

Randomized Controlled Trial



Nurse-Supported Web-Based Cognitive Behavioral Therapy for Chronic Musculoskeletal Pain: A Randomized Controlled Trial

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Background: Web-based cognitive behavioral therapy (CBT) has increased access to effective pain management. Though efficacy of web-based and face-to-face CBT may be comparable, fewer studies have examined whether remote clinical support in addition to web-based CBT can improve pain-related outcomes.

Objectives: The objectives of this study were to determine if the addition of phone-based support to web-based CBT could enhance pain-related outcomes in patients with chronic musculoskeletal pain (CMP).

Study Design: Randomized controlled clinical trial.

Setting: The internal medicine and rheumatology clinics at Atrium Health Wake Forest Baptist.

Methods: Patients were recruited from a major academic medical center. Sixty patients were randomized to web-based CBT with 6 phone calls (nurse support group, n = 30) vs web-based CBT alone (control group, n = 30). The purpose of the calls was to enhance patients' engagement in the online program. All patients had access to the program from baseline to week 16. Outcome measures were collected at baseline, week 8, and week 16. Adjusting for baseline measurements, analysis of covariance was used to determine within- and between-group differences.

Results: Both nurse support and control groups demonstrated significant within-group improvements in Brief Pain Inventory (BPI) pain interference (-1.3 [-2.0, -0.7, $P < 0.05$] and -1.7 [-2.3, -1.0, $P < 0.05$]), BPI pain intensity (-1.2 [-1.7, -0.6, $P < 0.05$] and -1.3 [-1.8, -0.8, $P < 0.05$]), Patient-Reported Outcomes Measurement System (PROMIS) pain interference (-5.0 [-6.9, -3.2, $P < 0.05$] and -5.4 [-7.2, -3.5, $P < 0.05$]), and PROMIS pain intensity (-1.4 [-2.0, -0.9, $P < 0.05$] and -1.4 [-1.9, -0.8, $P < 0.05$]), respectively. However, there were no significant between-group differences amongst the 2 treatment groups in all measures, except PROMIS sleep disturbance that favored the nurse support group (50.5 ± 1.3 vs 54.3 ± 1.3 , $P < 0.05$).

Limitations: Small sample size and lack of treatment fidelity assessment.

Conclusions: Web-based CBT was effective with and without motivational support from nurses. Phone-based support did not enhance pain-related outcomes of web-based CBT. If confirmed in a larger study, web-based CBT without motivational support may be considered as a low-cost treatment intervention for patients with CMP.

Key words: Chronic musculoskeletal pain, web-based cognitive behavioral therapy, Brief Pain Inventory pain interference, BPI pain intensity, Patient-Reported Outcomes Measurement System pain interference, PROMIS pain intensity, Pain Catastrophizing Scale, painTRAINER program, Patient Health Questionnaire 8-Item Depression Scale

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Pain is the most common reason patients seek health care and accounts for 20% of all outpatient visits. Each year, over 100 million pain-related ambulatory encounters take place in the United States totaling over \$634 billion in health care and lost productivity costs (1). Amongst all pain complaints, musculoskeletal pain is consistently ranked most common (2,3). Musculoskeletal pain will often begin acutely or subacutely at one or more sites, typically involving the cervical or lumbar spine, shoulders, hips, and knees (4,5). Not uncommonly, it can progress to chronic musculoskeletal pain (CMP), defined as pain of the musculoskeletal system lasting > 3 months, that can drastically impact patients' physical, emotional, and social well-being (3,6,7).

In such cases, pharmacologic treatment, in particular, has remained a challenge. For instance, use of opiates in CMP has proven to be ineffective, short-lasting, and potentially unsafe (3,8-10). On the other hand, psychosocial interventions, such as cognitive behavioral therapy (CBT), have shown benefits in improving pain, physical function, disability, and quality of life with minimal to no adverse effects (3,11-18). The observed benefits have been reported in a variety of chronic musculoskeletal painful conditions, including low back pain, neck pain, temporomandibular joint pain, knee osteoarthritis, and fibromyalgia (3,11-18).

Despite its well-demonstrated effectiveness, face-to-face CBT has limitations (i.e., lack of available subspecialized providers, potential for scheduling conflicts, and cost) that preclude its widespread use. Effective, accessible, and scalable psychoeducational treatment interventions are needed to manage CMP in real-world clinic settings.

