Title

Optimizing pain treatment interventions (OPTI): A pilot randomized controlled trial of collaborative care to improve chronic pain management and opioid safety-Rationale, methods, and lessons learned.

Authors

Seal, Karen H
Borsari, Brian
Tighe, Jennifer
et al.

Publication Date

2019-02-01

DOI

10.1016/j.cct.2018.12.006

Peer reviewed

Contemporary Clinical Trials 77 (2019) 76–85

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Optimizing pain treatment interventions (OPTI): A pilot randomized controlled trial of collaborative care to improve chronic pain management and opioid safety—Rationale, methods, and lessons learned

Karen H. Seal[a,b,*], Brian Borsari[a,b], Jennifer Tighe[a], Beth E. Cohen[a,b], Kevin Delucchi[b], Benjamin J. Morasco[c,d], Yongmei Li[a], Emily Sachs[a], Linda Abadjian[a], Erin C. Watson[a,b], Jennifer K. Manuel[a,b], Lea Vella[a,b], Jodie Trafton[e,f], Amanda Midboe[e]

[a] San Francisco Veterans Affairs Health Care System, United States
[b] University of California, San Francisco, San Francisco, CA, United States
[c] Center to Improve Veteran Involvement in Care, VA Portland Health Care System, United States
[d] Department of Psychiatry, Oregon Health and Science University, United States
[e] VA Palo Alto Health Care System, Center for Innovation to Implementation (Ci2i), United States
[f] Program Evaluation and Resource Center (PERC), VA Office of Mental Health Operations, United States

ABSTRACT

Veterans seeking care in VA medical facilities have high rates of chronic pain, which often co-occur with mental health and substance use disorders, including prescription opioid misuse. The overall goal of the Optimizing Pain Treatment Interventions (OPTI) study was to pilot a 12-week Collaborative Care intervention to improve opioid safety, chronic pain disability, and use of non-pharmacological pain management strategies in veterans in VA primary care. Between November 2014 and January 2017, 100 veteran patients with chronic pain and high-risk prescription opioid use (e.g., high-dose therapy, early refills, etc.) were enrolled and completed an initial one-hour study visit with a primary care provider (PCP) within 4 weeks of enrollment. Study PCPs were guided by a web-based opioid management decision support program and templated notes in the VA electronic medical record. After assessment and education, study PCPs used Shared Decision-Making to formulate a Pain Care Plan aligned with a participant's personal values and goals. After the initial visit, patients randomized to Collaborative Care received one Motivational Interviewing (MI) session with a Care Manager followed by 3 Care Manager-delivered brief telephone MI sessions at 6, 8, and 12 weeks to reinforce Pain Care Plans; patients randomized to an Attention Control condition met with a Care Manager briefly, followed by 3 brief scripted telephone psychoeducation sessions at 6, 8, and 12 weeks. Masked evaluators assessed outcomes at baseline, end of intervention (12 weeks), and after eight weeks of no contact (20 weeks). We present study rationale, detailed methods, preliminary results and lessons learned.

1. Introduction

Opioid addiction and overdose are the leading public health crisis in the United States [1,2,3]. Military veterans have been disproportionately impacted, largely owing to their high prevalence of musculoskeletal injuries and comorbid mental health disorders, which have been associated with a higher prevalence of chronic pain complaints, prescription opioid use and adverse opioid-related outcomes [4,5,6].

Evidence is mounting that opioid medications are not superior to non-opioid therapies in decreasing pain severity and worsen functioning and quality of life [7,8,9]. Cognizant of this new information, primary care providers (PCPs) often struggle with patients to limit opioid use for chronic pain with little to assist them [10,11]. Clinical Practice Guidelines (CPGs) have been disseminated to promote safer opioid prescribing in chronic pain patients [12,13], but are seldom used by PCPs in practice due to lack of access to guidelines at the point of care, lack of time, and discomfort in discussing opioid misuse with patients [14].

To enhance the delivery of guideline-concordant care for chronic pain, a computerized decision support system, ATHENA-OT (Assessment and Treatment in Healthcare: Evidence-based Automation-Opioid Therapy) was developed [15]. ATHENA-OT provides patient-specific, guideline-based recommendations to clinicians at the point of care [16]. Specifically, patient data, including prescription opioid therapy history, are pulled from the VA electronic medical record and compared with the 2010 VA/DoD Opioid Management Clinical Practice Guideline to guide point-of-care personalized recommendations [15].

* Corresponding author at: San Francisco VA Health Care System, University of California, San Francisco, Departments of Medicine and Psychiatry, 4150 Clement Street, Box 116-A, San Francisco, CA 94121, United States.
E-mail address: Karen.Seal@va.gov (K.H. Seal).

https://doi.org/10.1016/j.cct.2018.12.006
Received 12 September 2018; Received in revised form 27 November 2018; Accepted 16 December 2018
Available online 17 December 2018
1551-7144/ Published by Elsevier Inc.

While key stakeholders, including PCPs, have found promise in ATHENA-OT for delivery of guideline-concordant care, they cited several practical challenges to implementation, such as competing priorities, as well as persistent underlying discomfort in discussing opioids with patients, as barriers to using ATHENA-OT in clinical practice [17].

Collaborative Care is an evidence-based model in which Care Managers assist clinicians in motivating behavioral change, monitoring clinical outcomes and providing feedback [18,19]. Motivational Interviewing (MI) is a directive, non-judgmental, patient-centered approach to enhance patients' intrinsic motivation to change by exploring and resolving ambivalence [20]. MI has a strong evidence-base in primary care, particularly in decreasing substance use disorder symptoms [20,21], and has been used successfully by ancillary healthcare providers over the phone [22]. To date, however, MI has not been used in Collaborative Care models to motivate patients to decrease high-risk use of prescription opioids for the treatment of chronic pain.

The OPTI study was designed to pilot a modified Collaborative Care approach in which Care Managers used MI to attempt to decrease prescription opioid risk in favor of non-opioid management of chronic pain. Specifically, across both arms, study PCPs developed personalized Pain Care Plans using ATHENA-OT computerized decision support and Shared Decision-Making. We hypothesized that after the initial PCP visit, participants randomized to Collaborative Care MI sessions would be more likely to use their Pain Care Plans to reduce opioid risk and pain disability and improve use of non-opioid pain management strategies than those assigned to an Attention Control psychoeducation condition. Here, we detail the iterative development of the study methods, preliminary results and lessons learned in conducting this pilot pragmatic trial with veterans in VA primary care.

2. Methods

2.1. Trial overview

This three-year study was funded under a National Institutes of Health (R34) award, a mechanism which allows for the iterative development and pilot testing of a study intervention protocol (https://grants.nih.gov/grants/funding/r34.htm). Intervention development was conducted in three phases.

During Phase 1, which lasted four months, we recruited and trained four volunteer study primary care providers (PCPs) who assisted the two PCP co-investigators (KHS and BEC). Study PCPs were either board-certified internists or nurse practitioners on staff at the San Francisco VA Health Care System (SFVAHCS). The Principal Investigator (PI) and research staff provided training to study PCPs in pain management and opioid safety that incorporated use of the web-based ATHENA-OT decision support system. Study PCPs were also oriented to the study protocol, particularly in how to conduct the initial and two follow-up primary care study visits. These visits were guided by structured clinic note templates designed specifically for the study. Finally, providers were trained in the use of Motivational Interviewing (MI) and Shared Decision Making (SDM) [23,24] to formulate a personalized Pain Care Plan. In addition, the four Care Managers, who were clinical psychologists, post-doctoral fellows or psychology research staff at the SFVAHCS, received basic training in pain management and opioid safety as well as a refresher in MI and SDM (see Appendix-PCP and Study Staff Training.)

During Phase 2 (8 months duration), we pre-tested the randomized controlled trial (RCT) protocol with a small number of veteran participants (N = 10) to refine the study intervention and protocol before enrolling more participants. Specifically, we piloted recruitment and enrollment, PCP initial and follow-up visits, randomization, Care Manager protocols for the intervention and control arms, and the administration of patient self-report measures by trained evaluators masked to group assignment. All changes to the protocol were minor and were approved by the Institutional Review Board of the University of California, San Francisco with concurrence from the San Francisco VA Health Care System Human Research Protection Program. Importantly, during Phase 2, we monitored Care Manager fidelity to the Collaborative Care (MI) intervention, as well as to the Attention Control psychoeducation condition. The first five participant sessions from each arm were coded using the Motivational Interviewing Treatment Integrity Scale version 3.1.1 (MITI 3.1.1) [25] and the Care Managers were given detailed written and verbal feedback on their MI skills.

