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Original Research Article

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Abstract

Background. Veterans with significant chronic pain from musculoskeletal disorders are at risk of substance misuse. Veterans whose condition is the result of military service may be eligible for a disability pension. Department of Veterans Affairs compensation examinations, which determine the degree of disability and whether it was connected to military service, represent an opportunity to engage Veterans in pain management and substance use treatments. A multisite randomized clinical trial is testing the effectiveness and cost-effectiveness of Screening, Brief Intervention, and Referral to Treatment for Pain Management (SBIRT-PM) for Veterans seeking compensation for musculoskeletal disorders. This telephone-based intervention is delivered through a hub-and-spoke configuration. **Design.** This study is a two-arm, parallel-group, 36-week, multisite randomized controlled single-blind trial. It will randomize 1,100 Veterans experiencing pain and seeking service-connection for musculoskeletal disorders to either SBIRT-PM or usual care across eight New England VA medical centers. The study balances pragmatic with explanatory methodological features. Primary outcomes are pain severity and number of substances misused. Nonpharmacological pain management and substance use services utilization are tracked in the trial. **Summary.** Early trial enrollment targets were met across sites. SBIRT-PM could help Veterans, at the time of their compensation claims, use multimodal

pain treatments and reduce existing substance misuse. Strategies to address COVID-19 pandemic impacts on the SBIRT-PM protocol have been developed to maintain its pragmatic and exploratory integrity.

Key Words: Pain; Substance Use; Musculoskeletal Disorders; Veterans; Compensation and Pension

Background and Rationale

More than half of post-9/11 Veterans have a musculoskeletal disorder (MSD) with significant chronic pain [1]. These Veterans are at high risk of developing alcohol and other substance use disorders [1]. Individuals with chronic pain and a substance use disorder show worse treatment outcomes for both conditions [2, 3].

MSDs frequently originate from disabling injuries sustained while in military service. During separation from active military duty or after separation, Veterans may seek compensation for these disabilities by receiving a specialized compensation clinic examination. This examination determines which conditions are connected to their military service. Conditions are assigned a service-connection rating between 0% and 100%, with higher ratings indicating more impairment and, consequently, more financial compensation and prioritization for health care in the Veterans Health Administration (VHA) [4].

The number of Veterans receiving MSD-related compensation is large. As of 2019, 1,063,781 awards for lumbosacral or cervical strain had been approved for living compensation recipients, and during 2019, 76,050 new claims for these conditions were awarded [5]. Efforts to connect these Veterans to VHA services around the time of their MSD-related compensation examinations could improve their functioning and quality of life through engagement in the comprehensive array of multimodal nonpharmacological pain management and substance use treatments available at VA or in the community. Furthermore, focusing on post-9/11 Veterans with MSD, rather than older Veterans, provides an opportunity for early intervention before their pain and substance misuse becomes more chronic and difficult to treat.

Rosen and colleagues tested the efficacy of such an approach in a small clinical trial [6]. Veterans seeking compensation for service-connected MSD who had chronic pain and substance misuse were randomized to a motivational interviewing–based [7] Screening, Brief Intervention, and Referral to Treatment for pain management and substance misuse (SBIRT-PM), pain management counseling only, or usual care (UC). Both brief counseling interventions offered an initial 60-minute in-person session, with up to two 5- to 10-minute subsequent phone calls over 4 weeks. Follow-up data were collected at 12 weeks. Results showed that higher proportions of Veterans in SBIRT-PM and the pain management–only conditions received VA pain treatment than those in UC (51% vs 27%, respectively). In addition, Veterans in SBIRT-PM, with its added focus on reducing substance misuse, had significantly lower rates of self-reported problematic substance use than those of Veterans assigned to pain management counseling only or UC. Mean pain severity did not change over time, regardless of condition. A longer follow-up period may have been needed to detect effects of newly utilized pain treatments.

