Cover Page

Effect of Mindfulness-Based Breastfeeding Education on Breastfeeding Awareness, Self-Efficacy and Breastfeeding Rates in Postpartum Mothers: A Randomized Controlled Trial

Document Date: October 31, 2023

METHODS

Study Design and Participants

This study is a randomized controlled trial in which mothers were randomly assigned to either a group receiving breastfeeding education based on mindfulness or a control group receiving standard care. The study was conducted and reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines.

The study was conducted between February 2024 and April 2025 at four Family Health Centres (FHCs) in the provincial centre of Elazığ, located in eastern Turkey. These centres represent different socioeconomic levels and provide primary healthcare services, including postpartum follow-up, maternal and infant care, immunization, and counselling. Breastfeeding education based on informed awareness is not routinely provided at these centres.

The study population consisted of mothers registered at these primary healthcare centres who were in the first month postpartum and who were not exclusively breastfeeding. The sample consisted of mothers who met the inclusion criteria and agreed to participate in the study. The inclusion criteria were as follows: being 18 years of age or older, being in the first month postpartum, having a full-term, singleton, and healthy infant, and not exclusively breastfeeding the infant (i.e., using formula or other foods in addition to breast milk). The exclusion criteria for the study are as follows: having previously received mindfulness or similar training, having a diagnosed psychiatric disorder, and having any condition that impairs communication.

A priori power analysis was conducted using the G*Power program to calculate the sample size. In the analysis, the mean score for breastfeeding awareness—the primary dependent variable—reported by Korukcu (2023) [mean, standard deviation (SD), 13.01 (4.74)] was taken into account. The sample size for the study was calculated to be at least 43 for each group (breastfeeding awareness group n=43, control group n=43) based on an effect size of 0.54, a power of 0.80, and a margin of error of 0.05.

Randomization

Participants registered with FHCs who met the inclusion criteria were identified by the researcher, and a sample list was created. The participants included in this list were assigned to the mindfulness breastfeeding and control groups using a simple randomization method. During

the randomization process, participants were assigned to either Group 1 or Group 2 using a random number generation method; the resulting draw determined that "1" would represent the mindfulness breastfeeding group and "2" would represent the control group.

Since the mindfulness practice was conducted personally by the same researcher and the participants were, by nature of the study, aware of their group assignments, it was not possible to blind the participants or the researcher conducting the practice. Since the measurement tools were filled out by the participants, the evaluation of the results was not blinded. To minimize selection bias, a randomization list was prepared in advance and randomization confidentiality was maintained.

Measures

In addition to a Personal Information Form used to determine the sociodemographic characteristics (such as age, educational status, working status and income status), and obstetric characteristics (such as number of pregnancies, number of living children, mode of delivery at most recent delivery, baby's gender, and reason for starting supplemental feeding) of the participants, Mindful Breastfeeding Scale (MINDF-BFS), Breast-feeding Self-Efficacy Scale—Short Form (BSES-SF) and Breastfeeding Rate Questionnaire were used in the study.

Mindful Breastfeeding Scale (MINDF-BFS): The scale developed in Turkish by Körükcü et al. (2023) is a 9-item measurement tool designed to assess mindfulness-based breastfeeding practices during the postpartum period. The scale has a single dimension and is based on a 5-point Likert scale. Responses to the scale items range from "always" to "never." The total score on the scale ranges between 9 and 45; as the total score increases, so does the level of mindfulness regarding breastfeeding. The scale's Cronbach's alpha reliability coefficient was found to be 0.83.[21] In the present study, the Cronbach's alpha reliability coefficient for the scale was found to be 0.79.

Breast-feeding Self-Efficacy Scale—Short Form (BSES-SF): The scale is a 14-item assessment tool that evaluates how confident mothers feel about their ability to breastfeed. The BSES-SF is a 5-point Likert-type scale, with each item rated on a scale from 1 (not at all confident) to 5 (always confident). The total score on the scale ranges between 14 and 70. Higher scores on the scale indicate higher breastfeeding self-efficacy. The scale was adapted into Turkish by Aluş Tokat et al., and its Cronbach's alpha reliability coefficient was found to be 0.86.[35] In the present study, the Cronbach's alpha reliability coefficient for the scale was found to be 0.87.

