

How Effective the Mindfulness-Based Cognitive Behavioral Therapy on Quality of Life in Women with Menopause

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INTRODUCTION

Menopause is a normal part of aging.^[1] However, the menopausal transition can cause psychological and somatic disturbances which can affect woman health. About 75% of women may experience some of menopause-related symptoms such as vasomotor symptoms, sleep difficulties, depression, and anxiety as well as urogenital symptoms and sexual dysfunction.^[2-5] It has been reported that 40% of women have depression symptoms associated with menopause.^[6] It has also been suggested that the physical symptoms may be exacerbated by women's psychological reactions to vasomotor and somatic symptoms.^[7]

Some women cope well with their menopausal symptoms and embrace this point of change without any difficulty. However, there are others who struggle

psychologically to deal with the changes.^[8] Optimizing health at menopause may help to enhance healthy physical and emotional health into older age. Simple lifestyle modifications can provide benefits to women with menopausal symptoms. There are many relaxation techniques such as deep breathing, guided imagery, massage, or progressive muscle relaxation which can help menopausal women to cope with and relieve some menopausal symptoms. Different interventions in the field of individual and group treatment of menopause include supportive therapies and cognitive and interpersonal psychotherapy.^[9]

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ABSTRACT

Introduction: In woman's life menopause can cause psychological and somatic disturbances. Psychological and behavioural intervention is effective in reducing menopause-related symptoms. **Aims:** The present study was done to find effectiveness of mindfulness-based cognitive behavioural therapy (MBCT) on quality of life among menopausal women. **Methods and Material:** The present study was double-blind randomized trial conducted among menopausal women at tertiary care hospital, Chennai, Tamil Nadu. The study was conducted among 50 women who had attained menopause. They were randomly divided into intervention ($n = 25$) and control ($n = 25$) groups. The MBCT was given once a week to intervention group over eight one-hour sessions and control group received no intervention. The data collection instruments included a demographic questionnaire, Kupperman's index, and menopause-related quality of life questionnaire, which were fulfilled by both groups before, immediately after, and 2 weeks after completion of intervention. Paired t-test was applied before intervention and at 10 weeks for both the groups. **Results:** The difference between the scores before and after intervention i.e after 10 weeks in all the domains and total domain was significant in intervention group compared to control group. **Conclusions:** Mindfulness based approaches may improve severity of vasomotor and psychological symptoms of menopause, thus enhancing quality of life.

KEYWORDS: Cognitive behavioral therapy, menopause, quality of life

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Mindfulness may be defined as a nonjudgmental sense of awareness that helps with the clarity of vision and the acceptance of emotions and physical phenomena as they occur.^[1] Mindfulness-based therapies offer an helpful approach to increase self-acceptance and coping by providing systematic training in mindfulness meditation as a self-learned approach to stress reduction. There is evidence that mindfulness-based interventions have proven effective in both physical and psychological conditions. Many recent studies of psychological interventions to improve coping such as cognitive behavioral strategies and relaxation techniques have been reported to improve vasomotor and depression symptoms.^[10]

Mindfulness-based therapies have proven effective in improving physical and psychological outcomes in a variety of clinical and nonclinical settings, but there are only a few studies that have focus on women with menopausal symptoms.^[7] There is a dearth of literature specific to mindfulness-based interventions and menopause, especially in developing countries like India. Furthermore, few studies that have been done are limited by a lack of well-designed randomized controlled studies with adequate sample size. Apart from that, there is a lack of an active control group for comparison. Hence, it is difficult to differentiate the independent effects of mindfulness interventions from the nonspecific effects of group interactions and additional attention received from instructor and group. Hence, the current study was done to find the effectiveness of Mindfulness based Cognitive therapy (MBCT) on quality of life among menopausal women using a comparison group.

MATERIALS AND METHODS

Study design

The present study was a double-blind, placebo-controlled randomized trial conducted among 50 menopausal women. The trial was conducted from January 2021 to June 2021 at a tertiary care teaching hospital, Chennai city, Tamil Nadu.

