The Effectiveness of Persian Massage in Treating Radicular Chronic Low Back Pain: A Randomized Controlled Trial

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Abstract

Introduction: *At the best knowledge of our survey,* this is the first study to investigate the effect of Persian massage on pain, disability, and quality of life in radicular chronic low back pain, compared with conventional treatments. Methods: Design: a parallel randomized controlled trial. Setting: Massage clinic at Imam Reza Hospital, Mashhad, Iran. Participants: Forty eligible patients with a history of > 12 weeks duration of **radicular** pain below the knee [a sharp shooting pain that starts in the back and goes into one or both legs, as *the main problem]* that were *referred to the pain clinic* by a neurosurgeon and were selected randomly as well as placed in two groups of 20 into intervention group (n=20) and a control group (n=20). Intervention: Two trained physicians were assigned to participants in the intervention group: using Persian massage three times a week with Acetaminophen (325 mg qid), and in the control group: Acetaminophen was consumed (325 mg qid) for four weeks. Measurement: The Visual Analogue Scale assessed pain; Morris-Roland disability questionnaire assessed disability and World Health Organization questionnaire in quality of Life (brief form) assessed the quality of life improvement. Questionnaires were measured at baseline, after one and three months. Results: Persian massage led to statistically significant relief in pain after one month (p=0.03) as well as improvement in disability (p<0.05) and psychological quality of life (p= 0.03) after one and three months. Conclusions: These findings suggest that performing Persian massage on male patients with radicular chronic low back pain could be of considerable importance to health professionals.

Key words: Radicular Chronic Low Back Pain, Persian Massage, Randomized Controlled Trial

Introduction

Lumbar radiculopathy is one very common disease and is observed as one of the most important public health problems (Divano and Mabiglia, 2010). About 40% of cases with low back pain are radicular in origin and are considered under the umbrella of the sciatic syndrome. It is one pathology with pain dominant and considerably reduces human activity. The prevalence of low back pain during the

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lifetime is reported about 84%, and the prevalence of chronic low back pain is about 23%, with 11-12% –based on the condition- of the population disability. (Last and Hulbert, 2009) After a headache, this disease is observed as the most common problem of the neuromuscular system. (Gringmuth and Jackson, 2000) While low back pain rarely indicates a serious disorder, but it is a major cause of pain, disability, absence from work and social and medical costs; so that, it is one of the costly common medical conditions (van Tulder et al., 2000). The estimated annual national bill to care of low back problems is $38 to $50 billion in the USA (Frymoyer, 1997) as well as the global burden of chronic low back pain, at 2010, was reported to be comparable with cardiovascular disease, infectious disease, and cancer. (Dionne, Dunn and Croft, 2006; Hoy et al., 2010; Maetzel and Li, 2002)

In health facility- or clinic-based studies, is estimated that episode remission of low back pain at 1 year ranges is from 54% to 90%; as well as estimates of recurrence of its at 1 year range is from 24% to 80%.(Hoy et al., 2010) and conventional treatments such as Acetaminophen, NSAIDs and other conventional analgesics (Last and Hulbert, 2009), due to the limitation of effectiveness and undesirable side-effects on gastrointestinal, renovascular, and other systems, (Hernández-Díaz and Rodríguez, 2000; Van Tulder et al., 2000; Watkins et al., 2006) have not been effectively managed the problem and this has been led to turn over other forms of treatments, such as complementary and alternative medicine. So that, low back problems are the most frequently reported medical conditions among the patients who use alternative medicine, with applied massage. (Eisenberg et al., 1993) On the other hand, the studies of the National Center for Complementary and Integrative Medicine (NCCIM) show the usefulness of massage in the treatment of pain, especially the pain associated with articular diseases. Even NCCIM supports the researches and studies which examine the effects of massage therapy on chronic low back pain.[1]

