Evaluation of a Peer Coach-Led Intervention to Improve Pain Symptoms (ECLIPSE): Rationale, Study Design, Methods, and Sample Characteristics

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Clinical Trials Registration: NCT02380690

This is the author's manuscript of the article published in final edited form as:

Matthias, M. S., Daggy, J., Adams, J., Menen, T., McCalley, S., Kukla, M., … Bair, M. J. (2019). Evaluation of a peer coach-led intervention to improve pain symptoms (ECLIPSE): Rationale, study design, methods, and sample characteristics. Contemporary Clinical Trials. https://doi.org/10.1016/j.cct.2019.04.002

Abstract

Chronic pain is prevalent, costly, and a leading cause of disability. Pain self-management (i.e., employing self-management strategies including behavioral modifications) is an effective, evidence-based treatment. However, implementation and delivery of a pain self-management model is challenging because of time and resources. Peer supported pain self-management offers a promising approach to implementing pain self-management programs using fewer clinical resources. Evaluation of a Peer Coach-Led Intervention for the Improvement of Pain Symptoms (ECLIPSE) is a randomized controlled trial testing effectiveness of peer coach-delivered pain self-management intervention versus controls receiving a class on pain and pain self-management. ECLIPSE is a Hybrid Type 1 study testing effectiveness while examining implementation factors. ECLIPSE enrolled 215 veterans randomly assigned to the peer coaching (N=120) or control (N=95) arm. The peer coaching intervention lasts 6 months, with patient-peer coach pairs instructed to talk twice per month. Coaches attend initial training, are provided a detailed training manual, and attend monthly booster sessions. Outcomes are assessed at baseline, 6 months, and 9 months. The primary outcome is overall pain (intensity and interference), measured by the Brief Pain Inventory (BPI). Secondary outcomes are self-efficacy, social support, pain catastrophizing, patient activation, health-related quality of life, and health care utilization. To maximize implementation potential of pain self-management, innovative delivery methods are needed that do not require additional resources from healthcare teams. A novel and promising approach is a peer-coaching model, in which patients who are successfully managing their pain offer information, ongoing support, and advice to other patients with pain.

Keywords: chronic pain, self-management, clinical trial, social support, veterans

Introduction

Pain is prevalent and costly, affecting at least 100 million Americans and amounting to up to $635 billion annually in direct medical costs and lost worker productivity.[1] Chronic pain affects 40-70% of veterans and is a leading cause of disability, resulting in substantial negative impact on millions of veterans' lives.[2, 3] Pain reduces quality of life and is associated with emotional distress when it interferes with work, social and recreational activities, and family life.[1]

Pain self-management strategies, which involve activities such as treatment adherence, behavioral change, and coping skills, is an effective, evidence-based treatment for chronic pain[4-8] advocated by the National Academy of Medicine and the 2009 Veterans Health Administration (VHA) Pain Directive.[1, 9] However, implementation and delivery of a pain self-management support program can be challenging because of limited time and resources in primary care, where most chronic pain is managed. As a result, pharmacological treatments, including opioid analgesics, are frequently the first line of treatment, and pain self-management is under-utilized.

To maximize implementation potential of pain self-management, innovative delivery approaches are needed to provide patients with education and support to effectively self-manage their pain, without requiring additional resources from healthcare teams. A novel and promising approach is a peer-coaching model, in which patients with chronic pain who are successfully managing their pain offer information, support, and advice to other patients, with the goal of helping them more effectively manage their pain. Peer support models are effective in the management of a variety of chronic conditions, including diabetes and mental health.[10-16] Peer models are important complements to formal healthcare because peers provide sustained, between-visit support for patients, particularly for chronic conditions that require

consistent self-management. In addition, evidence suggests that peers themselves may benefit from providing peer support.[17-19]

Peer support involves "lay individuals with experiential knowledge who extend natural (embedded) social networks and complement professional health services."[20] Three attributes are believed to define peer interventions: provision of 1) emotional (caring, encouragement), 2) informational (advice, problem-solving), and 3) appraisal support (motivation to "keep going").[20] Higher levels of social support—especially illness-specific support—are associated with better illness self-management.[21] A Cochrane review found that lay-led self-management programs for chronic conditions led to reductions in pain, disability, depression, and improved self-rated general health.[14]

This manuscript describes the study protocol and recruitment outcomes for the Evaluation of a Peer Coach-Led Intervention to Improve Pain Symptoms (ECLIPSE) trial, a randomized controlled trial to test the effects of peer-supported pain self-management on patients' self-reported pain and secondary outcomes of self-efficacy, social support, pain coping, patient activation, and health-related quality of life at 6 and 9 months following enrollment. Health service utilization over the 9-month study period was also included as a secondary outcome. We hypothesized that patients randomized to the peer support arm would experience reduced overall pain (intensity and function) and improved secondary outcomes compared to patients randomized to the control group.

Methods

2.1 Design Overview

ECLIPSE is a 2-arm randomized controlled trial conducted with patients with chronic musculoskeletal pain. The trial compares a 6-month peer coaching self-management

intervention with a control group consisting of a 2-hour pain self-management class taught by a research team member with expertise in pain self-management. This 2-arm study design allows for direct comparison between patients receiving educational information on self-management in the control group and patients receiving self-management information combined with the motivation and support delivered by a peer coach. All study procedures were approved by the local Institutional Review Board (IRB) and medical center Research and Development Committee. All participants provided written informed consent.