Study participants

The study participants were women who had attained menopause. The inclusion criteria were literate women with the age of 45–60 years and the women who had a score of 15 or more on Kupperman's index. Women who were on hormonal replacement therapy, drugs such as tricyclic antidepressants, selective serotonin reuptake inhibitors, sedatives, and other hormones; women having history of neuropsychiatric illness, cancer, chemotherapy, and sudden stress in the previous 6 months (due to unfortunate events in the family); and those who had

undergone hysterectomy with oophorectomy were excluded from the study.

Sample size calculation

The sample size was calculated with the assumption of the expected mean and standard deviation (SD) of the Menopause-Specific Quality of Life (MENQOL) after MBCT in the control and intervention groups as μ_1, σ_1 (2.11, 0.7) and μ_0, σ_0 (1.46, 0.72), as per the previous study by Enjezab *et al.*^[1]

The SD of MENQOL was about 0.7, and considering DELTA difference across groups, a sample size of 19 per group was required to achieve power of 80% and allowing for 5% type I error. To account for a nonparticipation rate/loss to follow-up rate of about 10%, the sample size was revised and a final sample size of 25 study participants in each group was included. 143 participants were initially assessed and based on our exclusion criteria 93 were excluded from the study. Then 50 participants were included in the final study 25 in intervention and 25 in control group as shown in Figure 1.

Intervention

The intervention of the trial is MBCT which is a 1-h weekly session of the program for 8 weeks. The intervention was provided to the study participants of the intervention arm by a team of experts having clinical psychology credentials and expertise. The sessions were focused on developing a deep awareness of what happens with one's mind or body every moment. This included meditation techniques, breathing exercises, body scan meditation, yoga, and walking meditation. In addition, cognitive methods such as the link between feelings and thought and understanding mental expressions such as depression and stress were also used. The participants were motivated to spend time on the homework. The home practice involved meditation, body scan, eating practice, and 3-min breathing practice. Every time during the weekly session, difficulties faced

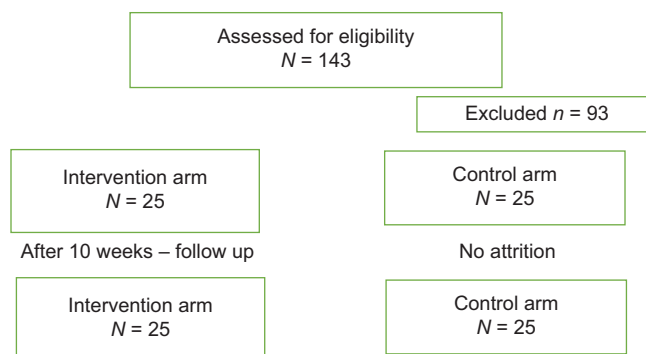


Figure 1: Randomization and allocation of 50 participants included in the analysis

were discussed and addressed by the experts. The study participants of the control arm were called separately and given general health advice and were assessed.

MBCT session details are given below:

- Session 1: Diet, nutrition, and eating practice exercises
- Session 2: Meditation types
- Session 3: Walking and sitting meditation
- Session 4: Thoughts and feeling – mind and body perception
- Session 5: Breathing exercises
- Session 6: Body scan
- Session 7: Yoga and practices
- Session 8: Overview of all aspects.

Conduction of study

Menopausal women who were visiting the outpatient department of the hospital were invited to take part in the study; after getting the written informed consent, the women who were fulfilling the inclusion criteria were included in the study.

Randomization and allocation concealment

Block randomization technique was followed to recruit the participants in the groups. The allocation of the study participants is based on the sequentially numbered opaque envelopes opened in the right order by the recruiting person. Not attending more than two sessions and being unwilling to attend and participate in the trial and other unfortunate events were considered attrition in the study.

