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A Brief Psychological Intervention for Chronic Pain in Primary Care: A Pilot Randomized Controlled Trial

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Abstract

Objective. Although evidence-based psychological interventions improve chronic pain, many patients do not engage in behavioral health services. Offering a brief intervention in a medical setting may provide benefits to patients with chronic pain. The purpose of this study was to examine preliminary outcomes of a brief psychological intervention for chronic pain delivered in primary care. **Design.** Pilot randomized controlled trial. **Setting.** Primary care clinic. **Subjects.** Sixty participants with chronic pain were randomized to a 5-session psychological intervention or treatment-as-usual control group. **Methods.** Participants completed pre- and post-intervention measures assessing pain severity, pain interference, pain catastrophizing, depression, and anxiety. **Results.** Most participants (76.7%) randomized to the intervention completed all sessions. Compared to the control group, those in the intervention had decreases in pain severity ($P = .048$), pain catastrophizing ($P = .04$), and depression ($P = .01$) from pre- to post-intervention. Within the intervention group, there was a significant improvement in pain interference scores ($P = 0.02$). Within the intervention group, effect sizes were medium to large for changes in pain severity, pain interference, pain catastrophizing, and depression scores. There were no significant changes in anxiety scores. **Conclusion.** Results suggest that delivery of a brief psychological intervention for chronic pain in primary care appears to offer improvements in pain severity, pain interference, pain catastrophizing, and depression. Findings suggest that shorter-term psychological interventions may offer similar benefits as longer-term ones. Furthermore, offering a brief intervention in primary care may increase access and engagement in behavioral pain management services. Future research should examine this through a fully-powered trial with longer-term outcomes.

Key Words: Chronic Pain; Psychology; Primary Care; Psychotherapy

Introduction

Chronic pain is a prevalent health condition affecting approximately 100–150 million Americans [1, 2]. Patients with chronic pain experience mood and anxiety disorders at approximately twice the rate as the general population [3], and those with greater pain severity report higher levels of depression and anxiety [4–7]. Additionally, the biopsychosocial model suggests that improvements in psychological symptoms can affect the experience of pain [8]. As such, psychological interventions have been developed and evaluated in an effort to manage pain, including cognitive-behavioral, mindfulness, and acceptance and commitment therapies. Cognitive-behavioral therapy

assists patients in altering misconstrued beliefs about the cause and course of their pain, and these pain beliefs are related to their adjustment to chronic pain [9–11]. Mindfulness interventions and acceptance and commitment therapy (ACT) interventions have also been useful for patients who have chronic pain [12–17]. Mindfulness is being in the present moment and being aware of one's thoughts and emotions without judgment [12]. ACT is composed of mindfulness strategies but extends this concept by teaching the patient to accept the chronic pain condition and engage in valued activities [18]. Patients who are mindful and are accepting of their pain report lower pain severity, distress, and disability [12–17].

Approximately one in four primary care patients has a chronic pain condition, and pain is one of the most common reasons patients present to a primary care visit [19, 20]. Until recently, chronic pain was managed primarily with opioid medications; however, chronic opioid use is now strongly discouraged by multiple agencies, including the American Academy of Neurology and the Centers for Disease Control and Prevention, because of the associated negative consequences including risk of hyperalgesia, an opioid use disorder, overdose, and death [21, 22]. Thus, patients need alternatives to opioids to manage pain, such as evidence-based psychological interventions.

Despite the existence of efficacious psychological interventions for chronic pain, there are several limitations. Many patients who would benefit from behavioral health services will not seek treatment at a mental health clinic for a variety of reasons, including stigma around mental health services [23, 24]. Even when patients pursue behavioral treatment, clinicians are often not trained to treat co-occurring chronic pain and distress, and it is also common for patients to drop out of behavioral treatment prematurely [25, 26]. Early dropout in behavioral pain management is problematic given that many existing psychological interventions for chronic pain are lengthy (i.e., 8–12 sessions, lasting 1–2.5 hours each) [27, 28]. Therefore, it may be helpful if treatments are brief and offered in a context outside of a behavioral health clinic. As mentioned, patients commonly seek pain management in primary care [19, 20], yet primary care providers report lacking options of nonpharmacological interventions for their patients with chronic pain [29].

