Research Paper

The Effect of Cognitive Functional Therapy on Psychological Variables in Women With Non-specific Chronic Back Pain: A Randomized Control Trial

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ABSTRACT

Purpose: Chronic non-specific low back pain (CNSLBP) is a common health issue caused by a mix of biological, psychological, and social factors. Cognitive functional therapy (CFT) is a comprehensive way to treat CNSLBP that focuses on changing negative thoughts and unhelpful habits through relaxation techniques. Since the evidence on the efficacy of CFT is still limited, it is essential to conduct clinical trials aimed at the effectiveness of CFT in the treatment of CNSLBP. This study aims to examine the effect of cognitive functional therapy on psychological variables in women with CNSLBP.

Methods: Thirty women with CNSLBP were recruited for the clinical trial. They were randomly divided into two experimental and control groups (15 patients in each group). Our experimental group will have 18 individualized CFT sessions, each lasting an hour, over two months. The control group received no intervention. Pain intensity, disability, and kinesiophobia were assessed via the visual analog scale, Oswestry, and Tampa scale, respectively. Two-way repeated measures analysis of variance (ANOVA) was used to compare results between groups.

Results: Two-way repeated measures ANOVA results showed that the experimental group compared to the control group in reducing pain (P=0.000, η_p^2=0.787), disability (P=0.005, η_p^2=0.457) and Kinesiophobia (P=0.000, η_p^2=0.561) had a significant difference.

Conclusion: CFT reduced pain, disability, and kinesiophobia in patients with CNSLBP. Further evaluation of the efficacy of CFT in high-quality randomized clinical trials among patients with CNSLBP is recommended.

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Highlights

• Low back pain has negative effects on people's psychological factors.

• Treatment of pain requires considering anatomical, psychological, and social factors.

• Cognitive functional therapy (CFT) is a multidimensional approach to the treatment of chronic non-specific back pain (CNSLBP) that focuses on negative cognitions and maladaptive functional behaviors.

• One of the key factors in functional cognitive exercises is matching the characteristics of each person with the exercise that is specifically given to him.

Plain Language Summary

Strong evidence shows that the cause of low back pain is an interaction between cognitive, physical, psychological, neurophysiological, lifestyle, and social factors. Although many of these factors are modifiable, most existing interventions have been developed based on a biomedical model focusing on pathology and do not target an individualized treatment approach for chronic low back pain. One alternative approach is cognitive functional therapy (CFT). CFT is a cognitive-behavioral intervention that is multidimensional and individual-oriented in nature. CFT aims to change the patient's beliefs, and the ability to cope with fear, teach pain mechanisms, and increase control of their body's flexibility.

Introduction

Chronic low back pain (CLBP) is one of the vital medical conditions worldwide in terms of reduced quality of life, disability, and increased social and economic costs [1]. The prevalence rate of CLBP has been reported by 84%, twice more common in women than in men [2]. The healthcare cost of LBP is estimated to be £14 billion in the United Kingdom and $14.5 billion in the United States [3]. LBP is grouped into non-specific and mechanical types [4]. Chronic non-specific back pain (CNSLBP) accounts for 90%-95% of the cases, affecting 20% of the world's population [5].

According to conducted research, the prevalence of CNSLBP continues to rise [6] because most existing interventions were developed based on a biomedical model focusing on the structure or pathology, and do not target an individualized treatment approach for each case of chronic low back pain [7] while LBP is commonly believed to be partly caused by biomechanical reasons. Compelling evidence suggests that LBP is associated with a complex interplay of cognitive [8], physical [9], psychological [10], neurophysiological [10], lifestyle factors [11], and social factors [12].

Recently, there has been an increased focus among researchers on the neurological and cognitive aspects of LBP. Studies have uncovered the significant role played by psychological factors, such as Kinesiophobia and the perceived intensity of pain, in exacerbating LBP [13]. According to the fear-avoidance model, painful experiences instill fear of movement or reinjury in individuals, often resulting in avoidance behavior and prolonged immobility, along with feelings of depression and increased disability [14]. Over time, a protective adaptation to pain occurs through motor learning, wherein new motor programs in the motor cortex replace natural movements. As a result, this pain response leads to an intensified experience of pain, increased fear of movement, and heightened focus and attention on painful movements [15]. Consequently, identifying the psychological factors contributing to the persistence of chronic pain in patients with CNSLBP can be a valuable complement to therapeutic interventions in the fields of sports rehabilitation, physiotherapy, and physical medicine [13]. As a result, treatment approaches for CNSLBP have undergone a significant shift away from purely biomedical models and towards biopsychosocial models.