ECLIPSE is a Hybrid Type I study design[22] to facilitate assessment of feasibility for clinical implementation alongside effectiveness outcomes to shorten the timeline to implementation. Accordingly, the study has one primary, one secondary, and one pre-implementation aim:

Aim 1 (primary aim)**:** To compare 6-month (primary endpoint) and 9-month (sustained) effects of peer-supported chronic pain self-management versus controls on overall pain (intensity and function).

Hypothesis 1: Patients in the peer support arm will experience reduced overall pain compared to controls.

Aim 2 (secondary aim)**:** To compare 6- and 9-month effects of peer-supported chronic pain self-management versus controls on self-efficacy, social support, pain coping, patient activation, health-related quality of life, and health service utilization.

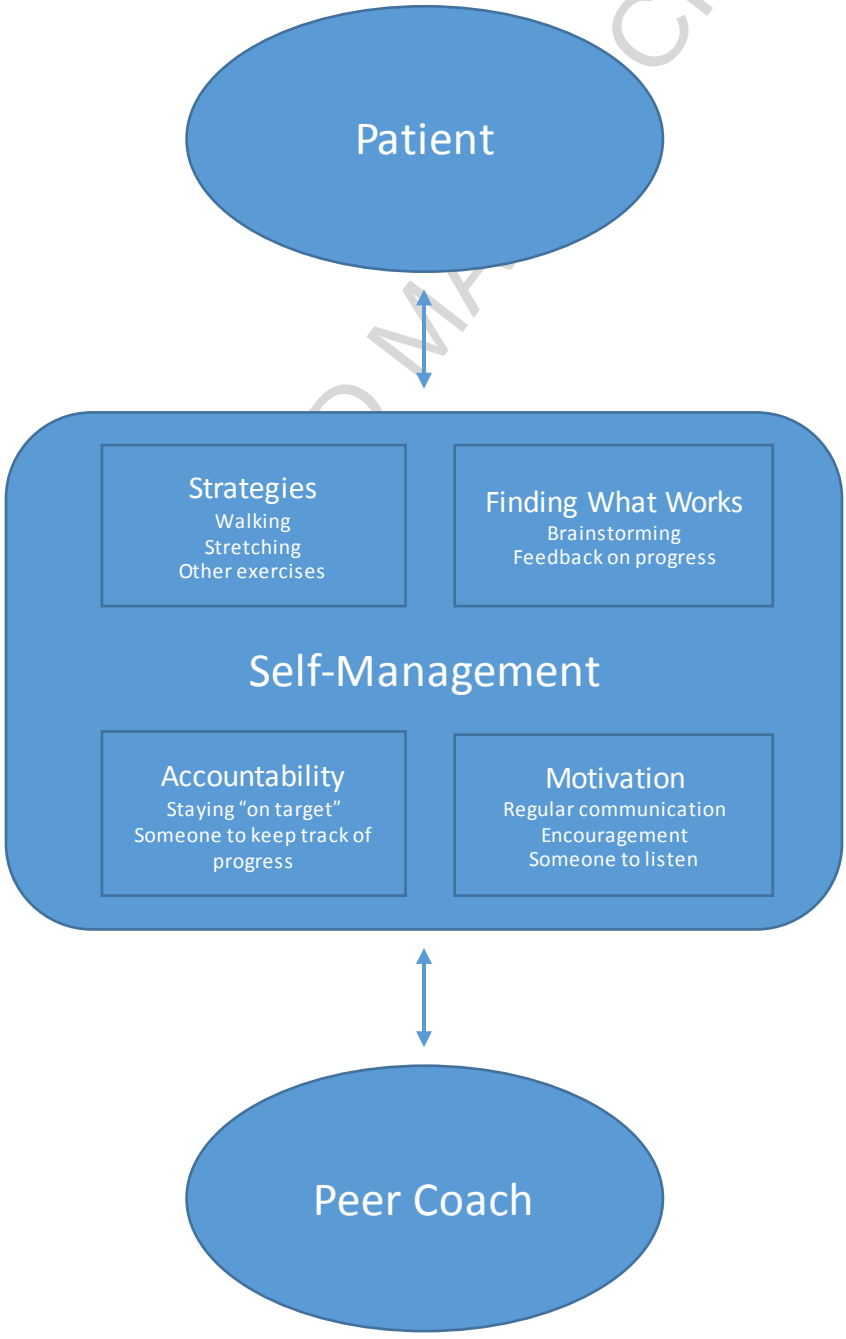
Hypothesis 2: Patients in the peer support arm will experience greater self-efficacy, social support, pain coping, patient activation, and health-related quality of life, and lower health service utilization, compared to controls.

Aim 3 (pre-implementation aim): To explore facilitators and barriers to implementation of peer support for chronic pain, intervention costs, and fidelity to the model.

2.2 Conceptual Model

ECLIPSE is guided by a conceptual model developed from our prior work on pain self-management.[23, 24] This model depicts pain self-management as consisting of four elements: strategies, making adjustments, accountability, and motivation and support. See Figure 1. Importantly, the top half of this model outlines practical aspects of pain self-management: self-management strategies and troubleshooting to find what works for each individual. The bottom half focuses on support, by helping patients to stay on target, motivated, and supported.

Figure 1



2.3 Recruitment and Training of Peer Coaches

Patients are eligible to be peer coaches if they have chronic (i.e., persisting ≥ 3 months) musculoskeletal pain as confirmed by ICD-9 codes in the patient's medical record. Peer coaches are recruited primarily from 1) Patients who completed the intervention arm of one of our previous studies involving chronic pain self-management [25, 26]; and 2) Patients with chronic pain who are successfully managing their pain and are recommended by their primary care providers. Peer coaches are also recruited from the pilot study, IMPPRESS [27] and, later in ECLIPSE, from completers of the ECLIPSE intervention who have been recommended as peer coaches by their peer coaches or study staff.

