Effect of Aromatherapy with Essential oil of Lavandula Angustifolia Mill- Citrus Bergamia and Mindfulness-Based Intervention on Sexual Function, Anxiety, and Depression in Postmenopausal Women: A Randomized Controlled Trial with Factorial Design

Abstract

Background: Due to the importance of psychological support for women during menopause as a period with a high prevalence of mental health problems, this study aimed to evaluate the effect of the essential oil of lavender-Bergamot (La-Ber) and Mindfulness-Based Intervention (MBI) on sexual function, anxiety (primary outcome), and depression score (secondary outcome) in postmenopausal women with sexual dysfunction. Materials and Methods: This controlled randomized trial with a factorial design was performed on 132 postmenopausal women. Participants were randomly allocated into four equal groups: Aromatherapy-Routine Care (Aroma-RC), MBI-Placebo (MBI-P), Aromatherapy-MBI (Aroma-MBI), or Routine Care-Placebo (RC-P). Two to three drops of La-Ber or a similar placebo were inhaled three times a day for 8 weeks. Eight sessions of MBI intervention were conducted. At the end of the intervention and eight weeks afterward, the outcomes were assessed. Results: The sexual function score improved significantly in Aroma-MBI (adjusted Mean Difference [aMD]: 2.4, 95% CI: 0.01 to 4.80) and MBI-P (aMD: 2.6, 95% CI: 0.2 to 5.1) groups compared to the RC-P group. The anxiety score was reduced in the Aroma-RC group at the end of the intervention (aMD: -4.12, 95% CI: -7.41 to -0.72; p = 0.020) and eight weeks later as well as in the Aroma-MBI group. In terms of depression, the mean score of depression was significantly lower than the RC-P group in Aroma-RC and Aroma-MBI groups at the end of the intervention (p = 0.011). Conclusions: MBI and aromatherapy seem effective on sexual function and menopausal anxiety. MBI improves sexual function, while aromatherapy ameliorates anxiety and depression.

Keywords: Anxiety, behavior therapy, complementary therapies, depression, menopause, psychological, sexual dysfunctions

Introduction

Menopause is one of the critical stages of women’s lives and is, in fact, the most important event for middle-aged women. Endocrine, physical and psychological changes occur during menopause. This period is accompanied by the appearance of symptoms such as decreased libido, vaginal dryness, sleep disorders, and memory decline, all of which may negatively affect mood. Previous studies have shown that sexual dysfunction and anxiety are bilaterally related. Severe anxiety can cause dyspareunia by reducing blood flow to the vagina and impairing sexual function. Lack of anxiety control may have negative health effects. On the other hand, high levels of anxiety may exacerbate menopausal symptoms. During this period, not only the symptoms of depression increase but also the major depressive episodes occurs more than the premenopausal period. Menopause is also associated with a risk of depression recurrence or initiation.

There are several pharmacological and non-pharmacological methods for treating women’s sexual problems, anxiety, and depression during the menopausal period. The side effects of chemical drugs have shifted attention to non-chemicals and medicinal plants. Today, the tendency to use counseling techniques to reduce the use of drugs...
is increasing. Counseling with a mindfulness-based approach improves women’s sexual function by increasing the sense of sexual arousal during sexual activity as well as the correspondence between genital and mental sexual arousal.[8] The Mindfulness-Based Intervention (MBI) also had a positive effect on depression[8-11] and anxiety.[10,12,13]

Another accepted method in the treatment or reduction of menopausal symptoms is aromatherapy, which is the use of essential oils extracted from plants and flowers to improve the mental, psychological, emotional state as well as to treat various diseases through inhalation, massage and bath therapy.[14] Studies have shown that aromatherapy has many benefits in reducing stress, pain, anxiety, and relaxation by stimulating endorphin production.[14-16] Essential oils are used individually or in combination and it is fully accepted that the effect of an oils mixture is superior to a single oil.[17] Common herbs for aromatherapy include Lavandula angustifolia Mill (Lavender) and Citrus bergamia (Bergamot).[18,19] Previous studies have shown that aromatherapy using essential oil of Lavandula angustifolia Mill improves human sexual function in postmenopausal women.[20-25] Aromatherapy has also been effective in reducing anxiety.[22] Despite sufficient evidence, Bergamot is widely used to reduce anxiety and stress through aromatherapy. Recently there is an increasing tendency to use mixed-method intervention including MBI in combination with aromas in the management of psychophysical disorders, especially aging-related symptoms. It seems that aromatherapy-enhanced mindfulness meditation is a feasible approach and may be a cost-effective therapeutic intervention.[17] Due to the importance of psychological support for women during menopause as a period with a high prevalence of mental health problems and also the lack of studies on the effectiveness of aromatherapy with the combined essential oil of Lavender and Bergamot (La-Ber) in combination and MBI approach, this study aimed to evaluate the effect of MBI or/and aromatherapy, on sexual dysfunction and mild or moderate anxiety as the primary outcome and depression score as the secondary outcome in postmenopausal women.

Materials and Methods

This is a randomized controlled trial (IRCT2013 1009014957N8) with a factorial design conducted on 132 postmenopausal women. Sampling, data collection, and follow-up were performed from March 30, 2019, to November 21, 2020. The researcher selected six community health centers of Tabriz city with different socio-economic statuses. After obtaining the required permission and referring to the above-mentioned centers, 22 postmenopausal women aged 50 to 60 years were selected through the convenience sampling method from each center. So that, after fully explaining the research objectives, the study criteria were examined and if they were eligible to participate and desired to participate, they were entered into the study.

Eligibility criteria were married postmenopausal women between the ages of 50-60, literate women, Female Sexual Function Index (FSFI) questionnaire score less than 28,[26,27] having mild to moderate anxiety based on the Beck Anxiety Scale, having sexual intercourses, monogamous family, normal menopause, no physical and mental illnesses (depression, diabetes, cardiovascular disease, olfactory disorders, mental disability) according to the women’s expression and health records, no use of drugs that affect sexual intercourse (sildenafil, antidepressants, antihistamines, diazepines, barbiturates, amphetamines, antihypertensive drugs, cocaine, thiazide diuretics, narcotics,[7,20,21] no consumption of herbal substances to increase sexual desire in man or woman (ginseng, cinnamon, ginger, etc.), no allergy to any of the herbal medicines, no addiction or habitual consumption of alcohol and tobacco by the woman, an unfortunate event at the last 3 months (death or acute illness of close relatives), no impaired smelling sense and other nasal disorders (fractures, deviations, rhinitis), and not using of hormone therapy for the past 6 months.

