

## Effectiveness of Non-Pain-Contingent Spine Rehabilitation in Females with Chronic Low Back Pain: A Randomized Controlled Trial

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### Abstract

**Background:** Evidence suggests that intensive rehabilitation programs (>100 hours) are effective in treating chronic low back pain (CLBP). However, less intensive, effective interventions are needed. Non-pain-contingent spine rehabilitation (NCSR) incorporating lifting training has been suggested, but its efficacy remains questionable.

**Objective:** This study aimed to evaluate the effectiveness of NCSR, based on cognitive-behavioral therapy and lifting training, in decreasing pain and functional disability and in improving physical performance in females with CLBP.

**Methods:** Fifty-four females with CLBP were randomized to receive either NCSR (n=28) or conventional physiotherapy (CPT) (n=26). Both groups received treatment twice a week for 6 weeks. Primary outcome measures were the visual analogue scale for pain and the Oswestry Disability Index. Secondary outcome measures included the range of motion for trunk flexion and extension, straight leg raising, Ito and Shirado tests, and progressive isoinertial lifting evaluation. Outcomes were assessed at baseline, week 4, and at discharge.

**Results:** Both groups had a significant improvement in pain, functional disability measures, and all physical measures, but clinically relevant improvement was achieved only in the NCSR group. The NCSR group also showed a significantly greater improvement in trunk muscle endurance and lifting capacity scores.

**Conclusion:** Patterns of improvement suggest that the NCSR approach is more effective than CPT in this subgroup of patients.

**Keywords:** Low back pain; Cognitive-behavioral therapy; Disability; Rehabilitation; Exercise; Non-pain contingent; Lifting training

### Introduction

Low back pain (LBP) is a substantial health problem [1,2] because of its high prevalence [3,4] and high recurrence rate [5]. Once LBP becomes chronic, it can have a profound effect on an individual's life, leading to disability and considerable socioeconomic costs [1,2,6]. Chronic low back pain (CLBP) is usually defined as pain lasting three months or more [7].

CLBP patients usually experience pain during activity [8,9]. Such pain results in fear of movement, especially lifting, leading to avoidance behavior and subsequent disability [10,11]. Unfortunately, that behavior may be reinforced by physiotherapists who fear that pain during activity may indicate harm to their patients [12-14].

Functional restoration biopsychosocial rehabilitation programs were introduced in the late 1980s [15-19]. These programs have evolved over the years to address the fear-avoidance behavior of CLBP patients by including cognitive-behavioral components [20-22], which provide positive short- and long-term effects on pain and functional disability [23-25] and are cost-effective [26]. However, the evidence behind the effectiveness of adding cognitive-behavioral treatments to exercise rehabilitation programs is still inconclusive [27,28].

Moreover, effective multidisciplinary rehabilitation programs have been found to be intensive and time-consuming (>100 hours of rehabilitation) [29]. Therefore, less intensive, effective rehabilitation programs are needed. We hypothesized that a less intensive, non-pain-contingent spine rehabilitation (NCSR) program based on cognitive-behavioral therapy (CBT) could target fear-avoidance behavior through lifting training, thereby restoring normal function. Nevertheless, there is a paucity of data on the effectiveness of this behavioral approach in CLBP patients compared to conventional physiotherapy (CPT). This study aimed to evaluate the effectiveness of the NCSR approach based on CBT in decreasing pain and functional disability and improving physical capacity measures in females with CLBP.

### Methods

A two-arm, parallel-group, prospective, randomized controlled trial design was used with concealed allocation and assessor blinding. Ethical approval for the study was obtained from the King Saud University Research Ethics Committee and King Khaled University Hospital (KKHU) Institutional Review Board. Concealed randomization was performed using a computer-generated table of random numbers, operated by an assistant who was not involved in the measurement. Participants were randomly assigned to either the NCSR or CPT group. Outcomes were measured at baseline, week 4,

and week 6 for all of the participants in both groups by the principal investigator, who was blinded to the group allocation.

