Cover Page

Official Title:
Comparative Effects of Intermittent Fasting Versus Mediterranean Diet on Obesity Management: A Randomized Controlled Trial

NCT Number:
Not yet assigned at time of document signing

Date of Document:
01 June 2022

Comparative Effects of Intermittent Fasting Versus Mediterranean Diet on Obesity Management: A Randomized Controlled Trial

INFORMED CONSENT FORM

Dear Participant,

A research study is being conducted at the Department of Nutrition and Dietetics, Faculty of Health Sciences, European University of Lefke, as a master's thesis project. The study aims to evaluate the effect of the intermittent fasting diet and Mediterranean diet on body weight control. You will take part as a member of the control group. The data obtained from you will be compared with those of the other study group to reach a conclusion.

Participation in this study is entirely voluntary. You have the right to refuse to participate or to withdraw from the study at any time without giving any reason. In either case, you will not be subject to any penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Study:

The purpose of this research is to evaluate the effect of the intermittent fasting diet on body weight control and to investigate its effectiveness as one of the new dietary approaches used in the management of chronic diseases such as obesity and type 2 diabetes.

Methods and Protocols:

This study will be conducted on a total of 120 participants. Personal information and dietary habits will be collected using a questionnaire. Body weight and body composition will be measured using a **TANITA BC-418 MA** analyzer.

Participants who agree to take part in the study will be divided into two groups, each receiving a different dietary intervention for a period of four weeks.

- Group 1 followed a time restricted intermittent fasting (IF) protocol. Participants were instructed to consume all daily meals within an 8-hour eating window (1:00 PM to 9:00 PM) and fast for the remaining 16 hours (9:00 PM to 1:00 PM). During the feeding period, participants consumed two main meals and one snack based on ad libitum intake without specific calorie restriction.
- Group 2 followed an energy restricted Mediterranean diet (MD) plan. This dietary model was adapted from both the PREDIMED criteria and the MedDietScore index. Participants were instructed to consume: ≥3 servings/day of fruits, ≥2 servings/day of vegetables, ≥3 servings/week of legumes,≥2 servings/week of fish or seafood, ≥3 servings/week of nuts, olive oil as the main fat source (≥4 tablespoons/day), moderate intake of dairy (1–2 servings/day) and poultry, limited intake of red or processed meat (≤1 serving/week), avoidance of refined grains, sugar sweetened beverages, and sweets, no alcohol consumption.

Duration of the Study;

All data from the intervention group will be collected within a four-week period. The data collected will be used solely for scientific research purposes. Participation in the study is completely voluntary.

Clinical Trial Registration:

This study has been submitted for registration on ClinicalTrials.gov. At the time of signing this consent form, the study does not yet have an assigned NCT number. Once available, the NCT number will be added to the study documents and will be accessible at https://clinicaltrials.gov

Consent Statement

I have been informed about the details of the study and voluntarily agree to participate.

Supervisor
Asst. Prof. Dr. Kamil DAĞCILAR

Researcher
Figen GÜLCAN
Faculty of Health Sciences,
European University of Lefke

Participant's Name and Surname:

Participant's Signature: