

ORIGINAL ARTICLE

Efficacy of a Short-Term Low-Calorie Diet in Overweight and Obese Patients with Chronic Sciatica: A Randomized Controlled Trial

AU2 ▶ AU1 ▶ Mir Bahram Safari,¹ Aisan Nozad,² Farzaneh Ghaffari,³ Saeid Ghavamzadeh,⁴ Fatemeh Alijaniha,⁵ and Mohsen Naseri⁵

AU3 ▶ Abstract

Objectives: Chronic sciatica is a common condition. According to Traditional Persian Medicine and recent studies, calorie reduction is thought to be helpful for this condition. The purpose of this work is to evaluate a short-term low-calorie diet (LCD) for ameliorating chronic sciatica in the context of pain relief and reduced disability for patients.

Design: In this randomized controlled trial, 96 candidates for the nonsurgical treatment of chronic sciatica were randomly assigned to two groups to receive a 1-month LCD (intervention) or ordinary diet (control), both in combination with NSAIDs. Afterward, patients were visited at baseline and on days 15, 30, and 60 after treatment. Pain and disability were evaluated using the short-form McGill pain questionnaire (SFMPQ) and the Roland-Morris disability questionnaire (RMDQ), respectively.

Results: Both mean RMDQ scores and SFMPQ scores decreased significantly in the LCD group compared to the control group. SFMPQ descriptor scale scores at baseline and on days 15, 30, and 60 in the LCD group were 7.71 ± 1.69 , 6.63 ± 1.61 , 5.54 ± 1.87 , and 4.96 ± 2.02 , respectively, and in the control group were 6.63 ± 1.44 , 6.69 ± 1.32 , 6.64 ± 1.98 , and 6.62 ± 2.53 , respectively ($p=0.001$). RMDQ scores at baseline and on days 15, 30, and 60 in LCD group were 11.17 ± 3.90 , 8.60 ± 1.97 , 7.50 ± 2.71 , and 6.77 ± 3.06 , respectively, and in the control group, 10.00 ± 2.20 , 9.98 ± 2.29 , 9.94 ± 2.94 , and 9.85 ± 3.32 , respectively ($p<0.001$).

Conclusion: A short-term (1-month) LCD is effective in decreasing pain and disability in candidates for nonsurgical treatment of chronic sciatica.

Keywords: chronic sciatica, low back pain, low-calorie diet, Traditional Persian Medicine

Introduction

SCIATICA IS DEFINED as a radicular pain along the path of the sciatic nerve, which is sometimes accompanied by back pain, sensory loss, weakness, or reflex abnormalities.¹ Chronic sciatica is one of the most common varieties of chronic low back pain (LBP) defined as a pain that persists for 12 weeks or longer even after an initial injury or underlying cause of acute LBP has been treated.² Although sciatica has

several causes, the principal source is explained as compression of a lumbar nerve root by disk material that has ruptured through its surrounding annulus.³ These conditions affect all patients who are not candidates for surgery. Because of variations in the definition of sciatica, studies have reported its prevalence as ranging from 1.2% to 43%.⁴ According to the Global Burden of Disease 2010 Study, LBP ranks first in terms of disability and sixth in terms of overall burden among other conditions. Because the incidence of

¹Department of Orthopaedics, Imam University Hospital, Urmia University of Medical Sciences, Urmia, Iran.

²Department of Traditional Persian Medicine, School of Medicine, Shahed University, Tehran, Iran.

³School of Traditional Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

⁴Department of Nutrition, Faculty of Medicine, Urmia University of Medical Sciences, Urmia, Iran.

⁵Traditional Medicine Clinical Trial Research Center, Shahed University, Tehran, Iran.

chronic LBP, including chronic sciatica, increases with age and considering the global population's aging trend, research to find effective treatments for this condition is important.⁵ There is evidence for the effectiveness of discectomy in the short term, but it is reportedly less effective than conservative treatments in the long term. A wide range of techniques commonly used in conservative management of chronic sciatica only provide limited and short-term relief, and their effect on sciatica is difficult to interpret.⁶ Dietary interventions, including calorie restriction, is one conservative treatment for sciatica that has recently been favored.^{7,8}

Although the prognosis is good in many cases, permanent pain and disability are major concerns in patients with chronic sciatica.³ Considering a limited number of clinical guidelines for the treatment of chronic sciatica and regarding the ineffectiveness of most current therapeutic strategies, evaluation of new approaches is of great importance.¹