An alternative approach gaining increasing attention in the management of CLBP is cognitive functional therapy (CFT) [16]. CFT consists of multidimensional and personalized exercises that not only emphasize motor control but also consider psychological factors as integral components of the exercises [17]. CFT aims to change the patient's beliefs, and the ability to cope with

fear, teach pain mechanisms, and increase control of their body's flexibility. Individuals are trained to reduce the overactivity of the trunk muscles and make behavioral changes related to pain in provocative postures and movements [18]. Clinical trials using CFT have shown promising results [16-18]. For example, in a randomized controlled clinical trial (RCT) conducted by Vibe Fersum et al. involving individuals with chronic low back pain, CFT demonstrated superior outcomes in terms of pain reduction and disability compared to manual therapy [19]. Additionally, another study revealed that CFT led to a reduction in pain intensity and disability during 3, 6, and 12-month follow-ups in people with chronic back pain [18].

Despite these promising initial findings, the body of research on interventions targeting psychological factors in individuals with chronic musculoskeletal pain remains limited [18, 20], and many questions remain, including the mechanisms of the effectiveness of these exercises in pain reduction and the design of therapeutic protocols. Therefore, it is necessary to conduct high-quality clinical trials to assess the effectiveness of CFT interventions commonly employed in clinical practice. Therefore, RCT was conducted to determine whether CFT is effective for CLBP. We hypothesized that CFT would lead to reduced pain, disability, and fear of movement.

Materials and Methods

Study design

This double-blind RCT (evaluators/patients) was planned with a pre- post-test design [21]. The statistical population included 40 women with CNSLBP who were recruited from orthopedic or sports medicine clinics in Hamedan Province, Iran. In this clinical trial, patients were randomly assigned into two experimental (n=20) and control groups (n=20). The experimental group followed CFT for 8 weeks and the control group received no intervention [22].

Sample size

We used G*Power software, to determine the sample size. According to the previous study, the power was 0.8, the α was 0.5, and the effect size was 0.8. The software output reported 40 subjects for this clinical trial.

Recruitment and participants

The statistical population of this clinical trial was women with CNSLBP. Patients were recruited from orthopedic and sports medicine clinics of Hamedan Province. An orthopedic surgeon evaluates patients before recruitment. Thirty women with CNSLBP were recruited for clinical trials based on the diagnosis of the spine orthopedic physician. The inclusion criteria included visual analog scale ≥3, Oswestry disability index ≥25, and Kinesiophobia >18, no history of spine surgery, and age range between 30-60 years. The exclusion criteria included pain in other segments of the body, lower and upper limb deformity, history of spine surgery, use of painkillers in the past 6 months, physical therapy in the past year, participation in sports, sciatica pain, spondylolysis, neuromuscular disorders, neurological, respiratory, muscle spasm, and vertebral fracture.

Randomization and blinding

Random allocation software, version 1.0 was used for randomization. Random codes were generated in blocks 4 and 6. We used sequentially numbered sealed envelopes to conceal allocation. A researcher who was not involved in data collection opened the sealed envelopes with consecutive numbers and delivered them to the patients. As a result, patients were randomly assigned to experimental (n=20) and control (n=20) groups. Patients were not aware of group allocation. In addition, to maintain blinding, patients were instructed not to disclose information about the group allocation to the evaluators.

Intervention

Experimental intervention: Cognitive-functional therapy (CFT)

This protocol has three main components that were chosen based on the study of O'Keefe et al. [18]. The first CFT session was approximately 60 minutes, and the 8-week individual follow-up was approximately based on individual characteristics from 30 to 45 minutes and for 18 sessions. The intervention was performed by another physiotherapist trained in CFT treatment. In this protocol, a physical therapist with more than 5 years of experience conducted an interview and physical examination of the patients to determine their unique training programs, considering modifiable cognitive, biopsychosocial, functional, and lifestyle behavior factors.

The three components include the following:

1. The cognitive component focuses on identifying what makes pain worse during the examination. This includes a discussion of the multidimensional nature of persistent pain and individual beliefs, and how emotions

and behaviors (movement and lifestyle) can reinforce the vicious cycle of pain and disability.

2. Specific exercises are designed to improve movements and posture. To perform these exercises, we ensure that the patient feels safe by being exposed to activities that are painful, feared, or avoided. This component is called exposure with 'control'.

3. Integrating functional exercises with activities of daily living such as bending and sitting. This phase varies between individuals but should integrate new behaviors with the goal of gradual exposure to activities in daily life, reducing fear as necessary. This component is called lifestyle change.

All participants underwent a comprehensive interview and physical examination by their therapist to identify any relevant multidimensional factors considered to be key drivers of their pain and disability [18]. Treatment with CFT will be individualized. The therapist listens to the person's story of pain and designs the therapy based on their needs. The first session involves discussing the pain and starting the treatment. The therapist asks questions and examines the person's body to understand what may be causing the pain [18, 23, 24].

