



The Effectiveness of Mindfulness-based Cognitive Therapy on Psychological Symptoms and Quality of Life in Systemic Lupus Erythematosus Patients: A Randomized Controlled Trial

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ABSTRACT

Objectives: This study was conducted to determine the efficacy of mindfulness-based cognitive therapy (MBCT) on psychological symptoms and quality of life (QoL) in patients with systemic lupus erythematosus (SLE). **Methods:** We conducted a randomized single-blind clinical trial in patients with SLE referred from the Imam Ali Clinic in Shahrekord, southwest Iran. The patients (46 in total in two groups of 23 each) were randomly assigned into the experimental and control groups. Both groups underwent routine medical care, and the experimental group underwent eight group sessions of MBCT in addition to routine care. The patient's QoL was assessed using the General Health Questionnaire-28 and 36-Item Short Form Health Survey before, after, and six months after intervention (follow-up). **Results:** A significant difference was seen in psychological symptoms and QoL between MBCT and control groups immediately after the intervention and at follow-up ($p \leq 0.050$). However, the difference was not significant for the physical components of QoL ($p \geq 0.050$). **Conclusions:** MBCT contributed to decreased psychological symptoms and improved QoL in patients with SLE with a stable effect on psychological symptoms and psychological components of QoL, but an unstable effect on physical components.

Systemic lupus erythematosus (SLE) is an autoimmune inflammatory disease with involvement of multiple organs and the production of autoantibodies against different components of the cell and with different clinical manifestations.^{1,2} Manifestations could be musculoskeletal, dermatologic, renal, cardiovascular, pulmonary, cardiac, hematologic, gastrointestinal, ocular, and neurologic.³ In a community-based study of rheumatic disease control, carried out by the Centre for Rheumatology Research, the prevalence of SLE in Iran was estimated 40 per 100 000 individuals.⁴ The incidence is eight-times higher in women than men.⁵ Lifetime chronic stresses lead to physical and mental effects and, subsequently, decrease the quality of life (QoL) of patients with SLE.⁶

Psychological therapies have been considered to reduce physical and mental complications. Segal and colleagues⁷ developed mindfulness-based cognitive therapy (MBCT) to prevent recurrence of depression (within eight group sessions). This approach is based on the mindfulness-based stress reduction by Kabat-Zinn. This approach increases the flexibility of cognitive activity and rumination, decreases overgeneralization of biographical memory and self-critical evaluation, and increases useful cognitive processes. Patients are encouraged to process an experience as it has already been developed and without judgment, and change their relationship with challenging thoughts and feelings and embrace them.⁷ The positive effect of this therapeutic approach on anxiety and mood

disorders, suicidal depression, chronic pain, cancer, and obsessive compulsive disorder (OCD) has been demonstrated.⁸⁻¹³ Some research indicates that the use of a stress management program can contribute to reducing pain and stress and improving mental and physical performance in patients with SLE.¹⁴ Navarrete-Navarrete et al,¹⁵ investigated predictive factors of QoL in patients with SLE and variations in them after cognitive-based therapy (CBT). The results demonstrated a remarkable improvement in patients health-related QoL.¹⁵ In another study, the experimental group received 10 sessions of CBT. The results demonstrated a significant reduction in daily stresses, anxiety, and depression. There was an improvement in QoL in the experimental group compared with the control group, but the reduction was not significant for the disease activity index.⁶ Cognitive therapies are reported to be effective in treating many mental disorders.¹⁶⁻²²

Considering that MBCT is an interventional method to decrease psychological symptoms, patients learn to become aware of their body sensation, thoughts, and emotions without being judged. This decreases negative judgments and thoughts, which are the main causes of psychological symptoms and leads to their elimination.

Most psychological interventions in people with SLE have been designed for Western populations. To our knowledge, no study has examined the impact of MBCT on psychological symptoms and indices of QoL in patients with SLE in Iran. This study was conducted to determine the efficacy of MBCT on psychological symptoms and QoL in patients with SLE residing in Shahrekord, Iran.

METHODS

This was a single-blind randomized clinical trial study and was registered as IRCT201412018253N3 in Iranian Registry of Clinical Trials.

