

Official Title Of The Study

The effect of Mandala application on menopausal symptoms and quality of life

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(The protocol should include the following items and necessary explanations)

C. Study Protocol

1. Project Name: The effect of Mandala application on menopausal symptoms and quality of life

2. Project Rationale: Menopause is the natural cycle of life that develops due to changes in the endocrine glands of the female body, mostly in middle age, and the menstrual cycle is permanently interrupted as a result of the ovaries losing their activity (Koyuncu et al., 2015; Gönenç, 2019). Many symptoms are seen in women during menopause, and these symptoms cause women to experience many physiological, mental, social and sexual problems in the short or long term and deteriorate their quality of life (Gönenç and Koç, 2019). In reducing the menopause symptoms experienced by women, hormone replacement therapy, traditional methods (Johanson, et al. 2019), mental or physical practices; Applications such as aromatherapy (Abiç and Yılmaz; 2020), hypnosis (Roberts, et al., 2021), Biofeedback and relaxation techniques (Huang, et al., 2015) are used. The aim of these applications is to relax women, reduce menopause symptoms and increase their quality of life. Mandala, which has been widely used in the field of therapy in the past and today, is seen as a meditation tool in art therapy (Ergül et al., 2021; Çelikbaş, 2022) and is defined as a complementary, safe and accessible activity that supports mental health (Çelikbaş, 2022). It has been determined that the mandala method, which is used in many areas in the literature, has not been examined how it affects the symptoms and quality of life of women in the menopausal period. For this reason, it is thought that this study will make a significant contribution to the literature.

3. Materials and Methods of the Study:

3.1. Location of the study: This study is planned to be conducted at Private Palmiye Hospital Gynecology and Obstetrics Polyclinics.

3.2. Time of the study: The study is planned to be conducted within 6 months after obtaining the ethics committee approval.

3.3. Universe, sample, research group of the study: The universe of the study will consist of women who apply to the gynecology and obstetrics polyclinics of the hospital where the study will be conducted and who have been diagnosed with menopause. The sample of the study was calculated using the G*Power program by taking as reference the study titled “Association of menopausal symptoms and menopausal quality of life with premenstrual syndrome” (Okutucu et al., 2023) ($\alpha=0.05$, $1-\beta=0.85$, effect size $d=0.68$) and was determined as 39 participants for the experimental and control groups.

As a result, the study sample will consist of 78 postmenopausal women (39 in the experimental group and 39 in the control group) as shown in the CONSORT 2010 flow chart.

Randomization: The random.org program will be used to assign participants to their groups. Women who are “1” in the randomization will be included in the control group, and women who are “2” will be included in the intervention group. Women participating in the study will be unaware of the current group number and which method will be applied in the group they are assigned to. The study will be conducted with two groups, one experimental and one control group.

Inclusion and exclusion criteria for the study;

Inclusion Criteria; Women who can communicate, read, understand and write Turkish, have been diagnosed with menopause, and do not have any physical or mental disabilities related to performing the mandala application will be included in the study.

Exclusion Criteria; Women who do not fill out the data collection forms completely, women who are receiving hormonal treatment to reduce menopausal symptoms, and women with dye allergies will be excluded from the study.

3.4. Type of study: This study is planned as a randomized controlled experimental study.

3.5. Manpower required for the research:

Emine Karacan: Analysis of data, writing the introduction

Emine Bakır: Determination of the topic, literature review, collection of data, writing the discussion

Emine Karacan: Writing the material/method section, making final checks

3.6. Research method and data collection tools:

Data Collection Tools: The data of the study were collected using the Menopause Symptoms Assessment Scale, Menopause Specific Quality of Life Scale and Mandala Application Follow-up Form.

Personal Information Form; The personal information form, which was created by evaluating the studies on menopause symptoms, quality of life in women and affecting factors in the literature review, consists of 12 questions (Gönenç, 2019; Abiç, 2020).

Menopause Symptoms Assessment Scale (MSS); MSS was developed by Schneider and his colleagues in 1992. The Turkish validity and reliability study was conducted by Gürkan in 2005. MSS consists of 11 items and 3 sub-dimensions. The sub-dimensions are called “Somatic Complaints”, “Psychological Complaints”, and “Urogenital Complaints”. The scale is answered on a 5-point Likert type and each statement is scored as 0: None, 1: Mild, 2: Moderate, 3: Severe and 4: Very severe. The lowest score that can be obtained from the entire scale is 0 and the highest score is 44. An increase in the total score obtained from the scale indicates an increase in the severity of the complaints experienced and that the quality of life is negatively affected. The Cronbachalpha reliability coefficient of the original scale is 0.84. The Cronbachalpha values of the sub-groups are 0.65 for somatic complaints, 0.79 for

psychological complaints and 0.72 for urogenital complaints. The Cronbachalpha value of MSDS was calculated as 0.80 in this study. The chronbachalpha values of the subgroups were found to be 0.66 for somatic complaints, 0.75 for psychological complaints, and 0.71 for urogenital complaints.