Massage is a systematic and scientific manipulation of the soft tissues with rhythmical pressure and stroking for the purpose of obtaining or maintaining health (Sritoomma et al., 2014). The massage therapy industry is continuously increasing. In 2009, U.S. consumers spent between $4 and $6 billion on visits to massage therapists. In 2015, research estimates that massage therapy was a $12.1 billion industry. Massage has developed continuously in China for over 5000 years. It is widely practiced and taught in hospital and medical schools and is an essential part of health maintenance and primary healthcare. (Khorsand, Yousefi and Zarvandi, 2018) Various types of massage have evolved from various cultural traditions. At least 16 **famous** massage styles are defined at the scientific societies that **some of the important types are included; Swedish massage, Myofascial release, Tui Na, Thai massage, Acupressure, Ayurvedic massage, Reflexology, Shiatsu (**Sagar, Dryden and Wong, 2007**)**

In Persian medicine, also called "Hikmat", massage be classified as one of the important manual actions, and normally is considered an ancient healing art of the hand and fingers, that it mentioned and emphasized at least from 1000 of years ago, not only for preventive, therapeutic and rehabilitative purposes but also to diagnosis in the Persian medicine texts, in particular, Avicenna and Razi books with using words such as "Dalk & Qamz". It is regularly used as a respected, useful and safe therapy method for a wide variety of conditions until recent decades, especially in bathrooms by rubbers. The main techniques include; "Dalk" (press Kneading or rub), "Ghamz" (pressing with a finger), "Mask" (grasping), "Mass" (to press softly) and "Mass´h" (anointment). Based on the Persian medicine texts, massage is a form of exercise, and mechanism of it is based on the principle of expulsion or elimination of morbid matter and diversion of morbid matter. In other words, it by heat creation in the body surface caused to the dilution and subtle disposal of the humidity of the tissues and body organs. The heat also helps to absorption of the blood and caused to the opening of the pores of the body and blood dilution and further penetration in the skin pores. So massage such as exercise strengthens muscles, nerves, and ligaments. Various types of Massage, the function of those, quantity, quality, and the speed of Massage movements have been defined in these texts. Should be noted, that general principles and methods of performing of Persian Massage (PM) is from the proximal to distal of limb, from the Center to perimeter of the body and gradually from gentle to intense. **(**Khorsand, Yousefi and Zarvandi, 2018**)**

Although there are differences between the PM and other massage styles, in some of the methods, techniques and subsequently clinical results but generally, in between of the conventional massage types, principles of the maneuvers of PM is approximately similar to some of the manual techniques of Swedish massage [such as; effleurage, petrissage and friction](Sagar, Dryden and Wong, 2007; Mahbobeh et al., 2017; Cowen et al., 2006) however must be noted **the novelty of PM and** *specify hallmarks of this type of massage in comparison with other massages* **is a very prominent position in the Persian medical texts, The fundamental theoretical principles, broad and easy performance range and the dramatic application of it in the category of prevention.** (Khorsand, Yousefi and Zarvandi, 2018)

In recent years, many clinical trials have been conducted to evaluate the efficacy of massage types, especially in neurological diseases. Several clinical trials have recognized its efficacy in these diseases on scientific parameters. (Jafar et al., 2015) Unfortunately, despite the simplicity of learning, performing, and safety of the PM, no study has examined its use for radicular chronic low back pain (RCLBP). The aim of the present study is to examine whether RCLBP can be reduced by PM.

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[1] https://nccih.nih.gov/health/massage/massageintroduction.htm.

The Methods of Study:

Study design

The present study is a single-blind parallel randomized controlled trial to investigate the effect of PM on RCLBP in Iran. The participants randomized into the two groups; an intervention group (IG): received Persian massage with Acetaminophen 325 mg qid, and control group (CG): received only Acetaminophen 325 mg qid for 4 weeks. Assessments were performed after one and three months of intervention.

Participants

Participants were screened prior to enrolling for treatment. Inclusion criteria were: men aged between 25-55 years; VAS score ≥ 3; no prior history of surgery or diagnoses of RCLBP by a neurosurgeon with history of > 12 weeks duration of pain below the knee (Nordin, Balague and Cedraschi, 2006), a physical examination [positive Straight Leg Raising test], and MRI findings [such as: degenerative processes of disks and facets, herniated disk, spinal stenosis, spondylitis, and internal disk disruption (Last and Hulbert, 2009)]. Exclusion criteria were: *Patient refusal,* adverse events such as changes in pain, syncope, vertigo, *hematoma formation,* and lumbar function degradation. Each participant was fully informed of the treatment process and their consent was provided. The trial was registered in the Iranian Trials Registry (IRCT2016052328013N1), (http://www.irct.ir/) with ethical code (IR.MUMS.REC.1395.404).