In addition, the case with the probability of not participating in mindfulness sessions for two times or more, or not using aromatherapy for more than one day, did not enter the current study.

The sample size was calculated to be 26 in each group based on (the difference between two independent means) in each of the sexual function and anxiety variables using G*POWER software (v. 3.1.2) and the below formula. According to the study of Malakouti et al.,[28,29] for the variable of sexual function, and considering m1 = 18.4, m2 = 22.9.08, sd1 = 5.40, sd2 = 3.30, power = 80%, α = 0.05 and two-tail test. Also, according to the study of Farshbaf et al.[30] on the variable of apparent anxiety and considering m2 = 40.74, m1 = 45.26 and sd1 = sd2 = 5.72, power = 80%, α = 0.05 and two-tail test, the sample size of 27 for each group was taken into account. Also, according to the latent anxiety variable and considering m2 = 39.35, m1 = 43.73 and sd1 = sd2 = 5.64, power = 80%, α = 0.05 and two-tail test, the sample size was estimated to be 27. Considering the possible 20% dropout, the final sample size for each group was estimated as 33 women.

The assignment sequence was determined using Random Allocation Software (RAS) by the random block classification method based on postmenopausal years (less than or more than 5 years) with quadruple and octave blocks with 1: 1: 1: 1 allocation ratio. Study subjects were classified into four groups receiving 1) La-Ber Aromatherapy-Routine Care (Aroma-RC), Aromatherapy-Placebo (Aroma-P),...
Aromatherapy and Mindfulness Based Intervention (Aroma-MBI), or Routine Care-Placebo (RC-P). In order to conceal the group allocation, the type of intervention, together with the intervention drugs (aroma or placebo), was written on a paper based on a random assignment sequence by the person not involved in the research and put in opaque envelopes numbered from 1 to 132. The first envelope was given to the first person who met the entry criteria, and the process continued until the samples were completed. The subject, the researcher, and the analyst did not know about the contents of the envelope (allocation concealment). In this study, after randomly assigning the individual to the study group, blinding the researcher and the participant was not possible in terms of counseling, but the outcome and statistical analyst were blind. Based on random allocation, a bottle containing La-Ber aroma or similar placebo was given to each participant, of which two to three drops were rubbed and inhaled on the forearm skin three times a day for 8 weeks. MBI was conducted once a week for eight sessions.

The researcher referred to the selected centers with a letter from the Vice-Chancellor of Research and Technology, and then the individuals were randomly divided between the study groups as previously stated. Since the duration of the intervention was 8 weeks, the dependent variables were measured three times (before, immediately after, and 8 weeks after the intervention).

In this study, the total essential oil of *Lavandula angustifolia Mill*, prepared by vapor condensation of related flowers and *Citrus bergamia* essential oil, prepared by cold pressing from the outer shell cells of bergamot fruit (sour orange family) was purchased from Gol Daru, Isfahan, Iran (https://www.goldaruco.com/). Then, in Biotechnology Research Center, under the supervision of a Pharmacognosy expert, after analyzing the essential oils, a combined aroma with a concentration of 0.04% of bergamot essential oil and 5% lavender was prepared in 60% ethanol solution. The main aroma and placebo (containing propylene glycol) were prepared in 30-ml sealed dark glass, which was similar in appearance, to be used for eight weeks. Injectable essential oil compounds were identified by comparing their mass spectra with the internal spectrometer reference library.[14]

MBI: A new approach to behavioral therapy that includes observation, feeling, awareness, and love, which focuses on the present and on facilitating concentration and attaining awareness. This intervention involves attention based on the present time and place with a non-judgmental approach that uses the building blocks of intention, attention, and attitude.[31]

In the present study, MBI was performed in 8-week counseling sessions in the training room of Tabriz health centers, and due to the COVID-19 pandemic, the sessions were held in a proper and large environment with the presence of a limited number of participants and using special techniques based on mindfulness. The content of the intervention sessions was as below: Session 1: Familiarity with members, description of rules and duties of group members, statement of goals, the introduction of mindfulness-based counseling, planning of meetings. Examining the participants’ main complaint, identifying the thoughts and feelings behind these actions, and identifying the participant’s empirical avoidance. Session 2: Obstacles that included meditation treatment included body examination, ten minutes of mindfulness breathing, and mind meditation. Home exercises were also defined as performing daily continuous activities to record the experience of a pleasant and enjoyable event of the day. Session 3: Breathing with mindfulness (physical movements with the help of this technique), conscious movements (“Exercise and Breathing Exercise” to keep thoughts and mind wide, were done by following mindfulness exercises and focusing on conscious breathing and body parts. The exercise began with brief mindfulness of “seeing” or “listening.” The daily exercises continued as before. Session 4: Staying in the moment, which includes five minutes of seeing or hearing in a mind-conscious manner (awareness of breathing, body parts, sounds, thoughts, and conscious choices). Walking with the mind was part of the session and homework exercises, which were done along with the exercises of the previous weeks. Session 5: Accept and allow (mindfulness sessions that are aware of breathing and body parts). In the sixth session, the origins of the thoughts and that they are not real were discussed in order to change the mood and attitudes, and the house exercises were continued as before. Session 6: The origin of the thoughts and that they are not real was talked about in order to change the moods and attitudes and the home exercises were still done according to the previous routine. Session 7: How to best take care of ourselves and also about future decisions, creating questions in participants to answer their personal reflections during this course and how to use mindfulness techniques in the future life of clients were discussed. Session 8: How to best take care of ourselves and also about future decision making, how to use mindfulness techniques in the future life of clients were discussed.

The researcher who was an MSc student of counseling in midwifery achieved the certification of attending an MBI workshop from MODAT Higher Education Institute in March 2019 Tehran.