Breastfeeding Rate Questionnaire: Three breastfeeding indicators defined by the World Health Organization were used in the study to determine the breastfeeding rate. These are:

1. Exclusive, Exclusive breastfeeding; no infant formula, other types of milk, or solid foods are given
2. Predominant, While breast milk is the primary source of nutrition for infants, they also consume liquids such as formula, water, water-based beverages, or fruit juices; and
3. Bottlefeeding, Babies consume any liquid or semi-solid food from a feeding bottle.[36]

The questionnaire includes a description of all types of infant feeding practices. The mothers were asked to select the option that best described how they had fed their babies during the previous 24-hour period. To analyze breastfeeding rates across all postpartum time periods, the number of mothers reporting predominant and bottle-feeding in each group was combined and defined as “not exclusively breastfeeding." The rate of exclusive breastfeeding was compared with the rate of not exclusively breastfeeding.

Ethical Considerations

Ethical approval (Protocol No. 2023/5132) was obtained from the İnönü University Health Sciences Non-Interventional Clinical Research Ethics Committee, and the necessary permissions were taken from the relevant institutions to conduct the study. Furthermore, the study was conducted in accordance with the principles of the Declaration of Helsinki. All participants were informed about the study, and their written and verbal informed consent was obtained. Participants were informed that they could withdraw from the study at any time. To ensure participant confidentiality, no personally identifiable information was used in the data collection tools, and all data were analyzed anonymously.

After the study concluded, in accordance with the principle of ethical equity, participants in the control group were provided with a breastfeeding education booklet, and those who requested were offered mindfulness-based breastfeeding education after the data collection process was completed.

Interventions

In the study, one of the researchers, who is a certified midwife (N.K.), provided mindfulness-based breastfeeding education to the mothers in the mindful breastfeeding group. The program consisted of a total of 8 sessions over 4 weeks, with two sessions per week, scheduled at times convenient for the participants. The researcher received training in Mindfulness-Based Stress Reduction (MBSR) and breastfeeding education. The education was provided to mothers individually in the education rooms in FHCs. Each session lasted an average of 50–60 minutes. A breastfeeding education booklet, compiled by the researcher through a review of the relevant literature, was distributed to the mothers prior to the education.[37-39] In addition, a doll and a

knitted breast model were used during the education to support participants in learning breastfeeding positions and techniques through hands-on practice.

The MBSR sessions conducted in the study were based on the meditation techniques of mindfulness therapy. In all sessions, the core techniques of mindfulness therapy—body and breathing meditation, body scan meditation, sitting meditation, sitting meditation with mindfulness of breath, mountain meditation, and Metta meditation—were practiced. Audio recordings of the meditations prepared by the researcher to be played after meditation, along with a mindful movement/yoga video, were provided to the mothers, and they were asked to practice these meditations and the yoga video daily at home. These meditation techniques helped participants focus their attention on the present moment and their emotions, observe their emotions and thoughts from within; stay present by focusing on their physical sensations while breastfeeding and experience the breastfeeding process more mindfully; avoid acting with prejudice and accept themselves as they are. The content of the Mindfulness-Based Breastfeeding Education Program sessions is provided in Appendix S1.

Participants in the control group received postpartum follow-up and breastfeeding counselling services routinely provided at primary FHCs. These services include brief information sessions and counselling provided as part of standard care.

Data collection

The baseline data for the study were collected by the researcher in FHC's education room by means of face-to-face interviews, using a Personal Information Form containing demographic and pregnancy-related questions, as well as the measurement tools employed in the study. At the end of the fourth week, a second set of measurements was obtained using the same method. The same measurement tools were collected via a survey form created using Google Forms and distributed via WhatsApp during the fourth month postpartum.

Statistical Analysis

The data obtained from the study were analyzed using IBM SPSS Statistics (version 25.0). The normality of continuous variables was assessed using the Kolmogorov–Smirnov test and measures of skewness and kurtosis. Descriptive statistics were presented as mean ± standard deviation for continuous variables and as frequency and percentage for categorical variables.