Physical examination includes examination of pain responses, analysis of functional behavior through observation, ability to change behaviors, and ability to control pain related to functional goals. The subjects' activity levels, such as their ability to relax the trunk muscles and normalize the posture and provocative movement behavior, will also be evaluated [18, 19, 24]. Where an ineffective behavior is observed, an alternative movement strategy is implemented. This component of the treatment is called exposure with control [16]. Safe exercises with low frequency are gradually developed and turned into functional exercises with more and more complex frequency. For example, if a participant is initially unable to relax her body muscles at first, diaphragmatic breathing exercises in relaxed positions, such as lying down, sitting, and standing were recommended. If the participant could perform this stage, she would enter the next stage, where more challenging tasks were performed from the point of view of mind, relaxation, and control.

During the treatment, the therapist might ask the person to do certain exercises at home, either by watching videos or reading instructions. With practice, the person learns new ways to move and do things without causing pain.

As the therapy progresses, the person learns how to use these new techniques in their daily life. They gradually do activities they used to avoid due to fear of pain. The goal is to make them stronger and less afraid of pain.

Outcome measures

Pain

Pain was assessed with a 10 cm visual analog scale. The patient was asked to indicate the pain intensity during daily activities [25].

Disability

Oswestry disability index was used to disability evaluate (intraclass correlation coefficient [ICC]=0.84) [26]. Disability is classified in four subcategories including, a score of less than 25 as the lowest level of disability, 25-50 as moderate disability, 50-75 as severe disability, and 75-100 as acute disability [27].

Tampa scale for kinesiophobia (TSK) questionnaire

In this study, the fear of movement was assessed using the Tampa scale for kinesiophobia (TSK) questionnaire in the pre-test and post-test. The questionnaire consists of 11 statements, and participants are asked to complete each statement based on their actual results. The purpose of this questionnaire is to evaluate the fear of movement from different dimensions, such as fear of injury and avoidance of activity. The scoring spectrum is based on a four-option Likert scale, where "completely disagree" scores 1 and "completely agree" scores 4. The validity of this questionnaire has been confirmed in a study by Rahmati et al. To calculate its reliability, Cronbach's α coefficient was used, and a Cronbach's α of 0.82 was obtained for this questionnaire [28].

Statistical analysis

We used SPSS software, version 26 for statistical analysis. Shapiro-Wilk test was used to ensure the normal distribution of data. The equality of error variances was checked using Levene's test. Two-way repeated measures analysis of variance (ANOVA) was used to analyze the effect of the intervention on bio-psychosocial indices (pain, disability, and Kinesiophobia variables). Partial eta squared effect size was assessed for two-way ANOVA (group×time interaction). A significance level of $P<0.05$ was considered. A covariance test was used for between-group comparison.

Results

Table 1 presents the demographic characteristics of the groups. The results of the Shapiro-Wilk test showed no statistically significant difference between the groups for demographic characteristics. Table 2 presents the results of the two-way repeated measures ANOVA test. Two-way repeated measures ANOVA results showed that CFT intervention had a significant difference with high effect size in reducing pain (P=0.000, η^2=0.787), disability (P=0.000, η^2=0.457), and Kinesiophobia (P=0.000, η^2=0.561). In Table 3, descriptive statistics showed that the experimental group had a 52% decrease in pain, 41% decrease in disability, and 12% decrease in Kinesiophobia.

Discussion

This clinical trial was conducted to evaluate the effectiveness of CFT intervention on pain, disability, and Kinesiophobia in patients with CNSLBP. The results of the research showed that CFT intervention has a significant effect in reducing pain, disability, and Kinesiophobia. Considering the

Table 1. Demographic characteristics of the participants in the study (n=30)

Variables	Groups	Mean±SD	P
Age (y)	Experimental	53.53±4.71	0.083
	Control	48.26±5.00	
Height (cm)	Experimental	161.06±4.84	0.114
	Control	166.86±4.20	
Weight (kg)	Experimental	67.58±5.36	0.929
	Control	68.08±7.67	
BMI (kg/m^2)	Experimental	26.09±2.30	0.949
	Control	24.46±2.51	

BMI: Body mass index.