Data collection tools included a questionnaire of demographic characteristics, fertility and medicine, FSFI questionnaires,[32] Beck Anxiety Inventory (BAI)[33] and Beck Depression Inventory (BDI-II).[34] daily aroma consumption checklist, possible side effects registration form and a five-point Likert scale (very satisfied; satisfied;
neither satisfied nor dissatisfied; dissatisfied; very dissatisfied) related to drug satisfaction.

Female Sexual Function Index

The standard FSFI was used to assess sexual function in postmenopausal women. This questionnaire consists of 19 items that are related to intercourse and surveyed women’s sexual function during the last four weeks in six areas including desire, arousal, vaginal lubrication, orgasm, sexual satisfaction, and pain. The final score is between 2 and 36, and with an increasing score, sexual function improves. The validity and reliability of the instrument have been confirmed in previous studies in Iran. Cronbach’s alpha for the whole instrument and each of the components of sexual response, pain, desire, and satisfaction are 0.93, 0.95, 0.93, 0.82, and 0.89, respectively, which indicates a high degree of internal consistency and the overall score of correlation was 0.82, and the score of each component was from 0.66 to 0.81.[32,35]

BAI was used to assess anxiety. In 1990, Beck and Steer introduced the BAI, which specifically measures the severity of individuals’ clinical anxiety symptoms. This questionnaire is a self-report questionnaire designed to measure the severity of anxiety in adolescents and adults. The questionnaire is a 21-item scale in each item of which, the participants choose one of four options that indicate the severity of anxiety. This questionnaire’s total score is in the range of 0 to 63 so 0-7 is classified as none or minimum anxiety, 8-15 mild anxiety, 16-25 moderate anxiety, and above 26 as severe anxiety 33. Cronbach’s alpha coefficient has been 0.92, the reliability coefficient with a one-week retest method has been 0.75, and the correlation coefficient of the items from 0.30 to 0.76.[36]

Beck Depression Inventory (BDI-II): This tool has 21 four-choice items consisting of questions on a four-point scale from zero to three, with an overall score ranging from zero to 63. The participant chooses the answers he feels to be true about his feelings over the past two weeks. A score of 28 or higher indicates severe depression. A score between 14 and 28 indicates mild to moderate depression. This questionnaire is standard and approved, and Beck et al.[34] obtained the test-retest coefficient of 0.93. Cronbach’s alpha coefficient is 0.86, and the reliability coefficient by the one-week retest method is 0.75. Also, the correlation of its substances is from 0.73 to 0.92. Individuals with scores above 28 were referred to a mental health care provider for appropriate action and were excluded from the study before randomization.

The above-mentioned questionnaires were completed by individuals before random assignment of groups, after 8 weeks of intervention, and also eight weeks after the end of the intervention period.

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Data were analyzed using SPSS software version 21 (SPSS 21, SPSS Inc., Chicago, IL, USA). Data normality was assessed using Kolmogorov-Smirnov test. Chi-square, Chi-square trend, and Fisher’s exact test for categorical variables, and also, one-way Analysis of variance for continuous variables in demographic characteristics and baseline variables were used. Tukey’s post hoc test was also used for multiple intergroup comparisons before the intervention. Analysis of covariance, and Mann-Whitney U test was used for study outcomes at the end of the intervention. In terms of within-group analysis, repeated measure ANOVA and Wilcoxon test was used. p value < 0.05 was considered statistically significant. All calculations were based on intention-to-treat analysis.

Ethical Considerations

This study was approved by the National Ethics Committee with the ID of IR.TBZMED.REC.1398.775 and was registered in the Clinical Trial Registration Center. All procedures have been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). Informed consent was obtained from each participant. The women who had a high score of depression and anxiety were referred to the psychologists.

Results

Baseline characteristics

In the present study, 678 women were evaluated in terms of inclusion criteria of which 546 women were excluded from the study due to the lack of these criteria (n = 221) and unwillingness to participate in the study (n = 325). Finally, 132 women were randomly divided into four groups (n = 33 in each group). However, five women in the MBI-P group and four women in three other groups did not receive the allocated intervention due to the fear of the COVID-19 pandemic. During the intervention, one participant in the MBI-P did not attend counseling sessions due to reluctance to continue. Finally the other women completed this study and analyzed as below: MBI-P (n = 27), Aroma-MBI (n = 29), Aroma-RC (n = 29), and RC-P (n = 29) [Figure 1].

In MBI-P, Aroma-MBI, Aroma-RC, and RC-P groups, the Mean (SD) age of postmenopausal women were 56.00 (3.21), 55.34 (3.32), 54.72 (3.21), and 56.59 (4.25) (p = 0.212), respectively. There was no significant difference in other basic characteristics of the participants in the study groups (p > 0.05) [Table 1].

Primary outcomes

In the MBI-P group, the mean changes in the “desire” component at the end of the intervention (p = 0.042) and 8 weeks later (Mean Change [MC]: 0.51, 95% CI: 0.11 to 1.02; p = 0.023), in the “lubrication” component at the end of the intervention (MC: 1.0, 95% CI: 0.20 to 1.90;
p = 0.014) and 8 weeks later (MC: 1.0, 95% CI: 0.00 to 1.90; p = 0.049), the pain score after the intervention (MC: 0.81, 95% CI: 0.11 to 1.52; p = 0.023) and the overall FSFI score at the end of the intervention (MC: 3.51, 95% CI: 0.31 to 6.71; p = 0.039), increased significantly compared to pre-intervention values. In the Aroma-MBI group, the desire score, 8 weeks after the intervention (p = 0.021) and lubrication, just after the intervention (MC: 0.80, 95% CI: 0.20 to 1.50; p = 0.011), and the overall FSFI score at the end of the intervention (MC: 3.01, 95% CI: 1.0 to 5.10; p = 0.003) and eight weeks after the intervention (MC: 2.40, 95% CI: 0.65 to 4.32; p = 0.007) showed a statistically significant increase [Table 2].