Web-based CBT addresses almost all the limitations of face-to-face CBT. Web-based programs utilize the same principles, content, and components as face-to-face programs. Generally self-guided and self-paced, web-based programs have been shown to improve pain and disability (15-17,19-21). Few studies (15,22-27) have compared web-based vs face-to-face delivery of CBT in the context of pain management. Most studies (15,22-27) have been conducted in other disease states (i.e., cancer, headache, tinnitus, anxiety, and depression) and have suggested comparable effectiveness of these 2 modes of delivery. Based on a recent systematic review (20), the treatment effect sizes from web-based CBT programs for pain were modest at best ranging from -0.42 (95% confidence interval [CI], -0.55 to -0.28) for pain interference/disability outcomes (15 studies) to

-0.35 (95% CI, -0.54 to -0.17) for pain severity outcomes (16 studies) with significant heterogeneity.

Two proposed theories for the small effect sizes of web-delivered CBT include: (1) poor patient engagement, and (2) absence of guidance from health providers in most published studies (28,29). In support of these theories, an Australian study (30) that examined a web-delivered CBT program involving regular support by a clinical psychologist (i.e., supported web-based CBT) found moderate-to-large improvements in various domains, including pain-related disability. Moreover, the authors reported a high completion rate suggesting perhaps that patients were well-engaged in the program (30). Based on the Australian study (30), it is reasonable to hypothesize that some level of support is needed to enhance clinical benefits. In this study, we sought to determine if an 8-week nurse-supported web-based CBT intervention was more effective than an 8-week web-based CBT intervention without nurse support for managing CMP (Figs. 1-4).

METHODS

Patients were recruited from the internal medicine and rheumatology clinics at Atrium Health Wake Forest Baptist. As patients were checked in for their appointments, the clinic support staff completed a 3-item cascading pain-screening questionnaire. Patients were asked: 1) Do you have a computer at home with Internet access, 2) Over the last 6 months, do you have DAILY or almost daily PAIN that interfered with your general activity or enjoyment of life?, and 3) Have you ever wondered if there is something that you could do on your own to better manage your pain? A "yes" response to all 3 questions generated a prompt to the clinician to alert their patient to expect an email containing a link to a 3-minute video. The video clip gave an overview of the web-based CBT program. From the pool of potential patients who responded "yes" to all 3 questions, the research coordinator made phone calls to ascertain interest and confirm eligibility.

THE painTRAINER program, a self-guided, self-paced, web-based CBT program providing interactive personalized training in cognitive and behavioral pain coping skills drawn from face-to-face CBT, was utilized (31). THE painTRAINER program has been shown to be effective in the management of pain related to knee and hip osteoarthritis (31-35). It contains eight 35- to 45-minute-long learning modules on the following topics: (1) understanding pain and relaxation, (2) brief relaxation with minipractices, (3) activity/rest cycles, 4)

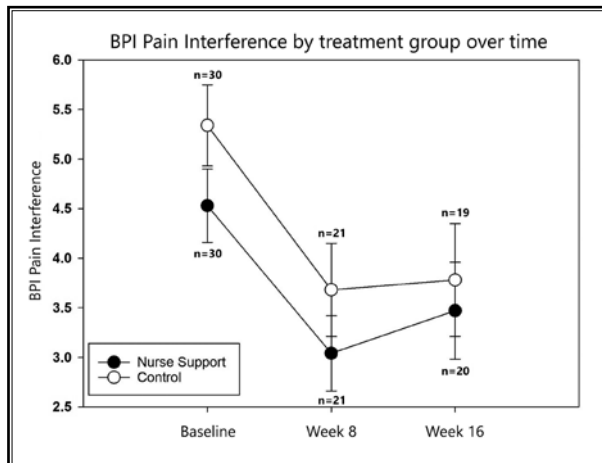


Fig. 2. *BPI pain interference by treatment group over time.* Nurse support and control groups demonstrating improvement in BPI pain interference at week 8 and week 16 compared to baseline. BPI = Brief Pain Inventory.