A total of 46 patients with SLE were assigned and selected to take part in the study (23 patients in the experimental group and 23 in the control group). Patients with SLE were enrolled according to the American College of Rheumatology criteria^{23,24} from the Rheumatology Specialty Clinic of Ayatollah Kashani Hospital of Shahrekord, southwest Iran. The sampling method was based on convenience sampling because the data on the variability of the psychological symptoms were not available in both

groups. The sample size was calculated based on a 95% confidence level and a power of 90% to see a difference equal to one standard deviation (SD) of the mean psychological symptoms score between the two groups.

A sample size of 21 patients in each group was calculated and raised to 23 to obtain more precision. Inclusion criteria consisted of meeting at least four American College of Rheumatology diagnostic criteria, education to at least third grade of guidance school, and consenting to participate in the study. Patients were excluded if they had a history of taking psychiatric medications and undergoing psychological therapies within the past six months. The follow-up lasted six months.

A trained clinical psychologist conducted MBCT. Adherence to treatment was examined by the participants' reports at the beginning of each session. In addition, a checklist was developed for the participants to self-record daily routines and home assignments. Assessments were conducted by a trained psychometrics expert.

Demographic data including age, gender, marital status, employment status, educational status, and disease history was collected for each patient. The patients were matched by demographic data and medical history. All the participants completed the study procedure.

The self-reported General Health Questionnaire (GHQ-28), developed by Goldberg and Hiller, was used to distinguish between mental health and mental illness. GHQ-28 has four subscales: depression, anxiety, social function, and somatization. GHQ-28 has satisfactory reliability and validity for many cross-cultural populations, including Farsi speaking.^{25,26}

The 36-Item Short Form Health Survey (SF-36)²⁷ was used to assess QoL. It has two subscales; mental and physical. The scores range from 0 to 100 and are directly proportional to health conditions; therefore, a higher score means a better QoL.^{28,29}

After the participants were enrolled, they were randomly (random number table) assigned to one of two groups: MBCT and control. The used tests were run for both groups. Both groups underwent routine medical care. In the experimental group, each participant individually underwent eight sessions (45–60 minutes) of MBCT. In addition to usual medical care, general advice was given to the control group on how to comply with the pharmaceutical and nutritional orders and get enough rest.

Table 1: Curriculum for sessions of mindfulness-based cognitive therapy.

Session number	Contents
1	Establish orientation of the session and set the rules, raising exercise to train being in the present moment, body scan practice, breath focus exercise.
2	Body scan practice, thought and feeling exercise, pleasant event calendar, mindfulness of routine activity.
3	Seeing and hearing exercise, sitting meditation, three-minute breathing space, mindful walking, unpleasant event calendar.
4	Seeing and hearing exercise, sitting meditation, defining the territory of depression, negative automatic thought, diagnosis criteria for depression.
5	Sitting meditation, breathing space, reading poems related to mindfulness, introducing the concept of "acceptance".
6	Sitting meditation, mood, thoughts and alternative points exercise, breathing space, observing thoughts and feelings technique.
7	Sitting meditation, exercise to explore links between activity and mood, behavioral activation (generate a list of pleasure and mastery activities), identifying actions to do in low-mood periods.
8	Body scan practice, review the whole course, discuss how to keep up what has been developed over the past seven weeks, discuss plans and positive reasons for maintaining the practice.

The participants were required to do their MBCT assignments within 30 minutes of the session, at home. The control group, alongside routine medical treatments, received conventional recommendations such as moderate exercise, balanced diet, and sufficient rest.

The content of MBCT sessions was developed per Segal et al.,⁷ manual. The main components of MBCT were formal meditation, yoga, and formal daily mindfulness practices [Table 1]. The patients were assessed with the GHQ-28, SF-36 pre- and post-intervention, and six-month post-intervention (follow-up).

Descriptive statistics were used to assess demographic characteristics and disease history. We used the Komogorov-Smirnov test for assessing normal distribution of scores and Levene's test for assessing the equality of variances. For both QoL and psychological symptoms, the variances were equal, and the means were normal. Therefore, we could use covariance test. For continuous variables, data were presented as means \pm SD and categorical variables as frequency and percent.