Analyses were conducted on participants who completed the study (per-protocol analysis). Participants who withdrew from the study were not included in the analyses. For baseline comparisons between groups, an independent samples t-test was used for continuous variables, and Pearson's chi-square test was used for categorical variables. In order to evaluate the change

over time and the group effect of mindful breastfeeding and breastfeeding self-efficacy scores, an analysis of variance for repeated measures (Repeated Measures ANOVA) was conducted. In the analysis, group (mindful breastfeeding/control) was treated as the independent variable, while time (baseline, 2nd measurement, 3rd measurement) was treated as the repeated-measures factor. Group, time, and group × time interactions were evaluated in the repeated measures analysis. Effect sizes were reported as Cohen's d for independent group comparisons and as partial eta-squared (ηp^2) for the repeated measures analysis. The Pearson chi-square test was used to compare feeding methods across groups. In addition, odds ratios (OR) and 95% confidence intervals (CI) were calculated to evaluate the likelihood of exclusive breastfeeding.

In all analyses, a p-value of <0.05 was considered statistically significant.

Informed Consent Form

Dear participant;

This study is a scientific research project being conducted by Research Assistant Nuray KURT as part of her doctoral thesis. The title of the study is "The Effect of Mindfulness-Based Breastfeeding Education on Breastfeeding Awareness, Self-Efficacy, and Breastfeeding Rates." The aim of this study is to evaluate the effect of mindfulness-based breastfeeding education provided to women on breastfeeding awareness, self-efficacy, and breastfeeding rates. The total number of participants expected to take part in this study is 86. There will be two different training groups in this study, and the group you will be assigned to will be determined by random selection. If you are assigned to the "Mindfulness-Based Breastfeeding Education" group, the training program will be conducted twice a week for 50–60 minutes over a 4-week period. Mindfulness-based breastfeeding education includes information sharing about the breastfeeding process, mindfulness-related practices, and meditation exercises. As part of the study, you are expected to participate in the 4-week education program.

First, you will be asked to complete a total of four questionnaires designed to help us get to know you, assess your breastfeeding awareness and self-efficacy, and determine how you feed your baby. Following these steps, a researcher trained in Mindfulness-Based Stress Reduction will provide you with face-to-face breastfeeding education, along with mindfulness and meditation exercises. Additionally, all mothers will receive a Breastfeeding Handbook prepared by the researcher during the initial visit. At the end of the 4th week and at the 4-month mark,

you are expected to complete the questionnaires designed to measure your breastfeeding awareness, assess your level of breastfeeding self-efficacy, and determine how you feed your baby. Completing the questionnaires will take no more than 5–7 minutes. To ensure the study achieves its objectives, you are asked to complete the forms provided to you fully and accurately. Studies have indicated that Mindfulness-Based Breastfeeding Education is beneficial. If you participate in the study, the provided education has no known side effects, and there is no risk or harm to you or your baby. You will be under the supervision of a midwife and supported throughout the study. If you receive a psychiatric diagnosis during the training or fail to attend the training for two consecutive weeks, you will be excluded from the study.

Any information collected about you during the study will be recorded using a unique identification number. All information pertaining to you will be kept confidential. The results of this study will be used solely for scientific purposes. Even if the study is published, your identifying information will not be disclosed. However, if necessary, study supervisors, ethics committees, and official authorities will have access to your information. You will also be able to access your own information whenever you wish.

I have been invited to participate in this study, the details of which are outlined above and have been explained to me, by the researcher, Ms. Nuray KURT, as a “participant” (subject). I have asked the researcher all the questions that came to mind, and I fully understand all the explanations provided to me, both in writing and verbally. I may withdraw from the study at any time without providing a reason (though I am aware that it would be appropriate to notify the researchers in advance to avoid putting them in a difficult position). I was given sufficient time to decide whether or not to participate in the study. I have been assured that my personal information will be carefully protected during the use of the research results for educational and scientific purposes. I am not assuming any financial liability for expenses related to the study. Under these conditions, I authorize the principal investigator to review, transfer, and process my personal information, and I accept the invitation to participate in this study of my own free will, without any coercion or pressure. I understand that by signing this form, I will not lose any rights granted to me by law.

Researcher’s Name

Phone No:

Signature:

First Name Last Name: Research Assistant Nuray KURT