Brief Report

Effectiveness of a multidisciplinary rehabilitation program in real-world patients with chronic back pain: A pilot cohort data analysis

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Abstract.

BACKGROUND: Randomized clinical trials (RCT) suggest a multidisciplinary approach to pain rehabilitation is superior to other active treatments in improving pain intensity, function, disability, and pain interference for patients with chronic pain, with small effect size (ds = 0.20-0.36) but its effectiveness remains unknown in real-world practice.

OBJECTIVE: The current study examined the effectiveness of a multidisciplinary program to a cognitive and behavioral therapy (pain-CBT) in real-world patients with chronic back pain.

METHODS: Twenty-eight patients ($M_{age} = 57.6$, 82.1% Female) completed a multidisciplinary program that included pain psychology and physical therapy. Eighteen patients ($M_{age} = 58.9$, 77.8% Female) completed a CBT-alone program. Using a learning healthcare system, the Pain Catastrophizing Scale, 0–10 Numerical Pain Rating Scale, and Patient-Reported Outcomes Measurement Information System[®] measures were administered before and after the programs.

RESULTS: We found significant improvement in mobility and pain behavior only after a multidisciplinary program (p's < 0.031; d = 0.69 and 0.55). We also found significant improvement in pain interference, fatigue, depression, anxiety, social role satisfaction, and pain catastrophizing after pain-CBT or multidisciplinary programs (p's < 0.037; ds = 0.29–0.73). Pain ratings were not significantly changed by either program (p's > 0.207).

CONCLUSIONS: The effect of a multidisciplinary rehabilitation program observed in RCT would be generalizable to real-world practice.

Keywords: Chronic back pain, multidisciplinary program, cognitive and behavioral therapy, acceptance and commitment therapy, physical therapy, a learning health system

1. Introduction

Chronic back pain is the leading cause of disability worldwide [1] and the one-year prevalence of activitylimiting back pain is about 38% [2]. Studies have shown

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that chronic back pain impacts physical [3,4] and psychosocial function [5,6]. This multi-factorial nature of chronic back pain makes it imperative that treatment approaches should be multimodal; and typically include medical, physical, and psychological intervention approaches. Cumulative evidence suggests a multidisciplinary approach to pain rehabilitation is superior to other active treatments in improving pain intensity, function, disability, and pain interference for patients with chronic pain, with small effect size (ds = 0.20-0.36) [7–10]. These randomized clinical trials (RCT) inform treatment efficacy in a homogenous patient population, but RCTs on a homogenous sample are limited in their relevance to real-world practice. Subsequently, real-world evidence is needed to understand the treatment effectiveness in complex real-world patients whom clinicians encounter in their daily practice [11]. Our pain center utilizes a learning healthcare system, called the Collaborative Health Outcomes Information Registry (CHOIR, https://choir.stanford.edu/), to optimize patient care and serve as a platform for real-world research discovery. The CHOIR enables to assess multidimensional health status at a point-of-care with reduced patient burden by implementing a computerized adaptive testing (CAT).

The most popular psychological interventions for chronic pain are Cognitive Behavioral Therapy (CBT) [12,13], Acceptance and Commitment Therapy (ACT) [14], and Mindfulness-based program [15]. CBT aims to reduce disability through learning adaptive cognitive and behavioral strategies, and it shows small to medium effects on pain outcomes [13]. ACT focuses on patient engagement in valued life activities while accepting unwanted pain, thoughts, and feelings, with the overall goal of enhancing 'psychological flexibility' [16], and ACT includes mindfulness strategy [17]. ACT is similarly efficacious in improving physical function [17,18]. Our new multidisciplinary rehabilitative program, labeled Backs in Action (BIA), has been offered to patients as an adjunctive treatment to their usual medical care. The BIA is comprised of an individualized physical therapy (PT) and psychological programs (CBT and ACT).

Using the CHOIR-CAT survey, the current study aimed to compare the effectiveness of a newly developed multidisciplinary rehabilitation program to the pain-CBT in a pilot cohort of real-world patients with chronic back pain. We hypothesized that treatment outcomes would be comparable between pain-CBT and BIA programs because we matched patients with their need for CBT only or intensive rehabilitation program.

