A New Educational Program could Reduce Disability and Improve Quality of Life in Patients with Chronic Low Back Pain

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Abstract: This randomized clinical trial examined the efficacy of a designed educational program versus oral drug treatment in Iran. A total of 197 patients with chronic low back pain were randomized into either intervention group (n = 97) receiving a five 2 hour– session educational program followed by continued monthly booster sessions and telephone counseling plus medication or to control group (n = 100) receiving just medication. At baseline and 3 months of follow up, participants completed demographic characteristic questionnaires as well as three other questionnaires including Short – form General Health Survey (SF-36 item), Quebec Disability Scale (QDS) and Ronald – Morris Disability Questionnaire (RDQ). Data were analyzed by SPSS 18. The two groups were comparable at baseline in terms of all baseline characteristics and the mean scores of the scales. However, after three months, the intervention group was significantly different from control group in all subscales of SF-36, QDS and RDQ (P values < 0.05). Furthermore, this study showed a statistically significant difference between two groups (P< 0.05) in terms of mean difference scores for SF -36, RDQ and QDS over time. The findings revealed that the designed educational program could improve all quality of life domains and reduce disability in chronic low back pain patients during a period of 3 months.

Keywords: Chronic low back pain, Educational program, Quality of life, Disability, Clinical trial study.

INTRODUCTION

Many evidences showed that lower physical and psychosocial function subsequent to Chronic Low Back pain could lead to lower health related quality of life (HRQOL) [1,2]. Furthermore, the patients with CLBP suffer from lower general health level [3]. Since it has been verified that psychosocial factors play an important role in chronic back pain disability, multidimensional programs included physical, psychological and social aspects of chronic pain has been suggested for its improvement [5]. Therefore, the patients suffering from this health problem be encouraged to apply coping styles [6, 7] rather than focusing on anatomical aspect of the disease [8-10]. In addition, evidence revealed that advice on continuing normal activities is better than usual care for CLBP improvement [11-13]. Moreover, it has been revealed that positive coping with CLBP could decrease absence from workplace [14]. In spite of these findings, a few documents are available to enable health care providers to treat LBP effectively [15]. However, applying cost-effective approaches in CLBP management is still a health research priority for researchers [16]. In this regard, development of multidimensional programs to consider different aspects of chronic low back pain is strongly recommended [17].

In Iran, oral medications such as non steroidal anti inflammatory drugs (NSAIDS), muscle relaxants and analgesics for CLBP treatment is common. Besides, the patients being referred to physiotherapists to get interventions focusing on physical training and exercises. Up to now, there has not been a setting to address all dimensions of chronic low back pain. Hence, this study aimed to design and evaluate the effects of the designed program on disability and quality of life of CLBP patients.

MATERIAL AND METHODS

This randomized clinical study was done in rheumatology research center of Tehran University of Medical Sciences (TUMS), Tehran, Iran. Inclusion criteria of the study were being aged ≥18 years and being suffered from chronic pain more than three months. The exclusion criteria were history of operation on the back within the past two years, fresh vertebral fracture, vertebral malignancy, infection in the back, spondylolisthesis, being unable to participate in multidisciplinary program sessions, pregnancy, living outside of Tehran, insufficient address and phone number for follow up, being unable to understand Farsi language, and unwillingness to enter the study or comply with the study protocols.

