Original article

International Journal of Musculoskeletal Pain prevention

Volume 1, Number 3, Summer 2016

Treatment of Low Back Pain: Extended follow up of an Original Trial comparing a Multidisciplinary Group-based Rehabilitation Program with Oral Drug Treatment alone up to 36 months

Sedigheh Sadat Tavafian[1], Ahmad Reza Jamshidi[2*], Kazem Mohammad[3]

1. Department of Health Education Faculty of Medical Sciences Tarbiat Modares University, Tehran, Iran.
2. Rheumatology Research Center Tehran University of Medical Sciences, Tehran, Iran.
3. Departments of Epidemiology and Biostatistics Tehran University of Medical Sciences, Tehran, Iran.

Background: This study is an extended follow up of the original trial study (NCT00600197) that has been published in the clinical journal of pain. This trial aimed to explore if the proposed multidisciplinary program could improve quality of life and disability of the patients suffering from chronic low back up to 36 months.

Methods and Material: In this Clinical Randomized trial seventy percent (139 of 197) of the participants who had taken part in the original study including 66 patients in intervention group and 73 patients in control group were followed up to 36 months after intervention. The intervention group continued receiving monthly motivational consultation and booster classes plus oral medication but the other group received just medication. Data on measures of Short Form 36 (SF-36) Quebec Disability Scale (QDS) and Ronald Morris Disability (RDQ) were collected at 3-6-12-18-24-30- and 36-month follow ups and analyzed through RMANOVA.

Results: The 2 groups were comparable regarding all baseline characteristics ($P > 0.05$) except for education level that was better in intervention group ($P = 0.01$). Two groups were improved regarding all studied variables over time up to 36 month ($P < 0.001$) Moreover the intervention group in comparison with the control group had consistently better outcomes regarding all variables. There were no significant differences within each group by time in terms of all variables ($P < 0.05$).

Conclusions: The proposed multidisciplinary program could reduce low back pain and improve quality of life and disability up to 36 months in chronic low back pain patients.

Keywords: Chronic Low Back Pain Multidisciplinary Group-based Rehabilitation Clinical trial study.

Introduction

Low back pain (LBP) is a major public health problem resulting in individual and society consequences in many communities (Eklund et al. 2014). LBP remains the primary cause of absenteeism and disability worldwide and patients who develop chronic Low Back Pain (cLBP) consume the majority health resources for their pain. Iinternational guidelines suggest intensive multidisciplinary approaches for individuals suffering from cLBP. These programs may not be complied by all cLBP patients because of being costly and time-consuming. Therefore lower intensity programs may be an alternative to full time hospital-based programs with valuable results of decreasing disability and pain severity for thepatients (Petit et al. 2014). Recently the physical and mental benefits of a multidisciplinary intervention program for treatment of chronic back pain has been subjectively rated significantly by the studied patients up to one month later (Keedy et al. 2014). However the long term effects of multidisciplinary approach is still challenging

Corresponding author: No. 11 Department of Rheumatology Faculty of Medical Sciences Tehran University for Medical Sciences Rheumatology Research Center Shariati Hospital Tehran Iran P. O. Box: 1411713137 Tel: 0098 21 84902405; Fax : 0098 21 88026956: E-mail: jamshida@sina.tums.ac.ir

Access this article online	
Website: ijmpp.modares.ac.ir	
DOI:	

(Vollenbroek-Hutten et al. 2004). In previous randomized controlled trial a group-based and relatively intensive outpatient multidisciplinary program continued with booster classes and telephone counseling was designed and evaluated. The program was accomplished by some qualified health care providers as a team and the findings at 6- 12- 24- and 30-month follow-ups verified the benefits of the program regarding disability and health-related quality improvement. This study aimed to explore the effects of the program among the baseline participants up to 36-months follow up.

Methods

This trial study is a 36-month extended follow up of an original randomized controlled trial that has been reported in detail in the clinical journal of pain (Tavafian Jamshidi & Mohammad 2011). This extended follow up is the last one. In present study the participants who took part in the original were followed up to 36 months. Here a summary of the study method is presented.

As it has been described previously (Tavafian Jamshidi & Mohammad 2011) the eligible participants of the original trial were recruited from three referral clinics affiliated with the Rheumatology Research Center of Tehran University of Medical Sciences (TUMS) in Tehran Iran. The inclusion criteria of the study was being aged ≥ 18 years with cLBP pain for more than 90 days. Patients who were suffering from infection spinal stenos or recent vertebral fracture were excluded from the study. Detailed inclusion/ exclusion criteria of the study were reported previously (Tavafian Jamshidi & Mohammad 2011).