During Phase 3 (24 months), we enrolled participants in the pilot RCT until we reached our target enrollment of 100 study participants. Study PCPs received booster training sessions at quarterly lunchtime meetings, which consisted of case conferences, review of the study protocol and use of the study materials. The second author (BB) continued to monitor Care Manager MI fidelity throughout the trial by randomly selecting 20% of the audiotapes of both the Collaborative Care and Attention Control conditions and rating them using the MITI 3.1.1. The Care Managers were provided written and verbal feedback on their use of MI techniques.

2.2. Study objectives

The overall aim of this study was to develop and pilot test a novel multi-component Collaborative Care intervention. Treatment targeted the [1] *system* by providing computerized clinical decision support for opioid therapy (ATHENA-OT) and templated pain management notes in the electronic medical record, and [2] *veteran* through MI sessions with a Care Manager to help patients implement a personalized Pain Care Plan. A primary endpoint for this pilot study was feasibility of the intervention and greater self-efficacy among PCPs and the Care Managers in developing Pain Care Plans with patients with chronic pain. We also evaluated the acceptability of the study procedures with the participants through a brief measure of satisfaction with pain care. Because this was a pilot study, our secondary objective was to evaluate the preliminary efficacy of the Collaborative Care intervention involving Care Manager MI sessions to improve prescription opioid safety, pain disability and use of non-opioid pain management strategies among primary care patients enrolled in the study.

2.2.1. Study setting

This pilot RCT was conducted in the main primary care clinic at the San Francisco VA Health Care System (SFVAHCS). The SFVAHCS is a large urban VA Medical Center with an ethnically diverse population of male and female veterans. It has a strong academic affiliation with the University of California, San Francisco, which facilitates research in primary care.

2.2.2. Recruitment and enrollment

Fig. 1 shows a flow diagram of the study protocol beginning with recruitment of study participants. The primary mode of recruitment was intended to be referral by PCPs in the SFVAHCS. In Phase 2, it became apparent that we needed to augment this recruitment strategy because of low rates of patient referrals by PCPs coupled with high rates of refusal by potentially eligible veterans. Thus, while we continued to encourage PCPs to refer their patients with chronic pain and high-risk opioid use, we also obtained a HIPAA waiver to identify potentially eligible veterans using VA administrative data. After receiving lists of potentially eligible veterans, study staff would check eligibility by reviewing the electronic medical record and if there were no obvious reasons for exclusion (see criteria below), they mailed study information letters to potentially eligible participants. Included were opt-out postcards that patients could mail back if they were NOT interested in being contacted. If after 14 days, a patient had not opted out, staff would call and, after obtaining verbal consent, would conduct a brief telephone screen to assess interest as well as study eligibility. Phone screening determined whether the participant was an adult veteran enrolled in care in the SFVAHCS and was taking prescribed opioids for

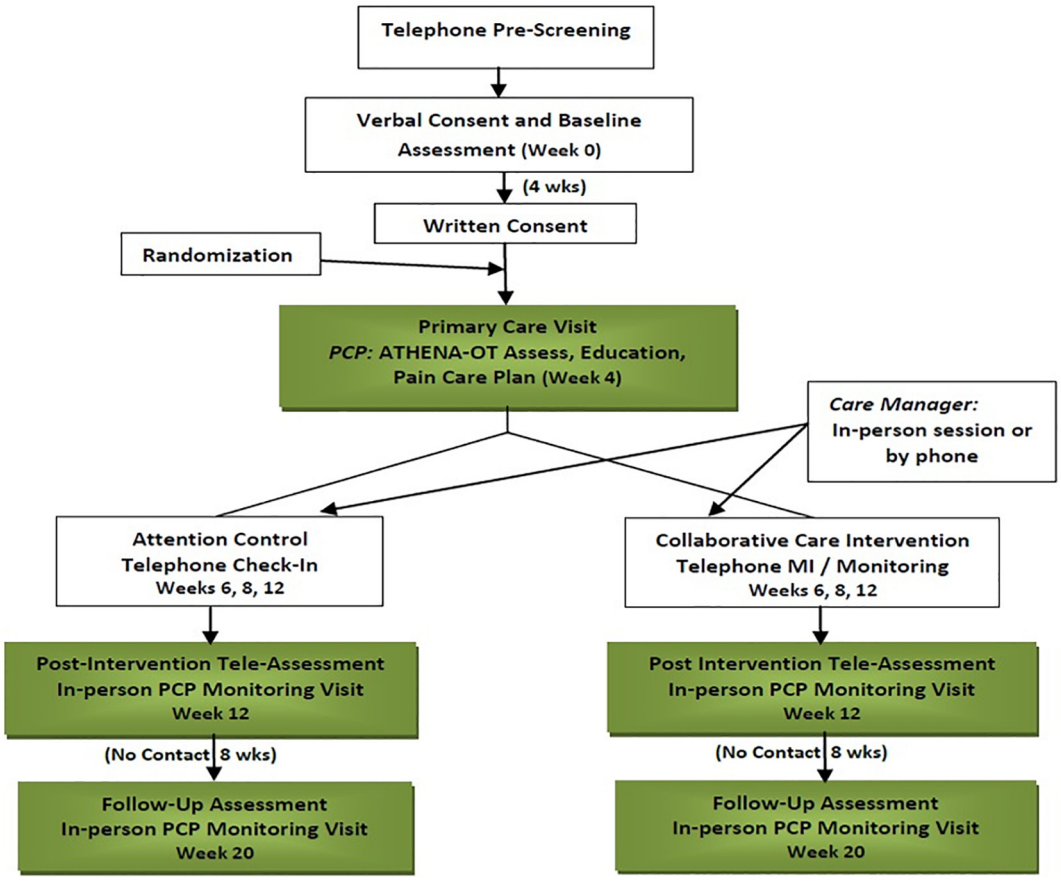

Fig. 1. Study flow diagram.

at least three months to manage pain (musculoskeletal/joint, back or neck pain, headache or fibromyalgia) that persisted for six months or more. Additionally, potential participants were screened for *serious untreated* mental illness (e.g., psychosis etc.), which was considered exclusionary for study enrollment (see below).

Participants who remained interested and eligible following the initial telephone screen were scheduled for a one-hour telephone baseline assessment to further confirm study eligibility (as well as gather baseline study data). Before conducting the telephone baseline assessment, the Study Coordinator obtained verbal informed consent by phone. Participants received a small stipend for participation in each of the three study assessments (baseline, 12 and 20 weeks), but study visits and telephone sessions were not compensated. Participants could receive a total of up to $100 for study participation.

2.2.3. Eligibility

Our inclusion criteria were intentionally broad to increase generalizability and external validity of our findings without incurring unnecessary risk. Inclusion criteria for the study included adult veterans (≥age 18) receiving care through the SFVAHCS with chronic pain (> 6 months duration), prescribed opioids for at least 3 months who demonstrated evidence of *one or more* of the following proxies for "high-risk" opioid use: [6,26,27] score of ≥9 on the Current Opioid Misuse Measure (COMM, see below); high-dose opioid therapy (≥45 mg morphine equivalents/day); current co-prescription of benzodiazepines; history of at least one early opioid refill in the last 12 months; current depression, posttraumatic stress disorder (PTSD), or anxiety disorder; or evidence of current or former drug and/or alcohol use disorder (e.g., positive urine drug screen(s) or from chart review). We excluded participants who could not comprehend English, those with a terminal illness prescribed opioids in the context of palliative or hospice care, those with a serious untreated mental illness (i.e., psychosis, bipolar disorder, or substance use disorder) or active suicidal/homicidal ideation or otherwise unstable as determined by study staff.

2.2.4. Primary care visits for all participants

All participants who remained eligible for the RCT were scheduled for an initial 60-minute visit in primary care SFVAHCS with a study PCP (as opposed to their regular PCP) within 4 weeks of the telephone baseline assessment. These 60-minute study visits typically occurred between study providers regularly scheduled primary care patients. At the initial study visit, participants signed written informed consent and were thereafter considered enrolled in the study.