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E-ISSN: 2313-0954/14

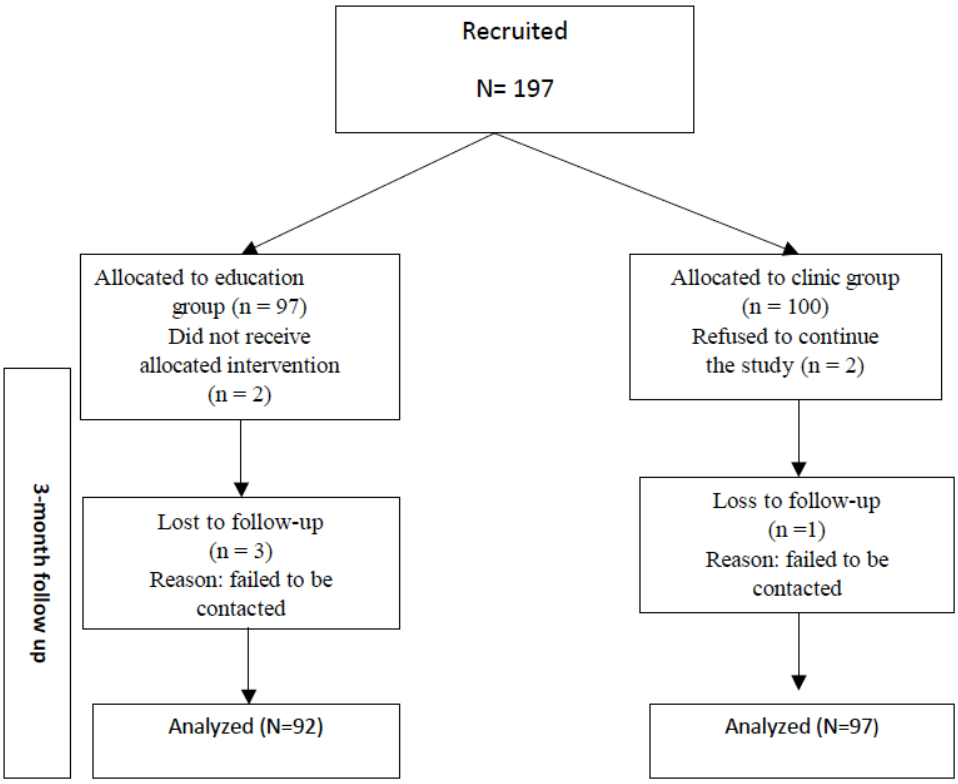

Figure 1. Flow chart of patients who took part in the study.

All inclusion and exclusion criteria were being checked by a single rheumatologist before the participants took part in the study. A research trained co-worker who was blinded to demographic and clinical characteristics of patients applied permuted-block randomization with blocks of every 6 cases to assign the participants into the intervention or control group Thus, 197 eligible participants were randomized into two groups of control (n = 100) who were took oral medications, and intervention (n=97) who underwent education program plus medication treatments.

Ethical principals were considered in this study. The participants were required to cope with the study procedure. Therefore, purposes and procedures of the research were explained to them first and written consent forms were signed. Patients in two groups were visited by the physician at the time appointed by his diagnosis. The participants could withdraw from the study whenever they requested. Considering mentioned ethical points, the ethics committee of Tehran University of Medical Sciences approved the present study.

Figure **1** shows the flow chart of participants' assignment and their follow up. A basic demographic questionnaire, the short Form Health Survey (SF- 36) and the Ronald _ Morris Disability Questionnaire (RDQ) were applied to collect data. The instrument of SF-36 has eight measurement scales and ranges from 0 to 100, while 100 is the best score and 0 is the worst. In this study, the Iranian valid and reliable version of SF-36 questionnaire was used [18].

RDQ is a twenty four - item questionnaire which specifically measures physical function affected by low back pain [19]. The RDQ score ranges from 0 (no disability) to 24 (maximum disability). The validity and reliability of this instrument has been well documented [20]. This tool has been validated in Iran [19].

The 20 – item QDS is a condition specific measure of disability in individuals with low back pain that was described by Kopec et al in 1995 [21]. The QDS scores range from 0 (no disability) to 100 (maximum disability). The reliability and validity of the original version of this instrument has been documented in different countries as well as in Iran [19, 21].

Study Intervention

The designed educational program consisted of five 2 - hour sessions including two physiotherapy classes, one rheumatology, one psychology and one health education classes. The physiotherapist explained the anatomy and physiology of the spine, lifestyle factors

that could moderate the CLBP process and the techniques for preventing back injury. Furthermore, the same physiotherapist evaluated the participants' skills regarding correct biomechanical posture of spine during their daily activities as well as doing stretching, strengthening and relaxation exercises for the muscles of back, abdomen and thigh.