## Participants

Seventy females with CLBP were consecutively recruited from a pool of patients referred to the physiotherapy department at KKHU in Riyadh over a period of 6 months. Clinical diagnosis, physician referral, and a signed informed consent form were mandatory for inclusion. The inclusion criteria were: between 20 and 50 years of age, LBP > 3 months, and the ability to visit KKHU twice a week for 6 consecutive weeks. The exclusion criteria were: previous spinal surgery or compression fracture; structural abnormalities in the lumbar spine resulting in serious neurological dysfunction, such as spondyloarthropathy, stage III–IV lumbar disc herniation, and grade III–IV spondylolisthesis; cauda equina and conus medullaris syndromes; severe musculoskeletal conditions, such as severe inflammatory arthritis and severe osteoporosis; cancer; morbid obesity; pregnancy; progressive neurological disease; any medical condition that precluded safe participation in an exercise program; psychiatric disease and cognitive limitations that could affect the ability to complete the study questionnaire. Patient medical information and history needed for exclusion were extracted from medical records.

## Trial interventions

### *Non-pain-contingent spine rehabilitation (NCSR)*

The NCSR program used in this study was adapted from the Quota-based Spine Rehabilitation Program, which follows the biopsychosocial model described earlier [30–32]. It aimed to decrease fear-avoidance behavior, improve flexibility, and strengthen the trunk muscles by improving their endurance and lifting capacity [33,34].

The NCSR program was performed in 90-minute sessions in a group of up to 6 participants under the supervision of two experienced physiotherapists. The NCSR program used non-pain-contingent exercises, which required preliminary CBT for the patients. At the beginning of the program, the physiotherapists educated patients on the types of pain they might experience during an activity. The participants were advised to stop exercising in the presence of sudden acute pain; they were encouraged to return to their previous daily activities and reassured of the safety of exercising in the presence of tolerable chronic pain by disregarding it and focusing on functional improvements [35].

Therapy sessions included flexibility exercises (active stretching of major muscle groups in the back and lower extremities). Strengthening exercises included isometric core strengthening exercises (bird dog, bridging, and side bridge) and dynamic strengthening exercises for the trunk muscles (abdominal curls, lat pull-down, and prone back extension using an exercise bench) [36,37]. Lifting training utilized crates with sandbag weights. The crates were lifted via the 'stoop' method from the floor to a waist-high shelf and then to a shoulder-high shelf [38,39]. One set of 10 repetitions was performed for each exercise; throughout the course of treatment, participants increased the amount lifted. Finally, endurance training was performed for 10 minutes using an exercise bicycle or a treadmill.

Operant and graded exercise principles were utilized to reinforce healthy behaviors [40]. Physiotherapists reevaluated the physical

outcomes weekly to guide treatment progression through a quota-based method and used verbal encouragement to reinforce the successful increase in exercise level [30,32].

### *Conventional physiotherapy (CPT)*

Participants in the control group had individualized 30-minute treatment sessions that included a routine physiotherapy protocol for LBP: thermotherapy (hot packs on the low back region), flexibility exercises (active stretching of the major back muscles and hamstrings), and light strengthening exercises (pelvic rocking, bridging, bird dog, and abdominal curls). All of the exercises were performed in one set of 10 repetitions until the limit of pain, and not beyond.

## Treatment frequency

For both groups, treatment sessions were scheduled twice a week, with a targeted treatment time of six weeks. Overall, the projected number of sessions was 13 (one for the initial evaluation and 12 for the treatment). The participants were called if they missed a session to determine the reason for their absence and encourage compliance.

## Outcome measures

Baseline information (age, body mass index, marital and employment status, LBP characteristics and diagnosis) was obtained from all participants. The primary outcomes were pain intensity and functional disability. LBP intensity was measured with a 10 cm visual analog scale (VAS) in which a higher score is indicative of more pain [41]. Back-related functional disability was measured by the Oswestry Disability Index (ODI, version 2.0) [42]. The ODI has 10 items, scored from 0 to 100, and is interpreted as a disability percentage with a higher score representing a higher level of disability. The ODI has been validated in Arabic [43]. The secondary outcomes were physical capacity measures: flexibility of the hamstring and trunk muscles, assessed by the range of motion (ROM) in trunk flexion, trunk extension, and straight leg raising (SLR) using a single inclinometer [44]; isometric endurance of the trunk extensor and flexor muscles, assessed by the Ito and Shirado tests, respectively [45]; and lifting capacity, assessed using the Progressive Isoinertial Lifting Evaluation (PILE) [46].