Intergroup analysis showed that in the MBI-P group compared to the RC-P group, the mean score of “desire” 8 weeks after the intervention (adjusted Mean Difference [Amd]: 0.60, 95% CI: 0.10 to 1.11; p = 0.025) and lubrication (aMD: 0.90, 95% CI: 0.20 to 1.72; p = 0.015) at the end of the intervention, the overall FSFI score at the end of the intervention (aMD: 2.62, 95% CI: 0.21 to 5.12; p = 0.032) and 8 weeks after the intervention (aMD: 2.82, 95% CI: 0.44 to 5.34; p = 0.024), and also in the Aroma-MBI group compared to the RC-P group, the components of desire and arousal at the end of the intervention (p = 0.048 and aMD: 0.51, 95% CI: 0.01 to 1.12; p = 0.045, respectively) and 8 weeks after (aMD: 0.68, 95% CI: 0.11 to 1.12; p = 0.013 and aMD: 0.52, 95% CI: 0.011 to 1.00; p = 0.047, respectively) and the overall FSFI score at the end of the intervention (aMD: 2.41, 95% CI: 0.01 to 4.83; p = 0.047) were significantly higher. Statistical results showed that the components of orgasm, satisfaction and pain were not significantly different between the study groups and RC-P group (p > 0.05) [Table 3].

In terms of anxiety, in the intergroup comparison, the anxiety score in the Aroma-RC group at the end of...
the intervention (MC: -5.72, 95% CI: -8.61 to -2.72; \( p < 0.001 \)) and 8 weeks later (MC: -4.61, 95% CI: -7.81 to -1.42; \( p = 0.003 \)) and also in the Aroma-MBI group at the end of the intervention (MC: -5.12, 95% CI: -7.21 to -3.12; \( p < 0.001 \)) and 8 weeks later (MC: -4.91, 95% CI: -7.41 to -2.42; \( p < 0.001 \)), reduced compared to baseline values. In the MBI-P group, only at the end of the intervention (MC: -3.82, 95% CI: -7.01 to -0.63; \( p = 0.007 \)), this score’s reduction was statistically significant. The General linear model test results by adjusting the baseline values of anxiety showed that the mean score of anxiety in the Aroma-RC group at the end of the intervention (aMD: -4.12, 95% CI: -7.41 to -0.72; \( p = 0.020 \)) and 8 weeks later (aMD: -3.31, 95% CI: -6.41 to -0.013; \( p = 0.049 \)) as well as in the Aroma-MBI group at the end of the intervention aMD: -3.52, 95% CI: -6.92 to -0.13; \( p = 0.043 \)) and 8 weeks later (aMD: -3.52, 95% CI: -6.82 to -0.34; \( p = 0.032 \)) significantly decreased compared to the RC-P group [Table 4].

**Secondary outcomes**

In terms of the depression score, the results of statistical analysis showed that in the Aroma-RC group at the end of the intervention (MC: -7.40, 95% CI: -11.30 to -3.50; \( p < 0.001 \)) and eight weeks later (MC: -6.90, 95% CI: -11.20 to -2.61; \( p = 0.001 \)) as well as in the Aroma-MBI group at the end of the intervention (MC: -3.40, 95% CI: -6.21 to -0.62; \( p = 0.015 \)) and eight weeks later (MC: -4.20, 95% CI: -8.21 to -0.11; \( p = 0.043 \)), the mean score of depression decreased significantly compared to baseline values. In comparing the study groups, the adjusted mean score difference in the Aroma-RC group was significantly lower than the RC-P group at the end of the intervention (aMD: -4.40, 95% CI: -7.80 to -1.0; \( p = 0.011 \)) [Table 5].

**Side effects**

In terms of reported side effects, vomiting was reported in one case in the MBI-P group and two cases in each of the Aroma-RC and Aroma-MBI groups. Tachycardia was reported in three cases in MBI-P, five cases in RC-P, two cases in Aroma-MBI, and four cases in Aroma-P groups. Headache was reported in one individual in the MBI-P group, five in the RC-P group, six in the Aroma-MBI group, and 10 in the Aroma-RC group. Only one person from the Aroma-RC group reported nasal congestion. Cough was reported in two individuals in the MBI-P group and one in the RC-P and Aroma-MBI group. These complications were shown early in the intervention and were partially resolved later in the study, and did not stop the study.

**Discussion**

Due to the importance of psychological support for women during menopause as a period with a high prevalence of mental health problems, this study aimed to evaluate the effect of the essential oil of lavender-Bergamot (La-Ber) and Mindfulness-Based Intervention (MBI) on sexual function, anxiety (primary outcome), and depression score (secondary outcome) in postmenopausal women with sexual dysfunction. According to our results, MBI-placebo or La-Ber aromatherapy was effective on the overall score of sexual function at the end of the intervention compared to the RC-P group, while its positive effect was observed only in the Aroma-P group 8 weeks after the intervention. The anxiety score at the Aroma-RC and Aroma-MBI groups at the end of the intervention and 8 weeks after the intervention was more effectively lower than the RC-P group. The changes in the mean score of depression at the end of the intervention

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**Table 1: Baseline characteristics of the study participants**

| Variable                | RC-P (n=33)   | MBI-P (n=33) | Aroma-RC (n=33) | Aroma-MBI (n=33) | \( p \) |
|-------------------------|---------------|---------------|-----------------|------------------|------|
| Age (year)*             | 56.59 (4.25)  | 56.00 (3.21)  | 54.72 (3.21)    | 55.34 (3.32)     | 0.212***|
| Menopause duration (year)* | 5.83 (3.75)  | 5.63 (4.11)  | 4.48 (3.34)    | 5.31 (2.81)       | 0.550***|
| ≤Five years             | 19 (57.57)    | 18 (55.84)    | 18 (55.44)     | 55.34 (54.54)     | 0.942**|
| >Five years             | 14 (42.04)    | 15 (45.46)    | 15 (45.46)     | 15 (45.46)        |      |
| Education**             |               |               |                 | 0.221****         |
| <Diploma of high school | 25 (75.76)    | 26 (78.78)    | 22 (66.67)     | 22 (66.67)        |      |
| Diploma or more         | 8 (24.24)     | 7 (21.22)     | 11 (33.33)     | 11 (33.33)        |      |
| Occupation**            |               |               |                 | 0.420*****        |
| Housewife               | 27 (81.83)    | 28 (84.85)    | 26 (78.79)     | 30 (90.91)        |      |
| Occupied or retired     | 6 (18.18)     | 5 (15.15)     | 7 (21.21)      | 3 (9.09)          |      |
| Weight (kg)*            | 75.30 (9.73)  | 73.57 (9.70)  | 75.53 (12.72)  | 77.43 (14.89)     | 0.682***|
| Hormone therapy (yes)** | 0 (0.00)      | 1 (3.03)      | 2 (6.06)       | 0 (0.00)          | 0.791*****|
| Soy consumption (yes)** | 0 (0.00)      | 0 (0.00)      | 2 (6.06)       | 2 (6.06)          | 0.072******|
| Taking vitamin D3 (yes)** | 19 (57.58) | 22 (66.67)    | 18 (54.55)     | 18 (54.55)        | 0.714*****|