The normal distribution and equality of variances of the scores were evaluated and confirmed using one-sample Kolmogorov-Smirnov and Levene's test, respectively. Analysis of covariance was used to compare the scores of QoL and psychological symptoms between the two groups.

Statistical analysis was performed using SPSS Statistics (SPSS Inc. Released 2008. SPSS Statistics for Windows, Version 17.0. Chicago, US) and *p*-values < 0.050 were considered statistically significant.

RESULTS

The mean age of the participants in the MBCT and control groups was 38 and 40 years old, respectively. The disease history of 13 participants was < 4 years, 5–8 years in 18 participants, 9–12 years in 10 participants, and > 13 years in five participants. Naturally, the longer the disease duration, the easier

Table 2: Participants' characteristics at the beginning of the study.

Characteristics	MBCT group	Control group	<i>p</i> -value
Age, mean \pm SD, years	38.0 \pm 13.6	40.0 \pm 14.1	Ns
Gender			
Male	8 (34.7)	7 (30.4)	Ns
Female	15 (65.2)	16 (69.5)	Ns
Education			
Lower level vocational school	5 (21.7)	3 (13.0)	Ns
Secondary and diploma education	10 (43.4)	13 (56.5)	Ns
Higher or university education	8 (34.7)	7 (30.4)	Ns
Disease duration, years			
< 4	6 (26.0)	7 (30.4)	Ns
5–8	10 (43.4)	8 (34.7)	Ns
9–12	5 (21.7)	5 (21.7)	Ns
> 13	2 (8.6)	3 (13.0)	Ns
Employment			
Employed	10 (43.7)	12 (52.1)	Ns
Unemployed	13 (56.5)	11 (47.8)	Ns

Data given as n(%) unless otherwise indicated.

Ns: not significant; MBCT: mindfulness-based cognitive therapy;

SD: standard deviation.

Table 3: Mean and standard deviation of scores on GHQ-28 and each subscales.

Measure	Group	Pre-treatment	Post-treatment	Follow-up
Psychological symptoms (GHQ-28)	MBCT	57.5 ± 9.7	37.2 ± 10.0	40.6 ± 8.8
	CG	54.3 ± 7.4	57.3 ± 8.1	57.5 ± 9.5
Depression	MBCT	13.6 ± 4.1	8.9 ± 2.3	9.8 ± 3.1
	CG	12.7 ± 2.5	14.4 ± 2.8	13.6 ± 2.4
Anxiety	MBCT	13.8 ± 4.2	9.2 ± 3.5	10.1 ± 3.2
	CG	13.4 ± 3.2	14.5 ± 3.5	13.8 ± 3.1
Social function	MBCT	15.6 ± 3.5	8.8 ± 2.7	9.5 ± 2.9
	CG	13.4 ± 3.7	14.7 ± 4.1	15.7 ± 4.3
Somatization	MBCT	14.4 ± 2.9	10.3 ± 2.3	11.2 ± 2.4
	CG	14.7 ± 2.9	13.7 ± 3.2	14.3 ± 3.6

GHQ-28: general health questionnaire 28-item; MBCT: mindfulness-based cognitive therapy; CG: control group.

the disease acceptance is and, therefore, the more difficult response to treatment. Fifteen participants in the MBCT group were women and eight were men. Most participants in both groups had secondary and diploma level education, 56.5% of participants in the MBCT group were unemployed (mainly housewives) and this figure was 47.8% in the control group [Table 2].

The mean score of psychological symptoms was 57.5 in the MBCT group and 54.3 in the control group. A significant difference was obtained in the mean score of psychological symptoms between the MBCT and control group pre-intervention, post-intervention, and at follow-up [Table 3].

Analysis of covariance indicated a significant difference in the mean score of psychological symptoms between the MBCT and control groups, both immediately after the treatment ($F = 98.60; p < 0.001$) and at follow-up ($F = 79.41; p = 0.001$). The effect size (Eta) after the treatment was 0.78, meaning that 78.0% of the derived difference was due to MBCT [Table 4]. The effects of MBCT on psychological symptoms were assessed by analysis of covariance immediately after treatment and at follow-up [Table 4].