Study tool

The study tool is a pretested, validated structured questionnaire. The questionnaire had three sections. Section I had details of basic sociodemographic details such as education, occupation, income, residence, marital status, parity, economic dependency, history of medical illness, and anthropometry. Section II is Kupperman's index^[11] which is a tool to assess menopausal symptoms. This index has three factors – psychological, vasomotor, and other related symptoms. The index assesses 11 menopausal symptoms, and each symptom was scored according to the severity such as 0 – no symptoms, 1 – mild, 2 – moderate, and 3 – severe and the maximum possible score of 51. The cumulative scores were categorized into classes with 1–14 indicating minimal, 15–20 indicating mild, 21–35 indicating moderate, and more than 35 indicating severe symptoms. This tool has been validated and has high precision. Section III is the MENQOL^[12,13] that assessed the quality of life that has 29 items on menopausal symptoms under four domains such as vasomotor, physical, psychosocial, and sexual. The total score is placed on a Likert scale from 1 to 6. The lower the score, the better is than the quality of life.

The MENQOL scores were calculated before and after the intervention. The participants were followed up after 2 weeks, and a follow-up assessment was also made.

Data analysis

The data were entered in a Microsoft Excel spreadsheet and analyzed with SPSS IBM version 22.0 (Armonk, New York: IBM Corp. 2012). The entire data were validated by checking for and correcting any unusual values and typographic errors. All the quantitative variables were being checked for compliance with normal distribution, within each study group by using visual inspection of histograms and normality Q-Q plots. Skewness and Shapiro–Wilk test *P* values were assessed. Then, the key primary and secondary outcome variables were compared between the two groups. The mean and SD of the normally distributed quantitative variables were compared between the two groups using an independent sample *t*-test. Paired *t*-test was applied before intervention and at 10 weeks for both the groups. *P* < 0.05 was considered statistically significant. *P* < 0.05 was considered statistically significant.

RESULTS

The mean (SD) age of study participants in intervention and control was 52.7 (±4.6) and 52.4 (±4.3), respectively. The mean (SD) age of the husband of the study participants was 56.5 (±4.6) and 56.4 (±4.4) in intervention and control, respectively. Baseline characteristics were comparable [Table 1].

The mean (SD) of total years since menopause was 5.4 (±2.1) and 5.8 (±2.2) in the intervention and control groups respectively. The mean (SD) of BMI was 24.5 (±4.1) and 24.4 (±5.7) in the intervention and control groups, respectively. Comorbid conditions such as hypertension and diabetes were found in 1 (4%) and 2 (8%), respectively, among the intervention group.

The mean (SD) of Kupperman's index of the intervention and control groups was 26.5 (±7.1) and 27.2 (±8.2), respectively. There was no significant difference between the Kupperman's index between the groups (*P* = 0.732).

At baseline, independent *t*-test was able to find no significant difference in individual domains and total domains of quality of life before intervention. After intervention of 8 weeks, in the intervention group, change was seen in all the domains – vasomotor, physical, psychosocial, and sexual and total domain (*P* = 0.000). Using paired *t*-tests, the difference between the scores before and after intervention, i.e., after 10 weeks in all the domains and total domain, was significant in the intervention group compared to the control

Table 1: Baseline characteristics of study participants (n=50)

Profile of study participants	Intervention (n=25), n (%)	Control (n=25), n (%)
Age group (years)		
45-50	9 (36)	9 (36)
51-60	16 (64)	16 (64)
Residence		
Urban	15 (60)	18 (72)
Rural	10 (40)	7 (28)
Occupation		
Housewife	18 (72)	17 (68)
Skilled	3 (12)	2 (8)
Semi-skilled	2 (8)	2 (8)
Unskilled	2 (8)	4 (16)
Socioeconomic status		
Upper	13 (52)	12 (48)
Middle	5 (20)	4 (16)
Lower	7 (28)	9 (36)
Education		
Primary	8 (22.9)	9 (25.7)
High school	18 (51.4)	12 (34.3)
Graduate and above	9 (25.7)	14 (30)
Marital status		
Married	24 (96)	23 (92)
Divorcee/widow	1 (4)	2 (8)
Parity		
No child	1 (4)	0
1	3 (12)	4 (16)
2	18 (72)	17 (68)
3	3 (12)	4 (16)
Economic dependency		
Yes	20 (80)	22 (88)
No	5 (20)	3 (12)
Kupperman's index		
Mild (16-20)	6 (24)	5 (20)
Moderate (21-35)	16 (64)	15 (60)
Severe (>35)	3 (12)	5 (20)

group ($P < 0.001$) [Table 2]. Figure 2 and Figure 3 show box and whisker plot of total MENQOL score among the two groups before and after intervention.