To scale up clinical innovations such as SBIRT-PM, VA often uses a hub-and-spoke approach, wherein a "hub" site deploys its expertise and administrative resources to "spoke" or satellite sites within the health care system. Examples include VA Epilepsy Centers of Excellence [8], Specialty Care Access Networks–Extension for Community Healthcare Outcomes (SCAN-ECHO) [9], and the use of Veterans Integrated Service Networks (VISN) to oversee health care policy and service delivery of medical centers in designated regions [10]. Compared with a non-networked model, a hub-and-spoke approach permits specialized personnel to serve multiple sites and is more cost-effective from a hospital [11] and societal perspective [12].

The present article describes the study protocol for a multisite randomized clinical trial that tests the effectiveness and cost-effectiveness of SBIRT-PM, compared with UC, for claim-seeking Veterans with MSD-related chronic pain. For pragmatic purposes, the trial includes a broad range of Veterans who have chronic pain with or without substance misuse. It also uses a hub-and-spoke configuration within the New England VISN involving phone-based recruitment and assessment of participants and counselor delivery of SBIRT-PM across eight medical centers.

Methods

Study Objective

The present study has three main objectives. *Objective 1* is to determine whether SBIRT-PM is more effective than UC in reducing pain severity and, secondarily, reducing pain interference with life activities, reducing overall pain, increasing nonpharmacological pain management service utilization, and improving health-related quality of life. We hypothesize that SBIRT-PM will be more effective than UC and that nonpharmacological pain management service utilization will mediate pain outcomes. *Objective 2* is to determine whether SBIRT-PM is more effective than UC in reducing the number of misused substances requiring intervention and, secondarily, reducing

use severity for individual substances. We hypothesize that SBIRT-PM will be more effective than UC and that nonpharmacological pain management and substance use service utilization will mediate reduced substance use. *Objective 3* is to determine the cost-effectiveness and budget impact of SBIRT-PM relative to UC. We hypothesize that SBIRT-PM, relative to UC, will be a cost-effective use of VA and societal resources and have no net budgetary impact on local VA resources.

Overall Design

This study is a two-arm, parallel-group, 36-week, multisite randomized controlled single-blind trial (see Supplementary Data). We will randomize 1,100 Veterans applying for service-connected, MSD-related compensation to either SBIRT-PM or UC across eight VA medical centers in New England. All study methods have been reviewed and approved by the VA Central Institutional Review Board and Yale University Human Investigation Committee and have been published on ClinicalTrials.gov (NCT04062214). The study balances pragmatic with explanatory features, as illustrated on the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) wheel (see Supplementary Data) [13, 14]. Several features make the trial pragmatic (i.e., testing SBIRT-PM in routine practice). The trial occurs in eight sites across New England rather than a single site, allowing for inclusion of a broad range of Veterans who have chronic pain with or without substance misuse. Data gathering includes primary outcomes (pain, substance use, and cost) of importance to Veterans, providers, administrators, and policy makers and is completed through review of the electronic health record (EHR). Moreover, the trial tests the effectiveness of SBIRT-PM compared with its real-world alternative, UC, rather than an active treatment control. Simultaneously, the trial has several explanatory features (i.e., testing SBIRT-PM with more internal controls). It relies on research staff to recruit and assess study-eligible participants. Counselors were hired to deliver SBIRT-PM, rather than existing medical center staff. In addition, the trial includes monthly SBIRT-PM adherence monitoring and supervision with performance feedback and coaching to maintain the integrity of the intervention.

Study Population

Participant inclusion criteria are: 1) post-9/11 Veterans who have applied for service-connected, MSD-related (specified as back, neck, shoulder, or knee) compensation as ascertained from a filed claim; 2) a score of $\geq$4 on the Brief Pain Inventory's Pain Severity subscale (threshold for moderately severe pain) [15]; and 3) access to a phone. Exclusion criteria are: 1) receipt of >2 nonpharmacological pain VA treatment modalities within the prior 12 weeks (because a goal of the trial is to increase engagement in such treatments); 2) self-reported inability to participate during the study enrollment period; and 3) participation in another NIH-DOD-VA Pain Management Collaboratory study [16] at time of study recruitment, as evidenced by an EHR alert.