Peer coach training occurs throughout the study as a new group of peer coaches is recruited. Training sessions are 2-3 hours and taught by one of our peer coach facilitators (CK or EP). Each training session is audio recorded to ensure quality and consistency. The didactic and participative training emphasizes the four elements of self-management and support highlighted in the conceptual model. Particular focus is placed on practice coaching—role-playing to help peer coaches work with their assigned patients to accomplish the four intervention elements.

Each peer coach is given a manual to refer to and serve as a guide during the intervention. The Peer Coach Manual consists of two parts: 1) Self-Management Information (this portion is identical to the patient manual); and 2) How to be a Peer Coach. The first part of the manual was adapted from a prior study on pain self-management,[26] and the second part was adapted from the Peer Specialist Manual used by VHA's Office of Mental Health Services and from our pilot peer support study.[27] See Table 1 for components of each section.

Table 1. Peer Coach Training

Part 1: Self-Management Knowledge	**Part 2. "How to be a Peer Coach"**
Chronic Pain Basics	What is a Peer?
-Biopsychosocial Model	Cultural Competence
-Gate Control Theory of Pain	Communication Skills
Relaxation Skills	Managing Crisis and Emergency Situations
Activity Pacing	Motivational Strategies
Cognitive Behavioral Skills	
Self-Care Skills	
Interpersonal Skills	

2.4 Peer Coach Supervision ("Booster" sessions)

Monthly booster sessions are offered for peer coaches during the study. Sessions alternate between in-person (with a call-in option) and a conference call. These sessions are relatively informal, involving discussion among peer coaches on how their calls/meetings with patients are going and providing follow-up tips on communication strategies and reinforcement. Booster sessions serve several key functions: 1) "Getting things going" at the beginning of the intervention when peer coaches and patients are making initial contact; 2) Reminding peer coaches to contact their patients regularly; 3) Troubleshooting issues or questions; 4) Providing additional training on the use of motivational strategies to address any difficulties with goal

attainment; 5) Providing motivation, encouragement, and reinforcement of their roles as peer coaches; and 6) Serving as a tool to check and maintain intervention fidelity.[28-30]

2.5 Recruitment of Patients

Patients are recruited from the primary care clinics at a large VA medical center in the Midwest. Eligible patients meet the following criteria: 1) musculoskeletal pain in the low back, cervical spine, or extremities (hip, knee, or shoulder) for ≥3 months; 2) at least moderate pain severity, defined by pain ≥ 5 on a 0 (no pain) to 10 (worst pain imaginable) scale; and 3) willingness to engage in phone or in-person contact on a regular basis with another patient. Patients are excluded if the electronic medical record indicates 1) psychiatric hospitalization in the last 6 months, 2) current substance dependence, 3) severe medical conditions precluding participation (e.g., New York Heart Association Class III or IV heart failure), 4) if the eligibility screener given to prospective participants reveals active suicidal ideation, severe hearing or speech impairment, or pending surgery for a musculoskeletal condition (e.g., back surgery), or 5) current participation in another pain study. Primary care providers granted permission to recruit their patients.

2.6 Randomization

Patients are randomly assigned to one of the two study arms using randomization lists created by the study statistician. To obtain the random treatment assignment for the 215 patients, permuted block randomization was used so that within each block the allocation ratio was maintained (19 control group: 24 intervention group).

2.7 Control Arm

Participants are randomized to either the peer coach arm or a control group consisting of a 2-hour class in pain “basics” and pain self-management. In this class, topics listed in Part 1 (Self-Management Knowledge) of Table 1 are reviewed (e.g., chronic pain basics, relaxation skills, activity pacing), and patients are given a set of pamphlets related to pain self-

management. The peer coach facilitators (CK, EP) lead the control group classes, which are offered quarterly.

2.8 Peer Coach-Patient Assignment

The number of patients assigned to an individual peer coach varies based on the peer coach's preference, but was expected to be approximately three patients. Peer coaches and patients are matched on 1) gender; and, when possible, 2) pain location.

2.9 Peer Coach-Patient Sessions

Peer coach-patient pairs choose whether they want to meet in person or have telephone contacts (or a combination), although they are encouraged to meet in person for the first session. Peer coaches are instructed to contact/meet with their assigned patients a minimum of two times per month via telephone or in-person. Patients are given a manual identical to Section 1 of the peer coaches' manual (i.e., without the section on being a peer coach. See Table 1, Column 1.) Peer coaches are asked to log their sessions with each patient, including date, length, format (phone, in-person), brief notes on content, and any other pertinent information, to allow us to track number and content of contacts.

Based on findings from our other pain self-management studies and pilot peer coach study, IMPRESS,[31-33] the content of each meeting is variable depending on a patient's particular needs. However, regardless of specific content (i.e., the specific self-management strategies discussed), coaches are asked to 1) review self-management strategies/exercises (based on manual, See Table 1, Column 1), 2) help the patient to make adjustments if strategies are not working, 3) help the patient to set, follow up on, and be accountable to goals, 4) and motivate and listen to the patient. Coaches are encouraged to discuss their personal experiences with pain self-management and how they overcame obstacles or handled setbacks and frustrations. Coaches do not advise on medications or medical questions, but are asked to recommend that patients see their physicians if such questions come up.