The initial PCP visit was conducted before participant randomization to avoid potential bias. Prior to the first visit, both the PCP and Care Manager were encouraged to review the patient's pain and opioid-related histories captured in the online ATHENA-OT clinical decision support system as well as in the VA electronic medical record. Either before or after the PCP visit, study staff conducted breath alcohol testing using a simple breathalyzer and escorted participants to the SFVAMC laboratory for a urine drug screen.

At the initial visit, study PCPs provided the patient a study folder with patient-centered informational materials related to pain and opioid management, which included: a cartoon, "Car with Four Flat Tires" (American Chronic Pain Association) to help explain the rationale/advantages of multi-modal pain care; a colorful diagram illustrating four categories of Multi-Modal Pain Care; a detailed pain management resource list; an illustrated step-by-step description of how to create a Specific, Measurable, Action-Oriented, Realistic and Timebound (SMART) goal, and a template for creating a Pain Care Plan. These were incorporated into the initial study visit as described below (see Appendix).

Using a templated study note embedded in the VA electronic medical record, PCPs were prompted to: [1] assess average pain severity and pain interference over the past 7 days using the Pain and Interference with Enjoyment and General Activity Scale, (PEG) [28] and determine the location(s) of chronic pain; [2] assess level of pain relief and adverse medication-related effects from different opioid and non-opioid pain medications; [3] evaluate prior non-pharmacological modalities for pain management, (e.g., yoga, acupuncture, walking); [4] evaluate aberrant opioid-related behaviors using the Addiction Behavior Checklist [29]; [5] provide VA opioid safety education, ("Taking Opioids Responsibly," https://www.va.gov/painmanagement/opioid_safety_initiative_osi.asp); [6] use visual decision aids (described above) to illustrate the rationale for multi-modal pain management and pain management modalities, i.e., medications, behavioral health, physical modalities, and procedural/manual therapies; [7] provide participants a detailed list of current pain management options through VA and the community; [8] inventory participants' personal values and life goals; [9] discuss the importance of defining goals that are specific, measurable, action-oriented, realistic and timebound or "SMART" goals that serve as incremental steps toward achieving larger life goals [30]; and [9] engage the participant in SDM to develop a personalized Pain Care Plan based on the participant's SMART goals to reduce opioid risk and improve non-opioid pain management (see Appendix).

Most participants had two additional in-person pain- and opioid-focused visits with the (masked) study PCPs at 12 weeks (after end of study intervention-see below) and a final visit at 20-weeks (after 8 weeks of no contact). In a minority of cases, the study PCP conducted these briefer follow-up visits by phone or, when not available, one of the Care Managers, who was masked to the participant's random allocation, conducted the visit. Follow-up clinical visits were 20 to 30 min with the main objective of repeating the PEG and ABC surveys and conducting the alcohol breath and urine drug screens. When conducted over the phone, participants were asked to come to the medical center for their urine drug screen within a 30-day window. Additionally, during these briefer follow-up visits, study clinicians could review the SMART goals listed in patients' Pain Care Plans, make changes if desired by the participant, order pain medications and/or place referrals. In the minority of cases in which Care Managers conducted these follow-up visits, no changes were made to the Pain Care Plan since Care Managers were not medical providers, but instead reinforced treatment goals using MI and problem-solved etc. After the study ended, participants were returned to the care of their own referring PCP for ongoing pain management. The original referring PCPs were apprised of study procedures, referrals and medication changes through the electronic medical record, which allowed for continuity of care after the study ended.

2.2.5. Randomization and masking

After the first PCP visit, enrolled study participants were randomized using standard software to either the collaborative care MI intervention or the psychoeducation attention control. Given the high prevalence of mental health and substance use disorders in the veteran population, we hypothesized a priori that current or former drug or alcohol use disorder would interact with intervention efficacy [31]. Therefore, block randomization was stratified on current or former substance use disorder to optimize random distribution of patients with differential likelihood of achieving opioid risk reduction. After randomization, only the study coordinator and Care Managers were aware of participants' group assignment; the PCP and study evaluators were masked to study arm.

2.2.6. Description of study interventions

2.2.6.1. Collaborative care intervention. The Collaborative Care intervention consisted of four Motivational Interviewing (MI) sessions with the first session occurring after the initial PCP visit (week 4), with three additional telephone MI sessions at weeks 6, 8, and 12, all conducted by the same Care Manager throughout the participant's enrollment in the study.

2.2.6.2. Care manager visit in primary care. After a participant's initial study visit, the PCP conducted a "warm hand-off" [32] to the Care Manager, who then engaged the participant in a 20- to 30-min visit to review the Pain Care Plan. Using MI and the "Readiness Ruler [33], the Care Manager worked to further align the Pain Care Plan with the participant's personal goals and values, assessing and resolving ambivalence about readiness to achieve the SMART goals they had agreed on through Shared Decision-Making with the study PCP. Finally, the Care Manager reviewed the schedule of future visits including the telephone MI sessions at 6, 8, and 12 weeks, PCP follow-up visits at 12 and 20 weeks, and telephone assessments at 12 and 20 weeks.

2.2.6.3. Care manager telephone MI sessions at 6, 8, and 12 weeks. This particular interval (6, 8, and 12 weeks) and dose of telephone MI sessions (three sessions) was selected based on the efficacy of our prior telephone MI trial [22]. All Care Manager telephone sessions opened with brief monitoring of [1] pain level and pain interference using the PEG (e.g., "On a scale from 0 to 10, how much is your current pain level interfering with your daily activities,) and [2] progress toward achieving the SMART goals in their Pain Care Plans – behaviors to increase opioid safety and non-opioid pain management. The Care Manager again used the Readiness Ruler to rate the participant's average importance, confidence and readiness for opioid risk reduction and adoption of non-opioid pain management alternatives.

In our prior MI study, we demonstrated increased MI efficacy using non-scripted MI techniques [22], a finding corroborated by other studies [21]. The Care Managers were trained to use a guide with MI principles and techniques such as reflective listening, affirmations, asking permission (before giving advice), and eliciting "Change Talk" [34]. Fidelity monitoring (described above) was used to assure fidelity to MI communication techniques (see Appendix, Telephone Care Manager Visit Outline).

2.2.6.4. Attention control psychoeducation arm. The same Care Managers conducted the Attention Control condition which consisted of 4 scripted opioid safety and pain psychoeducation sessions, with the first session occurring after the first PCP visit (week 4), with 3 additional telephone sessions at 6, 8, and 12 weeks (see Appendix, Attention Control Sessions).

2.2.6.5. Care manager visit in primary care. After the initial study visit, the PCP escorted the patient to the Care Manager and conducted a brief warm hand-off. The ensuing 10 to15 min in-person session with the Care Manager consisted of a brief (neutral) review of the participant's Pain Care Plan. The Care Manager answered the participant's questions without using MI-consistent communication, and reviewed upcoming study visits.

2.2.6.6. Telephone psychoeducation sessions at 6, 8, and 12 weeks. Each of the three telephone psychoeducation sessions at 6, 8, and 12 weeks was intended to be balanced with the MI Collaborative Care intervention with respect to attention. The Care Manager also did their best to balance for time, but in our prior trial, we learned that neutral telephone calls were, by their nature, shorter in length [22]. Because these neutral sessions served as a control for the MI intervention, the Care Managers attempted to avoid discussion of pain severity or interference, the Pain Care Plan, and did not use the Readiness Ruler. Instead, the neutral sessions consisted of psychoeducation about chronic pain, the association of chronic pain with mental health problems, prescription opioid safety and the logistics of study calls and visits.

2.2.7. Outcomes assessment for the randomized controlled trial

Outcomes for participants in the MI Intervention and Attention Control arms were assessed by phone, first at baseline by the study coordinator who was still masked to group assignment. The coordinator conducted the approximately 60-min telephone-administered baseline assessment, entering responses directly into "Qualtrics," a web-based data management system (https://www.qualtrics.com/). Follow-up assessments were conducted after treatment (at week 12) and at 20 weeks (8 weeks post-intervention), another staff member, masked to group assignment, conducted a briefer 45-minute structured telephone assessment, repeating the standard and non-standard measures listed below (except for those administered only at baseline). Listed below are measures used in the study:

2.2.7.1. Non-standard measures. These included sociodemographic characteristics (*administered at baseline only*); psychoactive medications (current and past year) including benzodiazepine or other sedative hypnotic and/or psychiatric medications; current pain medications, including opioid medications; adherence to participants' Pain Care Plans (i.e., adherence to SMART goals for opioid risk reduction and non-opioid pain management strategies since the last assessment, and if implemented, frequency and duration of the activity); and mental health treatment experiences, a non-standard inventory of current and prior mental health and substance use treatment.