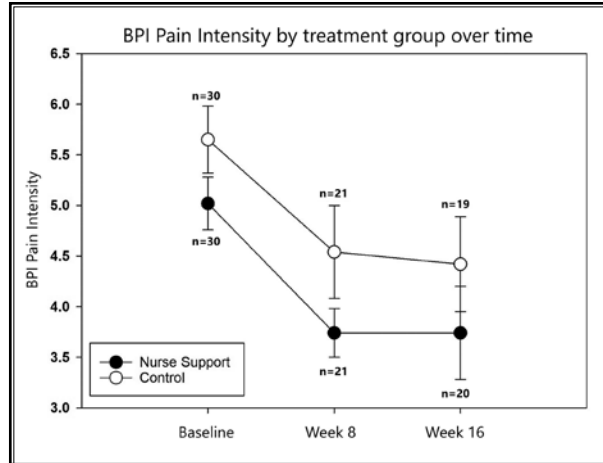


Fig. 3. *BPI pain intensity by treatment group over time.* Nurse support and control groups demonstrating improvement in BPI pain intensity at week 8 and week 16 compared to baseline. BPI = Brief Pain Inventory.

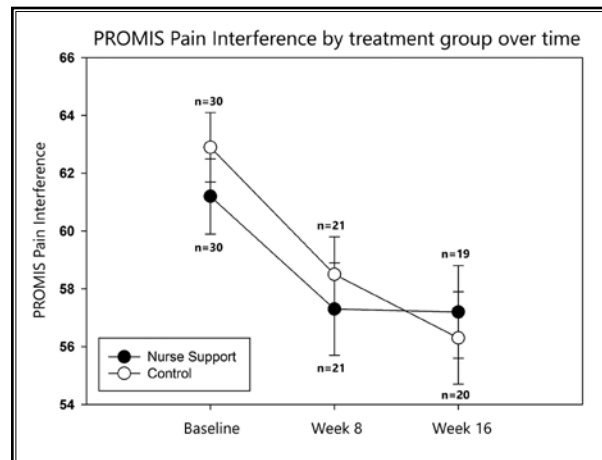


Fig. 4. *PROMIS pain interference by treatment group over time.* Nurse support and control groups demonstrating improvement in PROMIS pain interference at week 8 and week 16 compared to baseline. PROMIS = Patient-Reported Outcomes Measurement System.

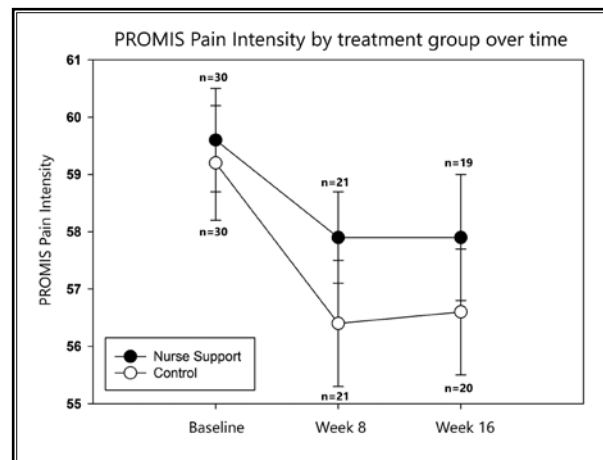


Fig. 5. *PROMIS pain intensity by treatment group over time.* Nurse support and control groups demonstrating improvement in PROMIS pain intensity at week 8 and week 16 compared to baseline. PROMIS = Patient-Reported Outcomes Measurement System.

pleasant activity scheduling, (5) coping thoughts, (6) pleasant imagery, (7) problem solving, and (8) relapse prevention. All patients had access to a computer with an Internet connection enabling them to login to their painTRAINER account to complete the learning modules. Learning materials were presented in English. Release of content was staged throughout the course duration with one new lesson released every 7-10 days.