Sample size calculations were based on an Iranian study done by Hashemi et al. (2016). Due to the absence of a similar study on this particular type of massage, we estimated the sample size calculation based on clinical judgment with a large effect size, alpha = 0.05 and power = 80%. The estimated sample size using G-Power was 20 participants in each group ($n = 40$ in total). We generated random allocation order by PASS software and based on www.randomizer.com. We used simple randomization method as well as the enveloped pocket method for concealment of interventions assigned for two groups. One person who was not involved in the study allocated the randomized numbers into opaque envelopes. The statistician was blinded to the study groups.

Intervention

The PM was carried out by two Ph.D. students of Persian Medicine who had passed courses of PM therapy in accordance with the educational curriculum. PM protocol was evaluated by two experts, who were both intimately associated with massage and complementary therapy treatments, and who were both academically qualified. The massage therapists were periodically assessed by trainers against the protocol.

The IG received PM that was combined with five basic motions; stage 1: soft rub; stage 2: scrub; stage 3: grasping; stage 4: pressing with a finger; stage 5: (again) soft rub for 15 minutes, three times a week, for a total of four weeks (in total, 12 sessions). The maneuvers of Persian massage are performed on the back and lower extremities. It started from the back and ended to the feet. It was also performed on a massage table while participants were merely covered with a hospital designed bed sheet. Acetaminophen (325 mg qid) was also ordered. In CG, Acetaminophen 325 mg qid was prescribed for four weeks. Suitable lifestyle recommendations were also provided for both groups and participants were instructed not to take other pain medication or receive additional massages.

Data collection and outcome measures

The collected demographics and data outcome from February to June 2017 were analyzed by a group of trained research staff. The outcomes of the data on the related-patient were measured as follows: pain as a primary outcome was measured by using the Visual Analogue Scale for low back pain (VAS) (Carlsson, 1983). Functional ability as a secondary outcome was measured using the Morris-Roland Disability Questionnaire (MRDQ), Persian version (Mousavi et al., 2006) as well as the quality of life as another secondary outcome were measured by using the World Health Organization Quality of Life (Short Form-WHOQOL) questionnaire (Nejat et al., 2006). Reliability and validation of each outcome were established according to the mentioned references. The study outcomes were evaluated on a baseline, one and three months after intervention in the Massage clinic in Imam Reza Hospital, Mashhad, Iran. Pain relief medication was monitored and no adverse event was recorded.

Data analysis

Data were analyzed using SPSS version 16.0 (SPSS, Inc. Chicago, IL, USA). Continuous variables were presented as means of standard deviations (SD) or median and interquartile range, depending on normal distribution. The t-test or Mann Whitney test according to the normality of data was used for comparing continuous variables and Chi-square test was used for categorical variables. Friedman or

repeated measures ANOVA compared the outcome trend at baseline, from the first to the third month after baseline. A value less than 0.05 was set as a significant level.

Results

Sixty-one potential participants responded to flyers, Emails, or word-of-mouth descriptions; 21 were excluded after screening for eligibility. A total of 40 patients met the inclusion/exclusion criteria and were randomly assigned to the IG: $n = 20$ and CT: $n = 20$; and finally analysis was performed for IG; $n = 18$ and CT; $n = 19$ (Fig.1).

Demographic and outcome data are summarized in table 1, 2, and 3. Mean age of participants was 38 ± 9.07. The highest percentage of patients in the IG held a bachelor (13.3%) and a bachelor and diploma in CG (36.8%) (P=0.41). The majority of participants in both groups held positions as employees (P=0.73). Additionally, the most common form of spine pathology was bulging in both groups (P=0.49). No significant differences were observed between the two groups on all other study outcomes in the baseline (table 2).