2.10 Fidelity

The following strategies are employed to optimize fidelity to the intervention: 1) use of a detailed intervention manual; 2) peer coach training; 3) regular peer coach booster sessions, which reinforce the importance of protocol adherence and provided constructive feedback to maintain strengths and identify areas for improvement.[34, 35]

2.11 Measures

Study measures include patient-reported outcomes at baseline, 6, and 9 months. Baseline outcomes are collected prior to randomization to mask assessors to treatment arm assignment. Although the study's focus is on the patients being advised by peer coaches, all outcome assessments are also administered to the peer coaches.

2.11.1 Primary outcome

Overall pain is measured with the Brief Pain Inventory (BPI) total score. The BPI was developed to assess the severity of pain and the impact of pain on functioning, and has been validated in primary care studies.[6, 36] The BPI is the average of two scores: pain intensity and pain interference. The pain intensity score is an average of 4 ratings of 0 (no pain) to 10 (pain as bad as you can imagine) for current, least, worst, and average pain in the past week. The BPI pain interference score averages seven ratings, 0 (does not interfere) to 10 (interferes completely), of interference with general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life. The BPI total score is the primary outcome measure because BPI total has been shown to be highly responsive to change in clinical trials.[37, 38] The BPI has been shown to have strong internal consistency,[36] and the BPI assesses the two most important domains—severity and interference—recommended for pain studies.[39]

2.11.2 Other Measures

Self-efficacy is assessed with a 6-item modified version of the Arthritis Self-Efficacy Scale.[40] Pain coping is measured with the Pain Catastrophizing Scale, a 13-item scale that assesses catastrophizing—a pain belief that has been found to be a strong predictor of poor treatment response. Validation studies for the Pain Catastrophizing Scale have found strong evidence of criterion-related, concurrent, and discriminant validity.[41] Social support is assessed with the Multidimensional Scale of Perceived Social Support. The MSPSS includes 12, 7-point Likert scale items. The test-retest reliability and internal consistency for the MSPSS are high, ranging from α=.84-.95 across a variety of studies.[42, 43] Patient activation is measured with Patient Activation Measure (PAM) Short Form, a 13-item scale that assesses patient knowledge, skill, and confidence for self-management of one's chronic health condition.[44] The PAM has been demonstrated to be reliable and valid in a variety of studies, α =.87-.88.[13, 44-46] Health-related quality of life is measured with the RAND SF-36, developed as part of the Medical Outcomes Study.[47] Health care utilization is assessed through chart reviews to identify outpatient visits, ED visits, phone visits, non-opioid and opioid analgesic prescriptions. A questionnaire is administered to assess pain treatment history. Additional exploratory measures include depression, assessed with the PHQ-8 [48], and anxiety, measured with the GAD-7.[49] Sociodemographic characteristics collected at baseline include age, sex, race, education, marital status, job status, and income.

2.12 Statistical Considerations

Sample Size determination

Sample size is determined to ensure adequate power for our primary hypothesis that patients in the peer support arm will experience greater improvement in overall pain (BPI total) than patients randomized to the control arm. Standardized effect sizes for the BPI in past studies by our team have ranged from .4 to .6. This study is conservatively powered to detect a small to medium standardized effect size of .45.[50] To test for a significant difference between

the BPI change from baseline to the primary 6-month endpoint between the intervention and control arm, the contrast will be estimated from a linear mixed model.[51] Sample size was initially determined based on the optimal treatment allocation ratio and control group sample size[52], assuming that the intra-class correlation (ICC) in the intervention group is .3, as observed in our pilot study, IMPRESS.[27] No preliminary data was available that would cause us to suspect that the variation in outcomes would differ between treatment and control groups; thus we assumed equal variance across the two arms. Not all peers wanted to coach 3 patients, and there was higher-than-expected peer coach turnover; thus a lower ICC was expected. With an ICC = 0.15, revised calculations with this allocation ratio indicate that a sample size of 102 intervention participants and 80 control participants provide 80% power to detect a .45 standardized effect size. A smaller sample size is required in the control group because they are not nested within peer coaches. Allowing for a 15% attrition rate, we enrolled 120 patients in the intervention arm and 95 in the control arm, for a total N = 215.

Statistical Analyses

All analyses will employ an intent-to-treat approach. Baseline patient characteristics, depression, and anxiety will be compared using appropriate test statistics (Chi-square test, Fisher's exact test, t-tests, or Wilcoxon rank-sum tests) to verify that randomization achieved balanced groups. To compare the primary outcome of total BPI score at each time point relative to baseline between two treatment arms, we will use a linear mixed-effects model fit to all time points. Fixed effects in the model will include an indicator for treatment group, time (baseline, 6, and 9 months), treatment group by time interaction, and baseline covariates found to differ significantly between intervention and control arm. Random effects will include a random patient-specific intercept and a random effect for peer coach within the intervention arm only.[51] SAS code is available in the literature.[53] Additionally, the variance may be allowed to differ between intervention and control arms. This model will allow us to estimate the primary

contrast of interest, the change in BPI from baseline to 6 months (primary endpoint) between treatment groups. All analyses will include checking of assumptions and model fit.

Our statistical model, which accounts for nesting of patients within peer coaches, will also allow us to calculate the intra-class correlation (ICC) in the intervention group to evaluate whether there are substantial variations among peer coaches. In secondary analyses, we will also look at the BPI subscales of pain intensity and interference separately, using a similar mixed-model approach and adjusting for multiple comparisons using the Šidák method to maintain the overall familywise type I error at .05.