2.3. Standard study measures

These included: [1] Current Opioid Misuse Measure [35], a 17-item self-report questionnaire that tracks current aberrant opioid-related behaviors. Items are rated from 0 = "never" to 4 = "very often" with a total maximum score of 68. The measure is reliable with an α coefficient of 0.86 for the 17 items. A cut-off score of ≥9 is considered positive (sensitivity of 0.77 and specificity of 0.66); [2] The Brief Pain Inventory (BPI) [36], an 11 -item measure of two domains: pain severity and interference with functioning. The average of the items of each domain (scored from 0 to10) is used to determine an overall continuous pain severity and interference score. The BPI has excellent internal consistency and test-retest reliability; [3] The World Health Organization Alcohol, Smoking and Substance Involvement Screening Test (WHO-ASSIST) [37], a validated screening instrument to detect presence/absence and severity of alcohol and substance use disorder, including smoking; [4] The Pain Treatment Satisfaction Scale (PTSS) [38], a valid and reliable instrument that measures patient satisfaction regarding pain-related care. We used two PTSS subscales that most directly related to the study intervention – pain-related information (5 items) and medical care (8 items); [5] The Patient Health Questionnaire-9 [39], which is the most widely used measure of depression in primary care. A score of ≥10 yields a sensitivity of 0.88 and a specificity of 0.88 for Major Depressive Disorder; [6] The Posttraumatic Stress Disorder Checklist (PCL) [40], which is a validated 17-item standardized PTSD inventory that mirrors DSM-IV criteria for PTSD. The PCL has high diagnostic validity when compared to the gold-standard Clinician Administered PTSD Scale and yields a continuous score; [7] Two sections of the PRIME MD [41] were used to assess generalized anxiety disorder and panic disorder; [8] Quality of sleep was assessed with the NIH Patient-Reported Outcomes Measurement Information System (PROMIS™) Sleep Disturbance measure [42]; [9] MOS Social Support Survey, which is a well-validated inventory of social support [43]; [10] The Addictions Behavior Checklist (ABC) [29], (administered by study PCPs) is a 20-item clinician-rated checklist to assess and track prescription opioid-related addictive behavior in chronic pain patients. The checklist has adequate reliability and internal validity. A cut-off score of ≥3 showed optimal sensitivity and specificity in determining aberrant opioid-related behavior.

2.4. Biologic measures

These included a urine drug screen in which each study participant submitted a 30-ml urine sample that was processed by the SFVAMC laboratory to detect the presence of the following eight substances: cocaine, cannabinoids, amphetamines, opiates, oxycodone, methadone, benzodiazepines, and barbiturates. In addition, participants underwent alcohol breathalyzer testing at all in-person PCP visits. Urine and breath biological results were evaluated together as one of four possible outcomes: [1] both negative, [2] positive for either alcohol or illicit substances, [3] urine positive for an opioid or benzodiazepine medication that was not prescribed (as indicated in the participant's record), or [4] urine negative for the opioid(s) prescribed, which was considered a negative result in the context of this study, which encouraged opioid dose reduction [44]. The presence of cannabis was counted as positive only if it was not present in the initial urine sample.

2.5. Fidelity monitoring

All telephone sessions in the Collaborative Care MI intervention and Attention Control conditions were audio-recorded. Digital files were uploaded to a secure server and were accessed by the second author for fidelity monitoring. Fidelity was monitored by listening to randomly selected sessions from both arms in their entirety. Subsequently, written and verbal feedback regarding adherence to MI was provided to the Care Managers. In order to monitor for possible treatment contamination or identify relational components (e.g., empathy) or skills (e.g., reflections) that could be improved, randomly selected 20 min segments from sessions from both arms were also coded using the Motivational Interviewing Treatment Integrity Scale version 3.1.1 (MITI 3.1.1) [25].

2.6. Data analysis

A primary endpoint for this pilot study was increased self-efficacy among PCPs and the Care Managers in co-creating and encouraging the use of SMART goals captured in the Pain Care Plans with participants, since this formed the foundation for both the Collaborative Care and Attention Control conditions. Beginning in Phase 2 and continuing throughout Phase 3, Dr. Seal (PI) and Dr. Cohen (co-investigator) evaluated PCP and Care Manager experiences with the study protocol by: [1] reviewing participants' Pain Care Plans, [2] reviewing study clinic visit notes in the electronic medical record, and [3] soliciting feedback through bi-monthly meetings with the study PCPs and Care Managers in order to catalogue their experiences as "lessons learned" and provide booster training. At the end of the study, the PI and research staff convened separate summative feedback sessions for the PCPs and Care Managers. PCPs and Care Managers completed brief questionnaires to rate and describe their experience participating in the study. This was followed by a structured discussion to probe for more detail about their experiences and to elicit constructive feedback. We also evaluated the acceptability of the study procedures with the participants through a brief measure of satisfaction with pain care.

Given the pilot nature of the funding mechanism, our secondary objective was to preliminarily test the hypothesis that veterans randomized to the Collaborative Care MI arm would be more likely to improve opioid safety, pain severity and disability and use of non-opioid pain management strategies at 12 weeks (post-intervention) and at 20-weeks (after 8 weeks of no contact) compared to the Attention Control arm.

There is no gold standard for determining opioid safety/prescription opioid misuse, but prior studies have found that internal validity is increased when objective measures are combined with clinical measures [44]. The definition of our main binary dependent variable (decreased prescription opioid risk-yes/no) is guided by a published trial of substance use treatment for chronic pain patients prescribed opioid

therapy, which is defined as follows: decrease in the Current Opioid Misuse Measure score (patient report measure) of at least ≥5 points or falling below a score of 9 (considered negative) *OR* a negative urine toxicology screen (objective measure) and a continuous decrease on the Addiction Behavior Checklist ≥1 point (clinician observation) or falling below a score of 3 (considered negative) [44]. The main binary independent variable was random group assignment (Collaborative Care vs. Attention Control). Planned covariates included socio-demographics, daily opioid dose (morphine equivalents/day), concurrent psychoactive medications, mental health disorders (i.e., PTSD, depression, anxiety, panic), sleep disorder, current/former substance use disorder, baseline scores of pain severity and interference with functioning, social support, and history of treatment for mental health/substance use disorder.

We also hypothesized that veterans randomized to Collaborative Care arm would be more likely to achieve sustained improvements in pain severity and pain disability. The dependent variable was change in the continuous average BPI score. Independent variables and covariates were the same as above for these final two analyses.

Finally, we hypothesized that veterans randomized to Collaborative Care MI would be more likely to initiate and sustain at least one non-opioid pain management strategy (or SMART goal). The main binary dependent variable was the initiation (yes/no) of ≥1 new opioid risk reduction or non-opioid pain management strategies on the Pain Care Plan at 12 and 20 weeks compared to baseline. We developed a hierarchical taxonomy to further classify the type of pain management strategy as opioid-based risk reduction (e.g., taper etc.) versus non-opioid-based (e.g., trial of a topical non-opioid medication or Tai Chi, etc.), then, if non-opioid-based, this was furthered classified as pharmacological vs. non-pharmacological. Then, if non-pharmacological, we further sub-divided strategies as complimentary and integrative health (CIH, e.g., yoga or acupuncture etc.) vs. non-CIH (e.g., walking, physical therapy etc.) and as clinician-directed vs. patient-directed (not requiring a clinician or facilitator) (Fig. 2).

2.7. Statistical analysis

We primarily used this pilot study to generate descriptive analyses. We also sought to determine if our methods allowed us to preliminarily isolate an effect of MI in the intervention arm to mitigate opioid risk and improve pain disability and adherence to Pain Care Plan goals.