Menopause-Specific Quality of Life Scale; was developed by Hilditch et al. in 1996, and its Turkish validity and reliability were made by Kharbouch and Şahin in 2005 (Kharbouch and Şahin, 2007). The scale consists of four areas: vasomotor, psychosocial, physical, and sexual, contains 29 Likert-type expressions, and as the score obtained from the scale increases, the severity of the complaint increases and the quality of life decreases. Since the average score is used in the total scale, the lowest score that can be obtained from the scale is 0, and the highest score is 6. Each subfield score in the MÖYKÖ is ranked from 0 to 6. A score of “0” indicates that no problem is experienced regarding the subject. A score of “1” indicates that the problem exists, is experienced but is not disturbing at all, while scores between “2-6” indicate the severity and increasing degrees of the existing problem. In the original study, the Cronbach alpha value of the sub-dimensions of the scale was found to be 0.73 for the vasomotor domain, 0.84 for the psychosocial domain, 0.88 for the physical domain and 0.84 for the sexual domain. In this study, the Cronbach alpha value of the total scale was found to be 0.90 and the Cronbach alpha value of the sub-dimensions was found to be 0.75 for the vasomotor domain, 0.83 for the psychosocial domain, 0.87 for the physical domain and 0.73 for the sexual domain.

Mandala application monitoring form; The monitoring form is a schedule where the daily mandala application time and application duration will be recorded during the two-week period. The schedule to be given to the women with the mandala was received in the second interview to be held with the women two weeks later (Table 1).

Table 1. Mandala Application Follow-up Form

Date	Application Time	Mandala Application Time
Day 1		
Day 2		
Day 3		
Day 4		
Day 5		
Day 6		
Day 7		
Day 8		
Day 9		
Day 10		
Day 11		
Day 12		
Day 13		
Day 14		
Day 15		

Intervention tools and equipment and their use: Mandala and 12-piece felt paint are planned to be used in the study as intervention tools. Mandala means “circle” or “completion”, and mandala consists

of circles arranged in sections surrounding a single central point. However, the result that emerges by filling in these circles is considered a complete reflection of its creator. Mandala painting session duration and session frequency were determined according to the report published by the Korean Art Therapy Association in 2013. According to this report; it was reported that the painting time of the mandala can vary between 20-30 minutes (Kim 2014).

3.7. Data Collection:

The intervention group; women who applied to the polyclinic and diagnosed with menopause will be informed about the study and mandala application in face-to-face interviews. Women who accept to participate in the study will be given an informed consent form, a personal information form, menopause-specific quality of life and menopause symptom assessment scales and will be asked to fill them out. After the women fill out the scales, a sample mandala, an empty mandala, crayons (consisting of 12 colors: red, orange, yellow, light green, green, sky blue, blue, purple, brown, reddish brown, white and black) and a mandala application follow-up form will be distributed. The mandala application will be performed by the women for an average of 20-30 minutes every day for 15 days. The women will be called every other day to evaluate their ability to perform the mandala application. After 15 days, the women will be interviewed again and the mandala application follow-up form will be collected. Finally, the menopause-specific quality of life and menopause symptom assessment scales will be given again and asked to fill them out. In addition, the routine care and treatments of the women will continue during the data collection period. The control group will be informed about the study during face-to-face interviews with women who applied to the outpatient clinic and were diagnosed with menopause, and the women who agreed to participate in the study will be given an informed consent form, a personal information form, and menopause-specific quality of life and menopause symptom assessment scales and asked to fill them out. The women will be interviewed again after 15 days and the menopause-specific quality of life and menopause symptom assessment scales will be given again and asked to fill them out. In addition, the benefits of the mandala application will be explained to the women to eliminate the ethical dilemma and the women who want to apply the application will be given mandala coloring pencils. The routine care and treatments of the women will continue during the data collection period.

3.8. Data analysis: The data will be analyzed with the SPSS 24.0 package program. When evaluating the data of the study, frequency distribution (number, percentage) will be given for categorical variables and descriptive statistics (mean, standard deviation) for numerical variables, and normality distribution will be done with the Shapiro Wilks test. Independent samples t-test will be used to determine whether there is a difference between two normally distributed groups, and one-way variance analysis will be used to determine whether there is a difference between more than two groups. In addition, Pearson correlation analysis will be used to examine the relationship between two numerical variables. $P < 0.05$ will be accepted as significance.

3.9. Kaynaklar:

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