Screening, Recruitment, and Randomization

Research staff identify Veterans scheduled for MSD-related compensation examinations by reviewing EHR and compensation clinic information. Next, Veterans with post-9/11 military service receive a recruitment letter and study information sheet; the letter and information sheet explain basic study details and provide instructions on how Veterans can opt out (by phone) of further outreach from research staff. Research staff call Veterans who do not opt out and explain the study, further screen for eligibility, and complete voluntary informed consent for study-eligible and interested Veterans. Veterans can enroll up to 6 weeks after recruitment materials are mailed to permit enough time for participant recruitment around the time of their examinations.

Next, participants complete baseline study assessments by phone, and then research staff provide the study director with key balancing variables, namely sex (male/female), race (White, Black, Other), ethnicity (Hispanic/Non-Hispanic), and any self-reported illicit drug use (including cannabis) within 90 days (Yes/No), for stratified randomization of participants to SBIRT-PM or UC through the use of a computerized urn program [17]. Illicit drug use is a balancing variable because unlike alcohol or tobacco, the efficacy of SBIRT for illicit drug use has been equivocal and site and population dependent [18]. The study director runs the randomization program and notifies SBIRT-PM counselors to contact participants assigned to SBIRT-PM and initiate the intervention; UC participants receive subsequent contact from research staff only to complete follow-up study assessments. Research staff conducting assessments are blinded to the participants' condition.

Participating Sites

The study is occurring at VA New England Healthcare System (VISN1), a network of eight medical centers in six New England states: Massachusetts (in the cities of Boston, Bedford, and Leeds), Connecticut (West Haven), Maine (Togus), Vermont (White River Junction), New Hampshire (Manchester), and Rhode Island (Providence). Each site provides MSD-related compensation examinations and several nonpharmacological pain, substance use, and mental health treatments. All sites deliver treatment according to a Stepped Care Model of Chronic Pain [19–21], which emphasizes multimodal care within a biopsychosocial framework and involves primary care and patient-aligned care teams (PACTs) as the nexus of pain treatment, secondary consultation with specialty care and evaluation, and tertiary

interdisciplinary pain centers. Every medical center has an interdisciplinary pain team, physical therapy, acupuncture, yoga, and cognitive behavioral therapy for chronic pain. Many facilities also have pain education workshops, chiropractic care, nutrition consultations, occupational therapy, physiatry, rheumatology, Tai Chi, and other complementary and integrated health options supported by the VHA Whole Health Initiative [22]. Also, community care treatment referrals, funded by VA, are available to VA-enrolled Veterans [23]. A local principal investigator helps research staff implement the trial.

Interventions: SBIRT-PM and UC

SBIRT-PM is a manualized, motivational interviewing–based [7], five-session, phone-delivered intervention, with four sessions occurring over an initial 12-week period and an additional booster session offered between weeks 12 and 32. All sessions aim to motivate Veterans to engage in multimodal nonpharmacological pain care and reduce substance misuse when present. Counselors from VA Connecticut provide SBIRT-PM remotely to Veterans throughout VISN1.

The first 1-hour session includes several elements: 1) an orientation that describes the counseling and explains its separation from service-connection claim determinations; 2) empathic exploration of the Veteran's MSD, pain experiences, and motivations for pain care; 3) psychoeducation about the benefits of multimodal pain care, judicious use of non-opioid medications, and available local pain management services and mental health treatments for conditions, such as depression or posttraumatic stress disorder, that might exacerbate chronic pain; 4) screening for substance misuse, including misuse of prescription medications, and motivational enhancement to change behaviors related to positive screens; and 5) for those committed to engaging in services or addressing substance misuse, making plans to achieve these goals.

Over the subsequent 12 weeks, counselors hold up to three additional 20-minute phone sessions with participants (about once per month) to check on their goal achievement and continue motivational enhancement for multimodal pain treatment and reduced substance misuse. Counselors offer one more 20-minute session during weeks 12–32 to sustain participants' motivation to engage in available pain and substance use services and address ongoing obstacles (e.g., transportation, relocation) or health care system changes (e.g., COVID-19 impacts).

SBIRT-PM also includes coordination between the counselors and primary care providers to support participants' improved pain and substance use treatment outcomes. Counselors communicate with primary care providers about the participants' interests in services primarily through notes placed in the EHR. These notes are read by primary care providers or health professionals, who may refer patients to services. Counselors also glean important information from the EHR (e.g., checking whether a primary care provider made a referral, reviewing notes indicating engagement with services) to inform their counseling sessions.

