, Ferwerda et al.'s study did not show a reduction in pain.[38] The effect of CBT on both pain and depression seems intuitive, as CBT, which was the treatment model incorporated into the Pain EASE program, has shown efficacy for addressing both chronic pain and depression symptoms in several patient populations [4, 5, 39-41]. However, a reduction in both pain and depression is not reported universally among internet-based self-management programs.[6] The findings for pain interference and depression in the current study should be substantiated in larger samples and compared with control conditions.

In this study, there was a 29% rate of attrition from baseline to the post-treatment assessment. Attrition reported by other internet-based pain management programs varies, but the Pain EASE study is largely consistent with the literature. A systematic review published in 2015 indicated that 10 out of 27 studies (2 of the 29 included studies did not report on attrition rate) of internet-based interventions for chronic pain reported 25% or higher rates of attrition (methodology varied, attrition ranged from 0 to 56%).[13] In the program described by Ferwerda and colleagues, 36% of those randomized to the intervention condition did not complete the program (intervention duration varied from 9 to 65 weeks) [38] and the Health *e*Ride program reported 36% attrition at 30 days' follow-up.[16] In contrast, the Pain COACH program reported only 3.5% attrition at post-treatment.[15] However, participants were screened for motivation to make behavior change, such as how important it was to the participant to complete the Pain COACH program in order to select a motivated and adherent sample.[15] Pain EASE participants were also screened for readiness and interest in participating in pain self-management but were not asked specifically about importance of completing the Pain EASE program.

The current study has several limitations. The study employed a small sample, which creates some difficulty with interpreting feasibility data, as this sample may not be representative of all veterans with cLBP who might use technology-delivered treatments. Although the study was primarily designed to assess feasibility, there are some limitations to the design of Phase II, wherein preliminary efficacy data were collected. For example, this study did not contain a control condition comparison; therefore, we cannot be certain that reductions in symptoms related to pain and depression were the result of Pain EASE and not some

other factor that was not examined in this study. An RCT is an important next step in addressing this issue. Participants in this study self-identified as "ready to change" and as interested in internet-based pain self-management. This may limit generalizability to the broader sample of veterans with cLBP who may not be as motivated or as likely to benefit from a self-guided CBT-based self-management program that encourages behavior change as participants who are further along in the stages of change. While consistent with other studies of internet-based pain management programs, the current study had a 29% rate of attrition at post-baseline assessment, which may also affect interpretation of results, as those who dropped out may have may have outcomes that are differently distributed than outcomes for those who stayed in the study (i.e. *missingness was not at random)*, and thus may have altered the results.

CONCLUSION

The current study provides promising evidence to support the feasibility, usability, and acceptability of a self-guided, internet- delivered, CBT-based pain self-management program for veterans with cLBP. Pain EASE has the potential to address VHA priorities, including improving access to non-pharmacological pain treatments, overcoming geographic barriers, and developing veteran-centric resources that address chronic pain. This study highlights the importance of continuing to develop and refine technology-delivered interventions and evaluating their implementation into clinical settings, by studying whether a significant proportion of veterans (and which veterans, specifically) may find use of an internet-based program without requiring interaction with a clinician to be effective.

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Figure 1. Pain EASE Flow Diagram

Table 1. Pain EASE Skill Modules*

	Skill name	**Skill content**
1.	Pain Education	Information about chronic pain, biopsychosocial model, chronic pain self-management
2.	Setting personal goals	SMART goals
3.	Planning meaningful activities	Choosing and adding productive, social, or fun activities to daily life
4.	Physical Activity	Pedometer-based walking program, stretching, body mechanics
5.	Relaxation	Diaphragmatic breathing, visual imagery, progressive muscle relaxation
6.	Developing Healthy Thinking Patterns	Identifying and changing unhealthy thoughts
7.	Pacing and Problem-solving	Time-based pacing, problem solving strategies
8.	Improving Sleep	Sleep hygiene
9.	Effective communication	Anger management and communicating effectively with healthcare providers
10.	Preparing for the Future	Skills consolidation and plan for addressing future pain flares

*All skill modules were available to participants at any time during their 10-week access to Pain EASE. Access was not restricted by week or order of presentation. Personalized Plans based on responses to the brief Chronic Pain Coping Inventory (i.e., self-assessment) suggested skills for participants to focus on, but all skills were accessible at any time.