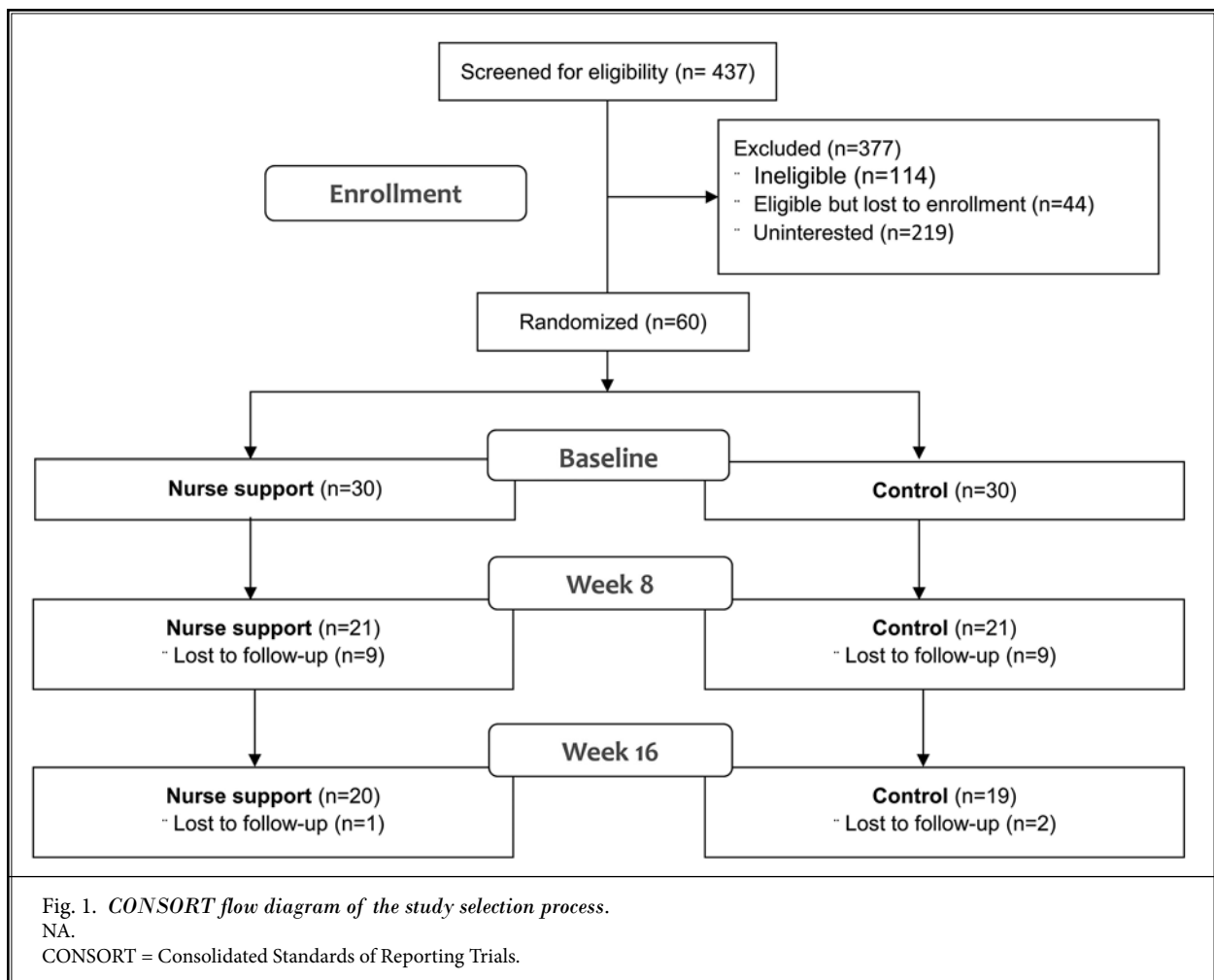
With each lesson, the patient had access to a downloadable lesson summary with practical homework exercises, related educational videos, relaxation audio files, and an "at home" exercise program. Patients were only able to progress to the next lesson if they had accessed each component of the current lesson. Instructions on how to navigate through the modules were embedded in the program. Patients were provided with contact

information to reach the study coordinator for technical support as needed.

The purpose of nurse support was to enhance patients' engagement in completing the 8 learning modules and in the real-life application of newly acquired pain coping skills. Our nurses received training in motivational interviewing (MI) by one of the coauthors (SK), a clinical psychologist and member of the MI network of trainers. MI (36-38) is a collaborative, goal-oriented communication style designed to elicit a patient's own reasons for health behavior change through an accepting and compassionate clinical relationship. While the nurse support was not meant to provide psychological treatment or medical advice, the purpose of using MI techniques was to invite patients to set their own goals in relation to pain management, to work collaboratively on maintaining commitment to the painTRAINER

program, and to explore potential barriers for change. Common elements of an MI-informed conversation included use of reflective listening skills, use of affirmations to identify and name patient strengths, as well as emphasizing open-ended questions and summary statements. Common MI-adherent questions employed by the nurses included asking about reasons for joining the study, what activities patients were hoping to resume participating in if they made progress with pain management, as well as eliciting ideas on how patients could overcome barriers to using the web-based learning modules.