For the five secondary scale measures, we will use the same linear mixed-effects model as described for the primary outcome. If this model does not seem appropriate for a given outcome, we will use a generalized linear mixed-effects model. We will use the Šidák method to maintain familywise type I error at .05 for the five secondary scale measures for the primary 6-month endpoint. For healthcare utilization measures which include the number of emergency department visits, hospitalizations, outpatient visits, and telephone visits that occur over the 9-month study period, we will use a generalized linear mixed model, assuming the counts follow a Poisson or negative binomial distribution. Explanatory variables in the model will include treatment group and, if necessary, a random effect for peer coach within the intervention arm only. Covariates that significantly differ between groups will be included. If data are sparse or if counts include a high proportion of zeros, alternative models such as logistic regression or zero-inflated count models may be required.[54] All analysis will included checking of model fit.

Statistical Analyses for Peer Coaches

While the study was designed and powered to determine effects of the peer coach intervention on patients, primary and secondary measures are also collected on the peer coaches to determine whether coaches experience positive (or negative) effects from the intervention. A linear mixed model approach assuming compound symmetry for the repeated measures will be used to estimate the mean change and associated 95% confidence intervals

at 6 months and 9 months relative to baseline. Fixed effects will include time as categorical (baseline, 6 months, and 9 months). Additional exploratory analyses will include examining peer coach characteristics (e.g. baseline pain catastrophizing, anxiety, depression) that may be associated with positive or negative impacts of participating as a peer coach.

2.13 Qualitative Interviews and Analysis

For aim 3, the pre-implementation aim, qualitative, semi-structured interviews are conducted with a purposefully selected subsample of intervention patients, peer coaches, and clinicians (e.g., primary care providers, pain clinic physicians, pain psychologists, physical therapists) who work with patients with chronic pain. We are using a maximum variation sampling strategy to obtain the broadest range of information and perspectives.[55] Interview questions for patients and peer coaches focus on experiences with the intervention, including facilitators and barriers to intervention participation and suggestions for strengthening the intervention. Questions for clinicians primarily focus on perceived facilitators and barriers to implementing the intervention in clinical settings. The RE-AIM framework[56] guided question formulation. We will sample each of the three subgroups until thematic saturation is reached (i.e., additional interviews to not yield new findings or insights).[57]

Qualitative analysis will occur in two broad phases: open coding and focused coding.[57, 58] Open coding facilitates development of a code list for further analysis. In this phase analysts will independently read through selected transcripts to gain a general understanding of the data and variation across participants. Then, analysts will independently label each line of data with initial codes, or categories, that reflect meanings or themes emerging from the text and meet to discuss these interpretations. This process will occur iteratively until analysts agree on emergent thematic categories (codes). In phase 2, focused coding, all transcripts will be divided evenly among analysts, who will apply the codes derived in the first analytic phase to assigned transcripts. A subset of transcripts will be coded by all analysts and discussed to ensure

consistency in coding, with discrepancies resolved by consensus.

3. Results

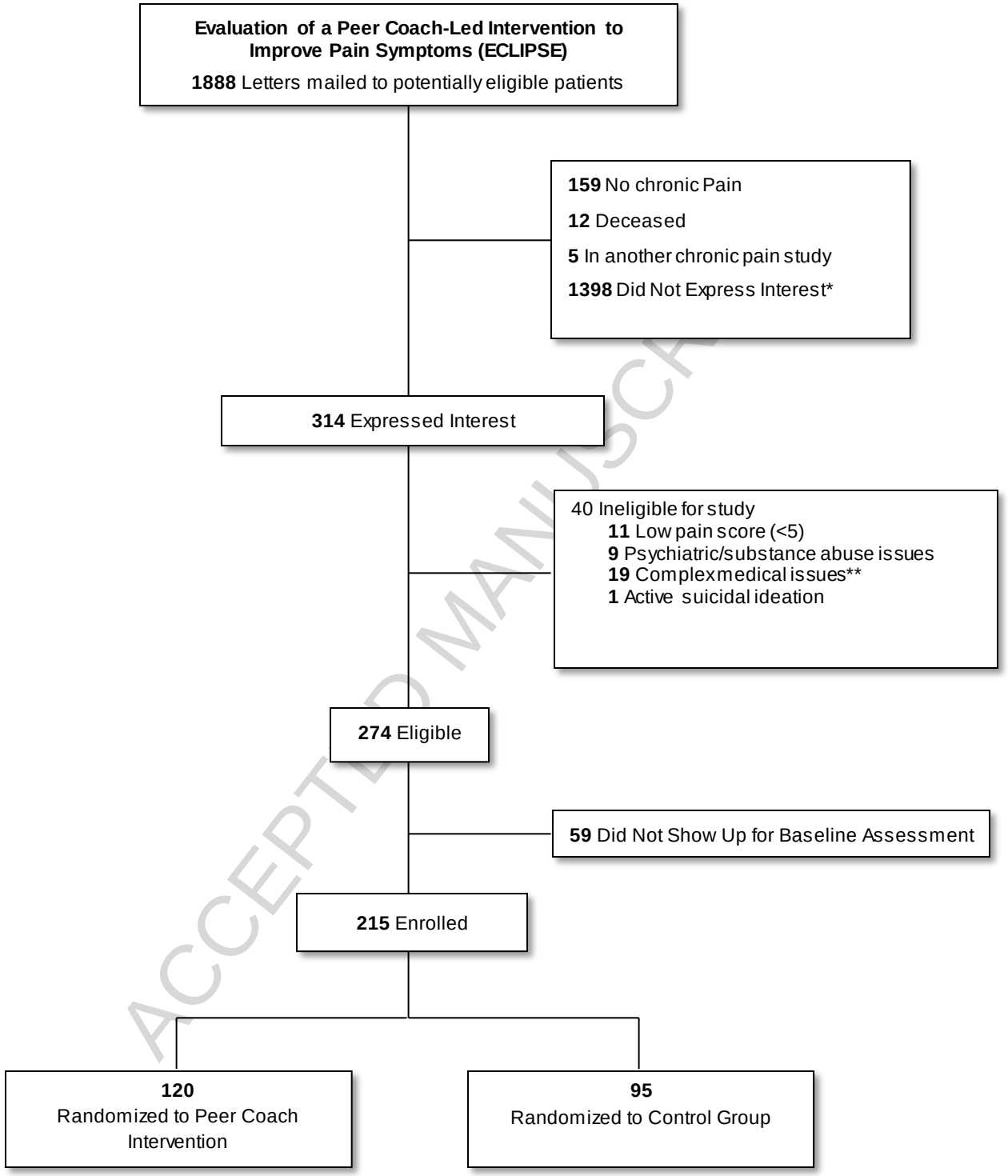
Figure 2 shows the results of screening, eligibility determination, and enrollment, which was conducted from July 2015 through August 2018. Letters were mailed to 1,888 potential participants, 314 of whom expressed interest. Of these interested patients, 274 met the eligibility criteria. Most common reasons for ineligibility were complex medical issues (e.g., stroke, cancer, dementia, COPD or emphysema requiring oxygen, congestive heart failure) and a pain score < 5. Of the 274 patients eligible for the study, 59 either cancelled or did not show up for their baseline assessment, even after rescheduling. A total of 215 patients were enrolled, with 120 randomized to the peer coach intervention and 95 randomized to the control group. Two patients who were enrolled withdrew from the study prior to completing their baseline assessments.