Integrating behavioral health services into a primary care clinic has shown to increase access [30]; thus, primary care is a promising location for psychological treatment for chronic pain.

The purpose of this study was to conduct a pilot randomized clinical trial to preliminarily examine the effectiveness of this brief, psychological intervention for chronic pain that is delivered within primary care. We hypothesized that this intervention is feasible to deliver and would improve pain severity, pain interference, and mood.

Materials and Methods

Participants

Sixty patients were recruited from a single Academic Internal Medicine Primary Care Clinic at an urban health system.

Materials

Brief pain inventory (BPI). The BPI is a widely used measure to assess pain severity and the extent to which pain interferes with physical functioning [31]. On a 0–10 scale, participants rated their average pain over the previous week. Participants also rated from 0–10 the extent to which their pain interferes in daily functioning over the previous week among the areas of general activity, mood, mobility, normal work, relations with other people, sleep, enjoyment of life, self-care, recreational activities, social activities, communication with others, and learning new information or skills. An average score of each of these 12 items was calculated to produce an overall pain interference score.

Hospital Anxiety and Depression Scale (HADS). The (HADS) is a 14-item self-report measure of emotional functioning that assesses anxiety (HADS-A) and depression (HADS-D) [32]. We chose this measure because it was created and validated for use among patients with physical illnesses in medical settings. Participants respond to what degree they have experienced anxiety and depressive symptoms over the past 7 days. Scores on each subscale can range from 0 to 21, and higher scores indicate greater distress.

Pain Catastrophizing Scale (PCS). The PCS is a 13-item scale that assesses three domains of catastrophizing [33]. Participants respond on a 5-point scale the degree to which they experience catastrophizing thoughts or feelings. For this study, we used the total sum of the items to have a single catastrophizing construct [34].

Procedure

This study was approved by the health system's Institutional Review Board, and all procedures were in accordance with the ethical standards on human experimentation and with the Helsinki Declaration. To enroll participants, the interventionists reviewed medical records for eligibility of patients with a primary care clinic appointment. Inclusion criteria included a visit with the primary care provider and a noncancer chronic pain condition listed in the patient's record (defined as persistent pain for 3 months or longer). Patients were excluded if they were currently seeing a behavioral health provider or if they were determined to have serious cognitive impairment that would impede their ability to understand the content of the intervention (i.e., cognitive disorder diagnosis in the chart or significant impairment on the Montreal Cognitive Assessment) [35]. If eligible, the interventionist notified the primary care provider that he/she was seeing a patient that day who was eligible to

be approached about the study. In order to follow the "warm handoff" model, the primary care provider notified the patient of the study, and if interested, the interventionist, who was located in the clinic, introduced the study to the patient and scheduled the patient for the baseline assessment. Participants completed written informed consent and baseline measures at the scheduled appointment with the interventionist in the primary care clinic. After completion of these measures, participants were randomized to the intervention or treatment-as-usual control group. Randomization was conducted by a random number generator, in blocks of 10, to ensure equal sized groups. Participants randomized to the intervention were asked to complete five (45 minute) sessions delivered weekly. Initially, the intervention was delivered in-person in the primary care clinic; however, after 35 participants enrolled, participants randomized to the intervention group were given the choice to complete the intervention in-person in the primary care clinic or through a telemedicine appointment (i.e., video visit) to minimize barriers to participation. The control group received all traditional care from their primary care provider and any other referrals that would normally be recommended, including a behavioral health referral. However, if a potential participant preferred to see a behavioral health provider outside of the study context, he/she would not have been eligible to enroll in this study. Participants in both groups completed follow-up measures at approximately 5 weeks post-baseline (i.e., post-intervention). Participants in the intervention group completed them in clinic at the fifth session, if attended. Participants in the intervention group who did not attend the fifth session and participants in the control group could elect to complete post-assessment measures via an online survey or through mail.

