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The medium-term effect of a modified yoghurt /pudding on appetite and weight loss following a 12-week exercise intervention in females who are overweight/obese

Submission date
16/09/2016

Recruitment status
No longer recruiting

Registration date
27/09/2016

Overall study status
Completed

Last Edited
23/03/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Changing the composition and structure of foods to have an effect on satiety (feeling full) and appetite by increasing feelings of fullness and reducing hunger. This has the potential to help people to lose weight, improve health and decrease the risk of long-term disease. The aim of this study is to find out whether a modified dairy product ("yoghurt/pudding") designed to enhance feelings of fullness and reduce energy intake would have beneficial effects on changes in body composition when consumed regularly during a 12-week moderate-intensity exercise programme.

Who can participate?
Healthy women aged between 18 and 55 years with a body mass index between 25 - 34.9 kg/m2.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given the modified (active) yoghurt/pudding and those in the second group are given the unmodifed (control) yoghurt/pudding. All participants are asked to eat the yoghurt/pudding they have been given four times a week for 12 weeks. During these 12 weeks, all participants take part in an exercise programme, which involves exercising five times a week for 12 weeks and burning 500 calories in each session (2500 per week). At the start of the study and after 12 weeks, participants in both groups are weighed and measured to see if there is any change to their weight or body composition. In addition, participants are also asked to wear a physical activity monitor and accelerometer and complete a physical activity diary for seven consecutive days at four time points throughout the study (at the start, during the first week and tenth week of the programme and after the end of the exercise programme). Finally, participants are required to have breakfast, lunch and dinner within the research unit on 4 occasions, two at the start of the study and two at the end, at which time blood samples are taken.

What are the possible benefits and risks of participating?
Undertaking regular moderate exercise has been associated with a reduction in resting heart rate, waist circumference, blood pressure, body fat and an increase in fitness. All these factors have been strongly associated with a reduced risk of many health problems including; strokes, heart conditions, some cancers, obesity, diabetes and many others. There is therefore a possibility that participants could benefit in this way. There are risks associated with exercising, which include, fainting, dizziness, muscle cramps and pulls. These risks are greatly reduced when the correct precautions are taken and the exercise is undertaken in a controlled and supervised environment. There is also a very small risk of exercise inducing a heart attack; again this is rare and especially rare when there is no pre-existing heart condition. There are also risks with eating food, which include food allergies and food contamination. To minimise the risk of these anyone who has a nut allergy or is allergic to any of the foodsbeing used will not be able to take part. All staff that will prepare food for participants will be required to pass a food hygiene and safety course. Staff will adhere to food safety regulations at all times. The final risks of taking part are those associated with blood samples being taken. The risks include; fainting, bruising and irritation. All researchers taking blood samples will be fully trained, and qualified first aiders.

Where is the study run from?
School of Psychology, University of Leeds (UK)

When is study starting and how long is it expected to run for?
June 2015 and June 2016

Who is funding the study?
European Union Framework 7 (Belgium)

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
LDS-2014-SMT

Study information

Scientific Title
The medium-term effect of a modified texture and flavor release yoghurt/pudding with Satiagel® on satiation, satiety, body composition and weight loss following a 12-week exercise intervention in overweight/obese females

Acronym
SATIN-MT

Study objectives
The aim of this study is to:
1. Determine whether repeated consumption of the Active compared to the Control yoghurt /pudding in conjunction with regular exercise had beneficial effects on body weight and changes in body composition
2. Examine the effect of regular consumption of the Active compared to the Control yoghurt /pudding alongside an exercise intervention on measures of appetite control (i.e. satiation, satiety, peptide biomarkers and food hedonics)

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & the Humber, 02/04/2015, ref: 09/H1307/7

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Overweight and obesity

Interventions
Participants are randomised to one of two groups using the website https://www.random.org/lists/.

Active group: Participants receive the dairy product that contains the active ingredients.
Control group: Participants receive a calorie and taste matched dairy product that does not contain the active ingredients.