SSRC-P: Routine Care-Placebo; MBI-P: Mindfulness-Based Intervention- Placebo; Aroma-RC: Aromatherapy-Routine Care; Aroma-MBI: Aromatherapy-Mindfulness-Based Intervention; * mean (SD); **n (%). *** one-way ANOVA, **** Chi-square, ***** Fisher exact test.
Table 2: Mean changes from the baseline in the total Female Sexual Function Index (FSFI) and its domains within the study groups

| Variable     | Mean (SD) RC-P* (n=29) | Mean Change [MC (95% CI)] p*** | Mean (SD) MC (95% CI) p**** | Mean (SD) Aroma-RC-P* (n=29) | Mean Change [MC (95% CI)] p***** | Mean (SD) Aroma-MBI**** (n=29) | Mean Change [MC (95% CI)] p****** |
|--------------|-------------------------|--------------------------------|-----------------------------|-----------------------------|--------------------------------|-------------------------------|---------------------------------|
| Desire       | 2.21 (1.20)             | Reference                       | 2.30 (1.02)                 | Reference                   | 2.61 (0.82)                   | Reference                      | 2.41 (1.13)                     |
| Month 2      | 1.82 (1.21, 3.01)       | 0.43*                           | 2.71 (1.92, 3.02)           | 0.043                       | 3.01 (2.41, 3.03)           | 0.150*                         | 3.01 (2.11, 3.63)               |
| Month 4      | 2.21 (1.02)             | 0.00 (-0.51 to 0.52)            | 2.81 (1.12)                 | 0.023                       | 2.53 (0.81)                   | -0.11 (-0.41 to 0.21)          | 2.91 (1.11)                     |
| Baseline     | 2.71 (1.31)             | Reference                       | 2.31 (1.21)                 | Reference                   | 2.51 (1.12)                   | Reference                      | 2.51 (1.22)                     |
| Orgasm       | 3.22 (1.51)             | Reference                       | 2.80 (1.20)                 | Reference                   | 3.10 (1.17)                   | Reference                      | 2.81 (1.12)                     |
| Month 2      | 3.12 (1.54)             | -0.11 (-1.03 to 0.72)           | 3.81 (1.40)                 | 0.20 (0.15 to 1.90)         | 3.61 (1.41)                   | 0.51 (-0.21 to 1.22)           | 3.61 (1.54)                     |
| Month 4      | 3.21 (1.52)             | -0.00 (-0.81 to 0.71)           | 3.70 (1.60)                 | 0.11 (0.00 to 0.99)         | 3.21 (1.42)                   | 0.11 (-0.61 to 0.72)           | 3.21 (1.53)                     |
| Baseline     | 3.21 (1.32)             | Reference                       | 2.60 (1.51)                 | Reference                   | 3.12 (1.62)                   | Reference                      | 2.70 (0.92)                     |
| Lubrication  | 4.31 (1.43)             | Reference                       | 4.21 (1.42)                 | Reference                   | 4.20 (1.51)                   | Reference                      | 4.00 (1.10)                     |
| Month 2      | 4.51 (1.01)             | 0.22 (-0.41 to 0.92)            | 4.12 (1.41)                 | -1.02 (-0.71 to 0.51)       | 4.31 (1.12)                   | 0.11 (-0.62 to 0.81)           | 4.22 (1.10)                     |
| Month 4      | 4.32 (0.90)             | 0.1 (-0.62 to 0.72)             | 4.20 (1.40)                 | -0.70 (-0.92 to 0.10)       | 4.12 (1.11)                   | -0.21 (-0.82 to 0.53)          | 4.01 (1.41)                     |
| Baseline     | 4.12 (1.91)             | Reference                       | 3.60 (1.91)                 | Reference                   | 3.72 (1.80)                   | Reference                      | 3.71 (1.30)                     |
| Satisfaction | 4.20 (1.10)             | 0.00 (-0.70 to 0.71)            | 4.41 (1.60)                 | 0.81 (0.11 to 1.52)         | 4.31 (1.60)                   | 0.61 (-0.21 to 1.42)           | 4.20 (1.50)                     |
| Pain         | 4.20 (0.90)             | 0.10 (-0.72 to 0.82)            | 4.30 (1.70)                 | 0.7 (-0.20 to 1.52)         | 4.11 (1.80)                   | 0.52 (-0.23 to 1.12)           | 4.31 (1.40)                     |
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MBI improved the symptoms of female sexual dysfunction. The mechanism of action of MBI is not well understood. However, it may increase the sense of sexual arousal during sexual activity by increasing the compatibility between genital and mental sexual arousal. The sexual experience will be more pleasing without getting caught up in marginal conversations or spontaneous distractions and the presence of intrusive thoughts.

The evidence supporting the positive effect of MBI on sexual function is contradicting. Some of them reported its efficacy, however, others refused it. In addition, they used different questionnaires to evaluate the sexual function and its domains, different duration of intervention, sample size, and populations.

Existing research has shown that a higher level of mindfulness is associated with higher levels of physical satisfaction and sexual body esteem. In a systematic review study by Krieger et al., the results showed that MBT leads to improved sexual motivation and desire, satisfaction and reduction of sex-related fear, and improved genital-mental stimulation response in women. This study showed that MBT did not significantly alter pain relief during sexual activity.

Another published systematic review in order to evaluate the effect of Mindfulness Meditation Based intervention for sexual dysfunctions, revealed that although MBT led to improvement in subjectively arousal and desire, sexual satisfaction, and a reduction of the fear linked with sexual activity in women, it did not make a significant change in a reduction of pain during sexual activities. However, they concluded that few studies available are affected by several methodological limitations, including small numbers of participants, patient selection, application of complex therapeutic interventions, and a lack of homework assessment, which makes definite conclusions difficult to draw, and future studies are needed to verify their potential of MBT in reducing symptoms of sexual dysfunction.

