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How do fruits and vegetables keep you healthy?

Submission date
18/08/2015

Recruitment status
No longer recruiting

Registration date
19/08/2015

Overall study status
Completed

Last Edited
13/12/2018

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
Research suggests that not eating enough fruit and vegetables may increase the risk of developing serious diseases such as heart disease and cancer. There are still many people who do not eat the recommended “5-a-day” however. The aim of this study is to see whether providing such people with 5 or more portions of fruit and vegetables every day for 12 weeks can improve their general health. The study also will find out what happens to the general health of these people after they have stopped eating these fruits and vegetables and resumed their normal diet.

Who can participate?
Healthy adults who usually consume less than 2 portions of fruit/vegetables per day.

What does the study involve?
Participants are randomly placed into one of two groups. The first group is asked to carry on with their normal diet for 2 weeks, then eat fruit/vegetables and fruit juices (2 portions of fruit, 1 portion of salad, 2 portions of vegetables and 2 glasses of fruit juice) with their normal diet every day for the next 12 weeks. The second group do not get the fruit and vegetables. They are a control group and are asked to just carry on with their normal diet. Over the course of the study, all participants have samples (e.g. blood, urine samples), taken which are tested for health markers, such as cholesterol and vitamin levels, as well as completing a food diary. Once the 12 weeks are complete, participants who changed their diet are asked to resume their normal diet. Samples are then taken after a further 6 weeks so that the health markers can be re-tested.

What are the possible benefits and risks of participating?
There is no direct benefit to participants. There are no known risks of participating other than the minor risks of bruising, discomfort or infection associated with blood tests.

Where is the study run from?
Rowett Institute of Nutrition and Health (UK)

When is the study starting and how long is it expected to run for?
March 2011 to March 2016

Who is funding the study?
The Scottish Government Strategic Research Programme (Food, Land and People) (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RINH 09/003

Study information

Scientific Title
Increasing fruit and vegetable intake of healthy volunteers with habitual low intakes by dietary intervention: impact on nutritional, VAScular and COLOnic biomarkers and attitudes to dietary change

Acronym
VASCOLO-Health

Study objectives
The aim of this study is to assess whether consuming a minimum additional 5 portions of fruits and vegetables daily by healthy volunteers with a habitual intake below current UK recommendations would impact positively on markers of human health and whether this would be maintained post-intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. North of Scotland Research Ethics Committee, 23/04/2009, ref: VASCULO-Health
2. Ethics Committee of the Rowett Institute of Nutrition and Health, 26/06/2009, ref: FRUIT and Vegetable INTERVENTION 09/003

Study design
A single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Low fruit and vegetable consumption is linked with an increased risk of all cause mortality and death from several conditions including vascular disease and cancer.

Interventions

Prospective volunteers are asked to fill out a questionnaire about their health, level of exercise and medication. They are then grouped by gender, and brigade based on BMI and age, and then randomized to two groups, one consuming the intervention diet and the other maintaining their habitual diet.
The intervention is for twelve-weeks bordered by a two-week lead-in and six-week wash out (total 20 week study; weeks 0-20). Biological sampling (blood, urine and faeces) takes place on a total of 6 days. Base-line sampling is at week 0; intervention is for a total of 12 weeks (week 2-14) with sampling at the start of intervention (week 2) and at the end of each intervention month (week 6, 10 & 14); washout sampling is at week 20 . Weighed intake diaries are also collected during lead-in week , 2nd and 10th week of intervention and last week of washout.
1. Weighing and blood pressure monitoring of the volunteers is undertaken prior to each fasted blood sampling. In addition, at each visit in vivo vascular function is assessed by Pulse contour analysis and Pulse-wave velocity. Both these methods are none invasive and potentially predictive for CVD risk in otherwise low risk individuals within the age group to be studied.
2. Up to 50mL blood is collected by a trained phlebotomist with minimal use of tourniquet by clean venepuncture with a green 21G butterfly or Vacutainer system.
3. Faecal samples are either collected at home by the volunteers and stored in faecal sample containers (supplied) within cold bags (supplied) until transport to the RINH Human Nutrition Unit for processing or are provided by volunteers on visiting the HNU.
4. Urine (24h) is collected only at week 0 and week 14 of the study. Samples are collected by volunteers in sealed bottles (supplied) and stored under cool/low light conditions, away from food, until transport to RNIH Human Nutrition Unit for processing.

