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# Time-restricted feeding in overweight women

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 22/01/2024 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 24/01/2024 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 23/01/2024 | Nutritional, Metabolic, Endocrine | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
This study aimed to determine the effects of ad libitum time-restricted feeding (TRF) applied for six weeks on body weight, body composition, and metabolic health parameters in overweight women in Balıkesir, Turkiye. This study aims to show that an 8 h food deprivation approach in participants from a developing country with limited education and social vulnerability is effective, feasible, and adaptable for treating obesity.

Who can participate?
Women aged between 19 and 65 who are overweight (BMI: 25-29.99 kg/m2)

What does the study involve?
This clinical trial will be conducted with a six-week follow-up period. In the TRF diet, women are instructed to eat ad libitum only for 8 hours (10:00-18:00). A survey form containing socio-demographic information, general health information, nutritional habits, and 24 h retrospective dietary recall will be administered to the individuals by the researchers via face-to-face interview technique. Anthropometric measurements, body compositions, biochemical parameters, and vital signs are evaluated before and after TRF.

What are the possible benefits and risks of participating?
It does not require buying different foods and offers participants flexibility in starting their fasting period during the intervention.

Where is the study run from?
Balıkesir Atatürk City Hospital (Turkey)

When is the study starting and how long is it expected to run for?
November 2020 to February 2022

Who is funding the study?
This research received no specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Who is the main contact?
Saniye Bilici, sgbilici@gazi.edu.tr (Turkey)

# Contact information

### Type(s)
Public, Scientific, Principal investigator


### Contact name
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
A clinical trial reveals the effects of time-restricted feeding in overweight women

### Study objectives
This study hypothesized that optional time-restricted feeding (TRF) administered for six weeks in overweight women has an effect on body weight, body composition, and metabolic health parameters.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 26/01/2021, Ethics Committee of the Gazi University (Emniyet Mah. Bandırma Cad. No: 6/1 , Ankara, 06560, Türkiye; +90 312 202 20 57; gaziuniversitesi@hs01.kep.tr), ref: 2021-134

### Study design

Longitudinal case crossover study

## Primary study design
Observational

## Study type(s)
Screening

## Health condition(s) or problem(s) studied
Overweight women

## Interventions
8-hour time-restricted ad libitum eating for six weeks intervention
While the beneficial impacts of time-restricted eating (TRE) on health extend beyond weight loss; it's crucial to recognize the potential influence of aligning eating patterns with the circadian rhythm. Nevertheless, the current body of TRE research remains limited, with clinical trials often a control group subjected to an identical energy intake as the experimental group. This limitation hinders our ability to definitively attribute observed effects to changes in food selection or the fasting regimen to overlook the potential influence of the circadian rhythm. Since different individual parameters will come into play in shaping food preferences, in TRE studies where ad libitum diet is offered, intervening in the same individuals and evaluating before and after TRE will be beneficial in eliminating individual differences in food selection and other variations. For these reasons, this study was planned to determine the effects of ad libitum TRE applied for six weeks on body weight, body composition, and metabolic health parameters in overweight women.

At the beginning of the study, the researchers administered a survey form containing socio-demographic information, general health information, nutritional habits, and 24-hour retrospective dietary recall via face-to-face interview. Six weeks after the beginning of the study, 24-hour dietary records for three consecutive days were taken from the individuals. The dietary records' energy, macronutrient, and micronutrient contents were analyzed using the BeBiS (Nutrition Information System) program (version 8.2). Body weight (kg), body fat mass (kg), body fat percentages (%), lean body mass (kg), and total body water (%) measurements were obtained by Tanita BC 545 N bioelectric impedance device-BIA. Height measurements of the participants were collected. The waist circumference measurement protocol used in the study was based on bony landmarks (the midpoint of the iliac crest and the last rib). The neck circumference was measured at mid-neck, between the mid-cervical spine and the mid-anterior neck, on women standing upright and facing forwards, with shoulders relaxed. After 12 h fasting, a 10-mL venous blood specimen was collected from the women, using a venous container, at baseline and after the sixth week of the research. Blood glucose, insulin, HOMA-IR, total cholesterol, LDL-C, HDL-C, triglyceride, AST, and ALT values of the women were measured and calculated by biochemistry technicians in the biochemistry laboratory of Balıkesir Atatürk City Hospital. The researchers measured the participants' blood pressure using an Omron M2 Basic HEM-7121J-E upper arm digital blood pressure monitor.

In the study, a single TRE intervention was performed, and the parameters to be evaluated in individuals were compared before and after the TRE. In the TRE diet, women were instructed to eat ad libitum only during an 8 h period (10:00-18:00) and fasted during the other 16 hours, from the last meal for a total duration of six weeks. The participants were not given any particular nutritional instructions, making the trial conditions resemble real-life scenarios. While fasting, the participants were encouraged to drink large amounts of water, tea with no sugar added,