A study by Jaderedk et al. showed that MBT improved mental arousal and libido, sexual satisfaction, and reduced sex-related fear, improved the relationship between mental stimulation and genital response in women, and reduced sexual dysfunction associated with anxiety. This study showed that MBT did not significantly alter pain relief during sexual activity. In our study, the sexual function score significantly improved in the Aroma-MBI group and the Aroma-P group, which is consistent with the above studies’ results. In a study by Hearn et al., MBI reduced depression significantly more than psychological training immediately after the intervention. Anxiety, pain, feelings of unhappiness, and feelings of occurrence bad events were significantly reduced in MBI compared to psychological training. However, in the study’s follow-up, the reduction

| Variable | Baseline | Month 2 | Month 4 |
|----------|----------|---------|---------|
| Total FSFI | 19.70 (5.70) | 21.21 (6.52) | 20.60 (5.90) |
| Desire | 19.61 (5.30) | 21.21 (6.52) | 20.60 (5.90) |

Table 2: Contd...

* RC-P: Routine Care-Placebo; ** MBI-P: Mindfulness-Based Intervention-Placebo; *** Aroma-RC: Aromatherapy-Routine Care; **** Aroma-MBI: Aromatherapy-Mindfulness-Based Intervention

**Data were analyzed using repeated measure ANOVA.**

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were statistically significant in the Aroma-RC group compared to the RC-P group.
### Table 3: The comparison of mean changes in the total Female Sexual Function Index (FSFI) and its domains between the study groups

| Variable | RC-p* (n=29) | MBI-p** (n=27) | Aroma- RC*** (n=29) | Aroma-MBI**** (n=29) | aMD (95% CI) | aMD (95% CI) p*** | aMD (95% CI) p**** |
|----------|--------------|----------------|---------------------|---------------------|--------------|------------------|-------------------|
| **Desire** |              |                |                     |                     |              |                  |                   |
| Baseline | 2.21 (1.20)  | 2.30 (1.02)    | 2.61 (0.82)         | 2.41 (1.13)         | 0.990        | 0.637            | 0.880             |
| Month 2  | 1.82 (1.21, 3.01) | 2.71 (1.92, 3.02) | 3.01 (2.41, 3.03) | 3.01 (2.11, 3.63) | 0.135**      | 0.068**          | 0.048**           |
| Month 4  | 2.21 (1.02)  | 2.81 (1.12)    | 2.53 (0.81)         | 2.91 (1.11)         | 0.60 (0.10 to 1.00) | 0.10 (-0.40 to 0.60) | 0.68 (0.11 to 1.12) |
| **Arousal** |              |                |                     |                     |              |                  |                   |
| Baseline | 2.71 (1.31)  | 2.31 (1.21)    | 2.51 (1.12)         | 2.51 (1.22)         | 0.641        | 0.940            | 0.957             |
| Month 2  | 2.51 (1.23)  | 2.92 (1.02)    | 2.81 (1.01)         | 2.91 (1.22)         | 0.60 (0.10 to 1.11) | 0.40 (-0.10 to 0.91) | 0.51 (0.01 to 1.12) |
| Month 4  | 2.51 (1.23)  | 2.81 (1.12)    | 2.72 (0.83)         | 2.91 (1.21)         | 0.50 (-0.00 to 1.00) | 0.31 (-0.21 to 0.81) | 0.52 (0.011 to 1.00) |
| **Lubrication** |              |                |                     |                     |              |                  |                   |
| Baseline | 3.22 (1.51)  | 2.80 (1.20)    | 3.10 (1.71)         | 2.81 (1.12)         | 0.587        | 0.990            | 0.673             |
| Month 2  | 3.12 (1.54)  | 3.81 (1.40)    | 3.61 (1.41)         | 3.61 (1.54)         | 0.90 (0.20 to 1.72) | 0.60 (-0.10 to 1.30) | 0.7 (-0.0 to 1.4) |
| Month 4  | 3.21 (1.52)  | 3.70 (1.60)    | 3.21 (1.42)         | 3.21 (1.53)         | 0.72 (-0.30 to 1.50) | 0.00 (-0.70 to 0.82) | 0.20 (-0.50 to 0.91) |
| **Orgasm** |              |                |                     |                     |              |                  |                   |
| Baseline | 3.21 (1.32)  | 2.60 (1.51)    | 3.12 (1.62)         | 2.70 (0.92)         | 0.354        | 0.993            | 0.500             |
| Month 2  | 3.11 (1.52)  | 3.31 (1.40)    | 3.42 (1.32)         | 3.41 (1.30)         | 0.51 (-0.2 to 1.2) | 0.32 (-0.31 to 1.01) | 0.52 (-0.82 to 0.62) |
| Month 4  | 3.12 (1.32)  | 3.31 (1.50)    | 3.21 (1.31)         | 3.20 (1.50)         | 0.50 (-0.20 to 1.21) | 0.10 (-0.61 to 0.70) | 0.30 (-0.41 to 1.02) |
| **Satisfaction** |              |                |                     |                     |              |                  |                   |
| Baseline | 4.31 (1.43)  | 4.21 (1.42)    | 4.20 (1.51)         | 4.00 (1.10)         | 0.937        | 0.999            | 0.837             |
| Month 2  | 4.51 (1.01)  | 4.12 (1.41)    | 4.31 (1.12)         | 4.22 (1.10)         | -0.41 (-0.92 to 0.22) | -0.20 (-0.71 to 0.42) | -0.21 (-0.71 to 0.32) |
| Month 4  | 4.32 (0.90)  | 4.20 (1.40)    | 4.12 (1.11)         | 4.01 (1.41)         | -0.12 (-0.71 to 0.50) | -0.20 (-0.81 to 0.32) | -0.22 (-0.70 to 0.42) |
| **Pain** |              |                |                     |                     |              |                  |                   |
| Baseline | 4.12 (1.91)  | 3.60 (1.91)    | 3.72 (1.80)         | 3.71 (1.30)         | 0.740        | 0.764            | 0.812             |
| Month 2  | 4.20 (1.10)  | 4.41 (1.60)    | 4.31 (1.60)         | 4.20 (1.50)         | 0.50 (-0.20 to 1.11) | 0.32 (-0.31 to 1.00) | 0.31 (-0.42 to 0.93) |
| Month 4  | 4.20 (0.90)  | 4.30 (1.70)    | 4.11 (1.80)         | 4.31 (1.40)         | 0.41 (-0.30 to 1.00) | 0.22 (-0.50 to 0.81) | 0.31 (-0.32 to 0.93) |
of anxiety and sense of imminent bad event continued. In our study, a significant difference was observed in the Aroma-MBI group and the Aroma-RC group in terms of anxiety scores, which confirms our study results. The reason for its inconsistency with our study on depression may be related to the age difference between the participants, the use of subjects over 18, gender, racial differences, the educational content of counseling sessions and the use of subjects with spinal cord injury. The presence of the COVID-19 pandemic can also be considered as a cause of ineffectiveness on depression.