The inclusion criteria were daily musculoskeletal pain for 3 months or longer affecting the lower back, neck, shoulders, hips, knees, joints, or all over, weekly average pain severity score of ≥ 5 , Internet access availability, and age cut-off of ≥ 18 years. The exclusion crite-



ria included those with planned elective surgery during the study period, active suicidal ideation or severe depression (as measured by a Patient Health Questionnaire 8-Item Depression Scale [PHQ-8] score of ≥ 20), ongoing unresolved disability claims, cancer-related musculoskeletal pain, physician-diagnosed bipolar disorder or schizophrenia, active inflammatory arthritis (e.g., lupus, rheumatoid arthritis, ankylosing spondylitis, etc), and daily opioid use for at least one year.

Based on feasibility and precision around estimates for designing future studies, a minimum of 12 evaluable patients per group may be considered for pilot studies (39). In our study, we overrecruited 60 patients (30 per treatment arm) to account for a potential large dropout rate due to the COVID-19 pandemic. Thirty patients were randomized into each of 2 treatment arms: (1) 4-month access to painTRAINER with 6 telephone contacts over an 8-week period by a trained triage nurse (nurse support; $n = 30$), and (2) 4-month access to painTRAINER alone (control; $n = 30$; Fig. 5). Both groups received 6 computer-generated email reminders to complete the online program.

The active intervention phase lasted for 8 weeks, followed by an 8-week follow-up phase. Patients randomized to the nurse support group received 6 phone calls from baseline to week 8. Patients randomized to the control group only received computer-generated email reminders. During the follow-up phase (week 8 to week 16), all patients maintained access to the painTRAINER program, but did not receive any communication or contact from the nurse or research staff.

Outcome assessments were conducted at baseline, week 8 (at the completion of the active intervention phase), and week 16 (primary endpoint). Research coordinators who collected outcome data were blinded to treatment group assignment. The primary outcome was the Brief Pain Inventory (BPI) pain interference (40). The BPI pain interference has 7 items that rate the interference of pain with mood, general activity, work, walking ability, relations with others, sleep, and enjoyment of life. The secondary outcome was the BPI pain intensity. The BPI pain intensity has 4 items that rate the least and worst pain in the last 24 hours, pain on average, and pain at the time of taking the survey. The BPI is a well-validated assessment tool for chronic non-malignant pain with higher BPI pain interference and BPI pain intensity scores correlating with greater pain. It has reliability across multiple languages and cultures and its psychometric properties (including sensitivity to change) have been demonstrated in a range of chronic

musculoskeletal pain conditions (40-43). A prior study (44) of chronic pain in primary care estimated a minimal clinically important difference of 0.7 points for both BPI pain interference and BPI pain intensity.

Exploratory outcomes included the National Institutes of Health (NIH) Patient-Reported Outcomes Measurement System (PROMIS) adult self-reported measures on physical health (fatigue, sleep disturbance, sleep-related impairment, pain behavior, pain intensity, and pain interference) and social health (ability to participate in social roles and activities), the 13-Item Pain Catastrophizing Scale (PCS) (45,46), and the PHQ-8. NIH PROMIS measures are patient-reported outcome measures of symptoms (physical and mental health), functioning, and quality of life (social health) that were validated across a variety of health outcomes and chronic conditions (47). We used the short forms of the PROMIS measures with higher scores indicating greater degrees of the measured parameter in question (i.e., fatigue, sleep disturbance, sleep-related impairment, etc.) (48,49), which have been widely utilized in comparative effectiveness studies (50-52). Higher PCS scores indicate greater degrees of catastrophizing, which has been correlated with greater self-reported pain and disability (53); and PHQ-8 scores ≥ 10 signify clinically significant major depression (47) (Table 1).

Statistical Analysis

The primary per protocol analysis consisted of repeated measures of analysis of covariance (ANCOVA), which included weeks 8 and 16 scores while adjusting for baseline measurements. Within-group differences of all BPI and PROMIS measures were expressed as 95% CIs and reported on overall mean change of repeated measures between week 16 and week 8 time points for each group separately. Between-group differences of all BPI and PROMIS measures were expressed as overall means with their corresponding standard errors by group at the same time points. For both within- and between-group differences, a P value of < 0.05 indicated a significant nonzero change. Finally, number and duration of nurse-delivered phone calls were expressed as median (interquartile range [IQR]). All analytic assumptions were verified, and analyses were performed using SAS Version 9.4 (SAS Institute Inc, Cary, NC).

RESULTS

As seen in Table 1, the 2 study groups were comparable in terms of baseline characteristics, including age, gender, race, education, marital status, and em-

Table 1. Baseline characteristics of enrolled patients.