2. Method

2.1. Enrollment process

This was a retrospective cohort study of patients who attend the BIA or pain-CBT at a tertiary pain clinic between January 2017 and November 2019. Inclusion criteria for both programs were patients with any chronic back pain (i.e., neck, upper, and lower back pain). The BIA was designed for those who significantly reduced daily function and needed an intensive outpatient program whereas the pain-CBT was for patients who had relatively better daily function and needed to learn selfmanagement skills. All patients in both groups were referred by pain physicians, but the enrollment process was different between the two programs. All patients in the BIA were evaluated by pain psychologists to determine their appropriateness for the group-based pain psychology program and by physical therapists to determine whether the patient could safely participate in the exercise-based interventions. Tests and measures during the physical therapy evaluation included lumbar ROM, core testing, balance testing, a six-minute walk test (6MWT) with BP/HR measurements pre-and post 6MWT [19]. Then, patients who had an insurance approval attended the BIA program. In contrast, not all patients in the pain-CBT underwent psychology evaluation because pain physicians could make a referral to the pain-CBT. The pain-CBT was periodically offered free of charge and insurance approval was not needed.

2.2. Intervention content

Our programs covered the published CBT [20] and ACT contents [21]. Specifically, the pain-CBT included pain psychoeducation and pain self-management techniques, listed in Table 1. The pain-CBT was run by a pain psychologist or 4 supervised postdoctoral psychology fellows. The 2-hour CBT was offered over 8 weeks (total 16 hours). In addition to the pain-CBT, the BIA covered the ACT content: values, mindfulness, committed action, defusion, and self as context [21]. The BIA was run by a pain psychologist and a physical therapist. The BIA consisted of 12 sessions over a 6-week period (total 24 hours of pain psychology and 24 hours of PT sessions). In each BIA session were 2-hour pain psychology and 2-hour PT (Fig. 1).

Our PT program included the evidenced-based educational contents and exercise interventions: pain neuroscience education as well as graded aerobic exercise and supervised/individualized resistance exercise [22,23]

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	Pain-CBT	BIA
Pain psychology		
Psychoeducation about pain	Х	Х
Relaxation techniques	Х	Х
SMART goal settings	Х	
Cognitive restructuring	Х	Х
Activity pacing	Х	Х
Sleep hygiene	Х	Х
Scheduled pleasant activity	Х	
Planning for discharge and pain flare-up	Х	Х
Values		Х
Mindfulness		Х
Committed action		Х
Defusion		Х
Self as context		Х
PT program		
Mindful Movement – Tai Chi for Rehabilitation Sequence*		Х
Mindful Movement-Gentle Yoga		Х
Gym Exercise Program – Graded Aerobic Exercise		Х
Gym Exercise Program-Individual Exercises		Х
Pain Neuroscience Education		Х

 Table 1

 Comparison of the content of the two programs

*:Full video can be found at https://www.youtube.com/watch?v=0DiwrHRWS4A.

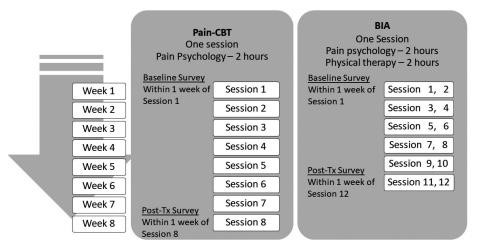


Fig. 1. Comparison of survey administration and the treatment course for Pain-CBT and BIA programs. Post-Tx: post-treatment.

(Table 1). Tai Chi and Yoga were also included as they had shown to reduce pain and improve disability for patients with low back pain [24,25]. The Tai Chi program was led by a Physical Therapist that was certified in Tai Chi for Rehabilitation Sequence [24]. The Tai Chi was taught in seated and standing positions. The yoga was based off the published protocol [25], including supine poses, seated poses and standing poses for 20 minutes each. Patients had a graded aerobic exercise program that increased in duration by 10–20% each week throughout the 6 weeks. The individual exercise program, which was created by the physical therapist at the initial evaluation, focused each individual's impair-

ments and self-selected goals. The individual program was also upgraded each week throughout the program.