Consistent with the national VA Evidence-Based Practice training model [24], SBIRT-PM counselors received an initial 2.5-day didactic and experiential workshop, followed by a certification process (i.e., audio-recorded practice phone sessions until adequate proficiency had been achieved) conducted by this article's first author (SM), an SBIRT-PM expert. All trial sessions are audio recorded; the SBIRT-PM expert reviews two sessions per month per counselor and holds monthly group supervision meetings to provide performance feedback and coaching. Independent verification of SBIRT integrity will occur through the use of the Independent Tape Rater Scale [25].

Veterans assigned to UC are contacted by research staff for research study assessments only. Veterans who apply for service-connected compensation do not typically receive orientation to the VA health care system or referral to treatment as part of the claims process.

Baseline and Follow-Up Procedures

The trial uses several measures [15, 26–35] at baseline and at the 12- and 36-week follow-up assessment points (see Supplementary Data for description of measures and schedule of assessments). Data are entered directly into the secure VA Research Electronic Data Capture (REDCap) data collection tool by research staff or are extracted from EHR or VA datasets.

Costs will be assessed for activities needed to replicate SBIRT-PM if it were adopted in routine practice. These activities include identifying and recruiting eligible Veterans, preparing for counseling, delivering counseling, following up and making referrals, and training and supervision. Micro-cost estimates will be based on study data on SBIRT-PM encounters, staff reports of time, and data on labor cost and overhead from the VA Managerial Cost Accounting (MCA) system. The cost of VA MSD-related care, pain medications, and other health services will be obtained from the MCA system, the claims data of the VA Community Care program, and patient self-report. The cost of non-VA MSD care will be estimated on the basis of self-reported quantities of pain treatments used and VA unit costs or published estimates of unit costs per treatment service.

Primary and Secondary Outcomes

The two primary outcomes are the Brief Pain Inventory pain severity subscale score [15] and the number of substances that either are above the "no-intervention" threshold in the Alcohol, Smoking, and Substance Involvement Test (ASSIST) [29] or found in toxicological analysis of nail clippings. The ASSIST generates an ordinal severity score based on self-reported negative consequences from individual substances used in the prior 3

months; scores above 3 indicate a need for intervention, apart from alcohol, which requires a score above 10. When a positive toxicology result disagrees with a self-report of no use, the middle value on the ordinal scale of the ASSIST will be used as the primary substance use outcome. Obtaining both self-report and toxicology data to determine substance use is a recommended best practice, particularly for patients seeking treatment for chronic pain who have been found to underreport opioid and other substance use [36].

Secondary pain outcomes include nonpharmacological pain service utilization, pain interference with life activities (Brief Pain Inventory), overall pain (Pain, Enjoyment of Life and General Activity scale), and health-related quality of life (EQ-5D-5L). Nonpharmacological pain management service utilization will be summed across modalities (emergency/urgent pain care, primary care, surgery, spinal cord stimulator, injections, transcutaneous electrical nerve stimulation, acupuncture, dry needling, acupressure, manipulation, massage therapy, yoga, reiki, biofeedback, education, counseling for pain, relaxation techniques, meditation/mindfulness, hypnosis/hypnotherapy, exercises/stretches, and other treatments not already mentioned). In addition, we will evaluate the frequency of use of each of these modalities over the prior 3 months. Secondary substance use outcomes will include severity measures for individual substances generated by the ASSIST and toxicology results for individual substances.

Statistical Methods

Sample Size Determination

With two primary outcomes (change in pain severity from the Brief Pain Inventory and change in the number of substances requiring intervention), Bonferroni correction was used to generate P values of 0.025 for the sample size calculations for each outcome. The sample size was calculated for power=0.90 by using two-tailed alpha=0.025 and an expected effect size of d=0.25 for pain severity, with 27% attrition, the rate observed in our previous pilot work [6]. The calculation is as follows: 400 per intervention condition (SBIRT-PM and UC) divided by "1 – loss to follow-up" (73%)=548×2 groups=1,096. The planned randomized sample size is 1,100, with sample selection at each site proportional to the size of the site. For substance use, the proportion converting to low risk on at least one substance in the treatment group per our pilot study [6] was estimated as 27%, and in UC it was estimated as 10%. Attrition was set at 27%. For 90% power with the alpha=0.025, the calculations resulted in a sample size of 128 per group divided by "1 – loss to follow-up" (73%)=176×2 groups=352 as the total sample size. Given that we expect at least 50% of our sample of Veterans with MSD-related pain to have at least one substance they use problematically (based on unpublished data gathered from our sites in preparation for this trial), we will have an adequate sample in the trial to detect an effect size of 1.83 in the substance use outcome.