Persian Traditional Medicine (PTM) is one of the most popular traditional medicine systems. It dates back about 10,000 years,^{9,10} and its potential advantages have been proven through many recent studies in various fields.^{9,11} Nutrition therapy has a long history in ancient Persia, and food reduction is one of the therapeutic methods proposed by Iranian traditional medicine scholars.¹² The effectiveness of the food reduction approach in reducing inflammation has been shown in their previous studies with animal models.¹³

In the case of chronic sciatica, much attention has been paid recently to the neuroprotective effects of dietary interventions such that they may be considered as simple and available conservative treatments.⁵ To the best of their knowledge, no study to date has investigated the effectiveness of low-calorie diet (LCD) or food reduction in patients with chronic sciatica. Inspired by the PTM approach, the current study was designed to investigate the effects of a short-term low-caloric diet in comparison with a normal diet when combined with NSAIDs on pain and disability outcomes in candidates with chronic sciatica.

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Methods

The current randomized, controlled clinical trial was conducted at Imam Hospital in Urmia, West Azerbaijan Province, Iran, from January 2012 to January 2013. The study followed guidelines of the Declaration of Helsinki for human research. Informed consent was obtained from all individual participants included in the study; the study protocol was approved by the Ethics Committee of Shahed University (No. 41/168152). In addition, the trial was registered at the Iranian Registry of Clinical Trials (IRCT2014030316819N1).

Patients

Participants were volunteers with chronic sciatica who referred to the orthopedic clinic of Imam Hospital. Patients were candidates for conservative (nonsurgical) treatment based on the diagnosis of an attending orthopedist. They were assigned into two groups, the LCD group and the control group, using the block randomization method (AB, BA) using Random Allocation Software 1.0.

Inclusion criteria were patients suffering from sciatic pain who were candidates for nonsurgical treatment based on the diagnosis of an attending orthopedist, patients suffering from low back pain lasting for more than 3 months, and

radiculopathy due to bulging or herniated disc (radiculitis pain both below and above the knee(, stable body weight (less than 6 kg weight change throughout the last 6 months before the study), age between 25 and 60 years, body mass index (BMI) of 25–40 kg/m², and normal cognition and verbal communication skills.

Patients with medical conditions such as malignancy, cardiovascular problems, pulmonary diseases, and infections; other causes of sciatica, including lumbar spinal stenosis, piriformis syndrome, and spondylolisthesis; spinal problems other than disc herniation such as kyphosis, scoliosis, spondylolisthesis, and so on; those with a history of previous operation on the spine; and pregnant or lactating women were excluded from the study.

Patient selection was based on clinical examination. Imaging modalities included anteroposterior and lateral lumbosacral views in flexion and extension positions for ruling out other spinal problems such as vertebral instabilities. Patients with prolonged pain also underwent magnetic resonance imaging of the lumbosacral vertebral column for evaluation of disc herniation severity and ruling out other disorders which need surgical intervention. Finally, the clinical findings were matched with imaging findings.

Study design and interventions

Eligible participants were selected by examination under the supervision of an attending orthopedist and a traditional medicine specialist. Their demographic data were assessed and documented on related forms. Allocation to the LCD group was concealed from all study personnel before randomization occurred. In this study, the statistical analyzer received the list of participants first, and then s/he allocated them to either the LCD or the control group; finally, this list was provided to the researcher. Based on their BMI and physical activity, patients in the LCD group were put on an LCD diet containing less than 1200 kcal/day with limitations on carbohydrate, fat, and protein consumption. The diet was designed and administered by an experienced dietitian (Table 1).

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The patients' diet was arranged as a simple 30-day weight-loss meal plan. In this meal plan, the LCD was arranged based upon estimation of the carbohydrate, protein, and fat overall amounts found in nutrient-rich foods. Adherence was ensured every 3 days by telephone call and mobile phone text messaging follow-ups. The patients in the control group followed their routine diet. All patients received a similar dose of an oral nonsteroidal anti-inflammatory drug (Celecoxib 200 mg/day; Razak Company, Iran) during the study period. Comparisons were made between the LCD and ordinary diets in combination with NSAIDs.

Questionnaires

Patients were visited at baseline and on days 15, 30, and 60. Patient weight, pain quality and intensity, and severity of sciatica-related disability were documented at each session. The measuring instruments were the short-form McGill pain questionnaire (SFMPQ) for pain quality and intensity and the Roland-Morris disability questionnaire (RMDQ) for severity of sciatica-related disability. SFMPQ is one of the most widely used tests for measuring pain; it provides valuable information on the sensory, affective, and evaluative

TABLE 1. THE LOW-CALORIC DIET (1200 KCAL) USED IN THE STUDY

Breakfast	Two pieces of toast or equal amount of traditional bread or 1/2 of a medium size boiled potato or 2/3 cup of boiled pasta +2 glasses of milk or two and a half glasses of low-fat yoghurt +1 teaspoon butter or 1 teaspoon creamy cheese or 6 almond or 2 walnut or 2 tablespoon cream or 1 tablespoon jam or 1 cookie + water or tea without sugar as much as you like
Forenoon snack	One piece of toast or equal amount of traditional bread or 1/4 of a medium size boiled potato or 1/3 cup of boiled pasta + water or tea without sugar as much as you like
Afternoon snack	One fruit medium size (apple or orange), 1/2 glass fruit juice, 1/3 cup dried fruits
Dinner	Two pieces of toast or equal amount of traditional bread or 1/2 of a medium size boiled potato or 2/3 cup of boiled pasta +1 teaspoon butter or 1 teaspoon creamy cheese or 6 almond or 2 walnut or 2 tablespoon cream or 1 tablespoon jam or 1 cookie + green leaf vegetable salad without dressing as much as you like +60 g (beef or chicken or fish) or 60 g cheese or 1 glass cooked beans/peas/lentils + water or tea without sugar as much as you like
Lunch	Three pieces of toast or equal amount of traditional bread or 3/4 of a medium size boiled potato or 1 cup of boiled pasta +1/5 teaspoon of butter or 1/5 teaspoon of cream cheese or 9 almond or 2 walnut or 2 tablespoon of cream or 1 tablespoon of jams or 1 cookie +60 g (beef or chicken or fish) or 60 g cheese + water or tea without sugar as much as you like

dimensions of the pain experience. It consists of 15 descriptors (11 sensory; 4 affective) scored from 0 to 3, expressing the pain intensity as none, mild, moderate, and severe, respectively. Three pain scores for sensory, affective, and total descriptors are derived from the sum of the intensity rank values. In addition, the Present Pain Intensity (PPI) index of the standard MPQ and a visual analog scale (VAS) are included in the SFMPQ.¹⁴ For the current study, the total descriptive scale score (0–45) and PPI (0–5) were reported.

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The RMDQ is a questionnaire designed to assess physical disability caused by low back pain in both research and clinical practice. Its score is calculated by adding up the number of items checked and ranges from 0 (no disability) to 24 (maximum disability).¹⁵ Reliable and validated Persian versions of the SFMPQ and RMDQ were used.^{16,17}

The SFMPQ total descriptor and RMDQ scores were considered primary outcomes of sciatica-related pain and disability in the current study. Considering the effects that obesity can have on pain and disability associated with sciatica, weight changes were considered as secondary outcome.

Statistical analysis

Data were analyzed in IBM SPSS Software Version 19. Descriptive and analytic statistics was used. Numeric data were shown as mean and standard deviation (SD), and data on categorical variables were shown as number and percentage. Treatment and control groups were compared using repeated-measures ANCOVA with the baseline value of the outcome as a covariate; groups were compared at each time point. Analysis was further used to evaluate change from baseline within groups across all time points. Normality distributions of numeric variables were assessed with the Kolmogorov–Smirnov test. A p -value less than 0.05 was considered to be significant.

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Sample size consideration. The sample size was calculated using $n = (\sigma_1^2 + \sigma_2^2) \left(\frac{Z_\alpha + Z_\beta}{\mu_1 - \mu_2} \right)^2$, the μ_1 , μ_2 , σ_1^2 , σ_2^2 are estimated using data that came from five sample pilot study with RMDQ. The mean \pm SD RMDQ pain change was -3.9 ± 6.7 and -0.14 ± 1.5 in the LCD group and control group, respectively. In this study, α and β were considered as 5% and 20%, respectively. Because there were

two main outcomes considered in this study, $\alpha=2.5\%$ was placed in the formula shown above. The sample was calculated for a two-tailed test of significance. The level of significance was set at 0.025 for two primary outcomes. Considering a dropout rate of 50%, the total sample size was estimated to be 96 ($n=48$).

$$n = \frac{(44.89 + 2.25)(2.24 + 0.84)^2}{(-3.9 + 0.14)^2} = \frac{47.14 \times 9.48}{14.13} = 31.62 = 32$$