Mean of pain in the IG (3.61 ± 1.94) was less than the CG (5.21 ± 2.32) (p=0.03) at the first month after intervention (Figure 2), results for the mean difference were also similar (table 3). Mean of disability and psychological quality of life score indicated no difference between the two groups at baseline, while a mean difference of those was significant at first and second follow up (table 2 and 3). We did not find a significant difference between the two groups regarding the physical quality of life score at first or second follow-ups.

Safety: no serious side effect reported either group.

Discussion

The present clinical trial is a comparative effectiveness study of Persian massage (PM) and conventional analgesics for pain relief and functional recovery in patients with RCLBP. The main massage techniques that used in this trial were a combination of "Dalk", Ghamz", "Mask" and "Mass". The methods applied in a manner which is consistent with the principles of Persian Medicine theory and is based on recognition of the general principles and methods of performing PM. (Khorsand, Yousefi and Zarvandi, 2018) According to Persian Medicine texts, health is a state of the quantitative and qualitative balance in humor and materials of the body that lead to the accuracy of the function of body organs (Homeostasis). Pain is usually caused by a sudden change in temperament or sudden mal temperament and separation of connections. Pathogenic factors such as blood stasis, phlegm, dampness, wind, and others can be identified as causative factors in the sudden mal temperament and separation of connections. (Ibn Sina, 2005) Thus, the central therapeutic goal of *PM* is to remove pathogenic factors which lead to mal temperament. This leads to circulation improvement and reduction of localized edema, which helps to reduce pain (Khorsand, Yousefi and Zarvandi, 2018).

 The current study is the first known trial using PM for RCLBP that is one novelty for this study. According to the results, PM is more effective than conventional analgesics such as acetaminophen in pain relief, improvement of disability and psychological quality of life in male patients with RCLBP.

The findings of Hashemi et al.'s study (2016), also showed that traditional Iranian massage is more effective in reducing pain and disability than other common treatments in patients with Lumbar Radiculopathy. In Sritoomma et al.'s study (2014), both Swedish massage with aromatic ginger oil and traditional Thai massage led to significant improvements in pain and disability in treating chronic LBP in older adults; which is similar to the findings of the current study. In Kocur et al.'s study (2014), obvious reduction of pain and disability was evident in both groups, in patients LBP who were treated with deep tissue massage and NSAIDs which is almost similar to the findings of the current study. Results of Samani et al.'s study (2017), also showed that the Myofascial Release Technique may be an effective treatment for the reduction of pain and disability in patients with chronic lumbar disc herniation, while results of the present study shows that PM is more effective than conventional treatments, particularly in patients with disability (Figure 3). Results of Kumar et al.'s study (2017) is representative of pain reduction and improvement of the mental quality of life in patients with chronic LBP who were treated with the Ayurvedic massage that is almost consistent with the findings of the present study because results of the mentioned study did not show recovery on the disability.

Each of these styles of massage is done with different intentions underlying theoretical frameworks. Therefore, it is important to develop a degree of specificity in referring to a style of massage, both in the study and in prescribing massage for a particular condition. (Yang et al., 2014)

Also must be noted; based on conventional medicine, several mechanisms might be responsible for the effect of the observed treatment; pain relief by physical and mental relaxation by increasing "pain tolerance" not "pain threshold" because there is no difference in pain

threshold according to the ethnicity, age, and gender (Kim et al., 2017); modulating nociceptor sensitivity, stimulation of A and C fibers; involving the spinothalamic-cortical pain pathways (Musial, Spohn and Rolke, 2013); stress regulation with promoting a sense of receiving good care (Imamura et al., 2008); reducing inflammation and promoting mitochondrial biogenesis for repair of damaged skeletal muscle (Crane et al., 2012); and finally one of the possible methods of relieving pain by Persian massage can be related to facilitating the release of inner endorphins, although studies in this field are paradox. (Bender et al., 2007; Day, Mason and Chesrown, 1987; Jiang and Yang, 1990; Kaada and Torsteinbø, 1989)

Limitations: Our study had some limitations such as whether all of the participants were male; relatively few participants in each of groups (~20) and the number of patients lost. Furthermore, we did not have a placebo (sham massage) group for comparison and estimate of the placebo effect. These limitations make difficult to generalize the results of the present study. This indicates that future larger studies are needed. Another limitation was the lack of a similar study done on this type of massage; causing problems in some statistical calculation and interpretation of the results.