Intervention Type
Other

Primary outcome measure
1. Plasma vitamin C concentration measured by high performance liquid chromatography (HPLC). ((baseline; weeks 0, 2), intervention (weeks 6, 10 and 14) and washout (week 20)).
2. Plasma vitamin E (alpha and gamma-tocopherol) concentration measured by HPLC. ((baseline; weeks 0, 2), intervention (weeks 6, 10 and 14) and washout (week 20)).
3. Plasma carotenoids (alpha-carotene, beta-carotene, beta-cryptoxanthin, lutein/zeaxanthin concentrations measured by HPLC. ((baseline; weeks 0, 2), intervention (weeks 6, 10 and 14) and washout (week 20)).
Whole blood folate and plasma B12 measured by radioassay ((baseline; weeks 0, 2), intervention (weeks 6, 10 and 14) and washout (week 20)).
4. Plasma concentrations of vitamins B2 and B6 measured by HPLC. [(baseline; weeks 0, 2), intervention ((baseline; weeks 0, 2), intervention (weeks 6, 10 and 14) and washout (week 20)).
5. Total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides (TG) and glucose measured using a Konelab 20 Clinical Chemistry Analyser (Thermo Scientific, Passau, Germany). ((baseline; weeks 0, 2), intervention (weeks 6, 10 and 14) and washout (week 20)).

Secondary outcome measures
1. Genotoxicity: Single cell gelectrophoresis (SCGE) is used to determine lymphocyte genostability and the influence of recovered faecal waters on established culltured colon epithelial cell line (e.g. HT-29, NCM460, RKO, RKO-E6, Caco-2) genostability in vitro.((baseline; weeks 0, 2), intervention (weeks 6, 10 and 14) and washout (week 20)).
2. Phenolic and related metabolites will be determined in blood and faecal waters by the colorimetric Folin-Ciocalteu micro-method and by LC-MS. ((baseline; weeks 0, 2), intervention (weeks 6, 10 and 14) and washout (week 20)).. These are also determined in urine (week 0 and

14, only).
3. Plasma homocysteine determined by high-performance liquid chromatography (HPLC).

Overall study start date
01/03/2011

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. Habitually consume less than 2 portions of fruits and vegetables per day
2. Healthy
3. Aged between 38 and 60 years
4. Body mass index between 18 and 39
5. Non-smoker
6. Resident of North East Scotland

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Regularly consume > 3 portions of fruit & vegetables per day
2. Smoker
3. Have a chronic medical condition e.g. inflammatory bowel disease, gall bladder disorder, diabetes, heart disease, cancer
4. Have a known allergy to any fruit or vegetables
5. Have given a large blood donation in the last three months
6. Taking any of the following medication:
6.1. Drugs to lower high cholesterol levels (HMG CoA reductase inhibitors)
6.2. Drugs to lower high blood pressure (calcium channel antagonists)
6.3. Non-sedating antihistamine
6.4. Drugs used in immuno-suppression therapy following transplantation
6.5. Drugs used in AIDS therapy
6.6. Drugs to lower inflammation (non-steroidal anti-inflammatories)
6.7. Aspirin (on a regular basis)

Date of first enrolment
01/04/2011

Date of final enrolment
01/11/2015

Locations

Countries of recruitment
Scotland

United Kingdom

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Sponsor type
University/education

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
The Scottish Government Strategic Research Programme (Food, Land and People)

Results and Publications

Publication and dissemination plan
The results will be submitted for publication in peer reviewed scientific journals. Journals and submission dates will be confirmed at a later date.

Intention to publish date
03/05/2017

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No