## Sample size

A priori sample size was estimated based on the primary outcome measures. A minimal clinically significant difference of 1.2 cm on the VAS was utilized to determine a meaningful difference between the group mean changes from baseline to the 6-week follow-up [47]. Based on previous data among CLBP patients, a within-group standard deviation of 2 cm on the VAS was assumed [32]. Taking these factors into consideration and using a specification of  $\alpha=0.05$  and  $\text{power}=0.80$ , a sample size of 22 participants per group was required to detect a 1.2 cm difference in the pain score using a two-tailed test and 5% significance level. In the current study, a 15% attrition from each group was allowed. Therefore, a sample size of 26 participants per group was recommended.

## Statistical analysis

Data were analyzed using the statistical software program SPSS version 19.0 for Windows. Summary statistics, including means and standard deviations, were generated for all outcomes. Baseline characteristic comparisons between the groups were computed by the

independent-sample t-test for parametric data and the Mann-Whitney U-test for nonparametric data. Within each group, the outcome measurement score differences among baseline, week 4, and week 6 (post-treatment) were examined using a general linear model and repeated measures ANOVA, with time as the within-subject factor. Pairwise comparisons with Bonferroni adjustment were used to highlight outcome differences between baseline and week 4, baseline and week 6, and weeks 4 and 6. All analyses used the intention-to-treat principle. Mean post-treatment improvements in all of the outcomes were compared between the groups using the independent-samples t-test. For all of the analyses,  $P \leq 0.05$  was considered to be statistically significant.

## Results

During the 6-month recruitment period, 70 females with CLBP were referred to physiotherapy, out of which 54 met the inclusion criteria and underwent the initial evaluation: 28 were randomized to the NCSR group and 26 to the CPT group. Figure 1 illustrates the flow of participants through the study [48]. Four participants withdrew after the initial physiotherapy evaluation and did not participate in any actual treatment session (two from the NCSR group and two from the CPT group). Three participants (11.5%) in the NCSR group discontinued the program. No participant was lost to follow-up in the NCSR group, whereas one participant (4.2%) in the CPT group was lost. Forty-six participants complied with all of the recommended treatments; of those, 23 were in the NCSR group (88.5%) and 23 were in the CPT group (95.8%). Compliance in both groups was greater than 85% for all follow-up time points, falling within the allowed 15% attrition specified for the study.

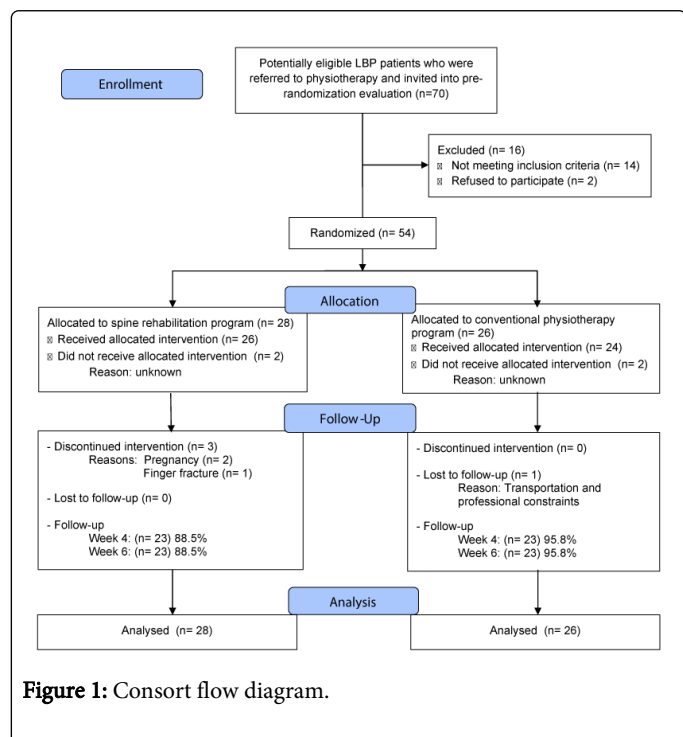


Figure 1: Consort flow diagram.

The baseline characteristics of the 54 participants are shown in Table 1. Both groups were homogeneous for all of the characteristics, except age. The mean age in the NCSR group was lower compared to the CPT group, but the age ranges were similar.

