

Effect on weight loss of a diet inspired by traditional nutrition

Submission date 03/05/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/05/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/01/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A diet which avoids processed foods, such as the Paleolithic diet, can result in weight loss but seems impossible in modern times where refined food is dominant. The aim of this study is to find out whether by excluding only a few refined foods involved in obesity, it is possible to overcome the limited food choices of the Paleolithic diet but still feel full and lose weight.

Who can participate?

Overweight and obese people

What does the study involve?

Participants eat a non-calorie restricted diet that excludes six refined foods (margarine, vegetable oils, butter, cream, processed meat, and sugary drinks) called the "1,2,3 diet". Participants are weighed at the start of the study and at visits over a period of 2 years.

What are the possible benefits and risks of participating?

Not provided at time of registration (study completed)

Where is the study run from?

Hospital Antoine Beclère (France)

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

January 2011 to December 2015

Who is funding the study?

Hospital Antoine Beclère (France)

Who is the main contact?

Dr Rodi Courie
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
123diet

Study information

Scientific Title

A low-intensity diet that excludes six processed foods for a moderately obese population: long-term feasibility and effect on weight loss of the "1,2,3 diet"

Study objectives

A diet devoid of food-processing procedure, such as the Paleolithic diet, is satiating and produces an important weight loss but seems impossible to implement in our modern times where refined food is dominant. This study investigated in humans whether by excluding only few refined foodstuffs implicated in obesity, it was possible to overcome the limited food choices of the Paleolithic diet but still restore early satiety and the subsequent weight loss.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Human subject's committee in Biomedical Research at Bicêtre Hospital, October 2010

Study design

Two-year single-arm open-label exploratory study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Obesity, diabetes

Interventions

105 overweight subjects were assigned to an ad-libitum diet that excludes six refined foodstuffs (margarine, vegetable oils, butter, cream, processed meat, and sugary drinks) called the "1,2,3 diet". Professional contact was minimal. The total duration of the study and follow-up was 2 years. Participants were suggested to come back for a first visit 1 month after the onset of the diet and every two to three months thereafter. There were no mandatory visits. Outcome measures were reported at 6, 12 and 24 months.

Intervention Type

Other

Primary outcome measure

Body weight, measured by weighing patients without shoes to the nearest 0.5 kg on the same scale calibrated daily, at baseline and at each subsequent visit (6, 12 and 24 months) over a period of 2 years

Secondary outcome measures

The number of patients who lost more than 5% of their initial weight, measured by weighing patients without shoes to the nearest 0.5 kg on the same scale calibrated daily, at baseline and at each subsequent visit (6, 12 and 24 months) over a period of 2 years

Overall study start date

05/01/2011

Completion date

05/12/2015

Eligibility**Key inclusion criteria**

1. Overweight and obese patients (body mass index (BMI) ≥ 25 Kg/m²) whose chief complaint was related to their excess weight
2. Age 18 to 74

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

105

Key exclusion criteria

1. Pregnancy
2. Recent modifications to the usual diet

Date of first enrolment

05/01/2011

Date of final enrolment

26/04/2013

Locations**Countries of recruitment**

France

Study participating centre**Hospital Antoine Beclère**

Outpatient endocrinology consultation of the Hepato-gastroenterology/Nutrition department

157 rue de la Porte de Trivaux

Clamart

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92141

Sponsor information**Organisation**

Hopital Antoine Belcère

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04sb8a726>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hopital Antoine Belcère

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rodi Courie (rodicourie@gmail.com) and Dr Hadrien Tranchart (hadrien.tranchart@aphp.fr)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/07/2018	23/01/2019	Yes	No