Evaluating a behavioural intervention to reduce meat consumption

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered[X] Protocol		
22/06/2018				
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
25/06/2018		[X] Results		
Last Edited		Individual participant data		
03/02/2023	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Background and study aims

Reducing meat consumption could help to improve population health and protect the natural environment. However, little is known about how to help people shift towards more plant-based diets. This study evaluates a behavioural intervention to support people to eat less meat. The intervention involves the provision of meat-alternatives for four weeks along with supporting material, including information about the benefits of eating less meat, success stories of people who reduced their meat consumption, and recipes. This study will test whether people who received the intervention have lower meat intakes than people who did not receive the intervention during the fourth intervention week and one month after the intervention ends. This study also explores the impact of the intervention on other components of participants' diet, some psycho-social variables (e.g. attitudes towards eating less meat), and some biomarkers of health risk (e.g. blood pressure).

Who can participate?

People aged 18 and over who eat meat regularly

What does the study involve?

Participants are randomly allocated to the intervention group or the control group. Participants in the control group receive no intervention. Participants in the intervention group are offered meat substitutes for 4 weeks and supporting written material, including information about the health and environmental benefits of eating less meat, success stories of people who reduced their consumption of meat, and recipes. Participants' daily meat consumption is assessed using a self-reported food diary from the start of the study to the follow-ups at 1 and 2 months.

What are the possible benefits and risks of participating?

This study is considered to have very few potential disadvantages or risks. Three finger-prick blood samples are collected and participants are advised to contact the appropriate medical services in the event of an infection following the finger prick. Participants are provided with commercially available foods that they might not have previously eaten, and will be advised to contact the appropriate medical services in the event of an allergic reaction resulting from eating these foods.

Where is the study run from? University of Oxford (UK)

When is the study starting and how long is it expected to run for? August 2017 to December 2020

Who is funding the study?

- 1. Wellcome Trust (UK)
- 2. Medical Research Council (UK)
- 3. National Institute for Health Research (UK)
- 4. Green Templeton College, University of Oxford (UK)

Who is the main contact? Mr Filippo Bianchi

Contact information

Type(s)

Scientific

Contact name

Mr Filippo Bianchi

ORCID ID

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Contact details

43 Woodstock Road Oxford United Kingdom OX2 6HG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Replacing meat with alternative plant-based products (RE-MAP study): a randomised controlled trial of a behavioural intervention to reduce meat consumption

Acronym

Study objectives

To test the effectiveness of a behavioural intervention in reducing meat consumption among healthy adult volunteers and to assess the intervention's impact on participants' habitual meat consumption, consumption of meat-alternatives and other food groups, psycho-social variables, energy, macro- and micro-nutrient intakes, and biomarkers of health risk, including body weight, body composition, blood lipids, and blood pressure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Sciences Interdivisional Research Ethics Committee of the University of Oxford, 07/11 /2017, ref: R54329/RE001

Study design

Single-centre two-arm parallel-group individually randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

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

Reducing meat consumption among healthy adult volunteers.

Interventions

Participants will be stratified by gender and individually randomised in a 1:1 ratio to the intervention or the control condition. The research team will be blinded to the computer generated randomisation sequence, but due to the nature of the intervention neither participants nor researchers will be blinded to the allocation. Members of the research team responsible to analyse diet diaries, will be blinded to participants' allocation.

Participants randomised to the control condition will receive no intervention. Participants randomised to the intervention condition will be offered a behavioural intervention based on the provision of meat-substitutes for four weeks and supporting written material, including information about the health and environmental benefits of eating less meat, success stories of people who reduced their consumption of meat, and recipes.