	Nurse Support (Treatment Group 1) (n = 30)	Control (Treatment Group 2) (n = 30)	P value	All Patients (n = 60)
Demographics				
Age (y)	52.3 (14.9)	51.8 (20.5)	.908	52.1 (17.8)
Gender, % women	26 (86.7)	23 (76.7)	.506	49 (81.7)
Ethnicity, % non-Hispanic	29 (96.7)	29 (96.7)	>.999	58 (96.7)
Race, % White	22 (73.3)	22 (73.3)	>.999	44 (73.3)
Education, % > high school	26 (86.7)	22 (73.3)	.333	48 (80.0)
Marital Status, % married	18 (60.0)	16 (53.3)	.794	34 (65.7)
Employment, % employed	17 (56.7)	12 (40.0)	.301	29 (48.3)
Clinical Variables				
Duration of Pain ≥ 1 years (%)	29 (96.7)	26 (86.7)	.353	55 (91.7)
No of Painful Body Sites (≥ 3 vs < 3)				
< 3	2 (6.7)	1 (3.3)	>.999	3 (5.0)
≥ 3	28 (93.3)	29 (96.7)		57 (95.0)
PHQ-8 Depression (score ≥ 10)	5 (16.7)	7 (23.3)	.748	12 (20.0)
BPI Pain Intensity (range 0-10)	5.0 (3.8, 6.0)	5.5 (4.8, 6.3)	.112	5.3 (4.3, 6.1)
BPI Pain Interference (range 0-10)	4.5 (3.0, 6.1)	5.4 (3.7, 6.6)	.152	4.9 (3.4, 6.6)
PCS Total (range 0-52)	15 (8, 24)	16 (9, 25)	.763	15 (8, 25)
Medications, % prescribed				
Nontricyclic Antidepressants€	7 (46.7)	9 (42.9)	>.999	16 (44.4)
Tricyclics*	0 (0)	6 (28.6)	.030*	6 (16.7)
Anticonvulsants‡	3 (20.0)	7 (33.3)	.468	10 (27.8)
Opioids†	4 (26.7)	5 (23.8)	>.999	9 (25.0)

€ fluoxetine (Prozac), duloxetine (Cymbalta), sertraline (Zoloft), paroxetine (Paxil), escitalopram (Lexapro), citalopram (Celexa), milnacipran (Savella), venlafaxine (Effexor), mirtazapine (Remeron), fluvoxamine (Luvox).

* amitriptyline, nortriptyline.

‡ gabapentin (Neurontin), pregabalin (Lyrica), carbamazepine (Tegretol).

† codeine, tramadol, hydrocodone, oxycodone, oxymorphone, morphine, methadone, buprenorphine, tapentadol, hydromorphone, meperidine, fentanyl.

Abbreviations: PHQ-8 = Patient Health Questionnaire 8-Item Depression Scale; BPI = Brief Pain Inventory; PCS = Pain Catastrophizing Scale; IQRs = interquartile ranges; n = number of patients.

Values are means (standard deviations) for age, medians (IQRs) for BPIs and PCS, and frequencies (percentages) for categorical variables; P values are from t tests, Wilcoxon tests, and Fisher's exact tests, respectively.

ployment, as well as most clinical variables including duration of pain ≥ 1 year, number of painful body sites (≥ 3 vs < 3), PHQ-8 depression scores ≥ 10, PCS, BPI pain intensity, and BPI pain interference. Furthermore, the distribution of pain sites amongst recruited patients was also comparable amongst both groups (Table 2). Compared to patients in the control group, none of the patients in the nurse support group were on tricyclic antidepressants at study entry (0% vs 28.6%, $P < 0.05$). Of 30 patients randomized to each treatment group, 20 (66.7%) in the nurse support group vs 19 (63.3%) in the

control group completed the study. The overall study completion rate was 65%. Ten patients in the nurse support group and 11 in the control group were lost to follow-up. Significantly more Whites did not complete than did complete the study (20 [90.9%] vs 24 [63.2%], $P = 0.03$), respectively. No other demographic or clinical variables differentiated those who completed vs those who did not complete the study. For the nurse support group, the median (IQR) number of completed phone calls and duration of the calls were 3.5 (2-5) phone calls and 7 (5-10) minutes, respectively.

