# Consent Form

Informed Consent Form for Participation in a Research Study about the Impact of Intermittent Fasting on the Mental Health of Perimenopausal Women

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Institution: American University of Beirut Medical Center (AUBMC)

Study Title: Impact of Intermittent Fasting on the Mental Health of Perimenopausal Women

Protocol ID: (SBS-2024-0499)

**Introduction**

You are invited to participate in a clinical research study conducted by the American University of Beirut Medical Center (AUBMC). This form explains the purpose of the study, what will happen during the study, the risks, and benefits of participation. This is six-month Randomized Controlled Trial (RCT) will assess the effects of intermittent fasting on mental health in women aged 45 to 55 who meet the criteria of perimenopausal stages -2 and -1, as defined by STRAW criteria and Menopause Rating Scale (MRS). Recruitment for this study has been approved by the Institutional Review Board (IRB). Please read this form carefully, and feel free to ask any questions.

**Purpose of the Study**

This study aims to investigate the impact of a six-month intermittent fasting intervention on the mental health of women during the perimenopause phase of their lives. By exploring potential alternatives to medication, such as dietary changes, we aim to provide insight into new methods of supporting women's overall health. A total of 98 participants will be enrolled (49 per group).

**Procedures**

If you agree to participate, the study will proceed as follows:

1. **Initial Screening:** A nurse will first ask you if you are interested in joining our research study. If you indicate interest, you will be escorted to a private room where a research assistant will provide a detailed explanation of the study and answer any questions you may have before you decide whether to participate. To qualify, participants must be between the ages of 45 and 55 years in the perimenopausal stage as defined by the STRAW criteria (stages -2 and -1) and have a score of 11 or higher on the menopausal rating scale. Women will be excluded if they are currently on hormone treatment, have severe illnesses that could prevent fasting (including uncontrolled diabetes, heart disease, hypertension, cancer or kidney issues), or have a formal mental health diagnosis as diagnosed by DSM V (whether taking medications or not and if in therapy). Additional exclusion criteria include women experiencing surgical menopause, premature ovarian failure, undergoing chemotherapy or radiotherapy, survivors of ovarian cancer, pregnant women, those receiving treatment for endometriosis, women with thyroid disorders, or those currently on hormone therapy. Participants who do not speak English will also be excluded. After confirming eligibility, the research assistant (RA) will explain the study in detail and review the consent process. If you agree, you will sign the consent form. After signing, you will begin by filling out the General Health Questionnaire along with other screening scales to determine eligibility for the study

2. **Questionnaires and Screening:** Upon signing the consent form, you will first complete a

General Health Questionnaire designed to assess your overall health and ensure that you do not have any chronic medical conditions that could affect your participation. This questionnaire is detailed in Appendix I of the study proposal and will take approximately 10 mins to complete. Next, you will be asked to fill out the Menopause Rating Scale (MRS). This scale helps determine your menopausal stage and eligibility for the study. The completion of both the General Health Questionnaire and the MRS will take approximately 20 minutes. After confirming eligibility, you will proceed with baseline assessments, which include completing additional scales related to mental and sexual health. Additionally, your body composition will be assessed using a bio-electrical impedance device. This device provides a non-invasive tool used to assess your body composition, including body fat and lean mass. This device works by sending a very small electrical current through your body, which is safe and painless. There are no known risks associated with using the BIA, as the electrical current used is extremely low and not harmful for your body. The device has been widely used in research and clinical settings, and its safety is well-established. You will be asked to remove any metal items (such as jewelry) before the assessment, and the process will be carried out in private and comfortable environment. The assessment will take place at the designated data collection site and will require approximately 40 minutes to complete.

3. **Random Group Assignment:** After completing the questionnaires, you will be randomly assigned to either the experimental group or the control group using a computer-generated process. You will receive a confidential note on your group assignment (either experimental group or control group).

4. **Intervention Details:**
   - **Experimental Group:** You will receive guidance on how to follow the 16/8 intermittent fasting regimen, which involves fasting for 16 hours and eating within an 8-hour window.