Table 4: Analysis of covariance of psychological symptoms outcomes post-treatment and follow-up.

Statistical test/Source	df	F	p-value	Eta squared	Observed power
Pre-test ^a	1	37.40	0.001	0.49	0.95
Treatment ^a	1	98.60	< 0.001	0.78	0.97
Pre-test ^b	1	22.80	0.009	0.27	0.88
Treatment ^b	1	79.41	0.001	0.38	0.94

^a:post-treatment; ^b:follow-up; df: degrees of freedom.

The mean QoL score was 43.7 in the MBCT group and 44.3 in the control group, with no significant difference. A significant difference was obtained in the mean score for psychological QoL between MBCT and control groups pre-intervention, post-intervention, and at follow-up. For physical QoL, the mean score in the MBCT group increased after the intervention (49.7), but decreased at follow-up (45.6) [Table 5]. The effects of MBCT on QoL were assessed by analysis of covariance post-intervention and at follow-up [Table 6].

Analysis of covariance indicated a significant difference in the mean psychological QoL score between the MBCT group and the control group after the intervention ($F = 968.97; p < 0.001$) and in the follow-up ($F = 66.39; p = 0.004$). The effect size immediately after therapy and at follow-up was 0.46 and 0.32, respectively, meaning that 46.0% and 32.0% of the derived difference between the two groups, respectively, was due to MBCT [Table 6].

Also, a significant difference in the mean score of physical QoL was derived between MBCT and control groups immediately after intervention ($F = 473.22; p = 0.001$) but not in the follow-up ($F = 23.56; p = 0.157$). The effect size in the follow-up was 0.12, meaning that only 12.0% of the derived difference between the two groups was due to MBCT [Table 6].

DISCUSSION

The mean score of psychological symptoms decreased significantly in the MBCT group compared with the control group in the post-intervention and follow-up periods. The findings indicate that MBCT could

Table 5: Mean and standard deviation of the quality of life (QoL).

QoL (SF-36)	Group	Pre-intervention	Post-intervention	Follow-up
MCS	MBCT	43.7 ± 11.0	51.6 ± 10.4	50.3 ± 11.8
	CG	44.3 ± 10.8	43.7 ± 11.5	43.7 ± 12.4
PCS	MBCT	44.0 ± 11.5	49.7 ± 10.6	45.6 ± 8.9
	CG	43.2 ± 10.4	44.3 ± 11.7	44.8 ± 9.7

SF-36: short form 36-item health survey; MCS: mental component summary; PCS: physical component summary; MBCT: mindfulness-based cognitive therapy; CG: control group.

contribute positively to reducing psychological symptoms in patients with SLE, which is consistent with a study performed by Navarrete-Navarrete et al.⁶ In their study, 45 patients with SLE underwent 10 sessions of CBT and exhibited a significant decrease in daily stresses, anxiety, and depression and an improvement in QoL compared with the control group. However, little variation was seen in disease activity index. In another study, 122 patients with SLE, accompanied by their spouses, underwent psychoeducational intervention for six months. Immediately after the intervention, there was a significant difference seen in the couples interactions and problem-solving skills, and at follow-up, there was a significant improvement in social support, self-efficacy, couples interactions, and daily chronic fatigue improved significantly,³⁰ which is consistent with our findings. Because psychological symptoms and problems are directly correlated with self-efficacy, couples interactions, and daily chronic fatigue removal of the psychological symptoms leads to improvement of the other factors.

Other studies have demonstrated the efficacy of MBCT on pain tolerance in patients with low back pain,³¹ inability, pain, daily stresses in rheumatoid arthritis patients,³² depression symptoms in diabetes

patients,³³ OCD,¹³ and generalized anxiety disorder and panic.^{9,10} The results of these studies are consistent with our findings on the efficacy of this approach in reducing psychological symptoms in patients with SLE.

