

# STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

**Study Title:**

*Development and Evaluation of a Mindfulness-Based Emotional Eating Reduction Program (MB-EER)*

**NCT Number:**

[To be filled after ClinicalTrials.gov registration]

**Document Date:**

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## Table of Contents

1. Introduction
2. Objectives
3. Study Design
4. Participants and Eligibility Criteria
5. Intervention Description
6. Outcome Measures
7. Data Collection
8. Statistical Analysis Plan
9. Ethical Considerations
10. Data Storage and Confidentiality
11. Timeline
12. Appendices

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## 1. Introduction

Emotional eating refers to the tendency to eat in response to emotional states rather than physiological hunger. Recent studies have indicated a strong link between emotional dysregulation and unhealthy eating behaviors. Mindfulness-based practices have shown promise in reducing emotional eating by enhancing awareness, emotion regulation, and interoceptive sensitivity. This study aims to develop and evaluate a Mindfulness-Based Emotional Eating Reduction (MB-EER) program tailored to adults with elevated emotional eating behavior.

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## 2. Objectives

**Primary Objective:**

To evaluate the effectiveness of the MB-EER program in reducing emotional eating.

### Secondary Objectives:

- To increase mindful eating skills.
  - To reduce emotional appetite and emotional eating
  - To evaluate the sustainability of changes in eating behavior after 3 months.
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### 3. Study Design

This is a **true experimental study** using a **pretest–posttest control group design** with **follow-up** measures and **mixed-method embedded** elements (qualitative and quantitative). The experimental group received a 7-week online MB-EER program, while the control group received no intervention during the study period. Data were collected at three time points: pretest, posttest, and 3-month follow-up.

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### 4. Participants and Eligibility Criteria

#### Recruitment:

135 applicants were screened. A total of 30 participants (15 per group) were randomly assigned.

#### Inclusion Criteria:

- Adults aged 18–65
- Moderate to high scores on the Emotional Eating Scale (Z scores between -2 and +2)
- Ability to attend 7 online sessions

#### Exclusion Criteria:

- Diagnosed eating disorder (e.g., bulimia, binge eating)
  - Chronic conditions affecting appetite (e.g., Hashimoto's, diabetes)
  - Pregnancy
  - Refusal to consent
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### 5. Intervention Description

#### Program Title:

Mindfulness-Based Emotional Eating Reduction (MB-EER)

#### Delivery Method:

Online via Zoom, once per week for 2 hours, over 7 weeks.

#### Components:

- Psychoeducation (emotional eating, mindfulness, body awareness)
- Experiential practices (e.g., raisin exercise, body scan, mindful movement)
- Homework and reflections

- Tools: Mindfulness Booklet, WhatsApp group communication

### Session Topics Include:

1. Awareness of how you eat
2. Recognizing autopilot behavior
3. Identifying stimuli (internal/external)
4. Honoring hunger/satiety
5. Self-compassion and body awareness
6. Cultural beliefs around food
7. Integration and future planning

Table 1. Experimental Research Sessions, Session Objectives, Materials Used, and Actions Performed.