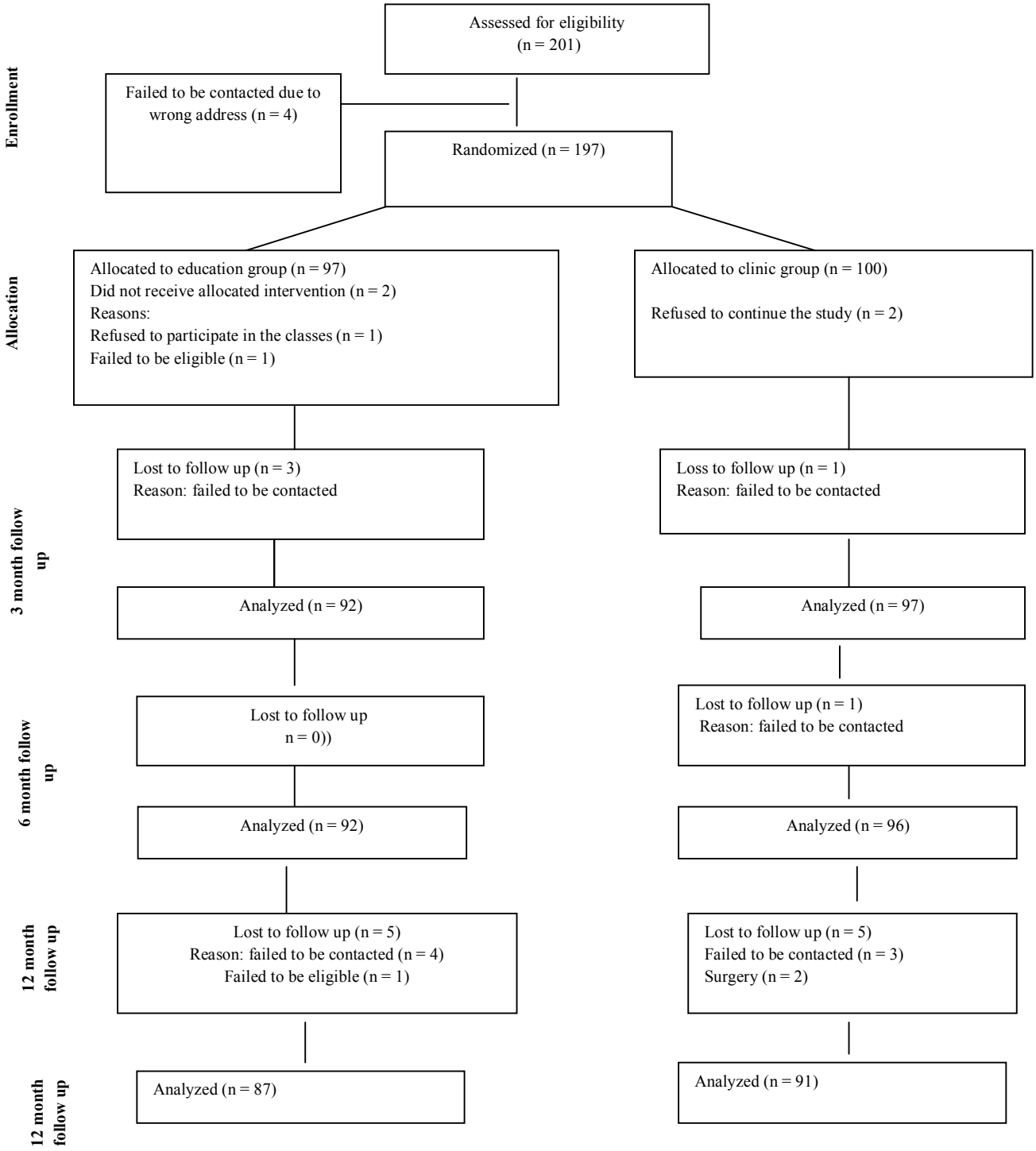
All participants in both groups were visited at the initial of the study and every 3 months by the same rheumatologist. Throughout the study medications such as analgesics NSAIDs muscle relaxants and antidepressant drugs were prescribed for the participants of both groups as necessary. Just intervention group had been provided with a group–based multidisciplinary rehabilitation program before and followed by monthly booster classes and telephone interview. The program included 5 two-hour sessions which were administered by different specialists. The full description of the program and contents of the sessions has been published in the previous article (Tavafian Jamshidi & Mohammad 2011). The monthly in-person booster classes and telephone counseling were facilitated by the health education specialist from 30- to 36- month follow ups. These sessions involved active motivational counseling during which the educator explored the knowledge perception beliefs and motivations of the participants in relation to preventive behaviors such as maintaining correct postures addressing fear avoidance managing daily stress doing specific exercise and improving coping skills regarding low back pain and disability. The full content and targets of the telephone counseling and booster classes have been described in original paper (Tavafian Jamshidi & Mohammad 2011).