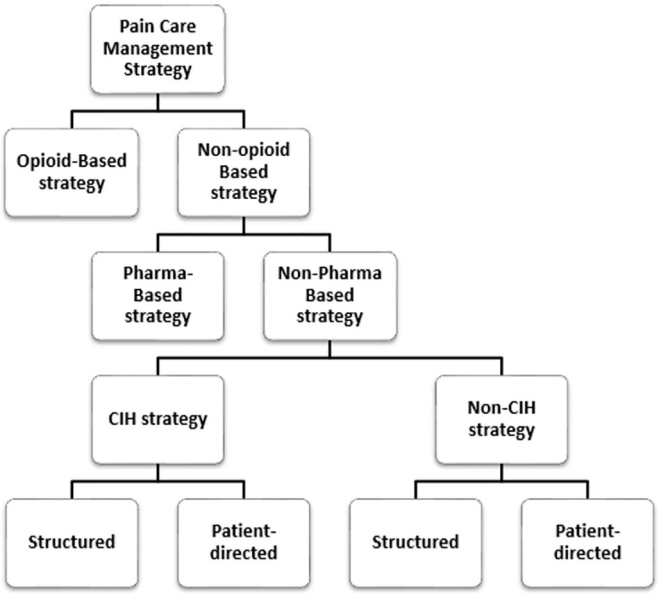

Fig. 2. Taxonomy of non-opioid-based pain management strategies.

Specifically, in Intent-To-Treat (ITT) analyses, multivariate logistic regression (binary outcomes) and linear regression (continuous outcomes) were planned to determine the effect of Collaborative Care MI (vs. Attention Control) in conjunction with structured PCP visits informed by web-based ATHENA-OT clinical decision support (both arms) on opioid risk reduction, pain severity and disability, and initiation and maintenance of pain management goals, after adjusting for potential confounding by measured covariates not evenly distributed by randomization. Analyses were planned that would compare groups on post-intervention (12 weeks) and follow-up (20-week) effects. We also planned to estimate and test mixed-effects models of change over time using maximum likelihood estimation. The threshold for significant p-values was set at $p \leq .05$. We intended to use this pilot to help estimate effect sizes for a larger fully-power trial.

2.8. Sample size and power

We primarily focused on feasibility and acceptability outcomes based largely on observation and clinician feedback to refine the intervention. Therefore, the sample size of N = 100 participants (50 in each of the two conditions) was set primarily for practical reasons and not driven by hypothesis testing. We planned however, to preliminarily evaluate the outcomes of the intervention and to conduct statistical tests.

3. Results

3.1. Recruitment and enrollment

The target sample size for this pilot trial was 100 veterans. Phase 2 study recruitment commenced in November 2014 and enrollment ended in January 2017, which was roughly 12 months longer than planned because recruitment of veterans with chronic pain and higher-risk opioid use (mean morphine equivalent daily dose = 178 mg) proved more challenging than anticipated. Thus, we needed to make several minor changes to the recruitment protocol to improve subject recruitment. First, in response to feedback from veterans, we changed the language and images used in the recruitment flyer sheet to be less stigmatizing. For example, the original study flyer displayed an overturned bottle of pills (presumably opioids) and read, “Do you have chronic pain? Concerned about taking opioids? Want to know more about your options? Contact the OPTI study etc.” The new flyer showed an elderly gentleman (presumably a veteran) walking through a park on an autumn day and read, “Are you managing chronic pain with medication? Want to learn about your options? Call the OPTI research study, etc.,” eliminating any reference to opioids.

Second, we shifted our main recruitment strategy away from PCP referral of individual patients to a “mail and call” strategy which involved identifying potentially eligible veteran subjects from VA administrative data, mailing study information and calling those who did not opt out. We did this because PCPs are typically overburdened and many preferred not to spend time discussing problematic opioid use and referring patients to the study. We continued to conduct brief presentations for clinic staff at different primary care clinics however, to encourage PCPs to refer potentially eligible patients, but did not rely on PCP referral as the sole method of recruitment.

Third, we re-allocated study funds to hire a part-time “recruiter” who dedicated their time to recruitment. While our recruiter was a psychology doctoral student with some clinical experience, we still provided training in how to best communicate with veterans with chronic pain and opioid misuse (e.g., use of MI etc.), as many potentially eligible veterans harbored anger and mistrust toward the VA surrounding opioid-related issues [45].

Thus, of 1318 veterans in the SFVAHCS catchment area who were identified through VA administrative data as being potentially eligible based on study inclusion criteria, the majority, 1218 were excluded

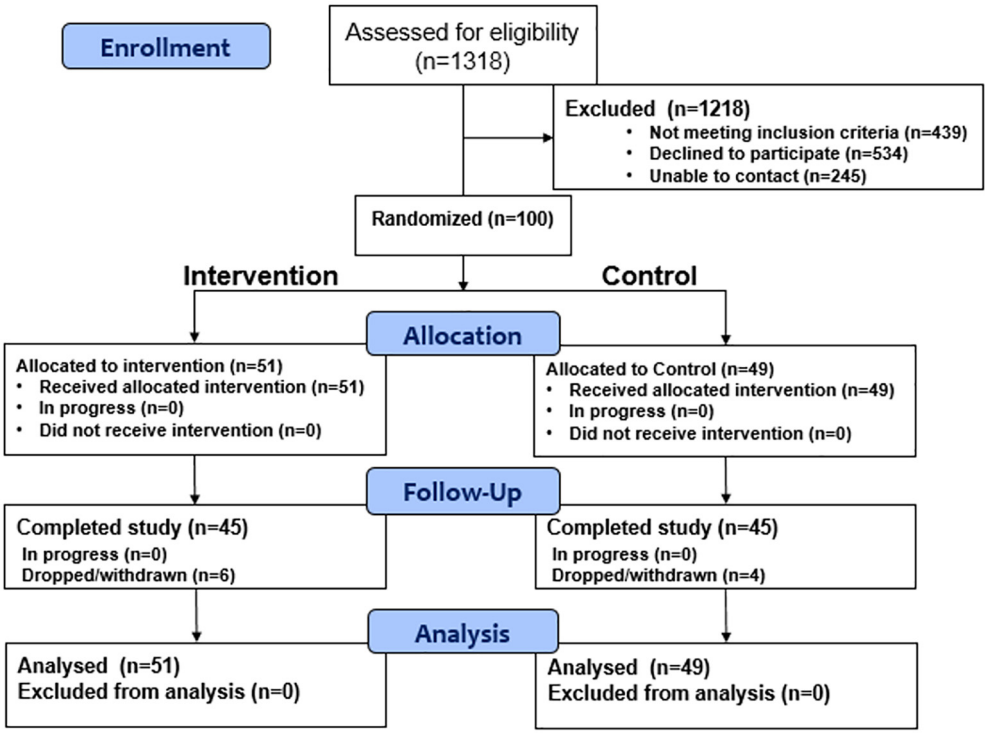

Fig. 3. CONSORT diagram.

before, during phone screening, or after the baseline assessment for the following reasons: [1] 439 did not meet one or more of the study inclusion criteria; [2] 534 declined to participate in the study, with the most common reason given being either time or distance constraints; and [3] 245 could not be contacted by telephone. A substantial proportion of veterans identified in VA administrative databases either did not have a current or accurate address and others could not be reached by phone after multiple attempts (Fig. 3, CONSORT diagram).

3.2. Randomization and follow-up

Following the baseline assessment, 100 participants were enrolled in the study and successfully randomized to either the Collaborative Care MI group (N = 51) or the Attention Control arm (N = 49). Sociodemographic characteristics of the study participants at baseline are shown in aggregate in Table 1. Participants had a mean age of 63 years; 9% were female veterans; 47% ethnic minorities; 57% had a VA service-connected disability; 50% reported either posttraumatic stress disorder, depression or both, and 65% reported having a substance use disorder diagnosis. The mean baseline morphine equivalent daily dose (MEDD) of enrolled study participants was 178 mg per day (SD ± 412).

Overall, 90 participants (90% of those enrolled) completed the trial and all study assessments. The most common reason for non-completion was study withdrawal (N = 6) or loss to follow up (N = 4) (Fig. 3, CONSORT diagram). There were few adverse events, the most common of which were increased emotional distress and physical pain. There were two serious adverse events- short-term hospitalizations in two separate participants determined not to be related to study participation. Of the original 100 participants, 37% had one or more aberrant urine drug screen results in follow-up, which were also considered adverse study events. Only two participants had a positive breath alcohol test during the study.

