

Alternate day fasting for obesity treatment

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Registration date 08/08/2017	Overall study status Completed	☐ Protocol
Last Edited 08/08/2017	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Obesity is an emerging epidemic health problem once it increases several risks of chronic diseases. Reductions in calorie intake, lifestyle changes, and exercise are the main approaches to manage obesity and related disorders, but successfulness is not achieved by most patients. Alternate day-fasting (ADF) has been reported as an effective method of weight loss and is, therefore, a promising obesity approach. This diet you fast every other day (or eat a small amount of calories) and then eat normally the next day. A more common way of dieting is known as calorie restriction (CR) where people restrict the amount of calories they eat in a day. However this method requires more research. The aim of this study is to evaluate biomarkers, metabolic profile, body weight and composition responses to ADF compared to calorie restriction.

Who can participate?

Adults aged 20 to 55 years old who have are overweight or obese.

What does the study involve?

Participants are allocated to one of two groups. Participants have a consultation with the nutritionist and to receive an individual meal plan, according to their health specifications and preferences. Those in the first group follow the meal plan everyday. Those in the second group follow the meal plan at one day and the following day is a free day where they can eat anything needed, with no quantity limitation. Participants are examined at the beginning of the study and at the end of the study to measure their body composition and indirect calorimetry. Participants also provide blood samples. During all the study, subjects had free access to the nutritionist by e-mail and phone and they should contact her if they had any symptom.

What are the possible benefits and risks of participating?

Participants may benefit from the control or reduction in their weight with free nutritional monitoring as well as increased knowledge of metabolism, body composition and individual responses to diet. Participants also have access to all laboratory results and body composition reports. There are few risks with participating including headache and irritability during the restricted eating days. Participants may experience discomfort when providing blood samples as well as bruising.

Where is the study run from?

1. Corpometria Institute (Brazil)
2. Sabin Laboatory (Brazil)

When is the study starting and how long is it expected to run for?

July 2015 to October 2016

Who is funding the study?

Universidade de Brasília (Brazil)

Who is the main contact?

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Contact information

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Additional identifiers

Protocol serial number

01/01

Study information

Scientific Title

Alternate day fasting as an intervention to improve body composition and blood biochemical markers in overweight patients

Study objectives

ADF is as effective as calorie restriction to treat obesity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Catholic University of Brasilia,30/03/2016, ref: 1.471.606

Study design

We performed a four-week, randomized, single-center, controlled and parallel two-arm trial to analyze the effects of alternate day fasting (n=11) and caloric restriction (n=9) in the 20 selected subjects.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obesity

Interventions

The 20 volunteers are randomly divided into two groups: Alternate day fasting and Caloric restriction. The interventions are employed for four weeks.

Participants are randomly allocated to one of two groups: Alternate day fasting and caloric restriction.

Alternate day fasting (ADF) group: Participants in this group have their calorie intake limited to 25% of the baseline energy needs on the fasting days and this is to be ingested within a 12-hour period and divided into six small meals. On the feeding days, ad libitum food intake was permitted over a 12-hour period. On both days, ingestion of food is not permitted in the remaining hours during which the participants are awake. On the feeding days, there is no restriction on calorie intake, but the participants are required to record the specific consumed foods in a food diary.

Caloric restriction (CR) group: Participants in this group have a hypocaloric diet that is restricted to 75% of the estimated calorie expenditure per day throughout the intervention period.

In both groups, the diet was hyperproteic (25%-30% protein), normoglycemic (~50% carbohydrates) and normolipidic (25%-30% fat/lipids).

Participants undergo body composition assessments at a specialised clinic, in the presence of the researchers, using the BodPod Gold Standard (Cosmed, Italy), an air displacement plethysmograph that uses whole-body density to determine body composition (total body weight, and fat and fat-free mass), and InBody 770 (BridgePower Corp., USA), a validated electrical bioimpedance instrument that provides the visceral fat area, water balance and lean and fat masses. These examinations are safe, fast, non-invasive, and comfortable, and have excellent repeatability.

Indirect calorimetry (Spirostik-REE, Geratherm, Germany) is used to measure the basal metabolic rate (BMR) and determine metabolic substrate utilization (carbohydrate and lipids). Indirect calorimetry is used to measure energy expenditure accurately and instantaneously based on spontaneous breathing, and the results are presented as the respiratory coefficient. BMR was measured by the nutritionist and it was performed in a noise-free and light-free environment with the subjects awake and lying down, and breathing naturally without talking.

Twelve-hour fasting blood samples are collected by qualified professionals in a specialised laboratory between 07:00 AM and 09:00 AM at baseline (at the beginning of week one) and at the end of the intervention (at the end of week four). Disposable syringes are used, and the collection is performed under the supervision of nurses and other hospital staff, who provided all the necessary support. Plasma samples are verified to analyze the plasma levels of cortisol (mg/dL), free T3 (pg/dL), free T4 (ng/dL), thyroid-stimulating hormone (TSH, mg/dL), total cholesterol (mg/dL), triglycerides (mg/dL), HDL cholesterol (mg/dL), LDL cholesterol (mg/dL) and blood glucose (mg/dL). Chemiluminescence assays are used to analyze free T3, free T4, TSH and cortisol levels. The glycemic index was calculated using the hexokinase method, and the cholesterol concentrations are determined using the oxidase/peroxidase method. Commercial kits are used for the laboratory for all these analyses.

Intervention Type

Other

Primary outcome(s)

1. Mean body weight loss is measured using the BodPod and InBody770 at baseline and 4 weeks
2. Fat loss is measured using the BodPod and InBody770 at baseline and 4 weeks
3. Lean mass loss is measured using the BodPod and InBody770 at baseline and 4 weeks
4. Carbohydrate burning is measured using indirect calorimetry at baseline and 4 weeks
5. BMR (Basal Metabolic Rate) is measured using Indirect calorimetry (Spirostik-REE) at baseline and 4 weeks

Key secondary outcome(s)

1. Body water is measured using InBody770 at baseline and 4 weeks
2. Food patterns is measured using a Food Reminder Form that was delivered for all subjects at baseline and 4 weeks

Completion date

01/10/2016

Eligibility

Key inclusion criteria

1. 20–55 years of age
2. BMI > 25 kg/m²

3. Previous sedentary lifestyle
4. Absence of diabetes, hypertension and cardiovascular diseases
5. No smoking

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Previously undergone bariatric surgery

Date of first enrolment

10/02/2016

Date of final enrolment

10/03/2016

Locations**Countries of recruitment**

Brazil

Study participating centre**Corpometria Institute**

SGAS 915 Lote 69 Sala 262

Centro Clinico Advance

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Brazil

70390-150

Study participating centre**Sabin Laboratory**

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Sponsor information

Organisation

Universidade Catolica de Brasilia

ROR

<https://ror.org/0058wy590>

Funder(s)

Funder type

University/education

Funder Name

Universidade de Brasília

Alternative Name(s)

University of Brasília, UnB

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Brazil

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from:

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IPD sharing plan summary

Available on request