Table 2. Post-Intervention Questionnaire (PIQ) responses for Phase I participants (N=15)

PIQ Item	Median [IQR] responses
1. I liked the layout of the website (for example, the general look of the website).	**7 [5; 8]**
2. I found it easy to navigate through the various parts of the website (for example, moving from one topic to the next, completing the modules on the website).	**7 [7; 9]**
3. I found the topics that were presented in the internet program to be relevant to my situation.	**8 [7; 10]**
4. I found the self-test at the beginning of the program helpful.	**7 [5; 7]**
5. I found the self-test at the beginning of the program easy to use.	**7 [7; 10]**
6. I found it easy understand the material presented in the program.	**8 [7;10]**
7. I found the amount of material presented in the program to be just the right amount (not too much and not too little).	**5 [3; 9]**
8. I liked the graphics or images in the program.	**7 [3; 7]**
9. I would prefer to complete this program via the internet rather than in-person with a counselor.	**5 [3; 7]**
10. Did you have any difficulty accessing the internet?**	**All 15 participants indicated "no"**
11. I would recommend this program to others with low back pain.	**10 [5; 10]**
12. Did you encounter any problems with using the program?**	**3/15 respondents answered "yes"**

*****0-10 likert scale (0=strongly disagree, 10=strongly agree).

** Items 10 and 12 on the PIQ were Yes/No response questions. Results are presented as frequencies rather than median [interquartile range (IQR)].

Table 3. Phase II Feasibility Measures (Credibility, Satisfaction, and Usability) at Post-treatment; N=40

Treatment Credibility (0-10 scale)	**Mean (SD)**
1. How logical did this type of treatment seem to you?	7.9 (SD=2.4)
2. How confident are you that this treatment successfully helped you with your pain?	7.3 (SD=2.4)
3. How confident are you about recommending this treatment to a friend who has a pain problem?	7.9 (SD=2.5)
4. How willing were you to participate in the pain treatment program described?	8.8 (SD=1.9)
5. How successful do you think that this program was in helping you with your pain?	7.1 (SD=2.5)
Treatment Satisfaction	**N (%)**
1. Overall, how satisfied are you with the treatment you received?	
Very satisfied	18 (45.0%)
Moderately satisfied	14 (35.0%)
Neither satisfied nor dissatisfied	7 (17.5%)
Moderately dissatisfied	1 (2.50%)
Very dissatisfied	0 (0.0%)
2. Overall, how would you describe your condition at present?	
Excellent	4 (10.0%)
Good	10 (25.0%)
Fair	16 (40.0%)
Poor	9 (22.5%)
Extremely poor	1 (2.50%)
3. Overall, how would you describe how you have changed since you began treatment?	
I'm much better	6 (15.0%)
I'm a little better	19 (47.5%)
I haven't changed at all	10 (25.0%)
I'm somewhat worse	2 (5.0%)
I'm much worse	3 (7.5%)

4. In your opinion, do you believe that whether you're worse, unchanged, or better (compared to when you began treatment) is related to the treatment you received?	
Definitely related	10 (25.0%)
Probably related	11 (27.5%)
May be related	5 (12.5%)
Probably not related	6 (15.0%)
Definitely not related	8 (20.0%)
5. How satisfied are you with the amount of treatment you received?	
Very satisfied	18 (45.0%)
Moderately satisfied	14 (35.0%)
Neither satisfied nor dissatisfied	7 (17.5%)
Moderately dissatisfied	1 (2.5%)
Very dissatisfied	0 (0.0%)
6. How satisfied are you with the Pain EASE program?	
Very satisfied	22 (55.0%)
Moderately satisfied	12 (30.0%)
Neither satisfied nor dissatisfied	4 (10.0%)
Moderately dissatisfied	2 (5.0%)
Very dissatisfied	0 (0.0%)
7. If you were to seek treatment in the future, would you return to this program?	
Definitely	14 (35.0%)
Probably	17 (42.5%)
Maybe	3 (7.5%)
Probably not	6 (15.0%)
Definitely not	0 (0.0%)
8. To what extent has this treatment program met your needs?	
Almost all of my needs have been met	2 (5.00%)
Most of my needs have been met	14 (35.0%)
Some of my needs have been met	19 (47.5%)