Table 1
Sociodemographic characteristics of study participants at baseline.[a]

	N = 100
Age (mean, Std)	62.9 (9.0)
Gender (n, %)	
Female	9 (9%)
Male	90 (90%)
Race/Ethnicity (n, %)	
Caucasian/White	61 (61%)
Black or African American	20 (20%)
Asian	3 (3%)
Multi-racial	10 (10%)
Hispanic or Latino	4 (4%)
Other or missing	2 (2%)
College graduate or higher (n, %)	
No	68 (68%)
Yes	31 (31%)
History of homelessness (n, %)	
No	54 (54%)
Yes	45 (45%)
Current employment status (n, %)	
Employed	21 (21%)
Unemployed	78 (78%)
VA-service connection for a military-service related health problem or disability (n, %)	
No	42 (42%)
Yes	57 (57%)
PTSD	15 (15%)
Depression	35 (35%)
Substance use disorder	65 (65%)
Morphine equivalent dose (mean, St.d)	177.6 (412.3)

[a] Includes missing data.

3.3. Study primary care provider feedback

Based on bi-monthly meetings and end-of study feedback, study clinicians reported that they rarely used the web-based ATHENA-OT clinical decision support system to prepare for the initial or follow-up participant visits for several reasons. First, most encountered technical problems, including ATHENA-OT not opening properly within the VA

electronic medical record and challenges navigating the multiple tabs and hyperlinks, all of which took too much time to be feasible during their clinic sessions. Second, clinicians perceived that the focus of ATHENA-OT on how to prescribe opioids more safely (based on 2010 DoD/VA Clinical Practice Guidelines for Pain and Opioid Management) was outdated and not consistent with updated VA initiatives and national guidelines [e.g., the VA Opioid Safety Initiative (OSI) in 2011, the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, 2016 [46] etc.] that advised clinicians to limit opioid prescribing for chronic pain in favor of non-opioid alternatives. Unfortunately, the ATHENA-OT technical team was not able to modify ATHENA-OT content in a timely fashion after the study had launched. Study PCPs reported that instead of relying on ATHENA-OT, they simply reviewed participants' VA electronic medical records because chart review was more familiar. During the study visit, they then liberally referred to OPTI study materials which included a patient-friendly VA OSI brochure entitled "Taking Opioids Responsibly." PCPs also appreciated being able to use the study decision aids that described the rationale and components of multi-modal pain management and included a list of current non-pharmacological pain management resources at VA and in the community, which imparted a sense of control to patients as they selected various pain management options.

Study clinicians experienced some challenges in implementing the OPTI study protocol. First, the study was implemented during their primary care clinics and they reported difficulties obtaining approval for and scheduling one-hour research study visits between regularly scheduled 30-minute patient visits. Second, despite training on Shared Decision-Making in which PCPs elicited participants' values and goals in order to construct SMART goals to develop the Pain Care Plan, some PCPs found it challenging to accomplish this task within the initial 60-minute visit, which also included detailed assessment and education about chronic pain and opioid safety. PCPs reported that some patients had difficulty articulating life values and goals and/or constructing "SMART" goals that were specific, measurable, action-oriented, etc. Third, study PCPs reported varying degrees of role confusion regarding their relationship with the participant's own PCP when it came to making changes to patients' pain regimens in accordance with the Pain Care Plans. Finally, study PCPs found it difficult to make referrals for non-pharmacological pain management services, especially complimentary and integrative health services in VA (because of a dearth of services) as well as in the community (because of limited resources or prohibitive costs to veterans). As the study progressed, study PCPs were strongly encouraged to assist participants in developing more self-directed SMART goals. Examples of self-directed goals are walking, meditating at home or engaging in pleasurable activities; in other words, activities that align with participants' values, shift attention away from chronic pain to more enjoyable activities and rely less on referrals to VA or community resources.

PCPs also had positive feedback about the OPTI study protocol. They appreciated the extensive training in pain and opioid management that they received by participating in the study. They also appreciated being given a full hour with study participants for pain- and opioid-related assessment, education, and Shared Decision-Making, culminating in the Pain Care Plans. Third, study PCPs universally found the structured study note templates embedded in the electronic medical record helpful in guiding them step-by-step through potentially challenging visits which addressed opioid reduction in patients, many of whom were resistant to change. Fourth, study PCPs found the compendium of OPTI study materials and decision aids helpful in the Pain Care Planning process. Finally, PCPs (who were all clinical faculty) perceived that being able to include their participation in the OPTI study in their Curriculum Vitae and receiving letters from the study PI acknowledging their participation in research, which were also sent to their supervisors and Departmental Chair, to be a plus.

3.4. Care manager feedback

Care Managers worked across both study arms and their feedback differed by study arm. For the Collaborative Care MI arm, Care Managers noted that many of the SMART goals in the Pain Care Plans involved medication changes, and as non-medically trained clinicians, they felt it outside their scope of practice to coach participants regarding medication changes. Thus, they often felt limited in their role in helping veterans to taper opioids or initiate non-opioid medications. Care Managers observed that many veterans encountered difficulties implementing some of the non-pharmacological strategies in their Pain Care Plans because many involved referrals to VA services or obtaining services in the community, many of which were either difficult to access or had long wait times associated with them. Additionally, in order to avoid unmasking study PCPs, Care Managers were not able to communicate feedback they received from participants, which at times seemed contrary to their role as Care Managers, which has traditionally involved providing feedback to clinicians. While Care Managers and study PCPs met for the bi-monthly lunch meetings, these were used more for general training and feedback rather than communication to PCPs about specific study participants.

Care Managers had different feedback about the Attention Control psychoeducation arm which involved a neutral check-in visit after the initial study visit and three subsequent telephone psychoeducation education calls. Care Managers reported that it was difficult to avoid responding to participant questions and comments and offering evidence-based treatment. They also noted that it was tedious to read from the scripted psychoeducation materials, particularly when participants complained about the material that was being read to them.

4. Discussion

The overall goal of the OPTI pilot study was to test the feasibility of a 12-week Collaborative Care intervention to improve opioid safety, pain disability and use of non-pharmacological pain management strategies in veterans with chronic pain and at heightened risk for prescription opioid misuse. This paper describes the study rationale, planned and final methods based on early experience, as well as some preliminary results for the aggregate sample. Most importantly, we distill lessons learned to facilitate implementation of similar behavioral interventions with high-risk patients living with chronic pain and over-reliance on prescription opioids.

Veteran patients with chronic pain, prescribed high-dose opioids (> 100 MEDD) and opioid misuse proved very challenging to recruit and enroll in a trial of a behavioral health intervention to improve opioid safety as noted in a recent similar trial [47]. Several modifications were needed in the recruitment strategy for the study to be acceptable to veterans; even so, most veteran recruits were either ineligible, declined to participate or could not be reached after a mailing and several attempts to call. The study started enrollment in 2014, shortly after the implementation of the national VA Opioid Safety Initiative (OSI). The OSI is an ongoing multi-pronged intervention to improve opioid safety that includes encouraging, and in some cases, mandating opioid tapering in veterans on high-risk opioid regimens. The VA OSI also monitors veterans' risk factors for opioid overdose, which includes many of the same risk factors that rendered them eligible for the OPTI study [48,49]. Thus, many of the veterans we contacted for OPTI had already been contacted by VA OSI staff. Veterans, not distinguishing these prior OSI calls from OPTI study recruitment calls often responded to study staff with anger and mistrust. This also hindered efforts to partner with PCPs for referrals because many, already struggling with patients over opioids, were not eager to discuss the OPTI study with them. To overcome these barriers, we modified our recruitment strategies and in pitches to clinic PCPs, framed the study as one way of meeting OSI endpoints for their patients. Nevertheless, the minority of veterans who agreed to participate in the OPTI study may

not have been typical of all veterans with chronic pain with high-risk opioid use and thus, it is not surprising that once enrolled, our retention rate was extremely high (90%).

The ATHENA-OT clinical decision-support application proved to be very limited in supporting study PCPs' care of study participants. In addition to many of the IT challenges experienced by our study PCPs, the more salient problem was that its content, focused on how to prescribe opioids more safely, lagged behind the new VA OSI and other national guidelines which focused on decreasing or eliminating opioid prescribing. Thus, study PCPs found ATHENA-OT to be neither feasible nor acceptable and, early on, largely abandoned their use of the clinical decision-support system, preferring instead to use OPTI study materials, especially the structured note template, which was consistent with VA OSI guidelines and helped them better navigate potentially charged conversations around the use of non-opioid strategies for chronic pain management.

We observed some variability in the creation of the Pain Care Plans, which occurred easily for some PCP and participant dyads, whereas others struggled with the task. Not having established a solid Pain Care Plan during the initial visit across both arms is likely to be one of the biggest obstacles to achieving study outcomes. In some cases, failing to create a Pain Care Plan was related to patient factors such as mild age- or medication-related cognitive impairment or mental health problems, such as depression, which made it hard to motivate any behavioral change. In other cases, provider factors, such as trouble collaborating with patients in Shared Decision-Making or explaining SMART goals made it difficult to complete this task. When Pain Care Plans consisted of non-specific or unrealistic goals (i.e., not SMART goals), patients struggled to implement them and, in the intervention arm, Care Managers struggled to motivate patients. Of note, Shared Decision-Making is not typically a part of medical training and thus the initial PCP training needed to be reinforced with booster trainings that included interactive practice and role plays. In addition, as the study progressed and delays in receiving CIH services became more apparent, study PCPs needed to modify pain care plans by encouraging patients to develop SMART goals that relied less on referrals to VA and community-based services and instead consisted of more self-directed activities, such as walking and engagement in activities participants found pleasurable, which improved mood and thereby pain [50,51].

We also found that the roles of the Care Managers, needed to be better delineated. Care Managers felt their role was too limited because they were unable to help participants with medication-associated SMART goals. Future studies might consider having nurse care managers or physician assistants trained in MI in this role instead, given their increased familiarity with and comfort in discussing pain medication with patients [52]. Also, although the study psychologists were referred to as “Care Managers,” in order to maintain the mask during the trial, they were not able to provide feedback from study participants to the study PCPs, thus limiting the extent to which this was a true Collaborative Care intervention [52,53]. PCPs were masked in this study in order to avoid bias which is important in an RCT with efficacy outcomes. A Collaborative Care intervention, because it is inherently embedded in primary care, would best be conducted as a pragmatic trial with effectiveness outcomes. Future similar, but more pragmatic trials should unmask clinical interventionists to prioritize evaluating the effectiveness of a true Collaborative Care intervention.

Finally, it proved challenging to implement this trial in primary care, as the initial one- hour visit and two subsequent 30-minute visits were sandwiched between regular primary care visits and required study PCPs to block clinic slots to accommodate study participants. Despite the fact that these study participants were patients in the general VA primary care clinic and at high risk for opioid use, clinic leadership was not initially in favor of scheduling visits for research because of pressure to meet new national VA Access to Care mandates to reduce patient wait times (Veteran Access to Care Act of 2014). After a series of meetings with leadership and clerks who scheduled the appointments, the scheduling of study visits improved, but individual study PCPs still perceived pressure around decreased access to care for their regular (non-study) patients. Many health care systems, including VA, value a Learning Health Care System (https://www.research.va.gov/pubs/varqu/fall2015/fall15-3.cfm) in which pragmatic trials conducted at the point of care have the potential to improve clinical outcomes. Nevertheless, when barriers to implementation exist, research staff may need to invest more time and effort up front to cultivate stakeholder buy-in.

In conclusion, several important lessons emerged from piloting this collaborative care intervention within VA primary care. First, whereas PCPs appreciated the note templates and study decision aids to guide them through potentially contentious visits related to opioid risk reduction, many abandoned their use of the web-based ATHENA-OT clinical decision support system early in the study because of technical hiccups and because it lagged behind new VA opioid safety initiatives. Second, we learned the value of matching clinical skillset to study objectives. In this case, since the goal was opioid medication risk reduction, instead of relying on psychologically-trained clinicians to deliver the MI intervention, the behavioral health providers could have instead trained nurses or pharmacists in MI, SDM and formulating SMART goals, which might have might have facilitated the interventionists' suggesting medication modifications. Third, when study clinicians act in a consultative role to other PCPs, their roles, especially regarding medication prescribing, need to be better delineated. Finally, as central to evidence-based implementation frameworks [54,55], context cannot be under-estimated. In this study, we were obliged to navigate the VA's roll-out of the Opioid Safety Initiative, which was negatively perceived by some veterans, reducing the pool of veterans willing to participant in research with similar objectives. This study was also implemented during the roll-out of two other competing VA initiatives: Access to Care and Learning Healthcare System initiatives, with mandates around access to care prevailing, requiring greater stakeholder buy-in to implement the study protocol in primary care. In sum, considering the challenges this team encountered and largely overcame, we are optimistic that future similar pragmatic behavioral interventions directed toward improving opioid safety can and should be implemented in VA (and non-VA) primary care settings.

Disclosures

This work was supported by the National Center for Complimentary and Integrative Health under Award No. 1 R34 AT008319-01. None of the authors have any conflicts of interest to disclose.

Acknowledgements

We are especially grateful for the contributions of all the veterans who participated in this study. We thank additional research staff, Gary Tarasovsky, Emily Schrodek, Amelia Lipscomb, Tamara MacAskill, PhD and Nicole McCamish, MA, who provided exceptional support for this study as well as the dedicated staff of the San Francisco VA Medical Practice Clinic. The study was supported by a grant from the National Center for Complimentary and Integrative Health under Award 1 R34 AT008319-01.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2018.12.006.

References

[1] R.A. Rudd, P. Seth, F. David, L. Scholl, Increases in drug and opioid-involved overdose deaths - United States, 2010-2015, MMWR Morb. Mortal. Wkly Rep. 65 (5051) (2016) 1445–1452.