2.3. Measurements

Retrospective chart reviews were conducted to assess medical diagnoses. The current study extracted data of the following measures completed within one week of the first and last sessions.

Our primary outcome was the Patient-Reported Outcomes Measurement Information System (PROMIS)[®], patient-centered outcome measures [26], which was administered using CAT [27]. The current study included

the PROMIS item banks for physical and psychosocial health domains. The physical health domains were upper extremity movement, mobility, pain interference, pain behavior, fatigue, and sleep-related impairment. The psychosocial health domains were depression, anxiety, social role satisfaction, emotional support, and social isolation. All PROMIS scores were converted to T scores, with higher scores indicating worse health status in each domain.

Secondary outcomes were the PROMIS Pain Intensity measure assessing the intensity of pain at worst and average for the past 7 days on a 0–10 scale [28] and the Pain Catastrophizing Scale (PCS) assessing levels of catastrophic thinking about pain [29]. The total PCS scores range from 0 to 52, with higher scores indicating greater pain catastrophizing. Finally, the body map was used to assess the number of painful sites, ranging from 0 to 45 [30].

2.4. Statistical analysis

Appropriate (χ^2 , Mann-Whitney U, and independent t) tests were conducted to examine whether the two groups' sociodemographic variables and clinical symptoms were significantly different at baseline. Two(time) by Two(group) repeated measures MANOVAs were conducted for the three sets of outcomes: a) PROMISphysical health measures, b) PROMIS-psychosocial health measures, and c) pain ratings and pain catastrophizing scores, followed by post-hoc univariate analyses. p values of < 0.05 were considered statistically significant. Cohen's d was computed to calculate effect sizes, and d of 0.2, 0.5, and 0.8 would indicate small, medium, and large effects, respectively [31]. Sensitivity analysis was conducted to examine whether significant difference in treatment outcomes (i.e., significant time by group interaction) would remain significant even after adjusting for the pre-existing difference in sociodemographic variables.

We collected data until our sample size was a total of 40 patients for the current pilot study and intended to have 20 for each group. However, our final sample included 18 patients for pain-CBT and 28 patients for BIA and the current study computed the effect sizes, which can be used for a future study's power analysis. No significant violation of multicollinearity and homogeneity were observed as all correlation coefficients were < 0.685 and p values of Box's M tests were > 0.600. There were no missing values except for education and legal claim.

3. Results

3.1. Baseline patient characteristics

Sociodemographic states were not significantly different between the two groups (p's > 0.426, Table 2). Patients were predominantly middle-aged, married female, and White/Caucasian with college or higher degree. About two thirds endorsed currently not working. A small percentage of patients in Pain-CBT and BIA programs reported receiving disability benefits (17.9 and 27.8%, p = 0.426), having injury-related pain (38.9 and 28.6%, p = 0.466), and taking a legal action for pain (23.5 and 3.6%). Because less than 5 patients with a legal claim, Fisher's exact test was conducted and the result indicated legal claim was marginally higher in pain-CBT group (p = 0.060).

The two groups were not significantly different in the number of painful sites (p = 0.295), but pain durations were marginally higher in the BIA group (p = 0.068). Most patients (67.4%) had comorbid diagnosis and patients in the BIA had a trend for more comorbid health conditions (p = 0.095). Different from our expectation, independent t tests indicated that pain, physical, and psychosocial health states were not significantly different between the groups at baseline (p's > 0.143, Table 2). The median of attended sessions was 7.0 (IQR = 6.0-8.0) for the pain-CBT and 11.5 (IQR = 9.6-12.0) for the BIA.

3.2. Health outcomes of the pain-CBT and BIA programs

A 2(time) \times 2(groups) repeated measures MANOVA for physical health outcomes (i.e., PROMIS-mobility, pain interference, pain behaviors, fatigue, and sleep impairment T scores) revealed a significant interaction effect, Wilks' $\Lambda = 0.71$, p = 0.014, and a significant main effect of time, Wilks' $\Lambda = 0.63$, p = 0.002. However, we did not find a significant group effect (p = 0.376). Post-hoc tests showed significant interaction effect only in mobility, F(1, 44) = 8.51, p = 0.006 (Fig. 2A), and pain behaviors, F(1, 44) = 4.99, p = 0.031 (Fig. 2C). Mobility and pain behaviors T scores were reduced by 2.32 and 2.25T after the BIA and < 1.0T after pain-CBT (Table 3). Additionally, post-hoc analysis revealed a significant time effect in pain interference, F(1, 44)= 21.01, p < 0.001 (Fig. 2C) and fatigue, F(1, 44) =9.12, p = 0.004 (Fig. 2D). Pain interference and fatigue scores were reduced by 3.30T and 3.89T, respectively, after the pain-CBT or BIA (Table 3). In summary, mo-