Only a few of my needs have been met	3 (7.5%)
None of my needs have been met	2 (5.0%)
Post-Intervention Questionnaire (PIQ) Item (0-10 scale)	**Mean (SD)**
1. I liked the layout of the website (for example, the general look of the website).	8.2 (1.7)
2. I found it easy to navigate through the various parts of the website (for example, moving from one topic to the next, completing the modules on the website).	8.3 (2.2)
3. I found the topics that were presented in the internet program to be relevant to my situation.	8.1 (2.4)
4. I found the self-test at the beginning of the program helpful.	7.8 (2.4)
5. I found the self-test at the beginning of the program easy to use.	8.2 (2.3)
6. I found it easy understand the material presented in the program.	8.6 (2.1)
7. I found the amount of material presented in the program to be just the right amount (not too much and not too little).	7.4 (2.4)
8. I liked the graphics or images in the program.	7.7 (2.1)
9. I would prefer to complete this program via the internet rather than in-person with a counselor.	5.8 (3.2)
10. Did you have any difficulty accessing the internet?*	10/40 (25.0%) answered Yes
11. I would recommend this program to others with low back pain.	8.3 (1.9)
12. Did you encounter any problems with using the program?*	8/40 (20.0%) answered Yes

*Items 10 and 12 on the PIQ were Yes/No response questions. Results are presented as frequency of "yes" responses, rather than mean (SD).

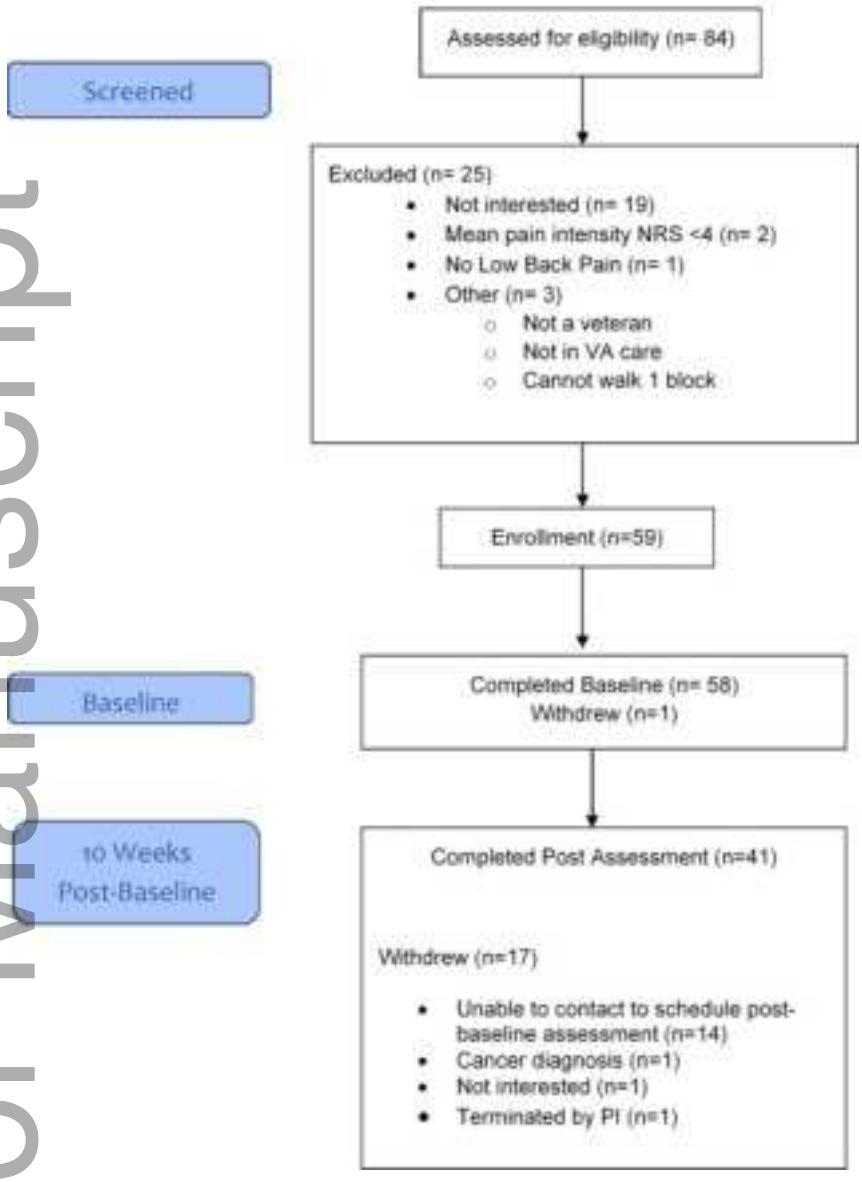
Table 4. Phase II Baseline and 10 weeks post-baseline assessment outcomes*