Results

Patients

Ninety-six participants completed the trial. The adherence rate to the diet was 100% (without any layout). All patients in both groups followed the study protocol, and there was no loss of follow-up. The flow diagram is shown in Figure 1. ◀F1

Patients' demographic information and general data are summarized in Table 2. The mean ages of the case and control groups were 39.67 ± 10.66 and 40.21 ± 10.46 years, respectively. There was no significant difference between groups in terms of gender, age, BMI, education, or smoking. ◀T2

Main findings

As shown in Table 3, the changes of the weight through 60 days were statistically significant in LCD group in comparison to control group (p -value <0.001). However, these weight changes do not appear to be clinically significant. Considering the score of the total descriptor scale of SFMPQ, the changes of the scores in both of SFMPQ and RMDQ in LCD group were significantly more than control group (p -value = 0.001 and p -value <0.001 , respectively). In addition, the score change of the PPI index, as well as sensory and affective subscales of SFMPQ in LCD group, was significantly more than control group with p -values as 0.006, 0.015, and 0.002, respectively. For variables such as weight, sensory, and affective subscales, total descriptor scale, and PPI index, the within group differences also were significant in LCD group but not in the placebo group and

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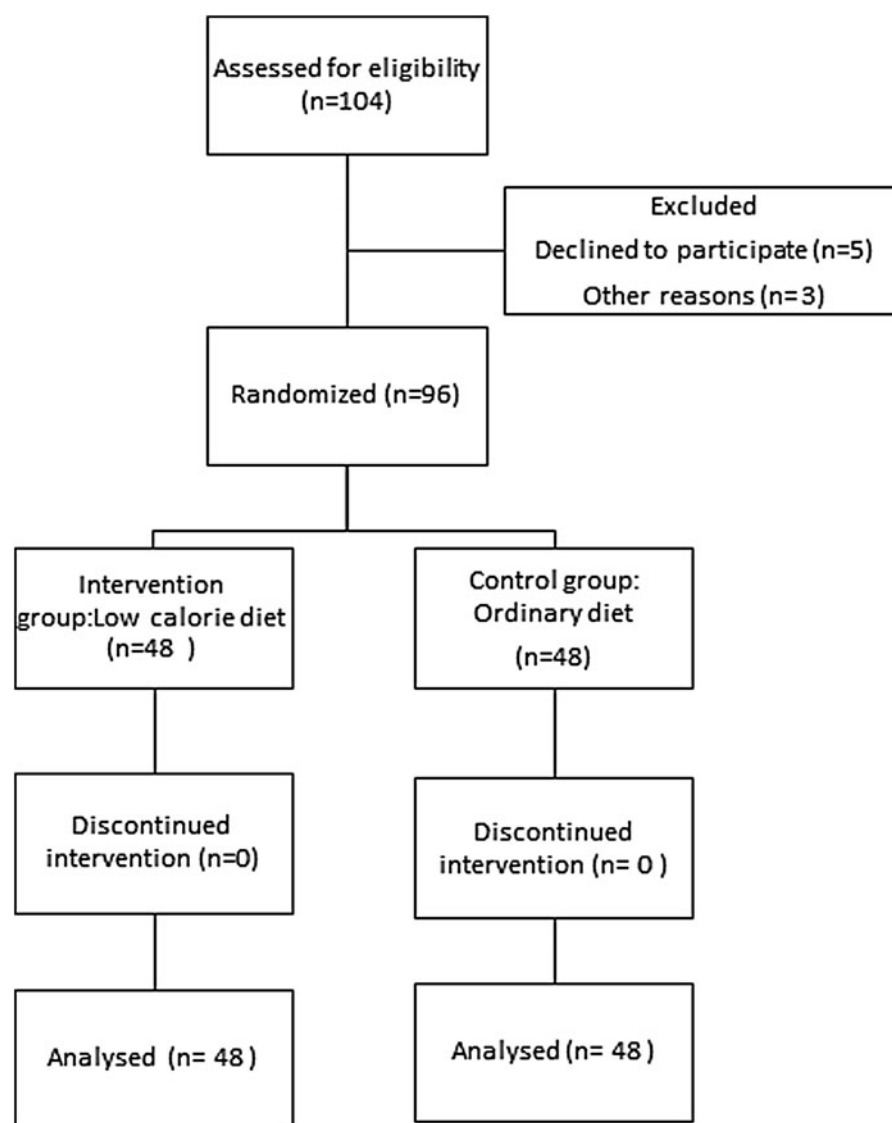


FIG. 1. Flow diagram of study participation.

their p -values were <0.001 , <0.001 , 0.002 , <0.001 , and 0.001 , respectively.