Treatment Groups	NCSR n=28	CPT n=26	P
<b>Anthropometrics and Demographics</b>			
Age (yr)	30.2 ± 7.9 (22-49)	35.2 ± 8.5 (21-49)	0.030*
Height (cm)	157.4 ± 6 (140-169)	158.7 ± 6.3 (145-170)	0.480
Weight (kg)	65.5 ± 13.1 (42.1-94)	69.5 ± 15.9 (37.7-91.5)	0.334
BMI (kg/m <sup>2</sup> )	26.4 ± 5 (18.5-36.9)	27.6 ± 6.2 (15.4-37.4)	0.451
<b>Marital status (%)</b>			
Married	42.9%	57.7%	0.320
Divorced	7.1%	3.8%	
Single	50%	38.5%	
<b>Employment status (%)</b>			
Employed	60.7%	50%	0.433
Unemployed	39.3%	50%	
<b>LBP characteristic</b>			
Duration of LBP symptoms (yrs)	5.2 ± 3.9	5.9 ± 5.7	0.609
VAS (0-10 cm)	5 ± 1.3	4.7 ± 1.9	0.426
ODI (0-100%)	23.1 ± 10.5	27.8 ± 8.7	0.081
<b>Diagnosis (%)</b>			
Lumber degeneration	3.8%	11.5%	0.574
Mild-moderate spinal deviations	15.4%	7.7%	
Spondylolysis/ Grade I spondylolisthesis	3.9%	7.7%	
Grade I lumbar Disc herniation	15.4%	19.2%	
non-specific LBP	61.5%	53.9%	
*P is significant at the <0.05 level (2-tailed).			
Abbreviations: BMI: Body Mass Index; CPT: Conventional Physiotherapy; NCSR: Non-pain-contingent Spine Rehabilitation; ODI: Oswestry Disability Index; SD: Standard Deviation; VAS: Visual Analogue Scale.			

Table 1: Baseline characteristics of the participants by treatment group presented as the mean ± SD (range) for continuous variables and as a percentage for categorical variables.

The pre- and post-treatment scores for VAS, ODI, and the physical performance measures are shown in Table 2. In both groups, the repeated measures ANOVA showed a significant improvement over time for all of the outcomes ( $P < 0.01$ ), and pairwise comparisons revealed significant differences in all of the outcome scores between baseline and week 6 (Table 2). Between baseline and week 4, significant differences were found in all of the outcomes only in the NCSR group. Four weeks post-treatment, the maximal attainment of pain reduction was only achieved in the NCSR group, whereas the greatest improvement in flexibility outcomes was found in the CPT group. Further improvement in the ODI scores after week 4 was found

in the NCSR group; the change in the ODI appeared to plateau in the CPT group.

	Mean ± SD			P	P (pairwise comparisons)		
	BL	wk 4	wk 6		BL - wk4	BL - wk6	wk4 -wk6
<b>VAS (0-10 cm)</b>							
NCSR group	5 ± 1.3	1.5 ± 1.7	0.7 ± 1.2	0.00**	0.00**	0.00**	0.061
CPT group	4.7 ± 1.9	4.1 ± 1.5	3 ± 1.9	0.001**	0.565	0.013*	0.007**
<b>ODI (0-100%)</b>							
NCSR group	23.1 ± 10.5	13.8 ± 8.6	10.5 ± 7.6	0.00**	0.00**	0.00**	0.002**
CPT group	27.8 ± 8.7	23.7 ± 10.5	20.5 ± 12	0.00**	0.009*	0.00**	0.216
<b>RSLR (°)</b>							
NCSR group	71.4 ± 15	79.9 ± 14.7	81.4 ± 11.9	0.00**	0.002**	0.005**	1.00
CPT group	64 ± 19.6	74 ± 16.5	78.9 ± 16	0.00**	0.011*	0.001**	0.665
<b>LSLR (°)</b>							
NCSR group	72.8 ± 17.4	79.8 ± 14	83.1 ± 12.9	0.00**	0.006**	0.004**	0.006**
CPT group	64.6 ± 17.8	75.1 ± 17.4	80.6 ± 16.9	0.00**	0.005**	0.00**	0.420
<b>Trunk flexion (°)</b>							
NCSR group	105.7 ± 18.4	113.4 ± 14.4	118.5 ± 12.5	0.00**	0.003**	0.002**	0.012*
CPT group	103.7 ± 20.2	110.6 ± 18.2	115.2 ± 16.2	0.00**	0.004**	0.00**	0.790
<b>Trunk extension (°)</b>							
NCSR group	30.9 ± 11.9	36.8 ± 11.1	42.9 ± 13	0.00**	0.018*	0.001**	0.006**
CPT group	28.9 ± 9.8	34.3 ± 14.1	36.7 ± 15.1	0.00**	0.077	0.001**	0.020*
<b>Ito test (s)</b>							
NCSR group	68.1 ± 50.4	96.3 ± 69.8	120 ± 73.2	0.00**	0.002**	0.00**	0.002**
CPT group	39 ± 37.6	47.6 ± 36.4	62.1 ± 48	0.003**	0.178	0.035*	0.015*
<b>Shirado test (s)</b>							
NCSR group	21.9 ± 14.9	38.9 ± 25.3	54.7 ± 30.2	0.00**	0.00**	0.00**	0.00**
CPT group	19 ± 15.8	26.8 ± 21.7	33.6 ± 24.6	0.00**	0.007**	0.002**	0.019*
<b>PILE (kg)</b>							
NCSR group	4.2 ± 1.8	7.9 ± 2.4	9.8 ± 2.3	0.00**	0.00**	0.00**	0.00**
CPT group	4.2 ± 2.2	5.4 ± 2.7	6.9 ± 3.7	0.00**	0.020*	0.001**	0.004**