Participants in both groups consume their respective dairy products 4 times per week and expended 500 calories 5 times per week for 12 weeks. At the start of each week throughout the 12-week intervention, participants collect 4 servings of their respective dairy product to be consumed at home over the following 7-days. Participants are required to weigh the dairy product before and after consumption, and to fill in details regarding the date and time of consumption to ensure compliance. In total, participants consumed 48 dairy products across the 12-weeks. In addition to consuming the dairy products, at the start of the intervention participants are prescribed an exercise plan. This plan includes a target heart rate (70-80% of the participants' maximum heart rate) and a number of minutes required for the participant to expend 500 calories. This is calculated using a cardiovascular fitness test to calculate VO2 max and was re-calibrated for each participant at Week 6. Participants complete their prescribed exercise 5 times per week (weekly expenditure of 2,500 calories) within the research unit.

Participants in both groups undergo weight and body measurements at baseline and 12 weeks. Blood samples are collected at baseline and on two probe days at the end of the intervention to assess appetite control, and participants have their physical activity monitored at baseline, 1, 10 and 12 weeks using a SenseWear armband mini.

Intervention Type
Mixed

Primary outcome measure
1. Body weight is measured using an electronic balance and recorded to the nearest 0.1kg at baseline, every week throughout the intervention and 12 weeks
2. Body composition (fat mass, fat free mass, and percentage body fat) is measured using air displacement plethysomography (BodPod, Concord, CA, USA) at baseline and 12 weeks
2.1. Standing height without shoes is measured to the nearest 0.5cm using a stadiometer at baseline and 12 weeks
2.2. Waist circumference (cm) is measured 1 cm above the top of the participants' naval after expiration. The measurement is taken 3 times with an average of these measurements being used. Waist circumference is assessed at baseline and 12 weeks
2.3. Hip circumference is measured at the widest part of the participants' hip region. The measurement is taken 3 times with an average of these measurements being used. Hip circumference is assessed at baseline and 12 weeks

Secondary outcome measures

1. Appetite control (satiety, satiation, energy intake, peptide biomarkers and food hedonics) is assessed through recording of food intake and blood testing during two probe days (one to assess the effects of the Active dairy product and one to assess the effects of the Control dairy product) at the start of the intervention and two probe days at the end of the intervention
2. Free-living physical activity levels and sedentary behaviour are assessed using the SenseWear armband mini (SWA; Body Media) for 22 hours per day for 7-8 days at baseline, 1, 10 and 12 weeks

Overall study start date
01/01/2015

Completion date
29/06/2016

Eligibility

Key inclusion criteria
1. Healthy female participants
2. Aged 18-55 years
3. BMI of 25 – 34.9 kg/m2
4. Not currently dieting to lose or gain weight
5. Not increased physical activity levels in the past 2-4 weeks
6. Regular breakfast eaters
7. Non-smokers
8. ≥4 liking of study foods (on 9-point Likert scale)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Female

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. Significant health problems
2. Taking any medication or supplements known to affect appetite or weight within the past

month and/or during the study
3. Pregnant, planning to become pregnant or breastfeeding
4. History of anaphylaxis to food
5. Any known food allergies or food intolerance
5. Vegetarians
6. Smokers and those who have recently ceased smoking (within the last 3 months)
7. BMI <25 kg/m2 or >34.9 kg/m2
8. Volunteers self-reporting currently dieting or having lost or gained a significant amount of weight in the previous 6 months (>5%)
9. Volunteers who have significantly changed their physical activity patterns in the past 4 weeks (defined as changing them by >150 minutes per week)
10. Participants receiving systemic or local treatment likely to interfere with evaluation of the study parameters
11. Participants (e.g. staff/students) who work in appetite or feeding related areas
12. Non-breakfast eaters

Date of first enrolment
02/06/2015

Date of final enrolment
22/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
School of Psychology
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Study results will be published in a peer-reviewed journal and will be presented at scientific conferences.

Intention to publish date
10/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from m.dalton@leeds.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	26/09/2010	28/09/2016	No	Yes
Results article	results	01/02/2019	23/03/2020	Yes	No