Discussion

Managing chronic sciatica as a common and disabling condition requires special attention. In some cases, it is successfully relieved by treatment, but in other cases, pain and related disability persist despite medical and surgical treatment, imposing a high burden on the health care system.¹⁸ Among various conventional treatments for chronic sciatica, there is no effective diet based on evidence recommended to improve its symptoms. In contrast, the effectiveness of food reduction as a therapeutic method for low back pain and chronic sciatica has been proposed by Persian scholars. Thus, to examine these hypotheses, the current short-term (1 month) LCD (<1200 kcal/day) was tried in a group of patients with chronic sciatica, and the results were compared with a well-matched control group.

The current findings showed that, although the mean 2-month weight variation did not differ as clinically signifi-

cant, the severity of pain and sciatica-associated disability at the same time decreased significantly in the LCD group compared with the control group. Both pain and disability are the most important targets for assessing the efficacy of treatment in patients with sciatica. Accordingly, this short-term LCD might be a useful therapeutic method for these patients, and the beneficial effect of LCD on chronic sciatica could be more than weight reduction.

Peul et al. found that early surgery induced more rapid relief from chronic and subchronic sciatica than conservative care; however, surgical outcomes were similar to those of conservative treatment after 1 year, and these did not change during the second year.¹⁹ A recent study proposed that ketogenic diets might provide a neuroprotective effect for chronic sciatica.⁵ The usefulness of calorie restriction has also been shown for other neurologic diseases such as Parkinson's and cerebral ischemia, and its mediators and molecular mechanisms have been proposed in some studies.^{20,21}

Based on several studies, obesity is one of the important risk factors involved in the pathogenesis of sciatica.²² Moreover, it has been shown that obesity causes chronic

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TABLE 2. DEMOGRAPHIC INFORMATION AND GENERAL DATA OF STUDY POPULATION

Variable	LCD group (n=48)	Control group (n=48)
Sex		
Male	28 (58.3)	27 (56.3)
Female	20 (41.7)	21 (43.8)
Age (year)	39.67 ± 10.66 (26–59)	40.21 ± 10.46 (24–60)
BMI (kg/m ²)	28.43 ± 3.50 (25–37.5)	27.97 ± 2.98 (25–35.10)
Education		
Illiterate	9 (18.8)	8 (16.7)
School	10 (20.8)	13 (27.1)
Diploma	8 (16.7)	9 (18.8)
University	21 (43.8)	18 (37.5)
Smoking	18 (37.5)	17 (35.4)

Data are presented as mean ± SD (min–max) or number (%).

**p*-Value <0.05 is significant.

BMI, body mass index; LCD, low-calorie diet; SD, standard deviation.

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low-grade inflammation by releasing causative mediators from adipose tissue.²³ This inflammation may aggravate pain; thus, reductions in weight and adipose tissue are expected to have a pain relief effect.²⁴ Based on these findings, it was expected that the reduction of pain and disability observed after LCD intervention in the current study was the result of weight loss. Nevertheless, surprisingly, weight changes from baseline to the end of the study were not clinically significant; therefore, there is no relation between weight loss and reductions in pain and disability.

The various advantages of calorie restriction have also been shown for nonobese adults²⁵; therefore, it seems that its effects are not limited to weight loss. This result is consistent with the result of the current study. In contrast with prolonged conservative treatments, it has been shown that even a 2-day calorie restriction is effective,²⁶ which is

in line with the results of the short-term LCD intervention in the current study.

The effect of food reduction on alleviating sciatica may occur through mechanisms that are still unknown. It is proposed that the reduction of inflammation may be one of the mechanisms involved in LCD effectiveness, as it was shown in their previous study with an animal model, the results of which indicated that inflammation was reduced after calorie restriction.¹² Although inflammation is not expected to be a major mechanism in chronic sciatica, some studies have suggested NSAID therapy for chronic sciatica,²⁷ so nerve root inflammation may be considered. In the current study, the NSAIDs administered in both groups could have exerted a synergistic effect with the LCD. Moreover, the relationship between calorie restriction and the control of autophagy may be a strategy to prevent neurodegeneration. The role of autophagy in the onset and chronicity of neurogenic pain has been shown in some studies to partly explain the mechanism of this effect.^{22,28,29} Furthermore, the antinociceptive effects of caloric restriction on neuropathic pain in rats³⁰ and the effectiveness of LCD for pain reduction in patients with osteoarthritis³¹ are in line with the current findings.