Abbreviations: BL: Baseline; CPT: Conventional Physiotherapy; LSLR: Left Straight Leg Raising; NCSR: Non-pain-Contingent Spine Rehabilitation; ODI: Oswestry Disability Index; PILE: Progressive Isoinertial Lifting Evaluation; RSLR: Right Straight Leg Raising; SD: Standard Deviation; VAS: Visual Analogue Scale; wk: Week.

\*P is significant at the <0.05 level (2-tailed).

\*\*P is significant at the <0.01 level (2-tailed).

**Table 2:** Within-group comparison between baseline, week 4, and week 6 measurements in the spine rehabilitation and conventional physiotherapy groups.

Table 3 shows the mean improvement in the outcome measures after six weeks of intervention in both groups. Participants in the NCSR group scored significantly lower on the VAS than the CPT group ( $P=0.00$ ), whereas no significant difference in the ODI score was found. The mean improvement in the VAS and ODI scores reached the minimal clinically important change (MCIC) (i.e., the smallest

effective change within the group) only in the NCSR group ( $MCIC_{VAS}=4.4$  cm,  $MCIC_{ODI}=12.1$  points). Participants in the NCSR group also showed significantly greater improvement in all secondary outcomes compared to the CPT group, except for the flexibility scores.

The majority of patients completed all 13 required sessions. There was no significant difference ( $P=0.841$ ) between the mean total

sessions in the NCSR group (mean, 12.3 ± 1.5) compared to the CPT group (mean, 12.1 ± 1.3).

Treatment Groups	Mean change in scores		Adjusted Mean Difference (95% CI)	P
	NCSR	CPT		
VAS (0-10 cm)	-4.4†	-1.7	-2.7 (-3.9 to -1.5)	0.000**
ODI (0-100%)	-12.1†	-7.4	-4.7 (-9.6 to 2.4)	0.062
RSLR (°)	10.5	14.5	-4 (-12.7 to 4.8)	0.368
LSLR (°)	10.4	15.5	-5.1 (-13.4 to 3.1)	0.218
Trunk Flexion (°)	13.2	11.8	1.4 (-6.1 to 8.9)	0.709
Trunk extension (°)	10.6	8.2	2.4 (-3.3 to 8.2)	0.400
Ito test (s)	49	22.6	26.4 (3.6 to 49.1)	0.024*
Shirado test (s)	32.8	14.6	18.2 (7.3 to 29.1)	0.002**
PILE (kg)	5.5	2.7	2.8 (1.6 to 4.2)	0.000**

\*P is significant at the < 0.05 level (2-tailed).  
 \*\* P is significant at the < 0.01 level (2-tailed).  
 † >MCIC  
 Abbreviations: CPT: Conventional Physiotherapy; LSLR: Left Straight Leg Raising; NCSR: Non-pain-Contingent Spine Rehabilitation; ODI: Oswestry Disability Index; PILE: Progressive Isoinertial Lifting Evaluation; RSLR: Right Straight Leg Raising; SD: Standard Deviation; VAS: Visual Analogue Scale.