The rheumatologist explained the process of developing chronic low back pain, the characteristics of pain and the effects of risk factors on pain severity. Finally, the different methods of diagnosis and treatments of low back pain were explained in this class.

In psychology class a clinical psychologist focused on individual understanding of stress and coping, perception of stressors or threatening events and how one's could control stressors or change the situation and managing emotional reactions leading to successful adaptation. The psychologist also explained the strategies for problem management and focused on problem solving or changing a stressful situation and changing the way one thought or felt about a stressor.

In health education class, the educator focused on behavioral interventions in CLBP control. The instructor tried to re-conceptualize patients' beliefs regarding low back pain, replace maladaptive thinking patterns and behaviors with adaptive patterns and behaviors such as exercise participation, relaxation skills and fear avoidance of movements that were critical to adjust with pain and injury. Furthermore, the health education specialist played an active role in follow up motivational counseling by phone and also moderating monthly booster classes. During these counseling sessions she motivated the participants to adapt with healthy behaviors, to comply with specific exercises for LBP and to cope with the stressors actively. As a core leader, if there were any specific questions, she asked them from different specialists of the team and provided the participants with appropriate responses.

Outcome variables including SF-36 subscales, RDQ and QDS scores were examined at baseline and 3-month follow up. Data were analyzed by SPSS 18.

RESULTS

Figure **1** shows the recruitment and randomization of patients took part in this trial. Accordingly, 197 eligible patients were randomly divided into either control or intervention group. Table **1** shows basic demographic characteristics in two groups. As this table shows there was no statically significant difference between two groups in terms of all examined variables at baseline (all P values > 0.05). Table **2** shows the mean scores of all SF-36 subscales. According to this table two groups were significantly different in terms of all SF-36 subscales except for role emotional dimension. Furthermore, the mean differences of all baseline subscales were significantly different between two groups ($P < 0.05$). However, the mean differences of mental health and vitality were not different between two groups ($P > 0.05$). Table 3 shows the mean scores of QDS and RDQ instruments. According to this table, two groups were statistically different in terms of QDS mean scores after 3 months ($P < 0.05$). However, RDQ mean score and the mean difference of RDQ were not significantly different between two groups (P-values > 0.05).

Table 1: Demographic Characteristics of Studied Participants of Two Groups at Baseline

Variables	Control group (N= 100)		Intervention group (N=97)		P-Value
	N(%)	M(SD)	N(%)	M(SD)	
Age		45.9 (11.3)		44.6 (10.2)	0.43
Weight		71.9 (12.2)		72.8 (12.5)	0.62
Education		10.7 (3.8)		11.4 (3.9)	0.19
Gender					0.09
Female	83 (83.0)		71 (73.2)		
Male	17 (17.0)		26 (26.8)		
Smoking					0.32
Yes	4 (4)		7 (7.2)		
No	96 (96)		90 (92.8)		

Table 1 Continue …

Variables	Control group (N= 100)		Intervention group (N=97)		P-Value
	N(%)	M(SD)	N(%)	M(SD)	
Marital status					0.27
Single	18(18)		13.4		
Married	82 (82.0)		84 (86.6)		
Duration of Pain		88.5 (108.9)		75.9 (71.4)	0.29
Duration of treatment		52.3 (80.27)		43.5 (57.6)	0.37
Sciatica					0.79
Yes	86 (86.9)		83 (85.6)		
No	13 (13.1)		14 (14.4)		

M(SD) = Mean (Standard Deviation); N= Number

Table 2: Comparison of Two Groups at Baseline and 3- Month Follow up in Terms of SF-36 Scales, QDS, and RDQ