PHYSICAL TREATMENTS

Table 2. Two-way repeated measures ANOVA test for bio-psychosocial indices (pain index, disability index, kinesiophobia)

Variables	Source	F	df	Men Squares	Sum of Squares	Power	Partial Eta Squared	P
Pain	Time×group	103.689	1	58.017	58.017	1.000	0.787	0.000*
Disability	Time×group	23.549	1	1242.150	1242.150	0.997	0.457	0.000*
Kinesiophobia	Time×group	35.795	1	93.750	93.750	1.000	0.561	0.000*

*Significant difference between groups (P<0.05)

PHYSICAL TREATMENTS

Table 3. Descriptive statistics

Variables	Group	Mean±SD		95% CI (Post-test)		Δ (%)
		Pre	Post	Lower	Upper	
Pain	Experimental	6.80±1.69	3.26±1.84	2.44	4.08	-52
	Control	6.13±2.23	6.53±2.29	5.26	7.80	6.52
Disability	Experimental	48.46±10.34	28.53±9.17	23.44	33.61	-41
	Control	42.53±11.35	40.80±11.77	34.28	47.31	-4
Kinesiophobia	Experimental	29.20±0.77	25.53±1.06	24.94	26.12	-12
	Control	36.60±4.03	37.93±4.21	35.59	40.26	3.6

PHYSICAL TREATMENTS

close relationship between the variables of pain intensity, disability, and Kinesiophobia index and the overlap of these variables, an attempt was made to interpret the mechanism of CFT on these variables together.

O'Sullivan's pain provocation classification system for LBP distinguishes between central and peripheral pain provocation. Central pain provocation is linked to psychological factors, such as fear of movement and depression, affecting around 30% of the LBP population. On the other hand, peripheral pain provocation stems from mechanical causes, movement impairments, and motor control issues, affecting approximately 30% of individuals with LBP [29]. Therefore, not only does the degree of injury have a role in shaping the level of functional limitation, and disability caused by chronic musculoskeletal pain, but people's cognitions, beliefs, and thoughts also have a major impact on the disability caused by pain, therefore, functional cognitive exercises are effective on cognitive factors, and in this way, it can cause a decrease in kensiophobia and, as a result, a decrease in pain and disability in a person [30].

CFT has been used as a new method to improve the cognitive factors of people suffering from chronic low back pain, and the results have shown that these exercises have a positive and meaningful effect on cognitive factors [23]. One of the key factors in functional cognitive exercises is matching the characteristics of each person with the exercise that is specifically given to him. In CFT, the functional behavioral approach is targeted, such as a person's awareness of her body, relaxation of contracted muscles, normalization of the wrong movement pattern, and reconstruction of a person's mental image of her body [31].

The results of this study are consistent with those of Caneiro et al. [23], O'Keefe et al. [18], and Vibe Fersum et al. [19], all of which investigated the impact of CFT on individuals with CLBP.

In a case report by Caneiro et al., they examined changes related to kinesiophobia and disability through the implementation of functional cognitive exercises. The results demonstrated positive alterations in both kinesiophobia and disability variables. Remarkably, individuals undergoing these exercises exhibited a shift in their attitude toward pain perception and pain control within a span of six to 18 months [23]. These outcomes suggest that CFT can potentially facilitate the performance of painful and physically challenging activities, reduce central nervous system sensitivity, enhance self-confidence, and ultimately lead to a reduction in kinesiophobia, accompanied by decreased pain and disability.

Additionally, O'Keeffe et al. conducted research comparing the effects of cognitive-functional exercises and combined exercises on individuals with non-specific chronic back pain. The results showed a reduction of pain and improvement of functional disability in people with LBP [18]. Therefore, functional cognitive exercises lead to the improvement of pain and disability by changing a person's attitude towards pain, pain control, and a person's efficiency in daily activities [32].

In a RCT conducted by Vibe Fersum et al. involving individuals with chronic low back pain, it was observed that CFT yielded superior results in alleviating pain and reducing disability when compared to manual therapy [19]. CFT plays a crucial role in helping patients mitigate autonomic processes, such as an excessive focus on pain (e.g. kinesiophobia) and avoidance behaviors. By fostering more adaptive and healthier responses, CFT transforms the way patients engage with painful stimuli or pain-related sensations, promoting proactive responses to pain and minimizing unnecessary mental turmoil. The reduction of these processes among patients contributes to a diminished fear of movement, increased physical performance, and an overall enhancement in disability management [33].

The goal of this approach is to reconceptualize pain from a psycho-social perspective, while eliminating unhelpful beliefs, and adopting a healthy lifestyle [18].

Conclusion

By reducing fear of movement, CFT reduces pain and disability and strengthens positive beliefs. Therefore, it is suggested to use functional cognitive exercises as a complementary method in improving people with non-specific chronic back pain.

In this study, we had two limitations. First, our sample was only women. Second, no conditions were observed to evaluate long-term results. Therefore, it is recommended that researchers evaluate CFT interventions in both genders of patients with non-specific chronic low back pain and assess the long-term effects.

Ethical Considerations

Compliance with ethical guidelines

This study has been approved by the Ethics Committee of Bu-Ali Sina University (Code: IR.BASU.REC.1401.026) and the Clinical Trials System of Iran IRCT (Code: IRCT20230430058033N1). Patients provided their informed consent before any collection and the Helsinki declaration of 2008 was followed.

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Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflict of interest.

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