Using a per protocol analysis, repeated measures ANCOVA of week 8 and 16 scores demonstrated statistically significant improvements in BPI pain interference and BPI pain intensity scores in both treatment groups as represented by negative values (Table 3). In the nurse support group, the observed changes were -1.3 (-2.0, -0.7, $P < 0.05$) for BPI pain interference and -1.2 (-1.7, -0.6, $P < 0.05$) for BPI pain intensity, respectively. For the control group, the observed changes were -1.7 (-2.3, -1.0, $P < 0.05$) for BPI pain inference and -1.3 (-1.8, -0.8, $P < 0.05$) for BPI pain intensity, respectively. Similarly, analysis of week 8 and 16 scores showed statistically significant improvements in PROMIS pain interference and PROMIS pain intensity scores in both treatment groups. In the nurse support group, the observed changes were -5.0 (-6.9, -3.2, $P < 0.05$) for PROMIS pain interference and -1.4 (-2.0, -0.9, $P < 0.05$) for PROMIS pain intensity, respectively. For the control group, the observed changes were -5.4 (-7.2, -3.5, $P < 0.05$) for PROMIS pain inference and -1.4 (-1.9, -0.8, $P < 0.05$) for PROMIS pain intensity, respectively.

As shown in Figs. 1-4, improvements in BPI and PROMIS pain interference and intensity scores were seen at weeks 8 and 16 compared to baseline. However, the 2 treatment groups were not significantly different for any of these outcomes. Per protocol analysis was also performed for all remaining exploratory PROMIS outcome measures and revealed no significant between-group differences throughout the study (Table 3), except for PROMIS sleep disturbance that favored the nurse support group (50.5 ± 1.3 vs 54.3 ± 1.3 , $P < 0.05$) over the control group.

As a measure of patients' engagement, the median number (IQR) of completed learning modules were no different between the 2 treatment groups (7 [1-8] vs 8 [1-8]). In addition, there were no significant between-group differences in the proportion of patients completing 6 or more learning modules (nurse support 56.7% vs control 62.1%), or 8 learning modules (nurse support 50% vs control 55.2%). Finally, no serious unintended adverse events were observed in either treatment group.

DISCUSSION

Numerous studies have highlighted a role for web-based CBT in chronic pain. Notably, systematic reviews and meta-analyses (20,54) of web-based CBT have found small but clinically significant improvements in several important domains, including disability (effect size = 0.39) and pain severity (effect size = 0.33). One meta-analysis (54) of 11 studies comprising 2,953 pa-

Table 2. Frequency distribution table of pain sites by treatment group.

Pain Site	Overall	Nurse Support	Control	P value
Head	8 (13.3)	6 (20.0)	2 (6.7)	0.2542
Neck	30 (50.0)	17 (56.7)	13 (43.3)	0.4389
Back	41 (68.3)	19 (63.3)	22 (73.3)	0.5796
Chest	0 (0)	0 (0)	0 (0)	n/a
Shoulder - right	34 (56.7)	18 (60.0)	16 (53.3)	0.7948
Shoulder - left	29 (48.3)	15 (50.0)	14 (46.7)	>0.9999
Elbow/hand - right	12 (20.0)	9 (30.0)	3 (10.0)	0.1042
Elbow/hand - left	11 (18.3)	9 (30.0)	2 (6.7)	0.0419
Hip - right	19 (31.7)	13 (43.3)	6 (20.0)	0.0946
Hip - left	22 (36.7)	13 (43.3)	9 (30.0)	0.422
Knee - right	26 (43.3)	15 (50.0)	11 (36.7)	0.4348
Knee - left	28 (46.7)	17 (56.7)	11 (36.7)	0.1954
Foot - right	31 (51.7)	14 (46.7)	17 (56.7)	0.6058
Foot - left	29 (48.3)	14 (46.7)	15 (50.0)	>0.9999
Abdomen	1 (1.7)	0 (0)	1 (3.3)	>0.9999
Arm - left	9 (15.0)	4 (13.3)	5 (16.7)	>0.9999
Arm - right	9 (15.0)	3 (10.0)	6 (20.0)	0.4716
Hand - left	36 (60.0)	16 (53.3)	20 (66.7)	0.4296
Hand - right	35 (58.3)	14 (46.7)	21 (70.0)	0.1154
Widespread	1 (1.7)	0 (0)	1 (3.3)	>0.9999
Other	0 (0)	0 (0)	0 (0)	n/a

Values are frequencies (percentages) with P values from Fisher's exact test.

tients examining web-based CBT in several chronic pain syndromes found a small yet clinically significant improvement in pain scores. A more recent meta-analysis (55) of 16 studies also demonstrated small effect sizes of under 0.4 for both pain intensity (10 studies) and pain-related disability (6 studies).

