

# Effect on weight loss of a diet inspired by traditional nutrition

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

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Rodi Courie

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**Additional identifiers****Protocol serial number**

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

**Study type(s)**

Other

**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(s)**

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

## **Key secondary outcome(s)**

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

## **Completion date**

05/12/2015

# **Eligibility**

## **Key inclusion criteria**

1. Overweight and obese patients (body mass index (BMI)  $\geq 25$  Kg/m<sup>2</sup>) whose chief complaint was related to their excess weight
2. Age 18 to 74

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Lower age limit**

18 years

## **Sex**

All

## **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

France

92141

## Sponsor information

**Organisation**

Hopital Antoine Belcère

**ROR**

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

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Hopital Antoine Belcère

## 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 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?
<a href="#">Results article</a>	results	12/07/2018	23/01/2019	Yes	No