Intervention. Our team developed a treatment manual for a brief psychological intervention for patients with chronic pain to be delivered through a primary care clinic. We then conducted focus groups with psychologists, primary care providers, and patients with chronic pain to solicit feedback regarding the content and logistics of delivering this intervention in primary care [36]. Providers reported that they would refer patients to this intervention and patients stated that they would engage in this intervention. The logistics and content of the intervention were revised based on feedback from providers and patients. The resulting five-session intervention was delivered for the current study by two trained clinical psychology postdoctoral fellows who were supervised by a licensed psychologist. The fellows had previous experience in delivering the components in the manual, thus training included reading the manual independently and then review of each session with the psychologist. Components included strategies that have been identified as efficacious for pain management and included cognitive behavioral strategies (i.e., psychoeducation, relaxation, self-talk, behavioral activation, pacing),

mindfulness, acceptance of pain, and values-based action [37–46]. Session 1 included psychoeducation and practice of diaphragmatic breathing. Session 2 focused on identifying negative thoughts and discussed behavioral activation. Session 3 had a discussion of mindfulness and practice of a mindfulness meditation. Session 4 taught about acceptance of pain, reviewed the patient's values, and how to incorporate activities that meets a patient's values. The final session reviewed the previously learned strategies and included a discussion regarding incorporating these into everyday life.

Treatment fidelity. All treatment sessions were audio recorded. Fidelity of the treatment was rated by a clinical psychology graduate student. Sessions were rated for the inclusion of the core components of each session. To ensure appropriate intervention delivery, all five sessions for the first five patients were rated for fidelity. Following 100% adherence, 25% of sessions were randomly selected for evaluation. There was 100% fidelity to the core components of the sessions.

Analyses. Analyses were conducted with SPSS version 22 [47]. Descriptive statistics and frequencies were conducted to obtain prevalence rates, means, and standard deviations for variables. We also calculated a percentage of participants in the intervention who experienced a clinically significant reduction in pain severity and pain interference, defined as at least a 30% reduction from their baseline rating [48, 49]. Repeated measures ANOVAs were conducted to determine whether there were significant changes between the intervention and control groups from pre- to post-intervention for pain severity, pain interference, and mood. Because this was a pilot study, we also explored whether there were significant within-group changes from pre- to post-intervention among these variables. Thus, paired samples t-tests were conducted to investigate whether there were significant changes within the intervention and control groups from pre- to post-intervention.