Analytic Methods

For clinical effectiveness analyses, descriptive statistics (e.g., mean, standard deviation, frequency, and percent) will be used to describe the sample and to check for baseline differences between intervention groups. Differences between intervention groups in the change in primary and secondary outcome variables from baseline through the end of the 36-week study period will be examined by using mixed-effects models with subject as a random effect and intervention group, time, and their interaction as fixed effects. We will explore various residual covariance structures (e.g., unstructured, compound symmetry, autoregressive), selecting the option with the lowest Akaike Information Criterion. The interaction between intervention and time will be included to test the effect of the intervention at 12 weeks and at 36 weeks relative to UC. For each outcome, we will estimate a Box-Cox regression to identify the appropriate link function and use the modified Park test to identify the appropriate distribution assumption [37].

If there are significant differences between treatment groups in any baseline variable, we will examine models that adjust for potentially confounding variables, including depression score, presence of traumatic brain injury, mental health diagnoses, and urn covariates (sex, race, ethnicity, and self-reported illicit drug use). Other potential confounders are distance to the nearest VA medical center, number of pain treatment modalities used at baseline, baseline service-connection percentage, type of MSD claim (back, neck, knee, or shoulder), months between discharge from active service and compensation and pension exam, and probability of study dropout.

Opioid use (misuse of prescribed agents and use of unprescribed agents) will be examined as a mediator as well as a tertiary outcome, given its relationship to pain. Actual participation in SBIRT-PM (Yes/No) will be examined as a mediator of response. Finally, analyses will examine site, sex, and race/ethnicity as moderators of treatment response through their inclusion of tests of interaction effects in models.

For cost analyses, cost of care will be measured from the date of randomization until the end of the 36-week follow-up. Health care cost as a continuous variable is likely to be highly skewed; a General Linear Model will be used to accommodate outcomes that are not normally distributed. To identify the appropriate link function, we will estimate a Box-Cox regression; we will use the modified Park test to identify the appropriate distribution assumption [37]. These tests often result in the choice of a log gamma regression, which accommodates the highly skewed distribution and heteroscedastic errors of most cost data [38].

Cost-effectiveness analysis will be done from both the VA health system perspective and a societal perspective and will be measured in quality-adjusted life-years (QALYs) [39]. The incremental cost-effectiveness ratio will be the ratio of the difference in cost (mean SBIRT-PM cost less mean UC cost) divided by the difference in outcomes (QALYs in SBIRT-PM group less QALYs in UC group). Using bootstrap sampling, we will plot a cost-effectiveness acceptability curve of the *P* values (percentage of replicates not cost-effective) over the range of $10,000 to $1,000,000 per QALY, which covers all plausible critical values for cost-effectiveness in the U.S. health care system. Decision makers can use cost-effectiveness acceptability curves to determine whether benefits justify the costs. If SBIRT-PM produces a QALY for less than $100,000 over 36 weeks, SBIRT-PM will be considered worth adopting.

Finally, we will follow guidelines for budget impact analysis developed by the International Society for Pharmacoeconomics and Outcomes Research [40]. We will determine the 36-week direct costs of SBIRT-PM exclusive of overhead on the basis of our micro-costing procedures and MCA data. We will consider the effect of the intervention on Veteran enrollments, which affect budgetary allocations to the regional network. The goal is to find the cost of the intervention net of its impact on these revenues. This represents the budget impact from the point of view of the regional administrator, who must decide whether to sustain SBIRT-PM after the trial has concluded.