	Pain-CBT $(n = 18)$		R	IA	1 0	
			$\begin{array}{c} \text{BIA} \\ (n=28) \end{array}$			
	$\frac{n}{n}$	(%)	$\frac{n}{n}$	(%)	χ^2	p
Sex (Female)	14	(77.8)	23	(82.1)	0.13	0.716
Race (White/Caucasian)	12	(66.7)	15	(53.6)	0.78	0.379
Marital status (Married)	9	(50.0)	17	(60.7)	0.51	0.474
Education (Bachelor's or higher)*	12	(66.7)	20	(74.1)	0.29	0.591
Currently not working	11	(61.1)	19	(67.9)	0.22	0.639
Currently being on disability	5	(17.9)	5	(27.8)	0.63	0.426
Pain caused by an injury/accident	7	(38.9)	8	(28.6)	0.53	0.466
Legal claim for pain*	4	(23.5)	1	(3.6)	-	0.060 ^F
	Median	(IQR)	Median	(IQR)	U	p
Number of painful sites	10.5	6.0-15.3	11.5	7.5-24.5	205.50	0.295
Pain duration (years)	4.6	2.9-10.3	9.8	4.3-17.3	171.00	0.068
Comorbid Conditions [^]	0.5	0.0-4.0	2.0	1.0 - 5.0	179.50	0.095
	M	SD	M	SD	t	p
Age	58.9	14.3	57.6	14.8	-0.29	0.773
PČS	17.7	7.8	16.8	10.0	-0.32	0.747
Worst pain	7.4	1.6	6.7	2.1	-1.18	0.245
Average pain	5.0	1.7	4.6	2.1	-0.66	0.510
PROMIS T scores						
Mobility	58.2	7.4	61.0	5.1	1.49	0.143
Pain Interference	64.2	5.3	64.6	5.4	0.27	0.788
Pain Behaviors	58.8	2.7	59.5	3.2	0.72	0.474
Fatigue	61.2	10.1	60.6	9.3	-0.20	0.843
Sleep Impairment	56.8	11.2	59.1	8.4	0.79	0.432
Depression	54.7	9.3	57.1	6.9	1.04	0.307
Anxiety	58.1	10.1	57.5	7.7	-0.23	0.823
Emotional Support	50.9	8.2	52.0	9.0	0.44	0.664
Social Isolation	51.7	9.9	52.8	6.5	0.47	0.644
Social Role Satisfaction	59.6	6.8	59.9	5.6	0.18	0.856

 Table 2

 Comparison of the baseline characteristics of the patients in the pain-CBT and BIA programs

*: missing n = 1 in the BIA for education and n = 1 in Pain-CBT for legal action; ^F: Fisher's Exact Test; The most common comorbid conditions are depression (31%), hypertension (23%), anxiety (21%), hyperlipidemia (19%), obstructive sleep apnea (13%), coronary artery disease (10%), insomnia (10%). All the other comorbid conditions were less than 10%.

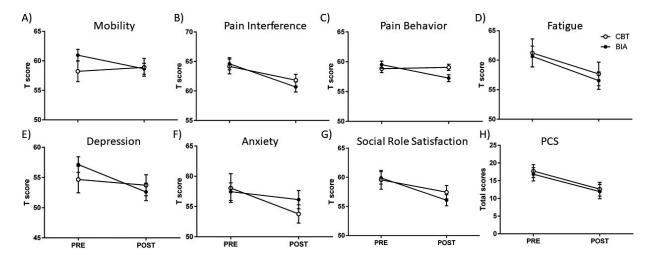


Fig. 2. Comparisons of pre- and post-treatment outcomes. A)–G) are PROMIS T scores of Mobility, Pain Interference, Pain Behavior, Fatigue, Depression, Anxiety, and Social Role Satisfaction, respectively, with higher T scores indicating worse health status in each domain. H) is PCS total score. Errors = SEM.