Aromatherapy which is the use of oils extracted from plants and flowers is used to improve psychological and emotional mood and to treat various diseases through inhalation, massage, and bath therapy.[14] Numerous studies have shown many benefits in reducing stress and pain, relaxation, and reducing anxiety by stimulating endorphin production. The probable therapeutic property of aromatherapy is through psychological and physiological (such as amygdala and hippocampus) routes. The mechanism of action of these essential oils is two main ways: The first is through the olfactory pathway, which stimulates the receptors located in the olfactory bulb and transmits the olfactory message to the limbic system. This system is the brain's emotional center and is effective on pulse rate, blood pressure, respiratory system, and stress response. The second way is through skin absorption. Molecules of essential oils are absorbed through the skin over 20-40 min.[43] In a meta-analysis and systematic review by Salehi-Pourmehr et al.,[20] the results of studies showed that aromatherapy with lavender or lavender-containing compounds positively affected sexual function, self-esteem, anxiety, and hot flashes in postmenopausal women. Another systematic review evaluated the quality of previously published systematic reviews in this regard and showed that all of them had limitations in their methodology as well as included studies, and conducted another survey. Their results indicated limited evidence of the benefit of aromatherapy (lavender or low dose of neroli) in improving total menopausal symptoms and sexual desire.[44] In a double-blind, randomized clinical trial by Malakouti et al.[29] for investigating the effect of Ginkgo biloba and inhalation aromatherapy (lavender, fennel, geranium, and rose) on postmenopausal women's sexual function, participants received two-three drops of Ginkgo biloba, aroma solution or placebo on their skin three times a day for 6 weeks. There was a statistically significant increase in the total score, and all aspects of sexual function, except pain, were present during intercourse in the Ginkgo biloba and the aromatherapy groups compared with the placebo group.

In our study, Aroma-MBI also improved all components of sexual function other than pain, which is consistent with the above study results. In the study of Murakami et al.,[45] lavender aromatherapy was performed in 30-min

| Variable | Total FSFI | RC-P (n=29) | Aroma-MBI (n=27) | Aroma-RC (n=29) |
|----------|-----------|------------|-----------------|-----------------|
|         |          | Mean (SD)  | Mean (SD)       | Mean (SD)       |
| Baseline| 19.70 (5.30) | 19.61 (5.90) | 17.70 (6.50)    | 19.21 (4.91)    |
| Month 2 | 19.50 (5.20) | 20.60 (5.90) | 21.20 (5.91)    | 2.62 (0.21 to 4.32) |
| Month 4 | 21.21 (6.52) | 19.70 (5.70) | 17.70 (6.50)    | 0.556           |

*RC-P: Routine Care-Placebo; **MBI-P: Mindfulness-Based Intervention-Placebo; ***Aroma-RC: Aromatherapy-Routine Care; ****Aroma-MBI: Aromatherapy-Mindfulness-Based Intervention; aMD: Adjusted Mean Difference for baseline values; p values after intervention were reported by ANCOVA adjusted for baseline values. p value* compared to RC-P. p value** compared to RC-P. p value*** compared to Aroma-RC. p value**** compared to Aroma-MBI. Mean (SD) were computed by independent t-test. All between-group p values after intervention were reported by ANCOVA adjusted for baseline. Aroma-RC intervention (month 2) had not normal distribution which analyzed using Mann-Whitney U test.
Table 4: The comparison of anxiety scores within and between the study groups

| Variable   | RC-p* (n=29) Mean (SD) | MBI-p** (n=27) Mean (SD) | Aroma-RC*** (n=29) Mean (SD) | Aroma-MBI**** (n=29) Mean (SD) | aMD (95% CI) p**** | aMD (95% CI) p3 | aMD (95% CI) p3x |
|------------|-------------------------|---------------------------|-------------------------------|-------------------------------|---------------------|----------------|----------------|
| Baseline   | 16.40 (6.11)            | 15.41 (6.82)              | 15.02 (6.41)                  | 15.01 (4.42)                  | 0.938               | 0.832          | 0.821          |
| Month 2    | 14.42 (6.61)            | 11.91 (5.42)              | 9.32 (4.51)                   | 9.91 (4.62)                   | -2.01 (-5.41 to 1.42) | -4.12 (-7.41 to -0.72) | -3.52 (-6.92 to -0.13) |
| Month 4    | 14.52 (6.32)            | 12.62 (5.82)              | 10.42 (5.11)                  | 10.12 (5.01)                  | -1.51 (-4.71 to 1.82)  | -3.31 (-6.41 to -0.13) | -3.52 (-6.82 to -0.34) |
| MC (95% CI)| -2.01 (-6.11 to 2.12)   | -3.82 (-7.01 to -0.63)    | -5.72 (-8.61 to -2.72)        | -5.12 (-7.21 to -3.12)        | -0.367              | 0.049          | 0.032          |
| p0.05      | 0.685                   | 0.017                     | <0.001                        | <0.001                        | -                | -             | -              |
| MC (95% CI)| -1.90 (-5.21 to 1.42)   | -3.12 (-6.52 to 0.31)     | -4.61 (-7.81 to -1.42)        | -4.91 (-7.41 to -2.42)        | -                | -             | -              |
| p0.05      | 0.485                   | 0.079                     | 0.003                         | <0.001                        | -                | -             | -              |

*RC-P: Routine Care-Placebo; **MBI-P: Mindfulness-Based Intervention-Placebo; ***Aroma-RC: Aromatherapy-Routine Care; ****Aroma-MBI: Aromatherapy-MBI CI: confidence Interval; MC: Mean Change; aMD: Adjusted Mean Difference for baseline values. All between-group P values at baseline were computed by independent t-test after intervention were reported by ANCOVA, p****: MBI compared to RC-P; p value$^*$: Aroma compared to RC-P; P value$^{**}$: Aroma-MBI compared to RC-P. $^{***}$ repeated measures ANOVA.