Randomization of patients yielded comparable groups on all measured variables. See Table 2. The sample had a mean age of 56.7 years (range 25.7-90.5; Standard Deviation [SD] = 13); 80.8% were male; 62% were White, 27.7% African-American, and 10.3% were other races. The majority (97.2%) were non-Hispanic; 52.4% were married, 33.5% divorced or separated, 7.5% never married, and 6.6% widowed. In terms of education, 20.3% held a 4-year degree or higher; 56.6% held a technical or 2-year degree; 18.9% completed high school or GED; 4.2% had some high school or less. 40.6% were employed; 32.5% were retired; the remainder were not employed. In terms of income, 47.4% described themselves as “comfortable,” 34.7% as having “just enough to make ends meet,” and 17.4% as having “not enough to make ends meet.” The mean baseline BPI total pain score was 5.8, with a mean severity of 6.1 and mean interference of 5.7, representing a moderate level of pain.

A total of 68 peer coaches were recruited. This is more than the 40 projected at the start of the study. Some (N=18) peer coaches withdrew from the study, some did not regularly

contact their assigned patient(s) and their patients were reassigned, and others did not want to work with 3 patients, leading to the need to recruit additional peer coaches. Baseline characteristics of peer coaches can be found in Table 3.

Figure 2



*explicitly said not interested or did not call back after 3 voicemails

**stroke, cancer, dementia, COPD/emphysema requiring oxygen treatment, congestive heart failure

Table 2: Baseline Characteristics of Veterans enrolled in the ECLIPSE study

		Intervention n=120	Control n=95	p-value
Demographics				
Age in years	mean(SD)	55.2 (12.6)	58.6 (13.3)	0.062
	median(min, max)	57 (25.7, 86.5)	60 (26.8, 90.5)	
Gender n(%)	Male	94(79.0%)	78(83.0%)	0.464
	Female	25(21.0%)	16(17.0%)	
Race n(%)	White Caucasian	77(64.7%)	55(58.5%)	0.279
	Black or African American	28(23.5%)	31(33.0%)	
	Other Specify	14(11.8%)	8(8.5%)	
Ethnicity n(%)	Hispanic	2(1.7%)	4(4.3%)	0.409
	Non-Hispanic	117(98.3%)	90(95.7%)	
Education n(%)	Some high school or less	8(6.8%)	1(1.1%)	0.074
	High School or GED	20(16.9%)	20(21.3%)	
	Technical trade/2-year college	62(52.5%)	58(61.7%)	
	4-year degree or above	28(23.7%)	15(16.0%)	
Marital Status n(%)	Married/Partner	59(50.0%)	52(55.3%)	0.172
	Divorced/Separated	46(39.0%)	25(26.6%)	
	Never Married	6(5.1%)	10(10.6%)	
	Widowed	7(5.9%)	7(7.4%)	
Military Status n(%)	Peacetime	29(24.6%)	23(24.5%)	0.358
	Vietnam Era	35(29.7%)	38(40.4%)	
	Gulf War	16(13.6%)	11(11.7%)	
	Post 9/11 Era	29(24.6%)	14(14.9%)	
	Other	9(7.6%)	8(8.5%)	
Employment Status n(%)	Employed	52(44.1%)	34(36.2%)	0.316
	Retired	33(28.0%)	36(38.3%)	
	Unable to work	22(18.6%)	13(13.8%)	
	Other	11(9.3%)	11(11.7%)	
Income n(%)	Comfortable	61(51.3%)	40(42.6%)	0.225
	Just enough to make ends meet	35(29.4%)	39(41.5%)	
	Not enough to make ends meet	22(18.5%)	15(16.0%)	