	(Pain-CE	Total (Pain-CBT and BIA) (n = 46)			Pain-CBT $(n = 18)$			$\begin{array}{c} \text{BIA} \\ (n = 28) \end{array}$		
	Mean difference	SD	d	Mean difference	SD	d	Mean difference	SD	d	
PCS*	-4.98	8.73	0.57	-5.11	7.48	-0.68	-4.89	9.59	-0.51	
PROMIS T scores										
[Physical Health]										
Mobility	-1.15	3.66	0.31	0.67	3.41	0.20	-2.32	3.38	-0.69	
Pain Interference	-3.30	4.54	0.73	-2.33	4.20	-0.55	-3.93	4.71	-0.83	
Pain Behaviors	-1.28	3.82	0.34	0.22	2.92	0.08	-2.25	4.06	-0.55	
Fatigue	-3.89	8.31	0.47	-3.56	7.49	-0.48	-4.11	8.93	-0.46	
Sleep Impairment	-1.35	6.89	0.20	-2.22	6.34	-0.35	-0.79	7.28	-0.11	
[Psychosocial Health]										
Depression	-3.13	7.19	0.44	-0.94	5.31	-0.18	-4.54	7.96	-0.57	
Anxiety	-2.48	8.63	0.29	-4.28	7.86	-0.54	-1.32	9.04	-0.15	
Emotional Support	-1.39	5.43	0.26	0.00	5.08	-0.00	-2.29	5.55	-0.41	
Social Isolation	-1.28	6.13	0.21	-3.06	5.37	-0.57	-0.14	6.41	-0.02	
Social Role Satisfaction	-3.15	5.79	0.54	-2.11	4.30	-0.49	-3.82	6.56	-0.58	

Table 3
The mean differences of T scores between the pre- and post-treatments

Note: *Changes in PCS total scores. The others are changes in T scores. Bolded values in the total (Pain-CBT and BIA group) column indicate a significant time effect in a post-hoc test and bolded values in the Pain-CBT and BIA column indicate a significant time by group interaction effect (p < 0.05).

bility and pain behavior were improved only after the BIA whereas pain interference and fatigue were improved after pain-CBT or BIA programs, with medium sized effects (d's = 0.47–0.73).

We conducted sensitivity analysis for the significant interaction effect. When entering legal claims as a covariate, the previously significant interaction effect in mobility, F(1, 42) = 14.23, p = 0.001, and pain behaviors, F(1, 42) = 14.77, p = 0.035, remained significant. This suggests that significant improvement of mobility and pain behavior only after BIA is unlikely to be driven by less legal claims in the BIA group.

Another $2(\text{time}) \times 2(\text{group})$ repeated measures MANOVA for psychosocial health outcomes (i.e., PROMIS-depression, anxiety, emotional support, social isolation, and social role satisfaction T scores) revealed significant interaction, Wilks' $\Lambda = 0.66$, p = 0.005 and time effects, Wilks' $\Lambda = 0.75$, p = 0.032. However, we did not find a significant group effect (p = 0.781; Fig. 2E-G). Post-hoc tests showed no significant time by interactions (ps > 0.099), but a significant time effect only in depression, F(1, 44) = 6.61, p = 0.014, anxiety, F(1, 44) = 4.64, p = 0.037, and social role satisfaction, F(1, 44) = 11.50, p = 0.001, of which T scores were improved by 2.48-3.15T (Table 3). This suggests that depression, anxiety, and social role satisfaction were improved after pain-CBT or BIA programs, with small to medium effects (ds = 0.29-0.73).

Finally, a 2(time) \times 2(group) repeated measures MANOVA was conducted to compare PCS scores and

the worst and average pain ratings. We found no significant interaction (p = 0.584) and group effect (p = 0.151), but a significant time effect, Wilks' $\Lambda = 0.75$, p = 0.006. Post-hoc tests indicated a time effect in PCS scores, F(1, 44) = 14.06, p = 0.001 (Fig. 2H), but not in worst and average pain ratings (p's > 0.207). PCS scores were reduced by 4.98 points after pain-CBT or BIA (Table 3), with a moderate effect (d = 0.57).