DISCUSSION

The purpose of the present study was to explore and compare the effects of MBCT on the quality of life in menopausal women. Overall, the results of the study provide support for the hypotheses that the MBCT intervention can help improve the quality of life in menopausal women.

The mean (SD) age of study participants in intervention and control was $52.7 (\pm 4.6)$ and $52.4 (\pm 4.3)$, respectively. This is comparable to a similar study done by Wong *et al.* in which the average age was

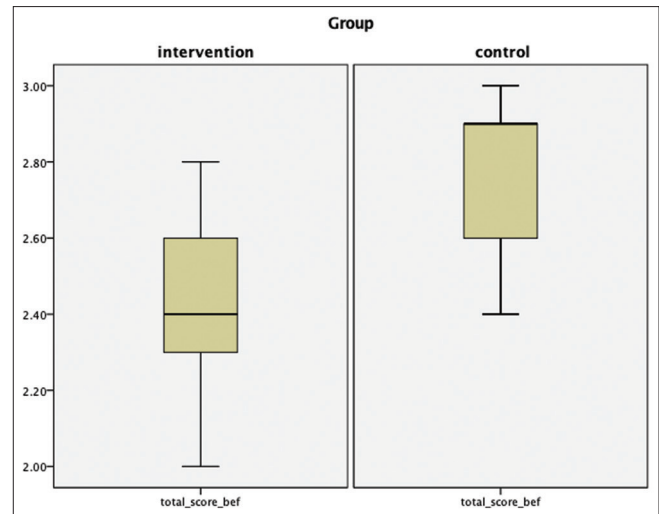


Figure 2: Total MENQOL score among the two groups before intervention ($n = 50$). MENQOL: Menopause-Specific Quality of Life

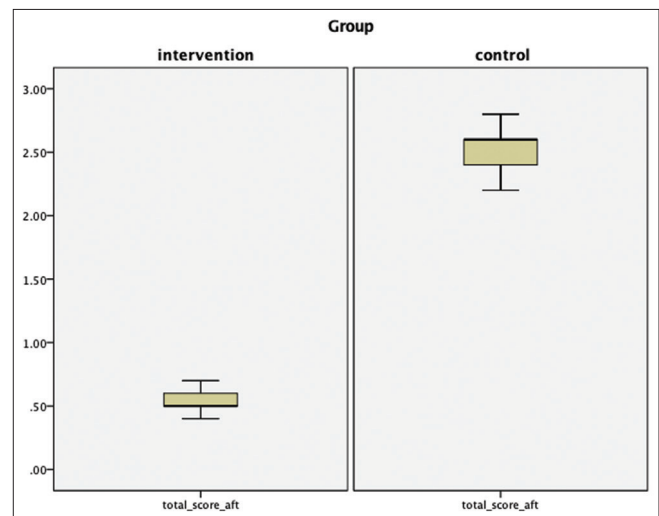


Figure 3: Total MENQOL score among the two groups after intervention ($n = 50$). MENQOL: Menopause-Specific Quality of Life

52.0 ± 3.09 years.^[7] Another study done in Iran, younger women were included where the mean age of the women was 50.89 ± 2.527 years in the intervention group and 49.67 ± 2.733 years in the control group.^[1] There were no significant differences between the two groups on demographic variables.

