CLINICAL TRIAL DOCUMENT COVER PAGE

Official Title of the Study:
Adherence to the Mediterranean Diet Following Nutritional Education and Its Effect on Anxiety, Depression, Fatigue, and Sleep Quality Among a Group of Lactating Women in Jordan: An Interventional Study

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Title of the project

Adherence to the Mediterranean Diet Following Nutritional Education and Its Effect on Anxiety, Depression, Fatigue, and Sleep Quality Among a Group of Lactating Women in Jordan: An Interventional Study.

The outcome:

The aim of our study is to compare the degree of adherence to MedDiet between women who received educational and nutritional interventions during 6 months of follow-up and those without such interventions, and to examine the impact of these interventions on mothers' nutritional status, anthropometrics, and mental health.

The objectives:

The objectives of the current study are:

1. Investigate the impact of an educational intervention on MedDiet among a group of lactating women aged 18-40 years and above in Jordan over a six-month follow-up period.
2. Investigate the relationship between MedDiet adherence, obesity, and mental health. among a group of lactating women aged 18-40 years and above in Jordan over a six-month follow-up period.

Protocol

Study design and setting

An intervention study is conducted for lactating mothers with follow-up at 3 and 6 months. Participant recruitment focuses on lactating women with infants aged 1-2 months.

The study is conducted at the Ministry of Health's childbirth vaccination clinics in Amman and Irbid, Jordan. The clinics have a fine reputation for maternal and child health services with organized working and research systems.

Ethical considerations

Ethical approval was obtained from the Ministry of Health (MOH/REC/2024/502) and the IRB at Philadelphia University (1/1/2024-2025). The research complies with the ethical principles for medical research involving human subjects of the Helsinki Declaration.("World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects," 2014). All participants provide written informed consent before starting, and their right to privacy, anonymity, voluntary participation, and confidentiality are observed.

Participants

Participants consisted of eligible lactating women aged 18–40. The exclusion criteria are (1) all women aged below 18 or above 40, (2) lactating women diagnosed with mental diseases, and (3) women who were already on supplementation for managing deficiencies such as iron, B12, and vitamin D or hormonal disturbances, mainly thyroxine.

Sample size:

The sample size is calculated using 95 % confidence and an RR of 1.9, considering a 20 % non-response rate in cohorts (Rahman et al., 2007), which assumes the number of participants to be 180 based on the population of all eligible candidates who are sequentially enrolled in the study for 6 months, with an expected total research duration of 8 months.

Instruments

Validated Arabic public-domain questionnaires are distributed to collect demographic data, including age, weight, pre-pregnancy BMI, nationality, income, education, employment, insurance status, marital status, gestational age, number of children, and smoking status. Also, anthropometry and possible confounders such as physical and psychological abuse. All participants are interviewed face-to-face, and trained nutrition researchers fill out questionnaires.

A. **Questionnaires:**

Validated Arabic version of:

- **MEDAS:** A 14-item Mediterranean Diet Adherence Screener (14-MEDAS) is used to assess the adherence of eligible participants to MedDiet
- **Food Frequency questionnaire:** The questionnaire assesses habitual dietary intake by questioning the frequency with which food items are consumed over one week. It is adjusted in a cultural context; foods not typically used in the Jordanian diet are omitted, while foods typically used are added (Tayyem et al., 2014).
- **A diet quality questionnaire**, the food-based diet quality index, was created by synthesizing current nutrition knowledge. The questionnaire includes 14 "healthy" and 7 "unhealthy" food components known to affect health and prevent major diet-related diseases (Kronsteiner-Gicevic et al., 2021).
- **Depression, Anxiety, and Stress Scale-21 Items (DASS-21)** is a set of three self-report scales developed to measure the emotional states of depression, anxiety, and stress that can effectively assess mental health symptoms for individuals (Bryson et al., 2021; Effati-Daryani et al., 2020; Khouj et al., 2022).
- **Modified Fatigue Impact Scale (MFIS):** The MFIS is a modified version of the FIS that measures physical, cognitive, and psychosocial fatigue. Participants rate the impact of fatigue on their lives over the past 4 weeks on a scale of 0 (no problem) to 4 (extreme problem) (Strober et al., 2020).
- **The Pittsburgh Sleep Quality Index (PSQI)** measures general sleep quality and is a recommended questionnaire for studying global sleep and insomnia symptoms (Zitser et al., 2022).
- **The Beck Depression Inventory (BDII):** This depression self-report measure has been extensively researched and used in clinical and non-clinical populations. It has strong psychometric properties and is widely implemented in depression-related research (Arnarson et al., 2008).

- **SF-36 ARABIC**

B. Educational Intervention:

The participants are divided into three groups. The first group receives nutritional education from a qualified nutritionist and a brochure about the Mediterranean diet. The intervention includes the importance and health benefits of MedDiet, mental health, good food sources, and lifestyle practices to maintain good nutritional status and mental health during lactation, with regular reminders about the importance of a healthy diet. These reminders are communicated through channels such as text messages or WhatsApp. The second group receives only the brochure. The brochure includes the definition and components of MedDiet, its health benefits, food sources, food alternatives rich in minerals such as iron, calcium, and B vitamins, and the importance of healthy lifestyles, including increasing physical activity and avoiding smoking. Lastly, the third group is the control group. They do not receive educational interventions or brochures. However, due to ethical considerations, the control group will receive the education and brochure after completing the study.

Statistical analysis

The database will be built in Microsoft Excel, with duplicate entries to verify data consistency. Data processing and analysis will be performed using SPSS 24 (IBM, NY, USA).

Descriptive statistics and correlations for all quantitative and categorical study variables are calculated at baseline and at the end of the study to present the prevalence of depression, anxiety, and stress severity. Appropriate descriptive statistics such as percentages, means, and standard deviation summarize the data depending on the variable type. The Shapiro–Wilk test will be applied to assess data normality. Data are described using means (SD) and percentages. The student's t-test will be used to compare the means and medians of independent variables between groups; Pearson's Chi-Square test will be used for categorical data to test for association and probability, especially the relationship between sociodemographic variables, nutritional status, and the severity of depression, anxiety, and stress. Moreover, the significance level was set at $p < 0.05$, along with logistic regression, to identify the determinants of the severity of depression, anxiety, and stress among pregnant women attending the clinics. For the ordinal regression modeling, the severity is coded as normal = 0, mild = 1, moderate = 2, and severe = 3. The multivariable ordinal logistic regression model includes Variables statistically significant at $P \leq 0.05$ in the bivariate analyses.

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