In this extended follow up study demographic data and data regarding health-related quality of life (36-item Short-form General Health Survey; SF-36) and disability questionnaires (Quebec Disability Scale and Roland-Morris Disability) were collected at 36-month follow up. An intention to treat analysis used to compare the responded and non responded participants to this follow up study. Furthermore among responded participants the two interventions and control groups were compared. To remove any selection bias similarity of those providing 36-month follow-up and who did not were assessed in terms of baseline characteristics. Subsequent analyses were restricted to those participants providing 36-month follow-up only. Characteristics of the sample providing this follow-up were compared by treatment allocation. Repeated-measures analysis of variance (ANOVA) was done to examine within and between group changes over seven time points of 3-6-12-18-24-30- and 36-month follow ups. All statistical tests were two sided. Analyses were performed using SPSS version 18.0 (IBM company US).

Results

Figure 1 shows the study flowchart of participants from enrollment to 36-month follow up Seventy percent patients (139 of 197) of the original study provided extended 36 -month follow-up data. Table 1 shows the baseline demographic characteristics of the subjects followed to 36 months (n = 139). As this table shows the two groups were the same in terms of all baseline characteristics except for education level that was significantly better in intervention group (Table 1). Within and between-group

changes from 3 to 36 month follow up as well as the interaction between times and groups were shown in Table 2. The pattern of changes in both groups during 36 months were similar although the between group analysis revealed that the intervention group had consistently better outcomes in terms of all studied variables at all follow-up time points (Table 2). According to this table the interaction between time and group did not show significant differences between two groups over time for any subscale ($p > 0.05$). Table 3 shows repeated measure ANOVA of QDS and RDQ scale. According the results of this table the pattern of changes in both groups were significant ($p < 0.0001$). Even if not significant the intervention group had better outcome in comparison with control group in terms of QDS and RDQ scale. As this table shows there is no significant interaction between two groups over time during 36 month follow up.



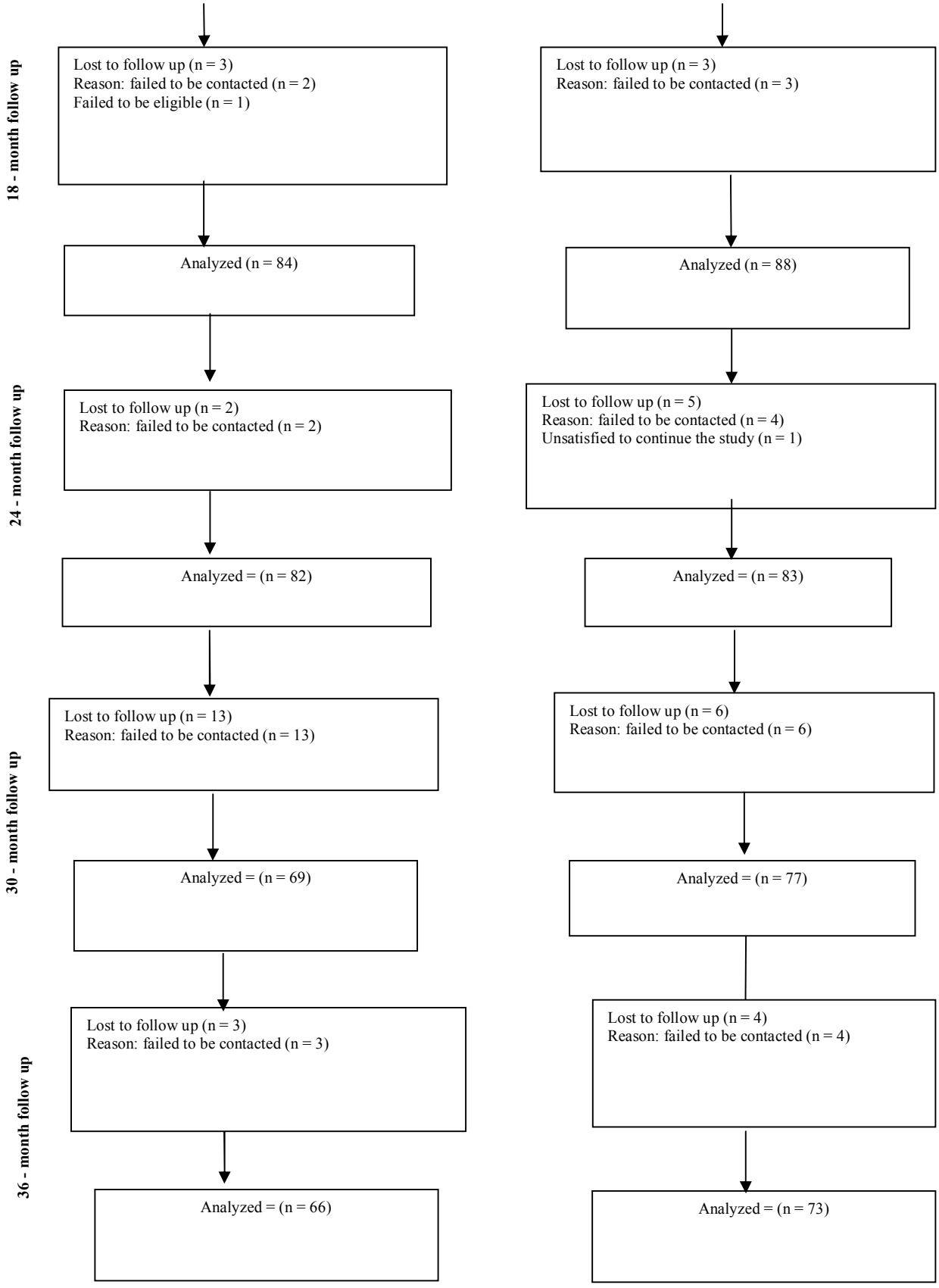


Figure 1. Flowchart of patients in eight points of time up to 36-month follow up.

Table 1. Demographic characteristics of participants who responded to 36-month follow up in two groups.

Characteristic	Responded (N = 139)		P value
	Intervention (N = 66)	Control (N = 73)	
	Mean (SD)	Mean (SD)	
Age (Yrs)	45.42 (9.54)	46.12 (11.47)	0.69
Weight (Kg)	71.36 (11.39)	71.25 (12.71)	0.95
Education (Yrs)	11.92 (3.74)	10.30 (4.04)	0.01
Gender	N (%)	N (%)	
Female	51 (77.3)	60 (82.2)	0.47
Male	15 (22.7)	1 3 (17.8)	
Marital Status	N (%)	N (%)	
Married	58 (87.9)	61 (83.6)	0.64
Single	5 (7.6)	6 (8.2)	
Widower/Divorce	3 (4.5)	6 (8.2)	
Smoker	N (%)	N (%)	
Yes	3 (4.5)	4 (5.5)	0.80
No	63 (95.5)	69 (94.5)	
Sciatica	N (%)	N (%)	
Yes	56 (84.8)	61 (83.6)	0.83
No	10 (15.2)	12 (16.4)	

Table 2. Repeated measure analysis of SF-36 sub scales for participants providing extended 36-month follow-up