Results

Figure 1 is the CONSORT diagram for participants who enrolled in this study. There were 238 patients attending a primary care appointment who were identified and approached by the primary care provider. Of these, 18 were ineligible, 160 declined to participate, and 60 were deemed eligible and consented to participate in the study (enrollment rate of eligible patients = 37.5%). Of the 30 randomized to the intervention, 23 (76.7%) completed it in-person in the primary care clinic and 7 (23.3%) completed it through video visits. The percentage of those who enrolled in the study when given a choice of in-person or video visits was higher (40.4%, n = 23/57), compared to the enrollment rate of those who were approached when the intervention was offered in-person only (22.7%, n = 37/163). There were three in the intervention group and one in the control group who were
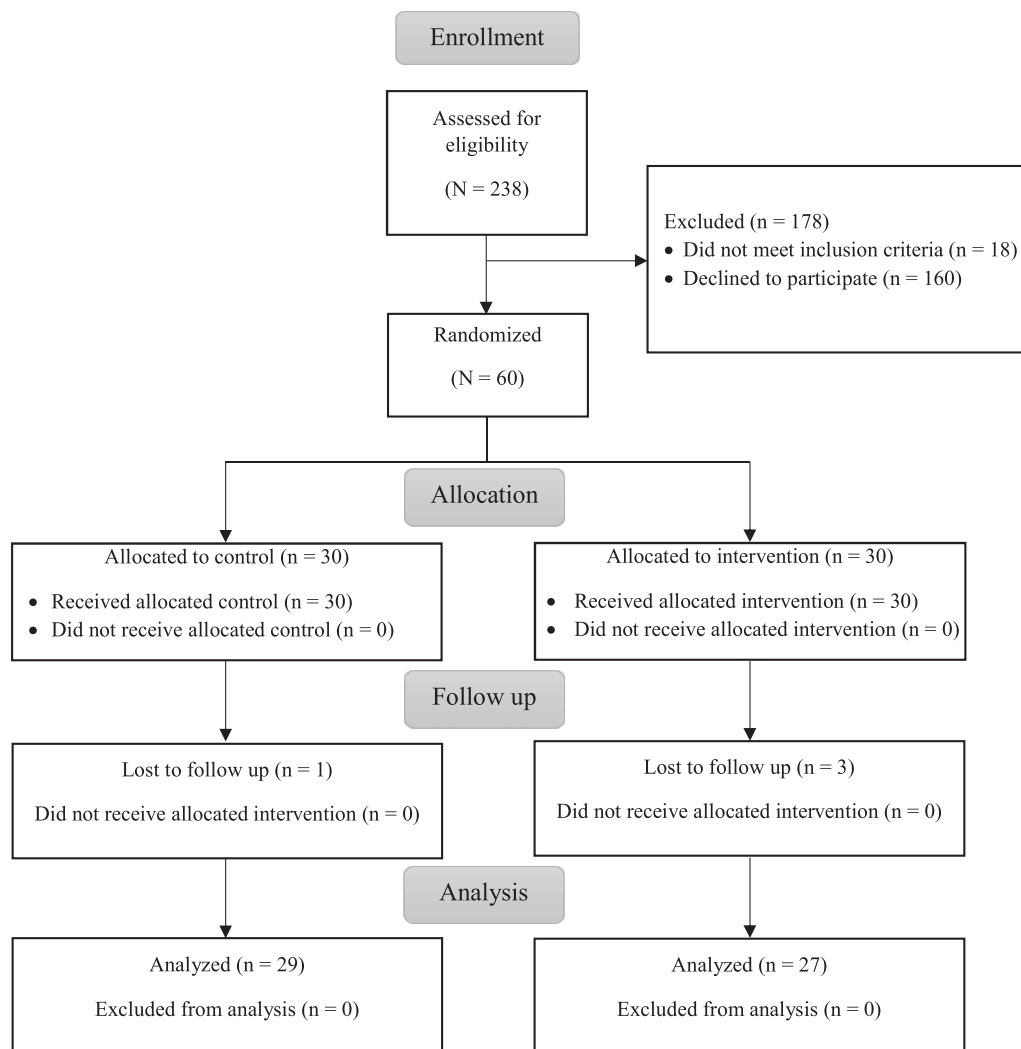
Figure 1. CONSORT diagram of participants in the study.

lost to follow-up and did not complete the post-intervention assessment. Thus, the majority of participants completed the post-intervention assessment measures (93.3%, n = 56).

Among the 60 who were randomized in this study, the mean age was 62.2 years (SD = 12.68), 78.3% (n = 47) were female, and 88.3% (n = 53) identified as Black. Participants in the intervention and control groups were similar in age and gender; however, those randomized to the control group were more likely to identify as Black (Table 1). The majority of participants randomized to the intervention completed all five sessions (76.7%, n = 23). Of those not attending all the intervention sessions, two participants (6.7%) attended two sessions, two (6.7%) attended one session, and three (10%) attended zero sessions.

From pre- to post-intervention, compared to the control group, those in the intervention group had statistically significant decreases in pain severity, pain catastrophizing, and depression (Table 2). There were not statistically significant differences between groups in changes from pre- to post-intervention for anxiety or overall pain interference (Table 2). Among those in the intervention group, paired samples t-tests suggested statistically significant improvements in pain severity, pain interference, pain catastrophizing, and depression from pre- to post-intervention (Table 2; Figures 2–5). Cohen's d effect sizes were medium to large. For participants in the intervention group, 74.1% (n = 20) reported a decrease in pain severity, in which 40.7% (n = 11) reported a clinically significant reduction. For pain interference, 73.1% (n = 19) had a decrease in pain interference, and 50% (n = 13) reported a clinically significant reduction. There was not a significant change in anxiety. Among those in the control group, there were no significant changes for pain severity, pain interference, depression, or anxiety from pre- to post-intervention.