		Intervention n=120	Control n=95	p-value
Primary Outcome [range]				
BPI Total [0-10]	mean(SD)	5.9 (1.9)	5.8 (1.9)	0.678
	median(min, max)	6 (2.1, 9.7)	6 (1.1, 9.7)	
BPI Severity [0-10]	mean(SD)	6.2 (1.6)	5.9 (1.7)	0.329
	median(min, max)	6 (3.0, 10.0)	6 (1.5, 10.0)	
BPI Interference [0-10]	mean(SD)	5.7 (2.5)	5.7 (2.4)	0.948
	median(min, max)	6 (0.6, 10.0)	6 (0.6, 10.0)	
Other Measures [range]				
Self-Efficacy [0-10]	mean(SD)	6.1 (2.2)	6.2 (2.3)	0.568
	median(min, max)	6 (0.0, 10.0)	6 (1.2, 10.0)	
Pain Catastrophizing Scale [0-52]	mean(SD)	21.0 (13.0)	21.5 (13.3)	0.858
	median(min, max)	20 (0.0, 52.0)	22 (0.0, 52.0)	
Perceived Social Support [12-84]	mean(SD)	62.3 (16.5)	62.6 (18.1)	0.605
	median(min, max)	65 (12.0, 84.0)	68 (12.0, 84.0)	
Patient Activation Measure Percent T-score [0-100]	mean(SD)	60.6 (13.5)	57.9 (13.8)	0.104
	median(min, max)	56 (38.1, 91.6)	53 (31.0, 100.0)	
Health-related Quality of Life [range]				
SF-36 Bodily pain [0-100]	mean(SD)	37.1 (21.7)	39.4 (19.4)	0.440
	median(min, max)	35 (0.0, 90.0)	35 (0.0, 90.0)	
SF-36 physical function [0-100]	mean(SD)	44.6 (25.3)	42.0 (22.0)	0.596
	median(min, max)	40 (0.0, 100.0)	40 (0.0, 100.0)	
SF-36 role limits due to physical health [0-100]	mean(SD)	26.5 (35.7)	19.9 (32.7)	0.180
	median(min, max)	0 (0.0, 100.0)	0 (0.0, 100.0)	
SF-36 Emotional well-being [0-100]	mean(SD)	67.8 (23.2)	70.4 (20.2)	0.587
	median(min, max)	72 (12.0, 100.0)	72 (16.0, 100.0)	
SF-36 role limits due to emotional problems [0-100]	mean(SD)	56.4 (43.0)	55.6 (44.3)	0.861
	median(min, max)	67 (0.0, 100.0)	67 (0.0, 100.0)	
SF-36 Social functioning [0-100]	mean(SD)	57.3 (30.5)	57.7 (29.0)	0.971
	median(min, max)	63 (0.0, 100.0)	63 (0.0, 100.0)	
SF-36 Energy fatigue [0-100]	mean(SD)	39.2 (24.4)	38.0 (21.4)	0.878

		Intervention n=120	Control n=95	p-value
	median(min, max)	35 (0.0, 90.0)	40 (0.0, 90.0)	
SF-36 General Health Perceptions [0-100]	mean(SD)	52.4 (20.9)	52.8 (21.1)	0.897
	median(min, max)	50 (10.0, 95.0)	55 (5.0, 100.0)	
Psychological Scales [range]				
PHQ-8 depression [0-24]	mean(SD)	9.5 (6.4)	8.9 (6.0)	0.544
	median(min, max)	8 (0.0, 23.0)	8 (0.0, 24.0)	
GAD-7 anxiety [0-21]	mean(SD)	6.1 (5.3)	6.2 (5.4)	0.996
	median(min, max)	4 (0.0, 19.0)	5 (0.0, 21.0)	

Table 3: Baseline Characteristics of Peer Coaches enrolled in the ECLIPSE study

		Peer Coaches n=68
Demographics		
Age in years	mean(SD)	56.6 (11.2)
	median(min, max)	59 (28.6, 73.3)
Gender n(%)	Male	51(75.0%)
	Female	17(25.0%)
Race n(%)	White	41(61.2%)
	Black or African American	23(34.3%)
	Other Specify	3(4.5%)
Ethnicity n(%)	Hispanic	1(1.5%)
	Non-Hispanic	67(98.5%)
Education n(%)	Some high school or less	1(1.5%)
	High School or GED	10(14.7%)
	Technical trade/2-year college	32(47.1%)
	4-year degree or above	25(36.8%)
Marital Status n(%)	Married/Partner	40(58.8%)
	Divorced/Separated	24(35.3%)
	Never Married	2(2.9%)
	Widowed	2(2.9%)
Military Status n(%)	Peacetime	16(23.5%)
	Vietnam Era	21(30.9%)

		Peer Coaches n=68
	Gulf War	9(13.2%)
	OEF/OIF/OND	17(25.0%)
	Other	5(7.4%)
Employment Status n(%)	Employed	28(41.2%)
	Retired	19(27.9%)
	Unable to work	15(22.1%)
	Other	6(8.8%)
Income n(%)	Comfortable	38(55.9%)
	Just enough to make ends meet	21(30.9%)
	Not enough to make ends meet	8(11.8%)
	Refused to answer	1(1.5%)
Primary Outcome [range]		
BPI Total [0-10]	mean(SD)	5.1 (2.2)
	median(min, max)	5 (0.8, 9.9)
BPI Severity [0-10]	mean(SD)	5.8 (2.1)
	median(min, max)	6 (1.5, 10.0)
BPI Interference [0-10]	mean(SD)	4.7 (2.5)
	median(min, max)	5 (0.0, 10.0)
Other Measures [range]		
Self-Efficacy [0-10]	mean(SD)	7.2 (2.2)
	median(min, max)	8 (0.0, 10.0)
Pain Catastrophizing Scale [0-52]	mean(SD)	11.9 (11.2)
	median(min, max)	10 (0.0, 52.0)
Perceived Social Support [12-84]	mean(SD)	65.7 (19.4)
	median(min, max)	73 (12.0, 84.0)
Patient Activation Measure Percent t-score [0-100]	mean(SD)	69.4 (14.6)
	median(min, max)	71 (32.2, 100.0)
Health-related Quality of Life [range]		
SF-36 Bodily pain [0-100]	mean(SD)	46.9 (22.6)
	median(min, max)	45 (0.0, 90.0)
SF-36 physical function [0-100]	mean(SD)	52.1 (27.9)
	median(min, max)	50 (0.0, 100.0)