Outcome variable	Intervention group (N = 66)	Control group (n = 73)	P		
Physical function			**Time diff**	**group diff**	**Time & group diff**
3- month follow up	68.33 (21.00)	59.18 (21.94)			
6- month follow up	78.33 (18.32)	63.22 (22.48)			
12- month follow up	80.60 (17.30)	64.04 (23.61)			
18- month follow up	81.14 (17.90)	66.64 (25.86)	< 0.0001	< 0.0001	0.68
24- month follow up	81.97 (17.07)	71.30 (20.88)			
30- month follow up	85.07 (32.43)	86.90 (24.55)			
36- month follow up	80.68 (21.81)	67.88 (27.19)			
Role physical					
3- month follow up	58.717 (75.89)	39.38 (36.04)			
6- month follow up	64.77 (36.689)	47.26 (38.77)			
12- month follow up	72.35 (37.24)	58.22 (37.74)			
18- month follow up	76.14 (34.65)	56.85 (40.45)	< 0.0001	0.002	0.56
24- month follow up	72.73 (38.41)	64.38 (38.84)			
30- month follow up	78.79 (33.18)	61.64 (40.20)			
36- month follow up	76.51 (36.66)	61.99 (42.10)			
Bodily pain					
3- month follow up	65.44 (19.99)	55.31 (22.46)			
6- month follow up	71.06 (22.68)	60.88 (24.99)			
12- month follow up	68.97 (17.35)	56.38 (22.11)			
18- month follow up	78.38 (18.25)	63.55 (22.27)	0.99	< 0.0001	0.63
24- month follow up	49.09 (15.37)	45.75 (15.59)			
30- month follow up	71.59 (16.75)	60.34 (22.37)			
36- month follow up	70.21 (17.99)	60.75 (23.39)			
General health					
3- month follow up	60.71 (19.64)	52.53 (22.11)			
6- month follow up	59.83 (21.61)	53.75 (21.51)			
12- month follow up	69.81 (21.33)	60.01 (24.40)			
18- month follow up	71.79 (20.91)	57.51 (22.39)	< 0.0001	0.005	0.62
24- month follow up	70.39 (23.18)	63.15 (24.56)			
30- month follow up	73.20 (24.14)	61.75 (25.71)			
36- month follow up	70.86 (27.61)	62.63 (27.71)			
Vitality	N = 66	N = 73			
3- month follow up	62.88 (20.51)	54.31 (20.69)	< 0.0001	0.002	0.26
6- month follow up	65.98 (20.80)	59.38 (23.45)			
12- month follow up	70.76 (21.70)	63.63 (23.31)			

18- month follow up	68.71 (23.34)	60.61 (19.44)			
24- month follow up	73.10 (19.90)	62.54 (21.60)			
30- month follow up	72.42 (21.90)	60.55 (20.96)			
36- month follow up	71.06 (22.16)	61.43 (22.23)			
Mental health					
3- month follow up	67.76 (19.05)	57.01 (23.41)			
6- month follow up	65.88 (22.03)	59.51 (23.30)			
12- month follow up	71.64 (20.60)	59.29 (24.20)			
18- month follow up	71.15 (20.38)	61.70 (21.65)	0.07	< 0.0001	0.19
24- month follow up	72.79 (19.29)	58.46 (23.94)			
30- month follow up	71.82 (21.97)	57.31 (24.62)			
36- month follow up	70.85 (21.36)	60.11 (21.80)			
Role emotional					
3- month follow up	51.51 (44.60)	43.83 (45.09)			
6- month follow up	57.07 (45.58)	52.05 (46.14)			
12- month follow up	73.23 (41.85)	52.05 (46.81)			
18- month follow up	74.24 (42.88)	52.05 (45.80)	< 0.0001	0.005	0.34
24- month follow up	72.73 (41.31)	61.19 (45.82)			
30- month follow up	72.22 (41.17)	51.60 (48.12)			
36- month follow up	70.20 (44.96)	58.44 (47.07)			
Social function					
3- month follow up	61.36 (19.60)	52.60 (20.00)			
6- month follow up	76.51 (21.54)	69.82 (28.02)			
12- month follow up	82.76 (18.83)	70.89 (28.34)			
18- month follow up	81.93 (23.03)	69.43 (22.27)	< 0.0001	< 0.0001	0.32
24- month follow up	85.29 (17.17)	77.23 (25.12)			
30- month follow up	86.93 (19.79)	73.63 (26.15)			
36- month follow up	83.71 (22.68)	71.74 (28.94)			

Table 3. Repeated measure analysis of Quebec Disability and Ronald Morris Disability scales for participants providing extended 36-month follow-ups

Outcome variable	**Intervention group N = 66**	**Control group N = 73**	**P**		
Qubec8	**Mean (SD)**	**Mean (SD)**	**Time diff**	**group diff**	**Time & group diff**
3- month follow up	25.50 (18.01)	32.72 (17.74)	< 0.0001	0.005	0.77
6- month follow up	19.74 (15.92)	27.30 (17.48)			
12- month follow up	17.07 (15.35)	24.15 (18.33)			
18- month follow up	15.10 (15.81)	23.09 (16.78)			
24- month follow up	15.51 (16.38)	21.39 (17.24)			
30- month follow up	13.84 (17.60)	21.55 (18.60)			
36- month follow up	11.82 (14.50)	17.85 (17.66)			
RDQ			< 0.0001	0.005	0.54
3- month follow up	9.19 (5.94)	10.50 (5.54)			
6- month follow up	6.51 (5.23)	8.87 (5.39)			
12- month follow up	5.84 (5.71)	9.08 (6.53)			
18- month follow up	5.63 (5.97)	7.83 (5.67)			
24- month follow up	5.34 (5.86)	7.52 (6.22)			
30- month follow up	4.20 (5.37)	7.30 (6.32)			
36- month follow up	5.35 (5.82)	7.27 (6.67)			