In our study, both nurse support and control groups showed statistically significant within-group improvements in BPI and PROMIS pain interference and pain intensity scores, consistent with prior studies (15-17,19) demonstrating significant improvements in pain and disability. Unfortunately, we did not observe benefits with the addition of motivational support to increase patients' engagement. In short, self-guided web-based CBT with nurse support was no more effective than self-guided (unsupported) web-based CBT for CMP.

To our knowledge, there is only one study that examined the benefits of remote clinician support added to a web-based pain self-management program. Dear et al (56) randomized patients with a broad range of

Table 3. *Between Group differences of primary and secondary outcomes by treatment group.*

Primary and secondary outcomes	Nurse support (Treatment group 1) (n = 30)	Control (Treatment group 2) (n = 30)	P values
BPI pain interference	3.5 (0.3)	3.5 (0.3)	0.924
BPI pain intensity	4.0 (0.2)	4.2 (0.2)	0.542
Exploratory measures			
PROMIS fatigue	51.5 (1.3)	53.4 (1.4)	0.316
PROMIS sleep disturbance	50.5 (1.3)	54.3 (1.3)	0.039*
PROMIS sleep related impairment	42.0 (1.2)	39.2 (1.1)	0.090
PROMIS social function	48.0 (0.9)	47.4 (0.9)	0.680
PROMIS pain intensity	4.4 (0.3)	4.7 (0.2)	0.476
PROMIS pain interference	57.4 (0.9)	57.3 (0.9)	0.889
PROMIS pain behavior	57.7 (0.6)	56.7 (0.6)	0.236
Process measures			
Proportion who completed 8 learning modules	15 (50.0)	16 (55.2)	0.796
Proportion who completed 6 or more learning modules	17 (56.7)	18 (62.1)	0.792
# of completed learning modules (median; IQR)	7 (1, 8)	8 (1, 8)	0.967
Pain catastrophizing (PCS)	9.2 (1.3)	11.1 (1.3)	0.315

The primary analysis (repeated measures ANCOVA) included week 8 and week 16 scores while adjusting for baseline measurement, with values given as means (standard errors).

* indicates a significant nonzero change.

Abbreviation: ANCOVA = analysis of covariance.

chronic pain conditions to 1 of 4 groups: (1) regular clinician contact, (2) optional clinician contact, (3) no contact, and (4) wait-list control group. Compared to the wait-list control group, the 3 treatment groups reported significant improvements in pain severity and disability. However, there were no significant differences observed among the 3 treatment groups. These results together with the findings of our study suggest that regular clinician (psychologist or nurse) support (via telephone and/or secure email) may not add much in optimizing pain-related outcomes amongst individuals involved in a web-based pain self-management program for CMP.

Our study is important because it raises a clinically relevant and testable hypothesis that web-based CBT with and without nurse support are equally effective and that good clinical outcomes may be obtained in the absence of personnel support. Andersson et al (57) postulated that human support might be less important if the Internet-delivered program is of high quality and is sufficiently engaging for patients. If our study findings are replicated in larger randomized controlled trials, web-based CBT without nurse support could be used as a lower resource treatment modality for CMP or as an initial step in a stepped-care approach where human support is added later.

There are a number of limitations to our study. First, we did not power the study based on an estimated treatment effect size. Instead, we used Julious et al (39) recommendation on a sample size of 12 per group for a pilot study. Second, although our nurses were trained in motivational interviewing (MI), we did not formally assess treatment fidelity. Thus, we cannot say whether MI-based support was actually delivered by the nurses. Third, bias related to patients' prior knowledge of their treatment assignments may have underestimated the effects of phone-based support. Given that all study patients were aware of the study aim (i.e., to determine if phone-delivered nurse support can improve the use of pain coping skills), patients in the control arm may have been more self-engaged in the program. Fourth, more frequent use of tricyclic antidepressants in the control group at baseline may have also underestimated the effects of phone-delivered intervention. Finally, due to the low number of patients on opioids at baseline, the findings of our study may not be generalized to long-term chronic opioid users.

CONCLUSIONS

The addition of phone-delivered motivational support by nurses to self-paced, web-based CBT was no more

effective than web-based CBT alone in our study. If confirmed in a larger study, web-based CBT should be offered as a first step in a step-care approach to pain management and should be made more widely available as an effective, low-cost treatment intervention for CMP.

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