Conclusion

The design and methodological rigor of this clinical trial will allow for the collection of valuable, high-quality data to evaluate the efficacy of a specific *PM* protocol for treating RCLBP, and so will contribute to providing a standard foundation for the treatment of RCLBP, as well as future studies in massage therapy. The current study also concludes that the integration of PM for male patients with CRLBP could be considered as an option for patient care.

Conflict of interest

No conflict of interest is declared by the authors.

Author's contributions

ZM, NY and Kh A contributed to conception and study design; ZM and NY contributed to data collection, intervention conduction at the clinic; ZM and MN contributed to data analysis; Kh A, NMR, Kh Z and YM contributed to supervision; MN and ZM and NMR contributed to manuscript preparation.

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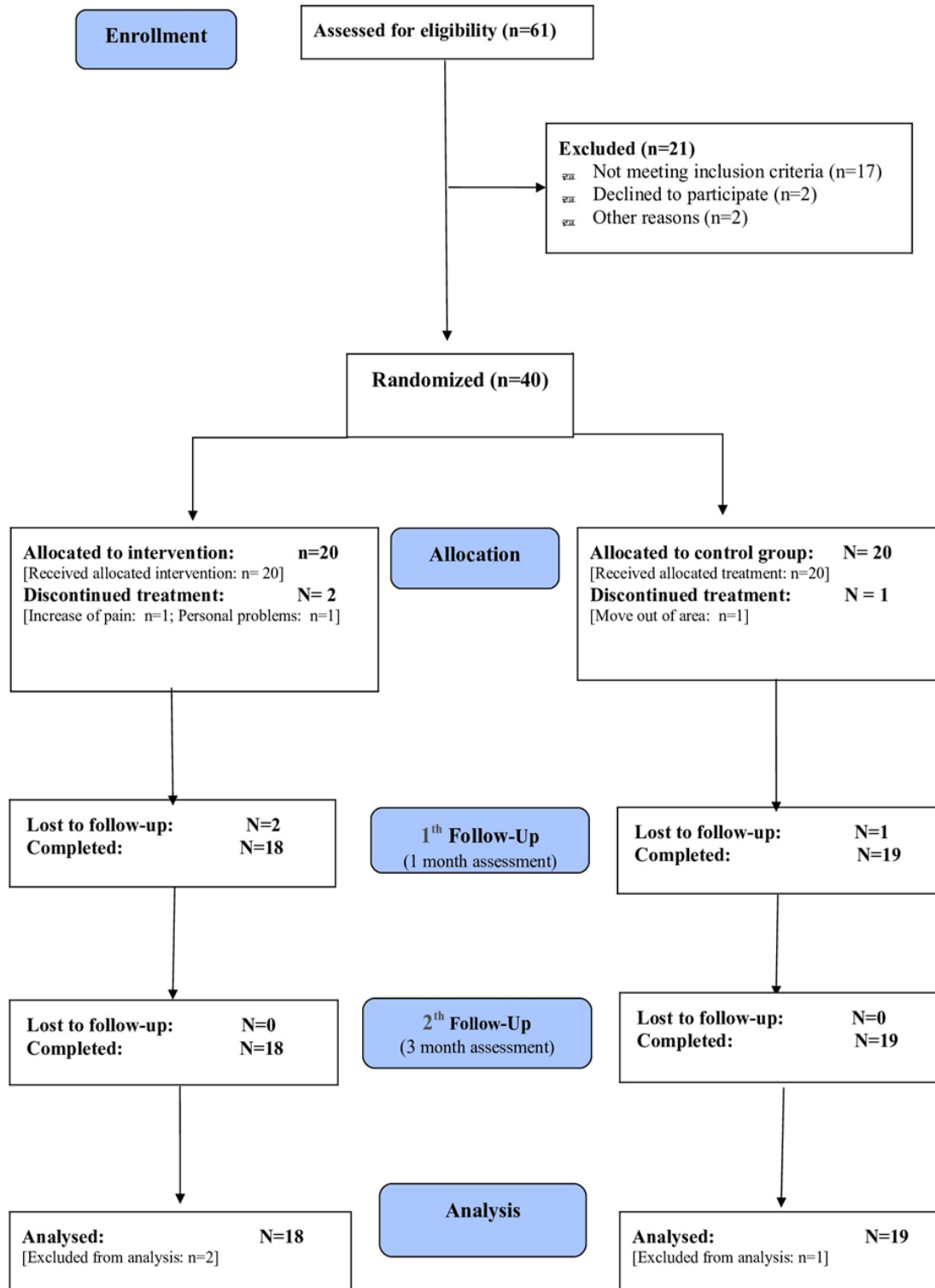
Fig. 1. Flow chart of the progression of participants through phases of RCT.
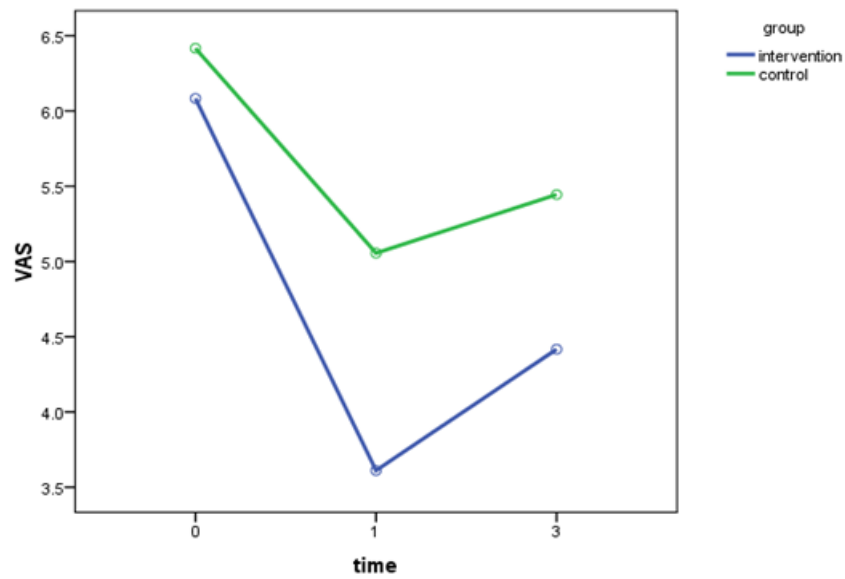
Fig. 2. Pain score mean between 2 groups
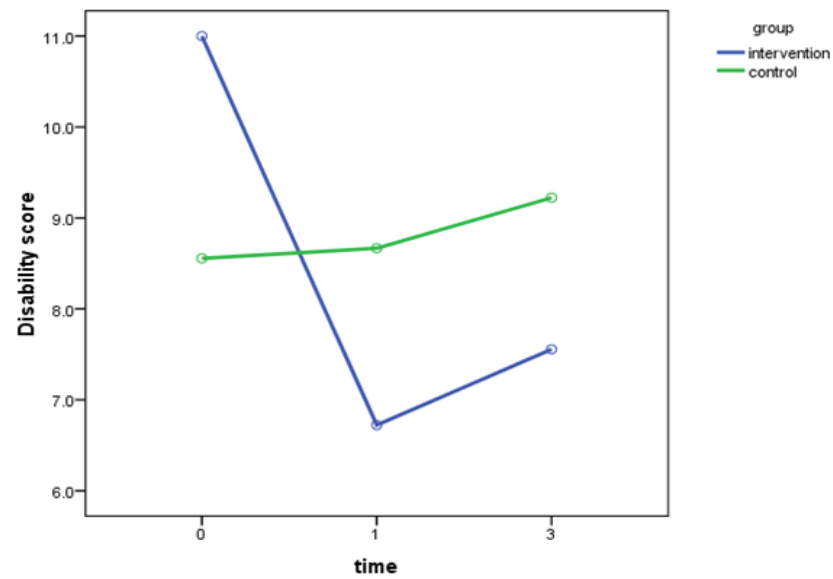
Fig. 3. Disability mean between 2 groups