Discussion

Results from this study demonstrated that it was feasible to recruit patients for this intervention and deliver the intervention in a primary care setting. Our randomization rate (37.5%) was lower than the randomization rate in

Table 1. Demographics of participants in the intervention and control groups

	Intervention (n = 30)		Control (n = 30)		t	P
Age, years (M ± SD)	61.9 ± 13.0		62.5 ± 12.6		0.18	.86
	%	n	%	n	X^2	**P**
Gender						
Female	70.0	21	86.7	26	2.46	.12
Male	30.0	9	13.3	4		
Race						
Black	80.0	24	96.7	29	4.04	.04
White	20.0	6	3.3	1		

**Table 2.** Scores from pre-intervention to post-intervention for the intervention and control groups

	Intervention					Control						
	Pre M (SD)	Post M (SD)	t*	P*	ES[†]	Pre M (SD)	Post M (SD)	t*	P*	ES[†]	F[‡]	P[‡]
Pain severity	6.52 (1.72)	5.15 (2.16)	4.46	<0.001	0.85	6.38 (2.32)	5.97 (2.32)	1.16	.26	0.21	4.08	.048
Pain interference	4.46 (2.21)	3.48 (2.23)	2.55	0.02	0.50	4.56 (2.78)	4.20 (2.81)	0.85	.40	0.16	1.14	.29
Pain catastrophizing	20.94 (11.84)	16.89 (10.13)	2.30	0.03	0.44	18.59 (14.61)	19.44 (12.08)	−0.59	.56	0.11	4.64	.04
Depression	5.15 (2.69)	3.81 (3.34)	2.43	0.02	0.47	4.52 (3.86)	5.24 (4.01)	−1.51	.14	0.28	8.04	.01
Anxiety	5.96 (3.98)	6.38 (3.94)	−0.80	0.43	0.16	5.38 (3.67)	6.21 (4.12)	−1.68	.11	0.31	0.31	.58

ES = effect size; SD = standard deviation.

*Within-group paired samples t-test.

[†]The Cohen's d effect sizes reported here were for within-samples means and included the correlation of the pre- and post-intervention variables in the calculation.
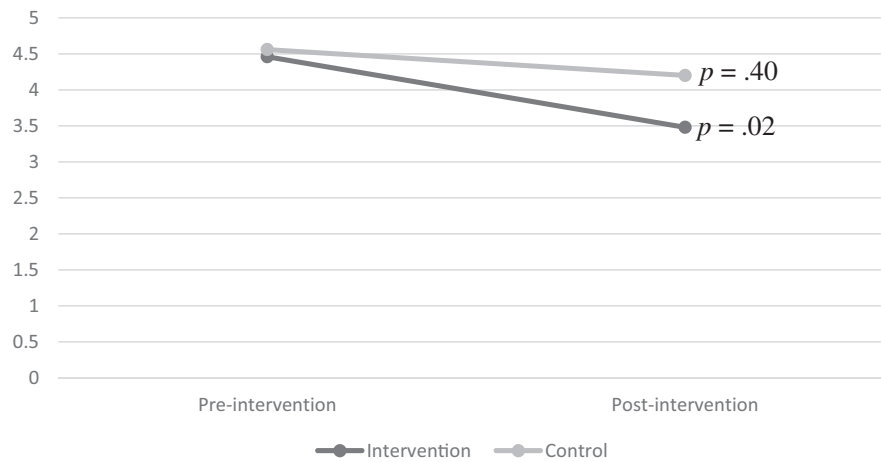
[‡]Repeated measures ANOVA.
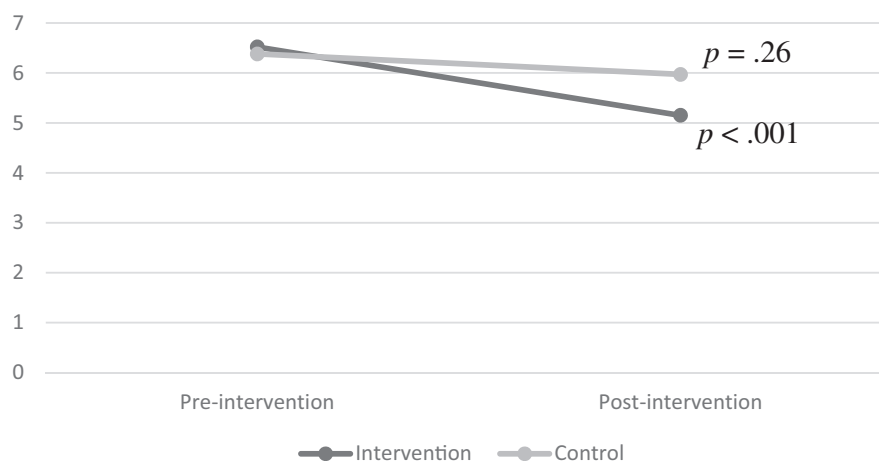
Note. Repeated measures ANOVA $F = 4.08$, $p = .048$