T0: baseline

T1: 1 month follow up T2: 2 months follow up

Intervention Type

Behavioural

Primary outcome measure

Mean daily meat consumption in grams assessed using a self-reported food diary from the baseline (T0) to the first follow-up (T1) at 1 month

Secondary outcome measures

- 1. Habitual meat consumption: Change in participants' mean daily meat consumption in grams assessed using a self-reported food diary from the baseline (T0) to the second follow-up (T2) at 2 months
- 2. Putative psycho-social determinants of consuming a low meat diet assessed through online questionnaires. In particular the following dimensions will be assessed:
- 2.1. Change in participants' attitudes, perceived behavioural control, subjective social norm, and intention to eat a low meat diet between the baseline and both follow-ups
- 2.2. Change in participants' attachment to meat between the baseline and both follow-ups
- 2.3. Change in participants' eating identity between the baseline and both follow-ups
- 3. General eating behaviour: Change between the baseline and both follow-ups in participants' mean number of daily servings of other principal food groups, including meat substitutes, assessed using a self-reported food diary and an online questionnaire
- 4. Nutritional intake: Change in participants' mean daily energy, macro-, and micronutrient intake between the baseline and both follow-ups, assessed using data from the self-reported food diary
- 5. Biomarkers of health risk: Change between the baseline and both follow-ups in participants' weight to the nearest 0.1 kg and body composition (measured with a Tanita SC240Ma scale); blood lipids (measured with an Alere Cholestech LDX® Analyzer), and blood pressure as the mean of the last two of three seated readings
- 6. Putative psycho-social determinants of meat-alternative usage assessed through online questionnaires: Change in participants' intentions, attitudes, perceived behavioural control, and subjective social norms of using meat-alternatives between the baseline and both follow-ups
- 7. Desire for similarity between meat and meat-alternatives assessed through online questionnaire: Change between the baseline and both follow-ups in participants' desire for meat-alternatives to be similar to meat overall and in specific aspects

Overall study start date

31/08/2017

Completion date

20/12/2020

Eligibility

Key inclusion criteria

Interested individuals will be included in the study only if they

- 1. Are ≥18 years old
- 2. Self-report to eat meat regularly
- 3. Belong to an adult-only household
- 4. Are willing to try meat-alternatives and own adequate food storing facilities

- 5. Possess a device compatible with the requirements of the online food diary
- 6. Provide informed consent

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100 participants completing the primary measurement timepoint

Key exclusion criteria

Interested individuals will be excluded from participating to the study if they

- 1. Self-report to have relevant food allergies;
- 2. Self-report to suffer from an eating disorder;
- 3. Are pregnant or plan to become pregnant while involved in the study;
- 4. Belong to the same household as a previously enrolled participant;
- 5. Consume meat-alternatives more than once a week on average;
- 6. Report baseline dietary records of insufficient quality for analysis;

The recruiting researcher deems the interested individual unable to adhere appropriately to the study protocol (e.g. insufficient knowledge of the English language, planned absences from main residence during the course of the study, enrolled in other longitudinal dietary intervention study).

Date of first enrolment

26/06/2018

Date of final enrolment

25/06/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Nuffield Department of Primary Care Health Sciences, University of Oxford

Radcliffe Primary Care Building, Radcliffe Observatory Quarter, Woodstock Rd

Sponsor information

Organisation

University of Oxford

Sponsor details

University Offices Wellington Square Oxford England United Kingdom OX1 2JD

Sponsor type

University/education

ROR

https://ror.org/052gg0110

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust, Our Planet Our Health programme (Livestock, Environment and People - LEAP), award number 205212/Z/16/Z

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

Medical Research Council

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

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Green Templeton College, University of Oxford

Alternative Name(s)

GTC

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

A protocol will be submitted for publication in due course. The results of the trial will be written up as a doctoral thesis, submitted for publication in a high-impact peer reviewed journal, presented at conferences and disseminated through established networks.

Intention to publish date

20/06/2021

Individual participant data (IPD) sharing plan

Individual participant data will be made available on request to bona fide academic researchers once final data analyses are published and provided participants consented for their fully anonymised data to be given to other researchers to be used in research studies. A secure data sharing system will be used to transfer data outside the research team.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	01/06/2019	19/05/2020	Yes	No
Results article	primary and secondary outcome results	01/05/2022	03/02/2023	Yes	No