Discussion

This study was conducted to examine the effects of extended 36- month follow up of the original trial (Tavafian Jamshidi & Mohammad 2011). In the previous original study it was indicated that quality of life and disability in the both patients of intervention who underwent oral drug treatment as well as multidisciplinary program and patients of control group who complied just with oral drug treatment were improved over time. However these outcomes were much better improved in patient group who provided with multidisciplinary program addition to oral drug treatment. In previous evidence (Tavafian Jamshidi & mohammad 2011) it was showed that mental health were better changed in intervention group over time. In original study it was shown both mental health and disability were significantly improved in intervention group much better than the

other group overtime (Tavafian Jamshidi & Mohammad 2011).In present study the results of 36-month follow up also showed that these improvements continued among both groups but significantly better in group provided with multidisciplinary program. It means while comparing two groups at each follow up regardless time trend it is obvious that the intervention group had significantly better outcome for all quality of life dimensions as well as mental health and disability. Therefore it has been argued that multidisciplinary treatment has been much more effective than oral drug treatment in reducing pain back pain–related disability and improving quality of life dimensions. Although improvements regarding these outcomes occurred within oral drug treatment but these improvements were at a much lower level and slower rate and with less impact on disability and quality of life. Throughout the previous studies we discussed how the designed multidisciplinary program caused its' effects on intervention group. Here it could be considered that the success of the program until 36 months may be due to continued motivation of the patients to comply with the educational multidisciplinary program through monthly booster classes and telephone counseling which continued up to 36 month follow up (Tavafian Jamshidi & Mohammad 2011). In consistent with these results Petit and co-workers revealed the benefits of a mixed and lighter intensive multidisciplinary strategy on disability and quality of life compared to two other approaches like intensive hospital-based program and outpatient program (Petit et al. 2014). In Petit study the programs took for 5 weeks and observational follow-up was done until 12 months (Petit et al. 2014). However in present study the impacts of the program was assessed up to 36 months that is a long term effects. However it has been argued that less-intensive multidisciplinary program could not cause better outcome than usual care (Guzmán et al. 2001). Although results from present study showed mental health of patients complying with multidisciplinary program were not significantly improved over 36-month follow up while compared with the patients just presumed medications-comparing the trend of mental health improvement between two groups-the differences between two groups at each follow up time were significant. This result indicated that the psychology section of the program as well as telephone interview focused on problem solving and stress management benefited the patients to control their worries and stresses. However a previous physically oriented multidisciplinary program concluded no more effects on mental health in comparison with usual care treatment due to less attention to bio psyche social characteristics of back pain (Vollenbroek-Hutten et al. 2004). Although it was evidenced that to treat chronic pain patients effectively initial assignment to functional restoration program or psychological pain rehabilitation programs is necessary (Malaty et al. 2014). in present study this assignment was not done so all patients who themselves reported no psychological disorders were entered into the study and randomly assigned into two groups. Although at initial of the study two groups were the same in terms of all demographic characteristics and quality of life as well as mental health this limitation of this study should be considered in future studies.

Lack of social support on behalf of health system in Iran has been evidenced (Tavafian Gregory & Montazeri 2008). In present study not only psychological and biological aspects of chronic pain have been stressed social aspects of both the patient and the pain have been paid attention. Therefore it seems the maintenance of the program effects on quality of life in present study might be due to social support of multidisciplinary team which provided through booster classes and telephone counseling up to 36 months after intervention. One of the latest studies verified that interventions targeting the biological psychological and social aspects of chronic pain could improve objective and subjective chronic pain symptoms (Zappaterra Jim & Pangarkar. 2014). The effects of motivation and social support on more satisfactory outcomes in cLBP patients was reported elsewhere (Vong et al. 2011). Hereby some limitations of the study and could be as confounding factors should be mentioned.