Outcome	Scale range	Baseline (N=58*)	10-week post-baseline (N=41**)	Within-subject change 10-week vs. baseline		
		Mean (SE)	Mean (SE)	Mean (95% CI)	p-value	Cohen's d
Primary outcome:						
WHYMPI interference	0 to 6	3.8 (0.2)	3.3 (0.2)	-0.5 (-0.9, -0.1)	0.008***	-0.4
Secondary outcomes:						
NRS pain intensity past week	0 to 10	5.9 (0.3)	5.7 (0.3)	-0.2 (-0.7, 0.2)	0.27	-0.2
POMS						
Tension	0 to 36	13.5 (1.0)	10.9 (1.0)	-2.6 (-4.3, -1.0)	0.002***	-0.5
Depression	0 to 60	16.7 (1.8)	13.6 (1.9)	-3.0 (-5.6, -0.5)	0.02***	-0.4
Anger	0 to 48	11.4 (1.3)	9.8 (1.4)	-1.6 (-3.5, 0.4)	0.11	-0.3
Vigor	0 to 32	14.0 (0.8)	14.2 (1.0)	0.2 (-1.6, 2.0)	0.82	0.0
Fatigue	0 to 28	13.4 (0.9)	11.7 (1.1)	-1.7 (-3.5, 0.1)	0.06	-0.3
Confusion	0 to 28	8.4 (0.8)	8.0 (0.8)	-0.4 (-1.6, 0.7)	0.44	-0.1
Total mood disturbance	-32 to 200	49.5 (5.6)	40.0 (5.9)	-9.6 (-17.7, -1.4)	0.02***	-0.4
Beck Depression Inventory I (BDI-I)	0 to 63	15.5 (1.4)	13.2 (1.6)	-2.3 (-4.4, -0.2)	0.03***	-0.4
Multidimensional Fatigue Inventory (MFI)						
General fatigue	4 to 20	14.1 (0.5)	13.7 (0.5)	-0.3 (-1.2, 0.6)	0.48	-0.1
Physical fatigue	4 to 20	14.2 (0.6)	14.5 (0.6)	0.3 (-0.8, 1.4)	0.59	0.1

Reduced activity	4 to 20	12.2 (0.6)	12.5 (0.6)	0.3 (-1.0, 1.6)	0.64	0.1
Reduced motivation	4 to 20	11.1 (0.5)	10.9 (0.6)	-0.2 (-1.3, 0.9)	0.77	0.0
Mental fatigue	4 to 20	10.9 (0.6)	10.5 (0.6)	-0.3 (-1.5, 0.8)	0.56	-0.1
MOS Sleep Scale						
Sleep disturbance	0 to 100	50.1 (3.8)	45.1 (4.2)	-4.9 (-12.3, 2.4)	0.18	-0.2
Snoring	0 to 100	51.0 (5.0)	39.2 (5.8)	-11.8 (-22.0, -1.7)	0.02***	-0.4
Sleep short of breath or headache	0 to 100	29.0 (4.5)	22.1 (4.3)	-6.9 (-15.6, 1.8)	0.12	-0.2
Sleep adequacy	0 to 100	37.4 (3.6)	42.0 (5.1)	4.6 (-4.7, 14.0)	0.32	0.2
Sleep somnolence	0 to 100	38.4 (3.3)	39.4 (3.9)	1.0 (-6.0, 8.0)	0.78	0.0
Sleep problems index I	0 to 100	48.3 (3.1)	43.2 (3.4)	-5.1 (-10.7, 0.4)	0.07	-0.3
Sleep problems index II	0 to 100	48.5 (3.1)	44.4 (3.3)	-4.0 (-9.5, 1.4)	0.14	-0.2
Sleep quantity per night (in hours)	0 to 12	5.9 (0.2)	6.1 (0.2)	0.2 (-0.3, 0.6)	0.43	0.1

*All estimates were obtained from mixed models fit on N=58 subjects. Cohen's d effect sizes were estimated as mean within-subject change at 10 weeks vs. baseline divided by the standard deviation of the change.

Figure 1. Pain EASE Flow Diagram



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