Evaluating whether repeated exposure to a smaller portion at lunch is an effective approach to reduce energy intake and if small enhancements to foods can increase meal satisfaction for a smaller portion

Submission date	Recruitment status No longer recruiting	Prospectively registered		
31/10/2017		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/11/2017	Completed Condition category	Results		
Last Edited		Individual participant data		
15/09/2021	Nutritional, Metabolic, Endocrine	Record updated in last year		

Plain English summary of protocol

Background and study aims

Since the 1970s, there has been a clear increase in portion size of both packaged and served foods. There is evidence that portion size within a single meal affects energy intake and that larger meals promote greater energy intake. Research also suggests that there is an additive effect when larger portions are served repeatedly over multiple days and weeks. This increase in portion size may be a key factor in the substantial rise in obesity seen in the Western world. Smaller portion sizes are typically seen as less acceptable to consumers, and therefore participants do not welcome this change. The aim of this study is to use an environmental intervention to explore strategies to increase the acceptability of smaller portions. First, it will explore whether a 50% reduction in portion size at lunch (from 600 calories to 300 calories) is effective in decreasing total 24-hour energy intake and if this effect is sustained over 10 days. Second, it will explore whether small enhancements to foods can offset the reduction in meal satisfaction and enjoyment seen after eating the 50% smaller lunch.

Who can participate?

Adults aged between 18 and 70, and have a BMI of over 20kg/m2, and are willing and able to consume all foods provided and comply with study procedures.

What does the study involve?

Participants are randomly allocated to one of three groups. Those in the first group called the standard (control) lunch group receives, for example, a lunch of a sandwich and dessert item, based on a typical 'meal deal' (600 calories). Those in the second group, the Nudge group (representing a single, simple dietary change) consume a 50% smaller portion of the same lunch. Those in the last group called the Nudge+ group consume a 50% smaller portion with the addition of increased variety, enhancing the intensity of flavour within the meal, and a hedonic label, bringing awareness to these enhancements. The participants consume their allocated

lunch on 10 consecutive weekdays (two Monday-Friday weeks), attending our Nutrition and Behaviour Laboratory on days one, three, and 10. On those days, they receive in the laboratory a breakfast, the test lunch, and dinner. In between meals, participants are free to return to their place of work or home as appropriate, but not permitted to eat anything other than the intermeal snacks we provide. This will allow a measure of 24-hour energy intake to be calculated. On days where participants are not in the laboratory, they collect their lunch from our lab, where they can take it to their place of work or home, as appropriate.

What are the possible benefits and risks of participating?

To complete the entire experiment, participants will need to spend a minimum of 6 hours in the laboratory across Days 1, 3 and 10, and it is estimated that they will spend at maximum one hour of their time each day outside the laboratory completing the tasks required of them. It was therefore determined that participants will be reimbursed £150 for their participation in the study. If participants withdraw before completing the experiment, they will be reimbursed an amount equal to the proportion of hours they have completed in the study. This research will not involve risks beyond that normally encountered by the participants in their life outside research.

Where is the study run from?

This study will take place in the Nutrition and Behaviour Unit laboratory space in the Experimental Psychology department of the University of Bristol (UK).

When is the study starting and how long is it expected to run for? June 2017 to August 2018

Who is funding the study? Biotechnology and Biological Sciences Research Council (BBSRC) (UK)

Who is the main contact? Peter Rogers peter.rogers@bristol.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Peter Rogers

Contact details

School of Experimental Psychology University of Bristol 12a Priory Road Bristol United Kingdom BS8 1TU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BBSRC-DRINC Reference: BB/L02554X/1

Study information

Scientific Title

Combining small changes to foods to achieve a sustained decrease in energy intake: a Randomised Controlled Trial (RCT)

Study objectives

- 1. A 50% reduced portion size at lunch will only be partially compensated for in 24-hour energy intake compared to the 100% portion size lunch
- 2. Addition of manipulations to enhance meal satisfaction for the 50% reduced portion size at lunch (increased flavour intensity and variety, with a hedonic label) will increase meal satisfaction and meal enjoyment when compared to the regular reduced portion lunches

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study has been approved by the Faculty of Science Research Ethics Committee at the University of Bristol, 16/10/2017, ref: Approval Number: 58961

Study design

Single-centre single-blind randomised parallel controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Obesity

Interventions

Participants are randomly allocated to one of three groups using a minimisation method, using a 4:1 element of chance. The groups are balanced for gender, age, predicted energy requirements and dieting status.