Variables	Control M (SD)	Intervention M (SD)	Group &Time Difference	Time Difference	Group Difference
ˀSF-36 Sub -Scale					
Physical function			<0.0001	<0.0001	0.007
Initial	54.53 (23.30)	54.61 (23.27)			
3-month	60.93 (22.04)	68.64 (23.39)			
Role physical			0.002	<0.0001	0.01
Initial	32.81 (36.86)	30.70 (33.98)			
3-month	39.58 (36.93)	57.88 (68.33)			
Bodily pain			<0.0001	<0.0001	0.03
Initial	47.45 (23.59)	43.27 (22.59)			
3-month	56.35 (23.62)	65.82 (22.56)			
General health			0.01	<0.0001	0.06
Initial	49.92 (19.80)	50.41 (20.16)			
3-month	52.65 (23.34)	59.67 (21.59)			
Vitality			0.03	<0.0001	<0.0001
Initial	53.95 (20.02)	53.58 (19.22)			
3-month	55.05 (20.74)	60.10 (23.25)			
Social function			0.04	<0.0001	0.08
Initial	63.02 (28.55)	62.22 (24.65)			
3-month	51.77 (21.20)	59.78 (21.12)			
Role emotional			0.03	0.006	0.7
Initial	49.65 (44.580)	38.04 (40.32)			
3-month	41.31 (44.25)	50.72 (45.15)			
Mental health			0.7	<0.0001	0.01
Initial	44.00 (13.10)	47.43 (13.96)			
3-month	57.70 (23.22)	65.13 (21.59)			
*QDS			<0.0001	<0.0001	0.04
Initial	33.08 (19.69)	35.45 (20.19)			
3-month	32.70 (18.19)	23.48 (18.54)			
RDQ			0.01	<0.0001	0.01
Initial	10.04 (5.28)	9.80 (5.07)			
3-month	10.56 (5.78)	9.01 (5.71)			

M(SD) = Mean (Standard Deviation); N= Number ; SF-36 = Short-Form General Health Survey; QDS = Quebec Disability Scale ; RDQ = Ronald - Morris Disability Questionnaire

DISCUSSION

This study revealed that the designed program could significantly improve patients' quality of life and reduce their disability during 3 months. Although some improvements were observed in the control group, the changes were much fewer than those in intervention group. As documents reported the relationship between overall HRQOL and pain intensity [22], one can interpret that the success of this educational program might be due to reduced pain in intervention group. Furthermore, the improved physical function and decreased disability of the patients has been resulted in improved HRQOL. This result is consistent with a previous study [23]. In the designed program muscles strengthening exercises and applying fear avoidance of movement has been led to decreased disability among individual of intervention group. This finding was supported by another study [24].

This study confirmed that the designed program could improve vitality, role emotional and general health among CLBP patients up to 3 months. This result might be due to significant reduction of bodily pain in intervention group which improve daily activities, vitality, role emotional and general health. These results were discussed in a previous study [25]. Additionally, the relationship between low back pain and depression has been well evidenced in another study [26]. Linton reported in 2000 that distress, depression, anxiety and related emotions were associated with pain and disability [27]. Therefore, one can indicate that lower bodily pain in educational group could consequently improve other domains of HRQL. Improved functioning consequent to doing relaxation, strengthening and stretching exercises and keeping correct position of vertebra that occurred in intervention program is another reason for improving vitality and role emotional in intervention group. One of previous studies indicated that improvements in muscle performance were associated with pain reduction and increased functional ability [28]. Furthermore, psychological part of educational program could decrease disability in 3 months. Thus, other reason for vitality and role emotional improvement in intervention group could be related to psychological part of the program that included stress management, coping and problem solving. This reason was supported by previous investigations [29].

A strong point of this study was improvement in most dimensions of HRQOL. The fact that medication and time failed to obtain improvement in intervention program might indicate that this program has had an independent effect. Another strength point of this study is that multiple specific tools such as RDQ and QDS as well as SF-36 scale were applied to assess disability. However, these instruments were self reported and this could be a kind of limitation for this study.

CONCLUSION

This study showed the designed educational program could improve quality of life and disability in patients with CLBP by 3 months.

ACKNOWLEDGMENTS

The authors would like to thank Research Deputy of Tehran University of Medical Sciences for its financial support.

CONFLICT OF INTEREST

Authors declare that they have no conflict of interest.

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Received on 27-02-2014 Accepted on 10-03-2014 Published on 02-06-2014

DOI: http://dx.doi.org/10.12974/2313-0954.2014.01.01.4