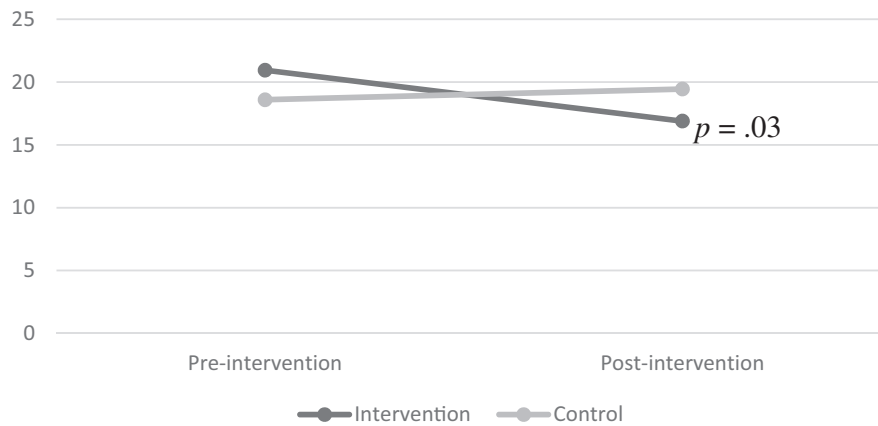**Figure 2.** Pain severity from pre- to post-intervention.

other pilot trials (about 50% [50]). There are a couple of potential explanations for this. First, we had a unique method of recruiting. Many studies recruit by asking participants to contact the study team regarding interest in participating, thus the participant is acknowledging interest in participating in research prior to being identified as eligible. In our study, we identified eligible patients through medical records and used the warm handoff model to attempt to engage patients; these patients did not initially voice interest in participating in research. Second, this primary care clinic is located in an urban city and serves predominantly Black patients; Black patients are less likely to engage in general psychological interventions [51–53], which may have affected our ability to enroll patients. The randomization rate in the current study improved once participants were given the

Note. Repeated measures ANOVA $F = 1.14$, $p = .29$

**Figure 3.** Pain interference from pre- to post-intervention.

Note. Repeated measures ANOVA $F = 4.64$, $p = .04$

Figure 4. Pain catastrophizing from pre- to post-intervention.

option of in-person or video visits. The majority of patients completed all 5 intervention sessions and the retention rate observed at the post-intervention assessment (93.3%) was higher than retention rates in other pilot trials (about 80%) [50]. This may be due to our protocol being shorter than other trials and we assessed outcomes at post-intervention (i.e., about 5 weeks post-baseline). Further, the intervention was easily delivered, as training was brief and there was 100% fidelity of the intervention by both of the interventionists.

Findings from this pilot randomized clinical trial also suggest that there are benefits of participating in this intervention. Among those who received the intervention, significant improvements were observed from pre- to post-intervention in pain severity, pain catastrophizing, and depression as compared to the control group. Within-group effect sizes for pain severity, pain catastrophizing, and depression were medium to large.