The three treatments include: Standard (600 kcal lunch), Nudge (300 kcal lunch), Nudge+ (300kcal lunch with increased flavour intensity and variety).

Participants consume this lunch for 10 weekdays (two consecutive Monday-Friday weeks). All outcome measures will be evaluated on days one, three and ten of exposure to the intervention. On those days, they receive in the laboratory a breakfast, the test lunch, and dinner. In between meals, participants are free to return to their place of work or home as appropriate, but not permitted to eat anything other than the inter-meal snacks we provide. This will allow a measure of 24-hour energy intake to be calculated. On days where participants are not in the laboratory, they collect their lunch from our lab, where they can take it to their place of work or home, as appropriate. On the first Tuesday following the 10-day trial, participants attend a final session. In this session, participants complete both the restraint scale from the Dutch Eating Behaviour Questionnaire (DEBQ) and the disinhibition scale from the Three-Factor Eating Questionnaire (TFEQ). In this session, participants are also debriefed provide both final consent and the necessary details to organise reimbursement. There are no other planned follow up sessions.

Intervention Type

Other

Primary outcome measure

- 1. 24-hour energy intake is measured using the 24-hour energy intake calcuated from the consumption of meals and snacks. Participants attend the laboratory to consume an ab libitum breakfast, the fixed portion lunch and an ad libitum dinner on day one, day three and day ten of the intervention.
- 2. Meal Satisfaction is measured using a 100-mm Visual Analogue Scale immediately after eating the test lunch on day one, day three and day ten of the intervention
- 3. Meal Enjoyment is measured using a 100-mm Visual Analogue Scale immediately after eating the test lunch on day one, day three and day ten of the intervention

Secondary outcome measures

Body weight is measured using scales at the start of each test day (day one, day three and day ten).

Overall study start date

18/06/2017

Completion date

31/01/2019

Eligibility

Key inclusion criteria

- 1. BMI ≥20 kg/m2
- 2. Aged between 18 and 70
- 3. Willing and able to eat all foods provided and to comply with study procedures

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

156

Key exclusion criteria

- 1. Non-English speaking
- 2. Vegetarian, Vegan, has food allergies or intolerances to any of the food to be provided
- 3. Smokes more than 5 cigarettes a day
- 4. Drinks more than 14 units of alcohol per week
- 5. Has diabetes
- 6. Has a history of eating disorders
- 7. Is pregnant, breastfeeding, or planning to become pregnant during the study
- 8. Is taking medication that may influence appetite (except for oral contraceptive pills)
- 9. Indicates that lunch is their main meal of the day
- 10. Does not indicate that they are familiar with eating sandwiches for lunch.
- 11. Taken part in any of the preparatory studies that informed this research previously undertaken in our laboratory

Date of first enrolment

31/10/2017

Date of final enrolment

14/08/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Bristol United Kingdom BS8 1TU

Sponsor information

Organisation

Biotechnology and Biological Sciences Research Council (BBSRC)

Sponsor details

Polaris House North Star Avenue Swindon United Kingdom SN2 1UH

Sponsor type

Research council

Website

http://www.bbsrc.ac.uk/

ROR

https://ror.org/00cwqg982

Funder(s)

Funder type

Research council

Funder Name

Biotechnology and Biological Sciences Research Council

Alternative Name(s)

UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

30/06/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository. We plan to upload our data to the data.bris Research Data Repository at https://data.bris.ac.uk/data/about The data.bris Research Data Repository is an online digital repository of multi-disciplinary research datasets produced at the University of Bristol. Data published through the repository are all openly available under a Non-Commercial Government License for public sector information, and each deposit is assigned a unique Digital Object Identifier (DOI).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		14/11/2017	15/11/2017	No	Yes
Protocol file		04/11/2017	15/11/2017	No	No