Whatever be the exact mechanism(s), this study showed that a simple short-term LCD resulted in consequential relief of pain and improved quality of life through decreased disability in patients with sciatica not treatable with surgery.

With these results, it appears that short-term LCD in combination with NSAIDs may affect sciatica, even if significant weight loss does not occur. The long-term consequences of this dietary intervention merit further studies. Designing a trial to analyze the serum biomarkers of inflammation before and after the dietary intervention may also be helpful in confirming its probable anti-inflammatory mechanism.

Limitation of study

The important factor was the variability of the patients' pain threshold, which could not possibly be consistent between the two groups. Outside care only focused on patient's dietary regimes, and other types of outside care such

AU13▶ TABLE 3. COMPARISONS OF MEAN WEIGHT, SHORT-FORM MCGILL PAIN QUESTIONNAIRE SCORE, AND ROLAND-MORRIS DISABILITY QUESTIONNAIRE SCORE IN CASE AND CONTROL PATIENTS AT DIFFERENT INTERVALS

	Group	Baseline 0	Day 15	Day 30	Day 60	<i>p</i> -Value 1	<i>p</i> -Value 2
Weight (kg)	LCD group	75.35 ± 13.9	74.34 ± 13.6	73.28 ± 13.43	74.59 ± 13.6	<0.001	<0.001
	Control	72.39 ± 10.5	72.7 ± 10.5	72.89 ± 10.7	72.92 ± 10.48	0.205	
Sensory	LCD group	6.73 ± 1.41	5.85 ± 1.29	4.94 ± 1.55	4.46 ± 1.71	<0.001	0.015
	Control	5.77 ± 1.45	5.81 ± 1.25	5.77 ± 1.71	5.74 ± 2.11	0.125	
Affective	LCD group	0.98 ± 0.64	0.77 ± 0.63	0.60 ± 0.61	0.50 ± 0.62	0.002	0.002
	Control	0.90 ± 0.63	0.88 ± 0.64	0.87 ± 0.71	0.87 ± 0.85	0.510	
Total descriptor scale (sensory + affective)	LCD group	7.71 ± 1.69	6.63 ± 1.61	5.54 ± 1.87	4.96 ± 2.02	<0.001	0.001
	Control	6.63 ± 1.44	6.69 ± 1.32	6.64 ± 1.98	6.62 ± 2.53	0.303	
PPI	LCD group	2.23 ± 0.47	1.94 ± 0.48	1.52 ± 0.74	1.02 ± 0.98	0.001	0.006
	Control	2 ± 0.68	1.96 ± 0.8	1.96 ± 0.93	1.79 ± 1.3	0.013	
RMDQ score	LCD group	11.17 ± 3.9	8.60 ± 1.9	7.50 ± 2.7	6.7 ± 3.0	0.077	<0.001
	Control	10.00 ± 2.2	9.98 ± 2.2	9.94 ± 2.9	9.85 ± 3.3	0.010	

Data are means of three replicates ± SD.

p-Value 1: within group *p*-value.

p-Value 2: between group *p*-value adjusted with baseline.

PPI, Present Pain Intensity; RMDQ, Roland-Morris disability questionnaire.

as visits to another doctor were not evaluated. Novel treatment bias, not reporting VAS scores, unoptimized duration of the study, and chosen calories of dietary intervention are some of the other limitations. Long-term follow-up for chronic back pain patients is very helpful. Because of the short duration of the current study, future studies with long-term follow-up for chronic sciatica patients might be very helpful.

Conclusion

According to the current findings, a 1-month LCD may be effective in decreasing pain and disability in candidates for the nonsurgical treatment of chronic sciatica when combined with NSAIDs. Therefore, nutritional intervention might be considered helpful as a simple and available complementary treatment for managing chronic sciatica, at least in the short term.

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Author Disclosure Statement

No competing financial interests exist.

AU8 ► Funding Information

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Address correspondence to: ◀AU10
Mohsen Naseri ◀AU11

*Traditional Medicine Clinical Trial Research Center
Shahed University
No. 1471, North Kargar Street
Enghelab Square
Tehran
Iran*

E-mail: naseri@shahed.ac.ir

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