The comparison of the means of scores of the quality of life in the two groups at different stages of the study showed the effectiveness of the MBCT in significantly improving the quality of life in the intervention group. In the present study, the mean scores of the quality of life and all of its domains – vasomotor, physical, psychosocial, and sexual – after the intervention and in the follow-up were significantly less in the intervention group than in the control group.

Table 2: Comparison of Menopause-Specific Quality of Life scores between the two groups (n=50)

MENQOL	Mean±SD		P
	Intervention (n=25)	Control (n=25)	
Domain - Vasomotor			
Before intervention	2.96±1.13	3.08±1.18	0.717
After intervention	0.98±0.58	1.88±0.66	<0.001
Follow-up (10 weeks)	1.52±0.82	2.44±0.65	<0.001
Domain - Physical			
Before intervention	2.6±1.08	2.7±0.98	0.683
After intervention	0.24±0.01	2.08±0.7	<0.001
Follow-up (10 weeks)	0.56±0.12	2.04±0.73	<0.001
Domain - Psychosocial			
Before intervention	2.80±0.81	2.88±1.26	0.792
After intervention	0.7±0.32	2.2±0.72	<0.001
Follow-up (10 weeks)	0.56±0.17	1.82±0.68	<0.001
Domain - Sexual			
Before intervention	3±1.08	2.84±1.267	0.601
After intervention	0.9±0.21	2.2±0.76	<0.001
Follow-up (10 weeks)	0.94±0.2	1.92±0.6	<0.001
All domains			
Before intervention	2.48±1.1	2.72±1.1	0.456
After intervention	0.56±0.19	2.44±0.65	<0.001
Follow-up (10 weeks)	0.76±0.12	2.0±0.645	<0.001

*Repeated measures. Independent *t*-test. *P* <0.05 is significant. SD: Standard deviation, MENQOL: Menopause-Specific Quality of Life

The findings of our study are in agreement with similar studies done on effectiveness of mindfulness program. In Carmody *et al.*'s study,^[14] mindfulness-based stress reduction (MBSR) significantly improved the quality of life and its dimensions in the perimenopausal women, and this improvement lasted for up to 3 months after the intervention. Similar results were noted in a study done by Enjezab *et al.* in Iran in which the mean score of quality of life and its dimensions (except for the sexual dimension) immediately and 1 month after the completion showed a significant reduction in the intervention group.^[1] Furthermore, in Habibi and Hanasabzadeh study,^[15] mindfulness-based art therapy improved the quality of life in postmenopausal women. Consistent with Wong *et al.*'s study,^[7] the MBSR significantly reduced the psychological symptoms of depression and anxiety in perimenopausal and postmenopausal women. However, there was no significant improvement in other somatic, urogenital, and vasomotor symptoms in Wong *et al.* which is in contrast to our finding. In another study done by Brotto and Basson study,^[16] mindfulness-based group therapy significantly improved sexual desire and other indices of sexual response through the 6-month follow-up period. In our study also, similar results were reported. The results of this study are also consistent with those of other mindfulness studies of groups and cancer patients.^[17]

Thus, the results of our study provide support for the hypotheses that the MBCT intervention can help improve the style of life. This is one of the first mindfulness-based studies for menopausal women in Indian setup and reporting significant outcomes. Besides the MENQOL questionnaire was used, which assessed the effect of mindfulness on all the dimensions of the quality of life in menopausal women.

As a part of comprehensive health care, Well Women Clinics services should be provided for both physical and mental health conditions experienced by middle-aged women. The existing health programs for life cycle approach to women i.e the Reproductive, Maternal, Newborn, Child, and Adolescent Health Program should also give priority to health needs of women approaching menopause. The Reproductive, Maternal, Newborn, Child, and Adolescent Health Program should also give priority to health needs of women approaching menopause. Health providers need to be sensitized to special health needs of middle-aged women so that the health crisis of menopausal women can be properly addressed.^[18]

CONCLUSION

Mind-body approaches such as MBCT and cognitive behavior therapy may improve the frequency and severity of vasomotor and psychological symptoms of menopause, thus enhancing the quality of life and experience during the midlife period.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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