Although the intervention may have been underpowered to detect a statistically significant difference for pain interference from pre- to post-intervention between the intervention and control groups, a paired samples t-test within the intervention group revealed a significant improvement in pain interference with a medium effect size. Furthermore, there was not a significant change in pain interference within the control group, suggesting that when adequately powered, there may also be a significant between-group difference. These results suggest that this psychological intervention may improve pain severity, pain interference, pain catastrophizing, and depression, which is consistent with previous studies that have examined benefits of psychological interventions for chronic pain [37–46]. However, this intervention is unique in that it was delivered in a much shorter timeframe compared to existing chronic pain interventions [27, 28]. Brief, evidence-based interventions are necessary to
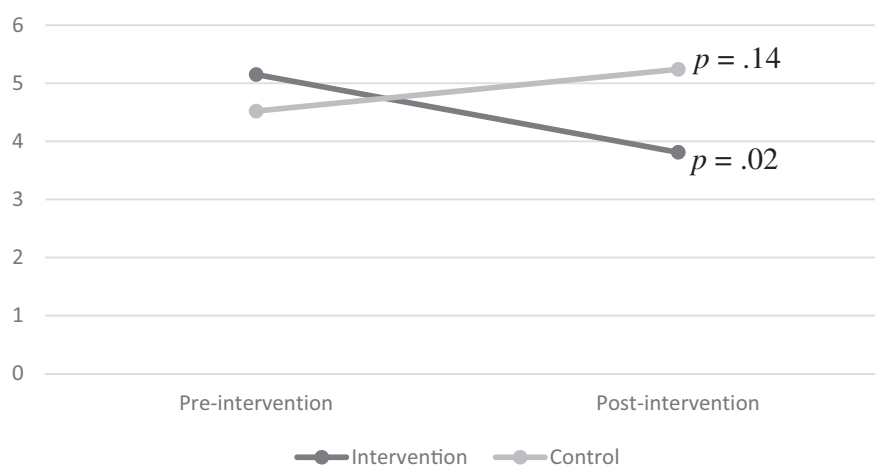
Note. Repeated measures ANOVA $F = 8.04$, $p = .01$

Figure 5. Depression from pre- to post-intervention.

minimize the barriers to chronic pain treatment, including transportation, finances, and stigma [54]. Designing this intervention from its inception to be delivered in primary care (compared to a behavioral health clinic) may have increased patient engagement in treatment, bolstering the chance for future implementation and long-term sustainment if determined to be effective in a full-scaled trial [24, 30, 55]. Integrated pain management is generally viewed favorably by patients, and transparency about treatment options, choices about care teams, attitudes towards integrated care, and various treatment options can impact patient preferences towards integrated care for pain management [56]. On the other hand, primary care providers have identified barriers to providing integrated behavioral services including the time investment from the primary care providers to speak to their patients about treatment options [36]. Future research should elucidate ways in which to screen and refer patients in primary care to psychological interventions for chronic pain to facilitate referrals and engagement in services.

Interestingly, improvements in anxiety were not observed across individuals in the control or intervention groups, despite existing evidence that anxiety can be improved through cognitive-based interventions among those with chronic pain [57]. However, findings may be explained by the fact that anxiety reduction following treatment for chronic pain has been shown to be stronger among men than women, and anxiety and pain are largely correlated among men but not amongst women [58]. Our study included predominantly female participants (78.3%), which may explain the lack of significant findings for anxiety. Alternatively, perhaps the intervention needed other components to produce a reduction in general anxiety symptoms but was still successful at reducing pain-related anxiety (i.e., pain catastrophizing).

One limitation that should be noted is that the intervention was initially delivered exclusively in-person and then was changed to allow the participant the choice of completing the intervention in-person or via telemedicine partway through the study period. Existing evidence demonstrates effectiveness of telehealth-based approaches for chronic pain [59]; however, we were underpowered to examine differences among those receiving the intervention in-person or via telemedicine. Future studies should examine whether there are differences between in-person and telemedicine delivery methods for treatment utilization and outcomes. In addition, most of the sample consisted of Black patients, which may limit generalizability. Future research could evaluate for racial differences in response to the intervention.

Conclusions

This study offers preliminary evidence that a brief psychological intervention for chronic pain offered in primary care is feasible to deliver and effective for improving patient outcomes. The next step is to conduct a larger, fully powered, randomized controlled trial to further examine the effectiveness of this intervention with longer-term outcomes. It would also be useful to measure constructs more frequently to ensure that differences are not explained by week-to-week variance in pain ratings. Future research should also consider examining whether this brief intervention is successful at reducing opioid use through improved pain management or used as an alternative or in conjunction with other treatment options (i.e., neuromodulators and complementary and alternative medicine interventions). If this intervention continues to demonstrate effectiveness, primary care clinics may consider integrating the intervention into routine management of chronic pain. This

intervention could be delivered through existing behavioral health consultant and/or collaborative care models within primary care, allowing for ease of implementation and sustainment.

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