[2] Centers for Disease Control and Prevention, Prescription Opioid Overdose Data [Internet], (2016).
[3] U.S. Department of Health and Human Services, HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis [Internet], (2017).
[4] M.D. Sullivan, M.J. Edlund, L. Zhang, J. Unutzer, K.B. Wells, Association between mental health disorders, problem drug use, and regular prescription opioid use, Arch. Intern. Med. 166 (19) (2006) 2087–2093.
[5] B.J. Morasco, S.K. Dobscha, Prescription medication misuse and substance use disorder in VA primary care patients with chronic pain, Gen. Hosp. Psychiatry 30 (2) (2008) 93–99.
[6] K.H. Seal, Y. Shi, G. Cohen, et al., Association of mental health disorders with prescription opioids and high-risk opioid use in US veterans of Iraq and Afghanistan, JAMA 307 (9) (2012) 940–947.
[7] E. Kalso, J.E. Edwards, R.A. Moore, H.J. McQuay, Opioids in chronic non-cancer pain: systematic review of efficacy and safety, Pain 112 (3) (2004) 372–380.
[8] A.D. Furlan, J.A. Sandoval, A. Mailis-Gagnon, E. Tunks, Opioids for chronic non-cancer pain: a meta-analysis of effectiveness and side effects, CMAJ 174 (11) (2006) 1589–1594.
[9] E.E. Krebs, A. Gravely, S. Nugent, et al., Effect of opioid vs nonopioid medications on pain-related function in patients with chronic back pain or hip or knee osteoarthritis pain: the SPACE randomized clinical trial, JAMA 319 (9) (2018) 872–882.
[10] M.S. Matthias, A.L. Parpart, K.A. Nyland, et al., The patient-provider relationship in chronic pain care: providers' perspectives, Pain Med. 11 (11) (2010) 1688–1697.
[11] C.C. Upshur, R.S. Luckmann, J.A. Savageau, Primary care provider concerns about management of chronic pain in community clinic populations, J. Gen. Intern. Med. 21 (6) (2006) 652–655.
[12] Department of Defense and Department of Veterans Affairs, VA/DoD Clinical Prcatice Guideline for Management of Opioid Therapy for Chronic Pain, (2010).
[13] Department of Defense and Department of Veterans Affairs, Management of Opioid Therapy (OT) for Chronic Pain (Washington D.C), (2017).
[14] B.J. Morasco, J.P. Duckart, S.K. Dobscha, Adherence to clinical guidelines for opioid therapy for chronic pain in patients with substance use disorder, J. Gen. Intern. Med. 26 (9) (2011) 965–971.
[15] J.A. Trafton, S.B. Martins, M.C. Michel, et al., Designing an automated clinical decision support system to match clinical practice guidelines for opioid therapy for chronic pain, Implement. Sci. 5 (2010) 26.
[16] M.K. Goldstein, R.W. Coleman, S.W. Tu, et al., Translating research into practice: organizational issues in implementing automated decision support for hypertension in three medical centers, J. Am. Med. Inform. Assoc. 11 (5) (2004) 368–376.
[17] J. Trafton, S. Martins, M. Michel, et al., Evaluation of the acceptability and usability of a decision support system to encourage safe and effective use of opioid therapy for chronic, noncancer pain by primary care providers, Pain Med. 11 (4) (2010) 575–585.
[18] S.K. Dobscha, K. Corson, N.A. Perrin, et al., Collaborative care for chronic pain in primary care: a cluster randomized trial, JAMA 301 (12) (2009) 1242–1252.
[19] J.M. Pyne, J.C. Fortney, G.M. Curran, et al., Effectiveness of collaborative care for depression in human immunodeficiency virus clinics, Arch. Intern. Med. 171 (1) (2011) 23–31.
[20] W. Miller, S. Rollnick, Motivational Interviewing: Preparing People for Change, 2nd ed, Guilford Publications, New York, 2002.
[21] J. Hettema, J. Steele, W.R. Miller, A meta-analysis of research on motivational interviewing treatment effectiveness (MARMITE), Annu. Rev. Clin. Psychol. 1 (2005) 91–111.
[22] K.H. Seal, L. Abadjian, N. McCamish, Y. Shi, G. Tarasovsky, K. Weingardt, A randomized controlled trial of telephone motivational interviewing to enhance mental health treatment engagement in Iraq and Afghanistan veterans, Gen. Hosp. Psychiatry 34 (5) (2012) 450–459.
[23] A.M. Stiggelbout, T. Van der Weijden, M.P. De Wit, et al., Shared decision making: really putting patients at the Centre of healthcare, BMJ 344 (2012) e256.
[24] G. Elwyn, D. Frosch, R. Thomson, et al., Shared decision making: a model for clinical practice, J. Gen. Intern. Med. 27 (10) (2012) 1361–1367.
[25] T. Moyers, T. Martin, J. Manuel, W. Miller, D. Ernst, Revised Global Scales: Motivational Interviewing Treatment Integrity 3.1. 1 (MITI 3.1. 1), Unpublished manuscript Albuquerque: Center on Alcoholism, Substance Abuse and Addictions, University of New Mexico, 2010.
[26] M. Von Korff, K. Saunders, G.T. Ray, et al., De facto long-term opioid therapy for noncancer pain, Clin. J. Pain 24 (6) (2008) 521–527.
[27] R. Chou, G.J. Fanciullo, P.G. Fine, et al., Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain, J. Pain 10 (2) (2009) 113–130.
[28] E.E. Krebs, K.A. Lorenz, M.J. Bair, et al., Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference, J. Gen. Intern. Med. 24 (6) (2009) 733–738.
[29] S.M. Wu, P. Compton, R. Bolus, et al., The addiction behaviors checklist: validation of a new clinician-based measure of inappropriate opioid use in chronic pain, J. Pain Symptom Manag. 32 (4) (2006) 342–351.
[30] T.J. Bovend'Eerdt, R.E. Botell, D.T. Wade, Writing SMART rehabilitation goals and achieving goal attainment scaling: a practical guide, Clin. Rehabil. 23 (4) (2009) 352–361.
[31] B.J. Morasco, K. Corson, D.C. Turk, S.K. Dobscha, Association between substance use disorder status and pain-related function following 12 months of treatment in primary care patients with musculoskeletal pain, J. Pain 12 (3) (2011) 352–359.
[32] C.J. Koenig, S. Maguen, A. Daley, G. Cohen, K.H. Seal, Passing the baton: a grounded practical theory of handoff communication between multidisciplinary providers in two department of veterans affairs outpatient settings, J. Gen. Intern. Med. 28 (1) (2013) 41–50.
[33] W.R. Miller, S. Rollnick, Motivational Interviewing, 3rd ed., Helping People Change, Guilford Publication, 2013.
[34] S. Rollnick, P. Mason, C. Butler, Health Behavior Change: A Guide for Practitioners, Churchill Livingstone, New York, 1999.
[35] S.F. Butler, S.H. Budman, K.C. Fernandez, et al., Development and validation of the current opioid misuse measure, Pain 130 (1–2) (2007) 144–156.
[36] C.S. Cleeland, K.M. Ryan, Pain assessment: global use of the brief pain inventory, Ann. Acad. Med. Singap. 23 (1994) 129–138.
[37] Group WAW, The Alcohol, smoking and Substance Involvement Screening Test (ASSIST): development, reliability and feasibility, Addiction 97 (9) (2002) 1183–1194.
[38] C.J. Evans, E. Trudeau, P. Mertzanis, et al., Development and validation of the pain treatment satisfaction Scale (PTSS): a patient satisfaction questionnaire for use in patients with chronic or acute pain, Pain 112 (3) (2004) 254–266.
[39] K. Kroenke, R.L. Spitzer, J.B. Williams, The PHQ-9: validity of a brief depression severity measure, J. Gen. Intern. Med. 16 (9) (2001) 606–613.
[40] E. Blanchard, J. Jones-Alexander, T. Buckley, C. Forneris, Psychometric properties of the PTSD Checklist (PCL), Behav. Res. Ther. 34 (8) (1996) 669–673.
[41] R.L. Spitzer, K. Kroenke, J.B. Williams, Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary care evaluation of mental disorders. patient health questionnaire, JAMA 282 (18) (1999) 1737–1744.
[42] L. Yu, D.J. Buysse, A. Germain, et al., Development of short forms from the PROMIS sleep disturbance and Sleep-Related Impairment item banks, Behav. Sleep Med. 10 (1) (2011) 6–24.
[43] C.D. Sherbourne, A.L. Stewart, The MOS social support survey, Soc. Sci. Med. 32 (6) (1991) 705–714.
[44] R.N. Jamison, E.L. Ross, E. Michna, L.Q. Chen, C. Holcomb, A.D. Wasan, Substance misuse treatment for high-risk chronic pain patients on opioid therapy: a randomized trial, Pain 150 (3) (2010) 390–400.
[45] M.S. Matthias, E.E. Krebs, A.A. Bergman, J.M. Coffing, M.J. Bair, Communicating about opioids for chronic pain: a qualitative study of patient attributions and the influence of the patient-physician relationship, Eur. J. Pain 18 (6) (2014) 835–843.
[46] Centers for Disease Control and Prevention, CDC guideline for prescribing opioids for chronic pain - United States, 2016, Recomm. Rep. 65 (1) (2016) 1–49.
[47] M.D. Sullivan, J.A. Turner, C. Dilodovico, A. D'Appollonio, K. Stephens, Y.F. Chan, Prescription opioid taper support for outpatients with chronic pain: a randomized controlled trial, J. Pain 18 (3) (2017) 308–318.
[48] W.F. Gellad, C.B. Good, D.J. Shulkin, Addressing the opioid epidemic in the United States: lessons from the department of veterans affairs, JAMA Intern. Med. 177 (5) (2017) 611–612.
[49] L.A. Lin, A.S.B. Bohnert, R.D. Kerns, M.A. Clay, D. Ganoczy, M.A. Ilgen, Impact of the opioid safety initiative on opioid-related prescribing in veterans, Pain 158 (5) (2017) 833–839.
[50] T.J. Sharp, A.G. Harvey, Chronic pain and posttraumatic stress disorder: mutual maintenance? Clin. Psychol. Rev. 21 (6) (2001) 857–877.
[51] T.J. Sharp, Chronic pain: a reformulation of the cognitive-behavioural model, Behav. Res. Ther. 39 (7) (2001) 787–800.
[52] W. Katon, M. Von Korff, E. Lin, et al., Collaborative management to achieve treatment guidelines. Impact on depression in primary care, JAMA 273 (13) (1995) 1026–1031.
[53] S.C. Hedrick, E.F. Chaney, B. Felker, et al., Effectiveness of collaborative care depression treatment in Veterans' Affairs primary care, J. Gen. Intern. Med. 18 (1) (2003) 9–16.
[54] L.J. Damschroder, D.C. Aron, R.E. Keith, S.R. Kirsh, J.A. Alexander, J.C. Lowery, Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science, Implement. Sci. 4 (2009) 50.
[55] C.D. Helfrich, L.J. Damschroder, H.J. Hagedorn, et al., A critical synthesis of literature on the promoting action on research implementation in health services (PARIHS) framework, Implement. Sci. 5 (2010) 82.