**Table 3:** Comparison of the mean improvement in outcomes after 6 weeks of intervention between the spine rehabilitation and conventional physiotherapy groups.

## Discussion

This study was designed to examine the effectiveness of the NCSR approach based on CBT in decreasing pain and functional disability and improving physical capacity in females with CLBP in comparison to CPT. Both treatment programs were effective. However, only patients who completed the NCSR program showed faster pain recovery time and greater improvement in almost all of the physical capacity measures. The duration of both programs in this trial was 6 weeks [31,49]. Interestingly, after one month of treatment, further reduction of functional disability was only found in the NCSR group, which is in line with the findings of recent studies [49,50]. Ostelo and de Vet [51] suggested that to demonstrate a meaningful improvement in pain and functional disability in CLBP patients, the MCIC should show a change of at least 2 cm in the VAS and 10 points in the ODI. In this study, the mean improvement for pain and disability was clinically relevant only in the NCSR group, which supports the results of a recent study [25].

Since the late 1990s, studies indicating the importance of adding CBT to the spine rehabilitation programs for the treatment of CLBP have emerged [24,25,31,32,50,52]. Our physiotherapists addressed fear-avoidance behavior and pain beliefs during the program, especially during the stressful lifting training, utilizing combined operant and cognitive behavioral principals. The NCSR program uses motivational strategies to encourage patients to work within pain limits and return to normal activities they avoided because of LBP. Aerobic exercises were only provided to the NCSR group. However, adding aerobic exercise to CPT has been reported not to lead to further improvement in pain and disability beyond that achieved with CPT alone [53]. On the other hand, adding a motivational component

to a CPT program was found to reduce pain and fear-avoidance behavior and increase lifting capacity in CLBP patients [54,55]. We argue that the functional and motivational strategies add value to the NCSR program as compared to CPT. We support the view that NCSR programs based on CBT are more beneficial than other physiotherapy LBP programs [24,32,50,55]. Our study contradicts Skouen et al.'s [56] finding that, in women, there is no significant difference between a spine rehabilitation program and the usual treatment. This may be explained by the dissimilarity in the content of the rehabilitation programs; the former study did not contain functional exercises, such as lifting. Our study also contradicts Kääpä et al.'s [57] finding that there is no difference between spine rehabilitation based on CBT for females with CLBP and individual physiotherapy. In the previous study, the physiotherapists who performed the individual physiotherapy had a cognitive-behavioral way of administering the treatment due to their previous work experience, whereas physiotherapists who performed the CPT in our study did not.

The treatment frequency remains a source of debate in the literature. In the present study, NCSR occurred twice a week, totaling approximately 18 hours of therapy. Reviewing five trials of less intensive spine rehabilitation programs, a rehabilitation program performed once or twice weekly with less than 30 hours of therapy was considered to be less intensive and no better than primary medical care [58]. Our study contradicts the previous trials. Adding CBT components to the less intensive spine rehabilitation program may positively influenced the speed of pain recovery and function in CLBP patients, which is consistent with recent trials [23,49,50].

Currently, choosing among the numerous treatment options for CLBP is challenging for clinicians and patients. The findings presented

here may help clinicians select the best approach for each patient, thereby minimizing the cost and time of treatment. This study has some limitations that should be considered when interpreting the findings. First, the gender of the participants in this study limits its generalizability. It has been recommended that men and women should be analyzed separately in trials concerning pain treatment because of the differences between the genders regarding pain perception and response to treatment [59-61]. Moreover, the generalizability of this study is limited to young and middle-aged women. Further studies to evaluate the effectiveness of NCSR in males and older females are recommended. Another limitation was the variability in the treatment session duration between groups. This was imposed due to the nature of the control therapy, which was built around the conventional one-to-one physiotherapist-led intervention. The NCSR program includes up to six patients per session under the supervision of two physiotherapists. Hence, the shorter duration effect was washed out by the individualized attention the patients received in the control group. Finally, our study only revealed the short-term effectiveness of the programs. The long-term effects of both treatment programs in patients with CLBP deserve further investigation.

## Conclusion

The NCSR approach appears to be more effective in the short-term than CPT for treating females with CLBP, as demonstrated by the faster pain recovery time, greater reduction in disability outcomes, and greater improvement in almost all of the physical measures. Implementing well-designed biopsychosocial programs for CLBP that incorporate cognitive-behavioral functional components is recommended.

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