ISRCTN13374800 https://doi.org/10.1186/ISRCTN13374800

Alternate day fasting for obesity treatment

Submission date
28/07/2017

Recruitment status
No longer recruiting

Registration date
08/08/2017

Overall study status
Completed

Last Edited
08/08/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] 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?
Mrs Gabriella Alves Ferrari
gabriellafalves@hotmail.com
Professor Rinadlo Wellerson Pereira
rinaldo.pereira@catolica.edu.br

Contact information

Type(s)
Public

Contact name
Mrs Gabriella Alves Ferrari

Contact details
Rue de la Birse 11
Courroux
Switzerland
2822
+41 079 720 3592
gabriellafalves@hotmail.com

Type(s)
Scientific

Contact name
Prof Rinaldo Wellerson Pereira

Contact details
Universidade Católica de Brasilia - Brazil
SGAN 916 Modulo B Avenida W5
Asa Norte
Brasilia
Brazil
70790-160

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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.

Carloric 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), normoglycidic (~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 measure
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

Secondary outcome measures
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

Overall study start date
20/07/2015

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

Age group
Adult

Sex
Both

Target number of participants
20

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
Brasilia
Brazil
70390-150

Study participating centre
Sabin Laboatory
915/715 Sul Centro Clínico Advance Lote 69 Salas 102, 103 e 104
Brasilia
Brazil
70390-150

Sponsor information

Organisation
Universidade Catolica de Brasilia

Sponsor details
SGAN 916 Módulo B Avenida W5
Asa Norte
Brasilia
Brazil
70790-160
+55 61 3448 7129
rinaldo.pereira@catolica.edu.br

Sponsor type
University/education

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

Publication and dissemination plan
We are intending to publish at the journal Obesity, from The Obesity Society, as soon as possible.

Intention to publish date
25/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from:
ALVES, Gabriella - gabriellafalves@hotmail.com
CADEGIANI, Flavio - superendocrinology@gmail.com
PEREIRA, Rinaldo - rinaldo.pereira@catolica.edu.br

IPD sharing plan summary
Available on request