black coffee, or no-calorie sparkling water. At the beginning of the study, the researchers administered a survey form containing socio-demographic information, general health information, nutritional habits, and 24-hour retrospective dietary recall via face-to-face interview. Six weeks after the beginning of the study, 24-hour dietary records for three consecutive days were taken from the individuals. In the study, during the 6-week follow-up period, routine control interviews were held with individuals via social media, online, and by phone, and their compliance with feeding hours was closely monitored. Participants kept 24-hour dietary records of their food consumption, noting meal items and quantities, or they captured photos of their meals and instantly shared them with the dietitian to maintain a more accurate food log. The dietitians maintained ongoing communication with the participants, offering information and words of encouragement. The dietary records' energy, macronutrient, and micronutrient contents were analyzed using the BeBiS (Nutrition Information System) program (version 8.2). At the beginning of the study, the researchers administered a survey form containing socio-demographic information, general health information, nutritional habits, and 24-hour retrospective dietary recall via face-to-face interview. Six weeks after the beginning of the study, 24-hour dietary records for three consecutive days were taken from the individuals. The dietary records' energy, macronutrient, and micronutrient contents were analyzed using the BeBiS (Nutrition Information System) program (version 8.2). Body weight (kg), body fat mass (kg), body fat percentages (%), lean body mass (kg), and total body water (%) measurements were obtained by Tanita BC 545 N bioelectric impedance device-BIA. Height measurements of the participants were collected. The waist circumference measurement protocol used in the study was based on bony landmarks (the midpoint of the iliac crest and the last rib). The neck circumference was measured at mid-neck, between the mid-cervical spine and the mid-anterior neck, on women standing upright and facing forwards, with shoulders relaxed. After 12 h fasting, a 10-mL venous blood specimen was collected from the women, using a venous container, at baseline and after the sixth week of the research. Blood glucose, insulin, HOMA-IR, total cholesterol, LDL-C, HDL-C, triglyceride, AST, and ALT values of the women were measured and calculated by biochemistry technicians in the biochemistry laboratory of Balıkesir Atatürk City Hospital. The researchers measured the participants' blood pressure using an Omron M2 Basic HEM-7121J-E upper arm digital blood pressure monitor.

The intervention was provided by 2 nutritionists and 1 dietician. The data was provided individually by a face-to-face mechanism at Balıkesir Atatürk City Hospital Diet Polyclinic, Bursa, Türkiye and Gazi University, Faculty of Health Sciences, Department of Nutrition and Dietetics, Ankara, Türkiye.

In the study, a single TRE intervention was performed, and the parameters to be evaluated in individuals were compared before and after the TRE. In the TRE diet, women were instructed to eat ad libitum only during an 8 h period (10:00-18:00) and fasted during the other 16 hours, from the last meal for a total duration of six weeks. The participants were not given any particular nutritional instructions, making the trial conditions resemble real-life scenarios. While fasting, the participants were encouraged to drink large amounts of water, tea with no sugar added, black coffee, or no-calorie sparkling water.
Intervention adherence or fidelity was not assessed. In the study, during the 6-week follow-up period, routine control interviews were held with individuals via social media, online, and by phone, and their compliance with feeding hours was closely monitored.
Intervention adherence or fidelity was not assessed.

## Intervention Type
Behavioural

## Primary outcome(s)

The following primary outcome variables were assessed before the intervention and after the six-week follow-up period:
1. Body weight was measured using Tanita BC 545 N bioelectric impedance device-BIA
2. Body fat mass was measured using Tanita BC 545 N bioelectric impedance device-BIA
3. Waist circumference was measured using a non-stretching measuring tape ruler
4. Neck circumference was non-stretching measuring tape ruler
5. Blood glucose concentration was measured and calculated by biochemistry technicians in the biochemistry laboratory of Balıkesir Atatürk City Hospital
6. Levels of insulin, HOMA-IR, LDL-C, HDL-C, triglyceride, and ALT were measured and calculated by biochemistry technicians in the biochemistry laboratory of Balıkesir Atatürk City Hospital.

### Key secondary outcome(s))
1. Dietary energy content was measured from the 24-hour dietary records of their food consumption using the BeBiS (Nutrition Information System) program (version 8.2).
2. Macronutrient levels were measured from the 24-hour dietary records of their food consumption using the BeBiS (Nutrition Information System) program (version 8.2).

### Completion date
15/02/2022

## Eligibility

### Key inclusion criteria
1. Female
2. Aged between 19 and 65 years old
3. BMI: 25-29.99 kg/m2
4. Stable body weight for at least one month
5. Non-smoking
6. Consumption of < 140 g/wk of alcohol
7. Light exercise (<60 min/week of moderate exercise)
8. Consent, is indicated by signing the human-subject research agreement form

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
19 years

### Upper age limit
65 years

### Sex
Female

### Total final enrolment
43

### Key exclusion criteria
1. Women on chronic medication use
2. Those with a pacemaker or platinum in their body
3. Individuals in the postmenopausal state
4. Pregnant or breastfeeding women
5. Individuals working shift work
6. Those with a history of cancer
7. Individuals with obsessive-compulsive disorder

### Date of first enrolment
01/02/2021

### Date of final enrolment
01/02/2022

## Locations

### Countries of recruitment
Türkiye

### Study participating centre
**Balıkesir Atatürk City Hospital**
Balıkesir Atatürk City Hospital Diet Polyclinic
Balıkesir
Türkiye
10020

## Sponsor information

### Organisation
Gazi University

### ROR
https://ror.org/054xkpr46

## Funder(s)

### Funder type
Other

**Funder Name**
Investigator intiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Saniye Bilici, sgbilici@gazi.edu.tr. The type of data that will be shared is raw data as an SPPS file. Requests can be made for 1 year. Consent from participants was obtained. Data will be anonymized. There are no ethical or legal restrictions.

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |