ISRCTN67529475 https://doi.org/10.1186/ISRCTN67529475

Foods for weight management (Elintarvikkeita painonhallintaan)

Submission date
04/10/2013

Recruitment status
No longer recruiting

Registration date
29/01/2014

Overall study status
Completed

Last Edited
05/06/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Success in weight management is challenging. Even after successful weight loss, weight regain is very common. Therefore it is important to identify factors that affect self-regulation of food intake and other behaviors related to weight management. The study aims to find out such factors associated with weight management, especially whether the satiety value of food as a part of a weight-maintenance diet would affect self-regulation of food intake and weight management.

Who can participate?
Obese men and women, aged 30-65 years, will be recruited into the study.

What does the study involve?
The study consists of weight-loss and weight-maintenance periods. During the weight-loss period, all participants receive a very low calorie diet for 8 weeks. During the 24-week weight maintenance period, subjects are randomly allocated to two groups to consume as part of their weight-management diet foods with either higher or lower satiety values.

What are the possible benefits and risks of participating?
The possible and expected benefit of participating in the study is weight loss along with its well-known beneficial effects on health and wellbeing. The risk of participating in the study is the possible disappointment to the participant if the weight loss is not as great as they have expected or in the case of possible weight re-gain.

Where is the study run from?
Institute of Public Health and Clinical Nutrition, University of Kuopio (currently University of Eastern Finland), Kuopio, Finland.

When is study starting and how long is it expected to run for?
The study started in May 2008 and ended in February 2010.

Who is funding the study?
Institute of Public Health and Clinical Nutrition, University of Eastern Finland, Finland.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40100/07 (Tekes)

Study information

Scientific Title
Foods for weight management: a randomized controlled trial

Acronym
ELIPA

Study objectives
It is hypothesized that foods with higher predetermined satiety values, when ingested as a part of a weight-maintenance diet, contribute to better self-regulation of food intake and reduced body weight.

Ethics approval required
Old ethics approval format

Ethics approval(s)

The Ethics Committee of the District Hospital Region of Northern Savo and the Kuopio University Hospital; Ref: 46/2008

Study design
Clinical randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Participants are randomized to two groups: high-satiety and low-satiety food groups
All participants will receive a very low calorie diet for 8 weeks. The weight maintenance period is 24 weeks.
Follow-up visit at 8-9 months after the end of the weight maintenance period, about which the participants had not been informed beforehand. This visit was added afterwards into the original study plan.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Body weight measured by a digital scale at baseline, 8, 12, 24 weeks and at follow-up.

Secondary outcome measures
1. Anthropometry and body composition: height measured using a wall-mounted stadiometer at screening; waist circumference using a calibrated tape measured at baseline, 8, 12 and 24 weeks; body composition using fat mass and fat-free mass by bioelectrical impedance measured at baseline, 8, 12 and 24 weeks
2. Eating behaviour by questionnaires at baseline, 12 and 24 weeks
3. Glucose and lipid metabolism and satiety-related hormones measured at baseline, 8, 12 and 24 weeks

3.1. Lipid metabolism: fasting serum HDL-, LDL-, total cholesterol, triglycerides and free fatty acids samples
3.2. Glucose metabolism: fasting and 2-hour oral glucose tolerance test (time points 0 min, 30 min, 60 min and 120 min) plasma/serum glucose and insulin samples
3.3. Satiety-related hormones: fasting plasma ghrelin, leptin, peptide YY samples
4. Inflammatory markers: serum/plasma CRP, IL6, IL1ra, adiponectin samples measured at baseline, 8 and 24 weeks
5. Adipose tissue and peripheral blood mononuclear cell gene expression: optional, performed only for those who were willing to give the samples. Measured by adipose tissue biopsies from subcutaneous abdominal fat and peripheral blood mononuclear cells (PBMCs) isolated from anticoagulated peripheral blood samples measured at baseline, 8 and 24 weeks
6. Gut microbiota composition by taking fecal samples measured at baseline, 8 and 24 weeks

Overall study start date
01/05/2008

Completion date
28/02/2010

Eligibility

Key inclusion criteria
1. Body mass index 3040 kg/m2
2. Age 3065 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
82

Key exclusion criteria
1. BMI >40 or <30 kg/m2
2. Pregnancy
3. Type 1 or 2 diabetes, abnormal liver, thyroid or kidney function or polycystic ovary syndrome
4. Less than 6 months since coronary event or operation
5. Myocardial infarction or susceptibility to arrhythmia
6. Diagnosed eating disorder
7. Neuroleptic or oral cortisone medication

8. Excess alcohol consumption (women > 16, men > 24 portions/week).
9. No other diseases, medications, or life situations that would prevent them from successfully completing the study

Date of first enrolment
01/05/2008

Date of final enrolment
28/02/2010

Locations

Countries of recruitment
Finland

Study participating centre
Institute of Public Health and Clinical Nutrition
Kuopio
Finland
70211

Sponsor information

Organisation
University of Eastern Finland (Finland)

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Sponsor type
University/education

ROR
https://ror.org/00cyydd11

Funder(s)

Funder type

Research organisation

Funder Name
The Finnish Funding Agency for Technology and Innovation (Tekes) (Finland) (Grant 40100/07)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol and results	01/01/2012		Yes	No
Results article	results	02/12/2020	03/12/2020	Yes	No
Results article		17/05/2023	05/06/2023	Yes	No