   **Control Group:** You will continue your usual lifestyle without fasting, but you will be provided with the official Lebanese Dietary guidelines for Lebanese adults that will give you comprehensive tips about healthy eating.
5. **Follow-up and Monitoring:**
   - At weeks 6, 12 and 24, you will return for a follow-up visit at AUBMC Psychiatry Department. During each visit, your physical composition (including weight, body mass index, and other body measurements) will be reassessed using the same method as at baseline. You will also complete additional scales to assess any changes in your symptoms. These sessions will take place in a private room to reduce social desirability bias. The scales to be administered at these follow-ups include the PHQ-9, which assesses the severity of depressive symptoms over the past two weeks; GAD-7, which measures the severity of generalized anxiety symptoms; the PSQI, used to assess sleep quality and disturbances; the BAS-2, which evaluates body image satisfaction and its impact on well-being; the FSFI, a scale for assessing female sexual function; the IPAQ, which measures physical activity levels and lifestyle habits, and the MoCA, a brief cognitive screening tool that assesses cognitive function. These scales will help us monitor changes in various aspects of your health throughout the study, and all sessions will be conducted in a private, confidential setting to ensure that your responses remain accurate and honest.
   - You will record your fasting schedule daily, noting the start and end of each fasting period. You will receive weekly periodic phone calls and motivational messages between the follow-up weeks (6, 12, and 24) to support adherence, and regular check-ins will monitor any symptoms or concerns.

6. **Compensation:** You will receive a total compensation of 100$ in total, distributed as 33$ after each of the three follow-up visits. Payments will be made in cash by the administrative coordinator at the Department of Psychiatry at AUBMC immediately following each session. Compensation will be processed through an approved expense report. No additional financial compensation will be provided.
7. **Confidentiality and Privacy**

Your information will be kept confidential. During data collection, all assessments will be conducted in a private setting to ensure your privacy. You will be assigned a unique identification code, which will be used instead of your personal information. This ID will be matched with a secure database created for the study, ensuring that your responses remain confidential. Only the study team and authorized personnel will have

access to your data, which will be securely stored at AUBMC for three years before being destroyed. All electronic records will be password-protected, and documents will be stored on the PI's desktop. No identifying information will be used in any reports or publications.

**8. Risks and Discomforts**

Participation in this study may involve minimal risks, including:

- Discomfort from answering sensitive questions about your mental or sexual health.
- Potential side effects from fasting, such as dizziness, fatigue, or low energy. Please report any adverse effects immediately to the research assistant. If any adverse effects related to fasting are reported by participants during the study, the RA will immediately assess the situation and refer the participant to the Family Medicine Department at AUBMC for a health evaluation. These medical evaluations will be provided free of charge as part of the study. Dr. Maya Romani, a collaborator on this research project, will be overseeing the medical evaluations to ensure participant safety. If symptoms are identified as moderate or severe, the participant's well-being will be prioritized, and based on Dr. Romani's clinical assessment, the investigator may ask the participant to withdraw from the intervention if necessary. Additionally, participants may also withdraw from the study if the fasting regimen leads to significant health complications, such as dehydration, extreme fatigue, or other health conditions that may compromise their safety. In such cases, the investigator will consult with the participant's physician and follow their advice on whether withdrawal from their intervention is necessary.

**9. Potential Benefits**

While there are no immediate personal benefits, this study may contribute to new insights into improving women's mental health, which could provide alternatives to conventional medication. We will ensure that women who do not receive the intervention will be given nutritional counseling.

**Participation and Withdrawal**

Participation in this study is entirely voluntary. If you choose not to participate or decide to withdraw at any time, it will not affect your medical care at AUBMC or result in any penalty or loss of benefits. Please inform the research assistant if you wish to do so at any point.

**Investigator's Statement:**

**I have reviewed, in detail, the informed consent document for this research study with __(name of patient) the purpose of the study and its risks and benefits. I have answered to all the patient's questions clearly. I will inform the participant in case of any changes to the research study.**

_____ _____

**Name of Investigator or designee** **Signature**

_____

**Date & Time**

**Patient's Participation:**

**I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Dr.** Nadia Tina Dandan **at** 01350000 ext. 7897 **or any of his/her designee involved in the study in case of any questions. If I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at** 01350000 5445 **. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will**

**not affect your relation with AUB/ AUBMC. I know that I will receive a copy of this signed informed consent.**

| | |
|---|---|
| **Name of Patient** | **Signature** |

**Date & Time**