Sessions	Session Objectives	Materials Used	Actions
<b>First Session:</b> Focusing on How You Eat Rather Than What You Eat and Meet and Greet	<p><b>Objective 1:</b> Establishing a relationship of trust between group members</p> <p><b>Objective 2:</b> To understand the basic concepts of the program (emotional eating, mindfulness and mindful eating, to be able to predict their relationships)</p> <p><b>Objective 3:</b> Understanding the concepts of physical and emotional hunger and their differences</p> <p><b>Objective 4:</b> Mindful eating as shown</p>	-Raisin	<p>-Meeting Events</p> <p>-Configuration of Group Process and Policies</p> <p>-Introduction and explanation of concepts</p> <p>-Raisin exercise</p> <p>-Breath awareness exercise</p> <p>-Evaluation</p>
<b>Second Session:</b> Recognizing Autopilot	<p><b>Objective 1:</b> Recalling the first session and talking about realizations</p> <p><b>Objective 2:</b> Understand and recognize the concept of autopilot</p> <p><b>Objective 3:</b> Recognize emotional triggers that activate autopilot</p>	<p>-Handwriting Metaphor: Recognizing Autopilot</p> <p>-Trigger food exercise (participants provided the food themselves)</p>	<p>Reminders about session -1 were made.</p> <p>-A group discussion was held to share the experiences of the 1st session practice assignments.</p> <p>-The concept of automatic pilot was explained. Examples from daily life were given and a 'handwriting metaphor' study was done on recognizing the autopilot. Then, the group talked about awareness.</p> <p>- Emotional triggers were discussed and examples were given. Participants were sent to breakout rooms (2-3 discussion groups) from time to time to gain awareness of the emotions that often trigger them.</p> <p>-They were shown how to eat the trigger food and then given time to practice it themselves. Afterwards, experiences of eating the trigger food were discussed.</p> <p>-Breath awareness exercise</p> <p>-Evaluation</p>
<b>Third Session:</b> Recognizing the Stimuli	<p><b>Objective 1:</b> Recalling the second session and reflecting on realizations</p> <p><b>Objective 2:</b> Recognize stimuli that accompany eating</p> <p><b>Objective 3:</b> Distinguish stimuli accompanying eating as internal or external</p> <p><b>Objective 4:</b> Experiencing the effect of stimuli accompanying eating on eating awareness</p>	<p>-Music</p> <p>-Article on emotions</p> <p>-Foods that participants brought with them to eat during the session</p>	<p>Reminders about session -2 were made.</p> <p>-A group discussion was held to share the experiences of the 2nd session practice homework.</p> <p>- Information was given about stimuli and the effect of stimuli on eating behavior. The group talked about recognizing the stimuli that accompany eating.</p> <p>-Experiential practice 1: Eating the specified food using eating awareness skills.</p> <p>-Experimental practice 2: Eating the food while listening to music and reading an article.</p> <p>-Awareness in practices 1 and 2 were discussed.</p> <p>-Breath awareness exercise</p> <p>-Evaluation</p>

<p><b>Fourth Session:</b> Honoring Hunger and Satiety</p>	<p><b>Objective 1:</b> Recalling the third session and reflecting on realizations <b>Objective 2:</b> Understand hunger and satiety signals and predict their relationship <b>Objective 3:</b> Assess and analyze hunger and satiety signals <b>Objective 4:</b> Finding the location of hunger and satiety in the body</p>	<p>-Hunger and Satiety Assessment Scale  -1 liter of water</p>	<p>-Reminders about the 3rd session were made. -3rd session practice homework experiences were shared as a group. -Information was given on hunger and satiety signals. -The Hunger and Satiety assessment scale was presented. They were asked to examine it. Awareness was discussed as a group on making an assessment about themselves. -Body Scan was practiced. Awareness was discussed after the body scanning practice. -Participants were asked to drink 1 liter of water when they were hungry for at least 3 hours. They drank water until they felt full and then talked about their awareness. -Evaluation</p>
<p><b>Fifth Session:</b> Honoring the Body</p>	<p><b>Objective 1:</b> Recalling the fourth session and reflecting on realizations <b>Objective 2:</b> To understand the concept of self-compassion and to be able to predict its relationship with the body <b>Objective 3:</b> Assess and examine the components of self-compassion, <b>Objective 4:</b> Recognizing the supportiveness and signals of the body, connecting with the body</p>	<p>Self-compassion Scale  -The metaphor of the weeping child  -Mindful movements</p>	<p>-Reminders about the 4th session were made. -4th session practice homework experiences were shared as a group. - The concept of self-compassion was explained and information was provided with research. - Awareness work on self-compassion was done with a metaphor over a crying child. - Self-compassion scale items were examined. The items that were most challenging for them were examined and their awareness was discussed. - Body awareness was practiced through mindful movements. After this study, awareness of the body was discussed. -Evaluation</p>
<p><b>Sixth Session:</b> Honoring the Past</p>	<p><b>Objective 1:</b> Recalling the fifth session and reflecting on realizations <b>Objective 2:</b> To evaluate and examine nutritional components and beliefs <b>Objective 3:</b> Explore and recognize the cultural connections of eating <b>Objective 4:</b> Recognize the influence of culture on food rules and habits</p>	<p>- Table of rules and false beliefs  -Table of clean plate values  -Last bite experiment (participants provided their own food)</p>	<p>-Reminders about the 5th session were made. -5th session practice homework experiences were shared as a group. -The table of rules and false beliefs about eating was examined and discussed. -The impact of culture on eating was discussed and awareness was evaluated. -Items related to nutrition rules were introduced. The most challenging items were examined, and their awareness was discussed. -The clean plate values table was questioned. - Last Bite Experiment was conducted. Mindful eating skills were reminded while eating the food. The ability to leave 1 or 2 pieces behind while eating the food was discussed. -Evaluation</p>
<p><b>Seventh Session:</b> Looking into the Past and Moving On</p>	<p><b>Objective 1:</b> Recognize improvements since the past weeks <b>Objective 2:</b> Make eating awareness skills sustainable <b>Objective 3:</b> To ensure the continuity of the positive skills acquired in the future. <b>Objective 4:</b> To evaluate the group process</p>	<p>-Story of the Battle of the Wolves</p>	<p>-Reminders about the 6th session were made. -6th session practice homework experiences were shared as a group. -The story of the War of the Wolves was read and discussed. - What can be done to make eating awareness sustainable from now on was discussed. Personal evaluations were taken in terms of where they came from. - The intentions file for each week was examined and self-evaluation and awareness talks were made about where they came from. -General evaluation of the program was made.</p>