Table 5: The comparison of depression scores within and between the study groups

| Variable   | RC-p* (n=29) Mean (SD) | MBI-p** (n=27) Mean (SD) | Aroma-RC*** (n=29) Mean (SD) | Aroma-MBI**** (n=29) Mean (SD) | aMD (95% CI) p**** | aMD (95% CI) p3 | aMD (95% CI) p3x |
|------------|-------------------------|---------------------------|-------------------------------|-------------------------------|---------------------|----------------|----------------|
| Baseline   | 14.32 (6.43)            | 14.62 (6.64)              | 17.74 (8.73)                  | 14.31 (6.80)                  | 1.00                | 0.398          | 1.00           |
| Month 2    | 13.02 (5.93)            | 11.01 (5.02)              | 10.34 (4.52)                  | 10.91 (5.10)                  | -2.20 (-5.60 to 1.21) | -4.40 (-7.80 to -1.00) | -2.10 (-5.50 to 1.30) |
| Month 4    | 13.04 (5.71)            | 10.91 (5.50)              | 10.82 (4.70)                  | 10.10 (4.70)                  | -2.30 (-6.11 to 1.61)  | -3.60 (-7.50 to 0.30) | -2.91 (-6.81 to 1.01) |
| MC (95% CI)| -1.30 (-5.20 to 2.61)   | -3.72 (-7.50 to 1.00)     | -7.40 (-11.30 to -3.50)       | -3.40 (-6.21 to -0.62)        | -0.251              | 0.070          | 0.141          |
| p0.05      | 1.00                    | 0.058                     | <0.001                        | 0.015                         | -                | -             | -              |
| MC (95% CI)| -1.32 (-5.23 to 2.82)   | -3.82 (-8.13 to 0.62)     | -6.90 (-11.20 to -2.61)       | -4.20 (-8.21 to -0.11)        | -                | -             | -              |
| p0.05      | 1.33 (-5.22 to 2.64)    | 0.115                     | 0.001                         | 0.043                         | -                | -             | -              |

*RC-P: Routine Care-Placebo; **MBI-P: Mindfulness-Based Intervention Placebo; ***Aroma-RC: Aromatherapy-Routine Care; ****Aroma-MBI: Aromatherapy-Mindfulness-Based Intervention CI: confidence Interval; MC: Mean Change; aMD: Adjusted Mean Difference for baseline values. All between-group at baseline were computed by independent t-test, p values after intervention were reported by ANCOVA, p-value$^{****}$: Mindfulness-Based Intervention compared to RC-P; p value$^*$: Aroma compared to RC-P; p value$^{**}$: Aroma-MBI compared to RC-P. $^{***}$ repeated measures ANOVA.
sessions of massage on women aged 50-60 and repeated 1 month later to improve the symptoms of depression,[46] which is consistent with the results of the present study. In the study of Taavoni et al.,[46] lavender, geranium, rose, and rosemary mixture was used on 90 postmenopausal women. The aromatherapy massage group received 30 min of aromatherapy sessions twice a week for 4 weeks. The placebo group received massage therapy with odorless oil, and the control group did not receive any treatment. Anxiety was significantly reduced in both intervention groups but was more effective in the massage therapy plus aromatherapy group.

Bitter orange, lavender, and geranium are common types of aromatherapy plants.[47,48] These three plants have effectively reduced climacteric symptoms such as hot flashes and depression and improved sexual function.[47] A review of the literature found no study examining the human and inhalation effects of BEO on sexual dysfunction, anxiety, or depression. Bergamot (Citrus Bergamia Risso) is a natural compound fruit derived from bitter oranges and lemons, all of which belong to the same family.[49]

In a study by Cho et al.[50] on 56 patients with percutaneous coronary intervention (PCI), the results showed that aromatherapy with orange blossom, chamomile, and lavender significantly reduced anxiety levels and increased sleep quality, which, despite the non-similarity of the compounds, is consistent with our results. A triple-blind randomized controlled clinical trial was performed by Farshbaf Khalili et al.[50] and Kamali et al.[51] on 156 postmenopausal women. Oral capsules of bitter orange blossom and lavender significantly reduced the mean score of anxiety and depression compared to the control group.[50] In this study, the intervention included oral essential oils, but the results are consistent with our study. In the systematic review of de Sousa et al.,[52] Citrus aurantium L, a species of bergamot, was used. The results showed that the dose of 1 g/kg of body weight was associated with significant anxiolytic effects. A study has shown that bergamot increases gamma-aminobutyric acid in the rat hippocampus and points to its anxiolytic role.[53,54]

According to the researchers, in this clinical trial, the combination of bergamot and lavender essential oils using MBI, both of which are complementary medicine, was performed for the first time to study its effect on sexual function, anxiety, and depression in postmenopausal women. Because the study coincided with the COVID-19 pandemic, sexual intercourse was associated with anxiety. The smell of the aroma placebo was not the same as the main drug, which was one of the study’s limitations. Due to cultural reasons and the subject’s sensitivity, the subjects may have avoided expressing sexual issues. This restriction was partially controlled by reassuring the patient that the first and last names were not included in the questionnaires and individual in-room counseling. It is suggested that future studies use MBI for the wives of postmenopausal women who complain of sexual dysfunction in their married life and examine its possible role in overcoming the anxiety and depression of their wives.

Conclusion

MBI and La-Ber aromatherapy were effective on the overall score of sexual function after the intervention. Usage of the Aroma-P and Aroma-MBI groups was effective on anxiety after the intervention. MBI was effective on sexual function, anxiety, and depression. Based on the results, it seems that MBI was effective on sexual function, while aromatherapy was effective on anxiety and depression. Aromatherapy has influenced depression only immediately after the intervention.

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Conflicts of interest

Nothing to declare.

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