4. Discussion

The current study compared the effectiveness of a multidisciplinary rehabilitation program to pain-CBT in real-world patients with chronic back pain. As hypothesized, we found that the BIA and pain-CBT groups showed statistically significant improvement in pain catastrophizing, pain interference, fatigue, depression, anxiety, and social role satisfaction. These treatment effects were small to medium effect sizes. Different from our hypothesis, only the BIA group showed a significant improvement in mobility and pain behaviors.

A meta-analysis reveals that multidisciplinary programs with functional restoration approach produce greater improvement in function for patients with disabling chronic pain than usual care [8]. Based on our results, pain interference improved in both groups, yet physical function/mobility improved only after the BIA, highlighting the additional benefit of improving physical function by the PT inclusion program. Our results are consistent with a meta-analysis showing that multidisciplinary programs with functional restoration approach produce greater improvement in function for patients with disabling chronic pain than usual care [8,10], but inconsistent with a RCT showing that both CBT alone and CBT and PT programs produce greater improvement in physical function at 3, 6, and 12-month follow-ups, compared to exercise only or usual care [32]. Potentially, the current study may be underpower to detect the effect of CBT on physical function or need to follow-up a longer period as there may be a delayed effect, referred to as "sleeper effect" [33]. ACT components in the BIA may also contribute to the improvement of physical function. The CBT is based on control strategies and it focuses on learning effective pain management skills to reduce pain and the impact of pain on life. In contrast, the ACT teaches that controlling or avoiding pain is ineffective and it focuses on reducing "avoidance" of unwanted thoughts, feeling, and sensations, allowing patients to engage in values driven behaviors that increase life satisfaction and meaning. In supporting this view, an experiment has demonstrated that physical impairment is decreased by acceptance strategies but increased by control strategies [34].

We also found that pain behaviors were reduced only after the BIA. Pain behaviors are verbal and non-verbal expressions of pain experience and suffering [35]. Greater pain behaviors are associated with worse pain and general health status [35]. Studies have noted that ACT [36,37] and PT [38] reduce pain behaviors such as less sick leave and medical visits whereas CBT prevents from taking more sick leave and medical visits in the future [39]. Notably, levels of acceptance and value-driven action do not predict medical visits after ACT [37]. We speculate that reduction of pain behaviors may be related to a) learning the relationships between behaviors moving away from their valued-life and the associated internal struggles, and b) engagement in strategies to reduce the internal struggles, by incorporating defusion and mindfulness skills.

Our small to moderate effects of pain-CBT or BIA on pain interference, fatigue, depression, anxiety, social role satisfaction, and pain catastrophizing were consistent with RCTs. More importantly, despite heterogeneity of our sample with multiple comorbidities and no randomization, our findings are similar to RCT of CBT [13], ACT [17], and multidisciplinary programs [7–10], suggesting RCT findings are generalizable to typical patients attending a rehabilitation program at an outpatient setting. Furthermore, different from patients in RCT, which usually offers compensation for participants' class attendance and time for surveys, our patients attended the programs as recommended by their treating clinicians and voluntarily completed the survey for no compensation. Therefore, our patients had less external motivation.

The current study has several limitations. Additional study with a large cohort of patients is warranted to determine the effectiveness of a multidisciplinary rehabilitation program in real-world practice. The current study assessed the outcomes of patients who attended the first and last session, and voluntarily completed the CHOIR survey before and after the program. Future study should conduct intent-to-treat analysis and examine the sleeper effect. Finally, our treatment effects related to PT or ACT components should be examined in a RCT. Despite these limitations, to the best of our knowledge, this was the first study to show that RCT results of multidisciplinary rehabilitation program for chronic back pain would be generalizable to real-world practice.

The current study showed that pain catastrophizing, pain interference, fatigue, depression, anxiety, and social role satisfaction were improved after pain-CBT and a multidisciplinary rehabilitation program. Yet, improvement of physical function and pain behaviors were observed only after the multidisciplinary rehabilitation program, which included additional ACT and PT components.

Conflict of interest

None to report.

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