## **6. Outcome Measures**

### **1. Emotional Eating Scale (EES-30)**

- Likert-type; 30 items
- Higher scores = higher emotional eating
- Cronbach's  $\alpha = .92$

### **2. Mindful Eating Questionnaire (MES-30)**

- 30 items; 7 subscales
- Higher scores = more mindful eating
- Cronbach's  $\alpha = .72$

### **3. Emotional Appetite Questionnaire (EAQ-22)**

- 22 items; emotional appetite under various emotional states
  - Cronbach's  $\alpha = .71$
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## **7. Data Collection**

### **Time Points:**

- Pretest: Week 0
- Posttest: Week 7
- Follow-up: 3 months after posttest

### **Tools:**

Google Forms, Zoom (recorded with consent), WhatsApp (coordination)

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## **8. Statistical Analysis Plan**

### **Software Used:**

SPSS version 26.0

### **Assumptions Tested:**

- Normality: Shapiro–Wilk
- Variance Homogeneity: Levene's Test
- Z-score range for inclusion

### **Tests Employed:**

- Mixed-design ANOVA (Repeated Measures)
- Bonferroni correction for post hoc pairwise comparisons
- Eta squared ( $\eta^2$ ) for effect sizes

- Wilks' Lambda for multivariate time x group interaction

#### Interpretation Thresholds for $\eta^2$ :

- Small: 0.01
  - Medium: 0.06
  - Large: 0.14 and above
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#### 9. Ethical Considerations

- Ethical approval was obtained from the **Düzce University Scientific Research Ethics Committee** (Date: 29.12.2022, Decision No: 493).
  - Informed consent obtained from all participants prior to data collection.
  - No participant data (names, identifiers) are disclosed.
  - Participants were free to withdraw at any point.
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#### 10. Data Storage and Confidentiality

- Data stored securely on a password-protected institutional drive.
  - Only the principal investigator and authorized team have access.
  - All data are anonymized using participant IDs.
  - Data will be stored for 5 years in compliance with institutional policy.
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#### 11. Timeline

Activity	Date Range
Recruitment	May 2023 – Nov 2023
Pilot Study	May – July 2023
Experimental Implementation	Sept – Nov 2023
Follow-up Assessments	Feb 2024
Data Analysis & Report Writing	Mar – May 2024

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