We also found a significant difference in the psychological parameters of QoL between the MBCT and control groups both immediately after and at follow-up, but the difference in physical parameters of QoL was significant both immediately after and six-months after the intervention. Bantornwan et al,³⁴ followed-up 15 patients with SLE for six months and compared them with the control group for QoL and normetanephrine use. The authors found no significant difference in normetanephrine use between the two groups, but the difference in psychological and physical QoL was significant.³⁴ The results of their study are consistent with our findings on the psychological parameters of QoL. The inconsistency of the findings in the physical parameters can be attributed to the intervention and its duration.

Navarrete-Navarrete et al,⁶ demonstrated that psychological interventions change psychological symptoms and QoL, but do not contribute to disease activity index. In their study, 45 patients were

Table 6: Analysis of covariance of quality of life outcomes at post treatment.

Statistical test/Source	df	F	p-value	Eta squared	Observed power
Mental health					
Pre-test ^a	1	153.42	0.010	0.68	0.94
Treatment ^a	1	968.97	< 0.001	0.46	0.78
Pre-test ^b	1	527.14	0.001	0.42	0.89
Treatment ^b	1	66.39	0.004	0.32	0.82
Physical function					
Pre-test ^a	1	295.14	0.000	0.72	0.91
Treatment ^a	1	473.22	0.001	0.38	0.84
Pre-test ^b	1	318.16	0.010	0.54	0.87
Treatment ^b	1	23.56	0.157	0.12	0.91

^a:post-treatment; ^b:follow-up; df: degrees of freedom.

assigned to an experimental or control group; the experimental group received CBT within 10 sessions. The results indicated a significant reduction in daily stresses, anxiety and depression, and improvement QoL in the experimental group compared with the control group. However, the reduction was not significant for disease activity index,⁶ which is consistent with our study. Since QoL is associated with different factors (e.g., stress, anxiety, and depression), which can be reduced by CBT, QoL can be improved. The predictive factors of QoL and the variation in them were examined in one study in patients with SLE after CBT.¹⁵ In agreement with our study, the authors found a remarkable improvement in patient's health-related QoL. Since patients with SLE patients suffer from higher daily stress compared to the general population, which is associated with severity of SLE symptoms,^{35,36} and psychiatric disorders, particularly mood and anxiety-related, are highly prevalent in these patients.³⁷ On the other hand, the disease is chronic and etiologically unknown,³ and patients with SLE have a lower QoL compared with the general population.^{38,39} Given that previous studies showed that psychological interventions, especially CBT, have positive effects on reducing stress and psychological problems as well as improving patient's QoL,^{6,15} so it is assumed that MBCT can also be effective in improving QoL and reduce psychological symptoms. MBCT has been reported to be influential in reducing anxiety, depression, suicide in soldiers,⁴⁰ reducing stress and improving the QoL in patients with breast cancer,⁴¹ improving the QoL and decreasing the severity of symptoms in patients with psoriasis,⁴² and reducing the symptoms of patients with irritable bowel syndrome.⁴³ Why the physical symptoms of QoL following intervention were not improved could be due to SLE being a medical condition, and MBCT can only improve psychological consequences of the disease and while medical interventions are needed to treat the physical symptoms.

The generalizability of the results is limited. Participants in this study may have completed the questionnaires with false information at post-intervention or follow-up, and because these questionnaires lack a lie detector, the results should be generalized with caution. Judgment about the effectiveness of MBCT in the groups was made based on the test scores (GHQ-28 and QoL), which is a common method but clinical interview was

not carried out to complete data on psychological symptoms and QoL in this study and, therefore, any generalization of the results should be conducted with caution. Additionally, the small sample size may affect the results of the study. Of the strengths of this study is the psychological intervention; MBCT is a new intervention method among the other types of studies conducted.

CONCLUSION

The findings of this study demonstrated that MBCT could improve patient's QoL and relieve psychological symptoms in patients with SLE, but was not effective in improving their physical symptoms because the main basis of treatment is medical. Medical treatments are only effective to remove the physical symptoms of SLE patients, and psychological interventions can only change their psychological outcomes although mental and physical problems interact in a complicated manner. Therefore, rheumatologists and psychologists are recommended to cooperate with each other to remove the psychological and physical symptoms of these patients.

Disclosure

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