Effect of reducing portion size on energy intake and appetite

Submission date	Recruitment status No longer recruiting	Prospectively registered	
07/02/2014		[_] Protocol	
Registration date	Overall study status	[] Statistical analysis plan	
17/02/2014	Completed	[X] Results	
Last Edited 18/10/2016	Condition category Nutritional, Metabolic, Endocrine	Individual participant data	

Plain English summary of protocol

Background and study aims

Large portion sizes are linked to an increased risk of overconsumption but there has been little research into whether reducing portion size is associated with a decrease in energy intake. The aim of the study was to investigate the effect of covertly reducing portion size of a main meal on later energy intake and appetite during the day.

Who can participate?

33 overweight and obese healthy participants aged between 18 and 60.

What does the study involve?

Participants were asked to attend HNR for a screening visit after an overnight fast to check they were eligible to take part. Height, weight, waist circumference and resting metabolic rate were measured and a blood sample was taken to measure blood glucose. Participants were also asked to complete several questionnaires about eating behaviour and physical activity levels. As the study was on appetite and knowledge of the aims of the study may have affected eating behaviour and the results of the study, the participants were informed that the study was investigating the relationship between diet and metabolism. They were then booked in for their 3 study visits at least a week apart. Each study day involved one of three breakfast portion sizes: a standard portion size based on 25% of the average estimated daily energy requirements; portion size reduced by 20%; and portion size reduced by 40%. All participants completed all 3 study conditions in a random order. After an overnight fast, participants were asked to consume the test breakfast in full. The breakfast included cereal, milk, eggs, ham, toast, butter and orange juice. Energy intake was measured at a lunch (pasta meal) and an afternoon snack (biscuits). After the afternoon snack, the participant was able to go home. The participant was asked to record everything they ate and drank for the rest of the day until they went to bed using a diet diary and scales. Questionnaires were given before meals and at half-hourly intervals between breakfast and lunch, and then at hourly intervals for the rest of the day to measure perceived appetite, including hunger and fullness. In a subgroup of 20 participants blood samples were taken before breakfast and at 30, 60, 120, 180 and 240 minutes after breakfast. These were used to measure insulin, glucose, and other hormones released from the gut as biochemical measures of appetite. After their last study visit each participant was asked to come back to HNR for a full debrief on the study and to discuss any questions they may have had.

What are the possible benefits and risks of participating? Participants were reimbursed for travel expenses and given an honorarium in recognition of their time commitment which was paid by HNR. Risks included slight uncomfortableness when using a needle to take the blood sample at the screening visit and a small risk of bruising, bleeding or infection after the using a cannula to take blood samples.

Where is the study run from? All participant visits were completed at the Medical Research Council Human Nutrition Research (HNR) volunteer suite in Cambridge, UK

When is the study starting and how long is it expected to run for? January 2011 to January 2013

Who is funding the study? Medical Research Council Human Nutrition Research (HNR) (UK)

Who is the main contact? Hannah Lewis hannah.lewis@mrc-hnr.cam.ac.uk

Contact information

Type(s) Scientific

Contact name Dr Hannah Lewis

Contact details

MRC Human Nutrition Research Elsie Widdowson Laboratory 120 Fulbourn Road Cambridge United Kingdom CB1 9NL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 6384

Study information

Scientific Title

Effect of reducing food portion size on energy intake and appetite control in overweight and obese subjects

Study objectives

To determine whether reducing portion size will result in compensation in energy intake at the next meal.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East of England - Cambridge Central (at time of application called Cambridgeshire 2 Research Ethics Committee), 22/11/2010, ref: 10/H0308/99

Study design

Randomised single-blind crossover experimental study

Primary study design Interventional

Secondary study design Randomised cross over trial

Study setting(s) Other

Study type(s) Treatment

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

Energy intake and appetite control for the purposes of obesity research

Interventions

Three study days - all participants complete all days.

The intervention was a manipulation of the size of the breakfast meal provided. Conditions were presented in a random order. Washout period is one week.

Each study day involved one of three breakfast portion sizes:

1. A standard portion size based on 25% of the average estimated daily energy requirements

- 2. Portion size reduced by 20%
- 3. Portion size reduced by 40%

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Energy intake at lunch measured by an ad libitum lunch meal 4 hours after breakfast.

Secondary outcome measures

1. Energy intake over the rest of the day measured at an ad libitum snack 6 hours after breakfast and by a weighed diet diary over the rest of the day.

2. Appetite (hunger, fullness, desire to eat and prospective consumption) measured using visual analogue scale (VAS) questionnaires before and after breakfast and lunch, at half hourly intervals between breakfast and lunch and then at hourly intervals for the rest of the day.
3. Perceived portion size of the breakfast meal measured using VAS questionnaires during the breakfast meal.

4. Biochemical measures of appetite (glucose, insulin, peptide tyrosine tyrosine (PYY), glucagonlike peptide-1 (GLP-1) and glucose-dependent insulinotropic peptide (GIP)) measured in the blood at fasting, and 30, 60, 120, 180 and 240 minutes after breakfast.

Overall study start date

01/01/2011

Completion date

01/01/2013

Eligibility

Key inclusion criteria

Healthy 18-60 year old men and women with a BMI of 25-35 kg/m^2

Participant type(s) Healthy volunteer

Healthy voluntee

Age group Adult

Lower age limit 18 Years

Upper age limit 60 Years

Sex Both

Target number of participants 33

Key exclusion criteria

1. Eating disorders assessed using the Eating Attitudes Test (EAT) score ≥11 (measured at a screening visit)

2. Depression using the Zung Depression Scale score ≥70 (measured at a screening visit)

3. Smoking

4. Excessive habitual alcohol intake (>14 units per week for women and >21 units per week for men)

5. Weight loss or gain within the last 3 months or actively trying to lose or gain weight (more than 4.5kg)

6. Medications affecting food intake and metabolic responses (insulin, weight loss medications, laxatives, selective serotonin reuptake inhibitors (SSRIs), oral hypoglycaemic drugs, oral corticosteroids), thyroxine and drugs acting on the sympathicomimetic system and drugs affecting gastrointestinal motility

7. Diagnosed psychiatric disorders controlled pharmacologically

8. Acute and chronic inflammatory conditions (i.e., cold, flu, inflammatory bowel disorders and coeliac disease)

9. Diabetes or fasting glucose <7 mmol/l (measured at a screening vist)

10. Any other medical condition or medications having a potential effect on regulation of appetite (i.e. neurodegenerative disorders, malignant cancer, liver diseases or severe anaemia).

11. Pregnancy, breastfeeding or planning a pregnancy

12. Athletic training

13. Allergies to, restriction or dislike of any test foods to be used, including vegetarians/vegans

14. Not regular breakfast consumers (classified as those consuming breakfast less than or equal to 3 times per week)

Date of first enrolment

01/01/2011

Date of final enrolment 01/01/2013

Locations

Countries of recruitment England

United Kingdom

Study participating centre MRC Human Nutrition Research Cambridge United Kingdom CB1 9NL

Sponsor information

Organisation Medical Research Council Human Nutrition Research (UK)

Sponsor details

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Sponsor type Research council

ROR https://ror.org/050pqs331

Funder(s)

Funder type Research council

Funder Name Medical Research Council (UK) (U105960389)

Alternative Name(s) Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type Government organisation

Funding Body Subtype National government

Location United Kingdom

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?
<u>Results article</u>	results	01/07/2015		Yes	No