		Peer Coaches n=68
SF-36 role limits due to physical health [0-100]	mean(SD)	30.9 (38.7)
	median(min, max)	25 (0.0, 100.0)
SF-36 Emotional well-being [0-100]	mean(SD)	76.7 (20.1)
	median(min, max)	80 (0.0, 100.0)
SF-36 role limits due to emotional problems [0-100]	mean(SD)	57.4 (39.4)
	median(min, max)	67 (0.0, 100.0)
SF-36 Social functioning [0-100]	mean(SD)	68.2 (28.5)
	median(min, max)	75 (0.0, 100.0)
SF-36 Energy fatigue [0-100]	mean(SD)	49.4 (26.1)
	median(min, max)	50 (0.0, 100.0)
SF-36 General Health Perceptions [0-100]	mean(SD)	63.5 (22.5)
	median(min, max)	68 (0.0, 100.0)
Psychological Scales [range]		
PHQ-8 depression [0-24]	mean(SD)	6.2 (6.1)
	median(min, max)	5 (0.0, 24.0)
GAD-7 anxiety [0-21]	mean(SD)	4.6 (5.1)
	median(min, max)	3 (0.0, 21.0)

4. Discussion

ECLIPSE enrolled 215 primary care patients with chronic musculoskeletal pain. Two intervention patients withdrew after enrollment but prior to administration of baseline measures. The remaining 118 patients randomized to the peer coach intervention were paired with one of 68 peer coaches. ECLIPSE is based on the premise that social support, including listening and offering motivation and accountability, is an important component of pain self-management.[23, 24, 31, 59, 60] Although studies have shown that the support patients with pain receive from healthcare providers is highly valued,[23, 24, 31, 60] receiving time and attention from providers is not always feasible due to time constraints and competing demands in busy clinical settings. Peer coaching represents a promising care delivery model to provide social support and self-management support to patients with pain, with potential benefits for both patients and coaches.[17]

High levels of social support—especially illness-specific support—are associated with better illness management.[21] Peer support in diabetes care has resulted in significantly lower hemoglobin A1c levels, increased diabetes-specific social support, and increased self-efficacy.[11, 12, 40] In addition, patients have reported phone calls from peers to be helpful in managing their diabetes symptoms, appreciated that their peer listened to them and addressed their concerns, and learned something new about diabetes management.[10] In mental health care, patients served by a case management team that included a peer support specialist improved significantly more on patient activation than control patients (usual care).[13] This finding is important, since highly activated patients with chronic conditions are more likely than less activated patients to adhere to treatment recommendations and self-management activities, and are more likely to report better experiences with care and care coordination.[46, 61, 62] ECLIPSE is the first study to test peer support on a large scale among patients with chronic pain. In addition, based on evidence indicating that peers may benefit from providing support to other patients, outcomes for peer coaches were assessed to ascertain whether this holds true for peer coaches in ECLIPSE. Notably, selection criteria were different for peer coaches, which likely accounts for the baseline differences between the two groups.

Based on the pilot study, we projected that peer coaches in ECLIPSE would work with approximately 3 patients each. However, because not all coaches were comfortable working with 3 patients, and because of peer coach attrition, we required 68 peer coaches (an average of 1.76 patients per coach). This has both practical and statistical implications. From a practical standpoint, coaching 3 patients at a time might be too much for many peer coaches, many of whom have other demands on their time. Statistically, this means that our ICC has essentially dissipated, resulting in greater power to detect effect sizes of interest.

A potential limitation of this study is that all participants were veterans, the majority of whom were White men. It is possible that veterans, with their shared history of military service, are especially suited to a peer support intervention since they already share common

experiences. If so, this may decrease the generalizability of ECLIPSE findings. Additional studies are needed to ascertain whether peers are beneficial in non-veteran patients with chronic pain. Another potential limitation is that, while steps were taken to ensure fidelity to the intervention, booster sessions and check-in calls have revealed that not all peer coaches deliver the intervention with the same frequency or in the same manner. These variations may potentially decrease fidelity. On the other hand, such variations may simply reflect peer coaches' skills at tailoring the intervention to the needs of each patient. Final outcome data will provide a better indication of the role of fidelity in patient outcomes.

In sum, ECLIPSE is a randomized controlled trial comparing a peer-supported pain self-management intervention to a control group that includes a pain self-management class. The primary outcome is total pain (intensity and interference), measured by the BPI total pain score. Secondary outcomes are self-efficacy, pain catastrophizing, perceived social support, patient activation, health-related quality of life, and service utilization. In this Hybrid Type I study, qualitative pre-implementation work is being conducted in an effort to shorten the timeline to clinical implementation if the intervention is found to be effective. Given the prevalence of chronic pain and the degree to which it interferes with patients' quality of life, it is crucial to identify additional, effective means to manage pain. The current opioid crisis makes finding alternative pain management options even more important.

Conflicts of Interest: The authors declare no conflicts of interest.

Funding: This work was supported by a Department of Veterans Affairs Health Services Research and Development Merit Review Award to Dr. Matthias (IIR 14-070). The sponsor had no role in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication. The views expressed in this article

are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

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