Table 1. Demographic information of the participants

Information and Histories		CG, n=19	IG, n=18	P value
		Number (%)	Number (%)	
Educations	Primary school	1(5.3)	0(0)	0.41
	Diploma	7(36.8)	3(16.7)	
	Associate's degree	1(5.3)	4(22.2)	
	Bachelor	7(36.8)	6(33.3)	
	Masters	2(10.5)	3(16.7)	
	Doctor	1(5.3)	2(11.1)	
Age	Mean & SD	39±8.46	38±9.68	0.47

Weight	Mean & SD	77.42±14.27	86.06±11.62	0.34
Smoking	Smoker	3(15.8)	2(11.2)	0.67
	Non-smoker	16(84.2)	16(88.9)	
Job	Employee	9(47.4)	11(61.1)	0.73
	Student	1(5.3)	2(11.1)	
	Free	4(21.1)	3(16.7)	
	Worker	2(10.5)	1(5.6)	
	Retired	3(15.8)	1(5.6)	
Dissemination of pain	To right	5(26.3)	4(22.2)	0.71
	To left	7(36.8)	5(27.8)	
	Both sides	7(36.8)	9(50)	
MRI report	Bulging	8(42.1)	9(50)	0.49
	Protrusion	8(42.1)	6(33.3)	0.68
	Canal stenosis	7(38.9)	5(27.8)	0.64
	Dehydration of disk	5(26.3)	8(44.4)	0.18
	Herniation of disk	4(21.1)	2(11.1)	0.45
	Rupture disc	1(5.3)	1(5.6)	0.28
	Edema of disc	1(5.3)	2(11.1)	0.33
	Spondylitis	1(5.3)	2(11.1)	0.33
	Extrusion	1(5.3)	2(11.1)	0.33

Table 2. Comparison of pain, disability and quality of life at baseline, 1 & 3 months after intervention between 2 groups.

Outcome	Time of assessment	Mean		P value*
		IG, n=18	CG, n=19	
VAS	Baseline	6.08±1.59	6.47±0.3	0.61
	after 1 month	3.61±1.94	5.21±2.32	0.03
	after 3 months	4.41±2	5.44±2.20	0.2
MRDQ	Baseline	11±5.16	8.94±3.97	0.2
	after1month	6.72±4.63	9±4.54	0.1
	after 3 months	7.55±5.40	9.22±4.82	0.4
SF-WHOQOL (Psychological)	Baseline	53.88±18.92	52.42±16.21	0.59
	after 1 month	56.33±17.85	48.94±14.21	0.1
	after 3 months	56.05±16.99	51.16±11.92	0.3
SF-WHOQOL (Physical)	Baseline	53.50±15.24	55.36±14.69	0.8
	after 1 month	60.05±14.71	55.10±13.86	0.3
	after 3 months	56.72±17.76	53.44±14.30	0.5

*A difference at the level of $p < 0.05$ is considered statistically significant.
SD = standard deviation; VAS = visual analogue scale; MRDQ = Morris-Roland Disability Questionnaire; SF-WHOQOL = short form- World Health Organization quality of Life questionnaire.

Table 3. Comparison of **Mean difference** measurement for pain intensity, disability and quality of life at baseline, 1 & 3 months after intervention between 2 groups.

Outcome	Group	Mean difference (95%CI) after 1 month	p-Value*	Mean difference (95%CI) after 3 months	p-Value*
VAS	IG	-2.47 (-3.36- -1.58)	0.03	-1.66(-2.32- -1.01)	0.1
	CG	-1.36 (-2.3- -0.4)		-0.97 (-1.8- -.11)	

MRDQ	IG	-4.27(-7.06- -1.48)	0.001	-3.44 (-5.4- -1.4)	0.02
	CG	0.11(-2.1-2.3)		0.66 (-1.6-2.9)	
SF-WHOQOL **(Psychological)**	IG	6.55 (1.13-11.9)	0.03	3.22 (-2.45-8.9)	0.03
	CG	0.11 (-5.7-5.9)		-2.88 (8.88- -3.05)	
SF-WHOQOL **(Physical)**	IG	2.44 (-4.08- 8.97)	0.1	2.16 (-3.09-7.42)	0.2
	CG	-4 (-9.34-1.34)		-3.44 (-8.58-1.69)	

*A difference at the level of $p < 0.05$ is considered statistically significant. CI = confidence interval