Official Title Of The Study

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

NCT Number

NCT number not received yet

Date of Document

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GAZİANTEP ISLAMIC SCIENCE AND TECHNOLOGY UNIVERSITY
NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS BOARD

GAZİANTEP ISLAMIC SCIENCE AND TECHNOLOGY UNIVERSITY INFORMED CONSENT FORM FOR "NON-INTERVENTIONAL CLINICAL RESEARCH"

Research Project Title: The Effect of Mandala Practice on Menopausal Symptoms and Quality of Life
Principal Investigator Name: Emine KARACAN
Other Investigators Name: Emine BAKIR, Emine KARACAN
Sponsor (if applicable): NONE

You have been invited to participate in a study titled "The Effect of Mandala Practice on Menopausal Symptoms and Quality of Life." You have been invited to participate because you are experiencing menopausal symptoms and their impact on your quality of life. This study is being conducted for research purposes, and participation is voluntary. Before you decide to participate, we would like to inform you about the study. After you have received full information about the study and your questions have been answered, you will be asked to sign this form if you wish to participate. This research is under the supervision of Dr. Emine KARACAN, Assistant Professor of Elderly Care, Vocational School of Health Services, Gaziantep Islamic University of Science and Technology.

What is the purpose of the study? How many people, in addition to myself, will participate in this study?
The following information should be included under this heading:
 The purpose of the study is to determine the effect of individual mandala practice on menopausal symptoms and quality of life in menopausal women.
 The number of participants planned to be included in the study (indicate if single-center or multi-center). The study population will consist of women who have been diagnosed with menopause and who have applied to the obstetrics and gynecology outpatient clinics of the hospital where the study will be conducted. The study sample was calculated using the G*Power program (α=0.05, 1-β=0.85, effect size d=0.68), using the study titled "Association of menopausal symptoms and menopausal quality of life with premenstrual syndrome" (Okutucu et al., 2023) as reference, and 39 participants were selected for each experimental and control group. Consequently, the study sample will consist of 78 menopausal women as shown in the CONSORT 2010 flow chart: 39 in the experimental group and 39 in the control group.

Should I participate in this study? (This section will remain intact)
Whether or not you participate in this study is entirely up to you. Even if you sign this form now, you are free to withdraw from the study at any time without giving a reason. If you do not wish to participate or withdraw from the study, your doctor will implement the most appropriate treatment plan for you. Similarly, the doctor conducting the study may decide that continuing the study would not be beneficial for you and may exclude you from the study. In this case, the most appropriate treatment will be selected for you.

What will happen if I participate in this study?
The following information should be included under this heading:

 Methods used in the study: The study is planned as an experimental, randomized controlled trial. Women will be interviewed face-to-face and asked to color the mandala.
 Duration of the study: The study is planned to be completed within 6 months after receiving ethics committee approval.
 If biological or imaging material belonging to the patient is to be studied, what exactly will be examined? NONE

Are there any risks or discomforts associated with the study?
Example:
1. NONE
2. In the event of any potential harm resulting from the study, we will provide all necessary medical interventions; all expenses in this regard will be covered by us.

What are the benefits of participating in the study?
The expected public benefit of the study must be explained.
By participating in this study, you will help determine how menopausal symptoms affect women and their quality of life, and the effect and role of mandala coloring methods in alleviating these symptoms.

What will it cost to participate in this study? (This section will remain intact)
You will not incur any financial burden by participating in the study, and you will not be paid.

How will my personal information be used? (This section will remain intact)
Your study physician will use your personal information to conduct the study and statistical analyses, but your identity will be kept confidential. Ethics committees or official authorities may review your information only when necessary. At the end of the study, you have the right to request information about your results. The study results may be published in the medical literature upon completion, but your identity will not be disclosed.

Who can I contact for more information?
If you need additional information about the study, please contact the person below.

NAME: EmineKARACAN
POSITION: Asst Prof.
PHONE: 0537 214 83 75

(Declaration of Participant/Patient)

Gaziantep Islamic University of Science and Technology, Health Services Vocational School, Elderly Care Assistant Professor Dr. Emine KARACAN informed me that a medical study would be conducted, and I was informed of the above information regarding this study, and I read the relevant text. After receiving this information, I was invited to participate as a "participant" in this research.

I have not been subjected to any coercive behavior regarding my participation in the study. I understand that refusing to participate will not compromise my medical care or my relationship with the physician. I may withdraw from the study at any time during the project, without providing any

reason. (However, I am aware that it would be appropriate to notify the researchers in advance of my withdrawal to avoid causing them any inconvenience.) I may also be excluded from the study by the researcher, provided that my medical condition is not compromised.

I assume no financial responsibility for research expenses. I will not be paid.

I understand that the confidentiality of personal information obtained from the research will be protected.

I have been given the necessary assurance that any medical intervention will be provided should any health problem arise from the research. (I will not be financially burdened with these medical interventions.)

If I experience any health problems during the research, I know that I can call Dr. Emine KARACAN, 0537 214 83 75, Gaziantep Islamic University of Science and Technology, at any time. (The doctor's name, phone number, and address must be provided.)

I have fully understood all the explanations given to me. Under these conditions, I agree to participate in this clinical trial voluntarily, without any pressure or coercion.

I will be given a copy of this signed form.

Participant	**Witness to the interview**	**Physician who met with the participant**
Name, Surname:	Name, surname:	Name, surname, title:
Address:	Address:	Address:
Phone:	Phone:	Phone:
Signature:	Signature:	Signature:
Date:	Date:	Date:

THE INFORMATION AND THE PARTICIPANT'S DECLARATION WILL BE A CONTINUATION OF EACH OTHER. THEY WILL NOT BE PLACED ON SEPARATE PAGES.