In this extended follow up not all baselines randomized participants provided 36-month follow-up data mostly due to not being accessible at the time of data collection. Despite this limitation which is common in prolong clinical trials statistical analysis verified two studied groups of those who responded were the same in terms of all studied variables except for education so that the patients in intervention group were higher educated that might be affected on the results. Furthermore there were no data regarding using other service resources or additional visits during this extended follow-up from 30 to 36 months.

However this trial has its own strength to reveal that the long term effects of multidisciplinary among Iranian patients.

Conclusion

In present study it was acknowledged that the effects of multidisciplinary intervention on improving CLBP and disability could be continued up to 36 months. It seems more researches should be done to confirm this result.

Conflict of Interest

There is no conflict of interest for this article.

Acknowledgement

This work was funded by Research Deputy of Tehran University of Medical sciences. The author would like to thank them for this financial support.

Authors ' contribution

SST: conducted whole study and had full access to all of the data for analysis. Also she was involved in drafting the article

ARJ: assessed the patients and confirmed their eligibility for the study. He took responsibility for conducting the study and the integrity of the data and the accuracy of the data collection.

KM: participated in conducting the study. All authors approved the final version of the manuscript.

Funding/Support

We would also like to express our gratitude to Tehran University of Medical Sciences for financially supporting this research.

References

Eklund A. Axén I. Kongsted A. M. Lohela-Karlsson M. Leboeuf-Yde C. & Jensen I. (2014) Prevention of low back pain: effect cost-effectiveness and cost-utility of maintenance care-study protocol for a randomized clinical trial. *Trials.*15-102.

GuzmánJ. Esmail R. KarjalainenK. MalmivaaraA. Irvin E. & Bombardier C. (2001) Multidisciplinary rehabilitation for chronic low back pain: systematic review. *British Medical Journal*. 322 1511-1516.

Keedy N. H. Keffala V. J.Altmaier EM. & Chen J. J. (2014) Health locus of control and self-efficacy predict back pain rehabilitation outcomes. *The Iowa Orthopaedic Journal.* 34 158.

Malaty A. Sabharwal J. Lirette S. Chaiban G. Eissa H. & Tolba R. (2014) How to assess a new patient for a multidisciplinary chronic pain rehabilitation program: a review article. *The Ochsner Journal.* 14: 96-100.

Petit A. Roche-Leboucher G. Bontoux L. Dubus V. Ronzi Y. Roquelaure Y. et al. (2014) Effectiveness of three treatment strategies on occupational limitations and quality of life for patients with non-specific chronic low back pain: Is a multidisciplinary approach the key feature to success: study protocol for a randomized controlled trial. *BMC Musculoskeletal Disorders.* 15 131.

Tavafian S. S. Jamshidi A. R. & Mohammad K. **(**2011) Treatment of Chronic Low Back Pain. A Randomized Clinical Trial Comparing Multidisciplinary Group-based Rehabilitation Program and Oral Drug Treatment with Oral Drug Treatment Alone. *The Clinical Journal of Pain*. 27 (9) 811-818.

Tavafian S. S**.** Gregory D. & Montazeri A. (2008) The experience of low back pain in Iranian women: a focus group study. *Health Care For Women International.* 29 (4) 339-348.

Vollenbroek-Hutten MM. Hermens HJ. Wever D. Gorter M. Rinket J. & IJzerman MJ . (2004) Differences in outcome of a multidisciplinary treatment between subgroups of chronic low back pain patients defined using two multiaxial assessment instruments: the multidimensional pain inventory and lumbar dynamometry. *Clinical Rehabilitation.* 18 (5) 566-579.

Vong SK. Cheing GL. Chan F. So EM. & Chan CC. (2011) Motivational Enhancement Therapy in Addition to Physical Therapy Improves Motivational Factors and Treatment Outcomes in People With Low Back Pain: A Randomized Controlled Trial. *Archives of Physical Medicine and Rehabilitation.* 92 (2) 176-183.

Zappaterra M. Jim L. & Pangarkar S. (2014) Chronic pain resolution after a lucid dream: A case for neural plasticity? *Medical Hypotheses.* 82 (3) 286-290.

How to cite this article: Tavafian, S. S., Jamshidi, Ah. R., Mohammad, K., Treatment of low back pain: Extended follow up of an original trial comparing a Multidisciplinary Group-based Rehabilitation Program with Oral Drug Treatment alone up to 36 months. IJMPP. 2016; 1 (3): 93-100.