Procedures for Handling Missing Data

The study will minimize missing data by using regular reminder calls and by calling contacts of Veterans who miss appointments. Some missingness nevertheless may occur. It may not be completely at random. Participants may be less likely to share more sensitive information, such as use of illicit substances. In addition, on the basis of our previous study [6], we anticipate that there might be differences in follow-up rates in the two trial arms, with Veterans in UC likely to drop out more frequently. Patterns of missingness will be examined by each individual covariate in the data (univariate, monotone, or non-monotone). Chi-square and *t* tests will be run to see if missingness is related to other baseline variables in the analysis (e.g., intervention status, substance use). Multiple imputation will be used in the case of variables missing either completely at random or at random. To reduce the likelihood of missing not at random, the multiple imputation model will include "auxiliary variables" that are highly correlated with both the variable that has missing data and the probability that the variable is missing. Sensitivity analyses will be conducted as part of the multiple imputation procedure (PROC MI) in SAS 9.4 (SAS Institute Inc., Cary, NC, USA). All statistical tests will be based on analysis of variance between the multiple imputations.

Implementation and Dissemination

The VISN1 Director will be briefed on trial findings. At a national level, we will share our findings with VA operational leaders in the National Pain Management Program Office and the National Pain Research Working Group, which includes pain investigators who teleconference regularly to identify priorities for pain research and develop collaborative projects. Moreover, we will share the results with the Veterans Benefits Administration leadership, including the Disability Examination Management Office, which sets policy for compensation examination procedures, as well as the Program Policy Implementation Office of Mental Health Services, which oversees the conduct of service-connection examinations in VA.

Discussion

Trial recruitment began on October 23, 2019, and is expected to last 32 months. Enrolled participants at the time of the study protocol manuscript submission (n = 184) have shown substantial pain symptomatology (mean past week Brief Pain Inventory pain severity subscale score=5.3; standard deviation=1.2), and more than half of the sample (53%) has reported problematic use of at least one substance in need of intervention. Approximately 83% of participants assigned to SBIRT-PM received at least one counseling session. There have been no serious study-related adverse events to date. These early indicators bode well for the trial to reach the targeted sample and safely test the effectiveness and cost-effectiveness of SBIRT-PM.

The trial has several strengths, including a large targeted sample size; multisite randomized controlled design; pragmatic measures of pain, substance use, and costs; and long follow-up period to detect treatment effects. Moreover, SBIRT-PM is a simple and flexible intervention delivered by phone to Veterans in a VA regional network. Providing SBIRT-PM to Veterans at the time of their compensation claims could foster their use of multimodal pain treatments and reduce existing substance misuse early. If cost-effective, SBIRT-PM could be implemented in other regional VA health care systems.

Challenges to conducting the trial have been related largely to the worldwide COVID-19 pandemic. Beginning in March 2020, most in-person VA and community-based pain management and substance use services were halted and, when possible, converted to virtual delivery. In addition, because of coronavirus health risks, there was a reduction in the number of Veterans filing compensation claims and/or having scheduled exams. Because the study is conducted entirely by phone, the trial has continued uninterrupted, albeit at reduced

recruitment volume. Consulting the VA Pain Management Collaboratory [16], we amended the SBIRT-PM protocol to include a COVID-19 questionnaire (developed within the Phenotypes Workgroup) to identify how the pandemic affects participants' health, social determinants of health, and access to health care. We also have anticipated (with input from the Biostatistics Workgroup) necessary adjustments to our analytic methods to accommodate potential pandemic effects that vary over time on primary and secondary outcomes. Furthermore, we have modified the SBIRT-PM intervention to permit discussion of pandemic-related stressors and updated information about available virtual and self-help pain and substance use services accessible to Veterans at all sites. Finally, we added the booster session between weeks 12 and 32 as an additional opportunity to counsel Veterans when services are more likely to restart.

With the VA and community health care systems now "reopening," we anticipate that recruitment will gradually resume to pre-pandemic levels, given the backlog of Veterans needing compensation examinations and treatment. Ongoing collaboration and consultation with our site principal investigators, VA Pain Management Collaboratory workgroups, VA partners, and Data Safety and Monitoring Board will be essential to maintain the pragmatic and exploratory integrity of the SBIRT-PM study protocol moving forward.

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Supplementary Data

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

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