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Wholegrain diet and blood pressure study: the WISH study

Submission date	Recruitment status	[ ] Prospectively registered
15/11/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/11/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/02/2019	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It has been shown previously that daily consumption of three portions of wholegrain foods can significantly decrease blood pressure in healthy individuals, potentially reducing the risk of stroke or heart attack. These findings could be even more significant for people with elevated blood pressure but not under medication, such as people with recently diagnosed hypertension suitable for lifestyle interventions before drug therapy. The aim of this study is to assess whether the consumption of three servings of whole grain foods (WGF) per day can decrease blood pressure in subjects with high blood pressure.

Who can participate?
Adults aged 30-65 years old with borderline high or elevated blood pressure.

What does the study involve?
Participants go on a two week wholegrain-free (WGF) diet. After that, participants are randomly allocated to one of two groups. Those in the first group eat three portions of WGF daily for six weeks and those in the second group continue with the control diet. All will then consume a control diet for two weeks before switching to the other arm of the intervention. Participants are followed up for a further six weeks after the end of intervention to see if any changes are maintained or removed when WGF are withdrawn from the diet. Blood collection and BP measurements are performed several times during the study. Blood vessel hardening and blood flow from the heart is measured, as well as chemicals in the blood which are involved in BP regulation.

What are the possible benefits and risks of participating?
The study may not help participants personally but the information we collect may help to find ways of reducing other people's risk of developing diseases such as heart disease. However, a confidential personal feedback report will be sent to all volunteers at the end of the study containing blood pressure, weight, blood glucose and cholesterol measurements we have recorded during the study. This will however not contain the overall study results which will be made available once the overall study is completed. We will also inform GPs of the volunteer's participation to the study, and the blood and blood pressure results will also be made available to the GPs.

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

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

Who is funding the study?
Scottish Government (Rural and Environmental Science and Analytical Services) (UK)

Who is the main contact?
Dr Frank Thies
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The effect of increased Wholegrain food consumption on blood pressure in pre-hypertensive and non-treated stage 1 Hypertensive Subjects (WISH)

Acronym
WISH

Study objectives
Three daily portions of wholegrain foods over 6 weeks can significantly decrease blood pressure in pre-hypertensive and non-treated hypertensive individuals.

Ethics approval required

Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 28/06/2017, ref: 17/NS/0062

Study design
Single centre randomised controlled single blind cross over dietary intervention study involving two treatments ('whole grain' and 'refined grain')

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Pre-hypertension

Interventions
As this is a crossover study with treatment assessed within volunteer, stratification of allocation to treatment sequences will be done within gender only, and also by sequence of joining the study (to account for any seasonal or other order effects). No validation is therefore required. The participants are allocated to the two possible sequences in small randomised sets using a programme created by Dr Graham Horgan from BIoSS (Bioinformatic and statistics Scotland) who routinely create randomisation programmes for intervention studies carried out at the Rowett Institute. The HNU manager carries out the randomisation.

The two groups are:
The control arm is a refined diet, avoid of wholegrain products
The treatment arm is a diet including 3 portions per day of whole grain products. The duration of the intervention is 20 weeks, with two weeks run-in period on a control diet, followed by 6 weeks intervention in one arm (control or wholegrain), followed by 6 weeks on the other arm (control or wholegrain), followed by a follow up period on normal diet for 6 weeks.

The dietary interventions proposed for this project are designed to compare a diet based on refined cereal products with the substitution of 3 servings of refined cereals foods with 3 servings of whole grain foods. The interventions are designed to be practical and realistic for individuals to achieve. The proposed interventions are designed to bring intakes close to the Dietary Reference Value of 30g AOAC fibre per day. People on the refined arm are asked to avoid eating wholegrain products. The participants are thoroughly explained how to comply with this diet and a guidance sheet indicating suitable and non-suitable foods is provided, with a list of suitable refined bread brands available in the main supermarkets/retail outlets. Participants are also provided with suitable refined breakfast cereals.

Participants in the wholegrain arm are asked to replace 3 servings of refined cereal foods per day with 2 slices of whole wheat bread (70-80g per day) and 1 serving of a prescribed whole wheat breakfast cereal. Participants are provided with a list of suitable 100% wholemeal bread brands available in the main supermarkets/retail outlets. In addition, participants are encouraged to check the suitability of any product they are in doubt about with the study staff.

Participants are also supplied with wholegrain cereals and asked to eat a serving (30-40g) of either one on a daily basis. Photos of the adequate amount of cereals in various bowls are demonstrated to the volunteers, and photos made available.

Intervention Type
Behavioural

Primary outcome(s)
Blood pressure is measured using blood pressure cuffs and 24hr ABPM at six weeks follow up.

Key secondary outcome(s))
1. Arterial stiffness (Aix) and central aortic pressure is measured using Sphygomocor at six weeks follow up
2. Diastolic blood pressure is measured using blood pressure cuffs and 24hr ABPM at six weeks follow up
3. Aldosterone and angiotensin concentration in plasma measured using blood tests at six weeks follow up
4. Kidney function is determined using estimated glomerular filtration rate (eGFR) based on serum creatinine concentration at six weeks follow up

Completion date
01/09/2020

Eligibility

Key inclusion criteria
1. Men and women
2. Aged 30-65 years
3. Body mass index (BMI) between 18.5 and 35kg/m2
4. 135mmHg<SystolicBP<159 mm Hg and/or 85 mm Hg<DiastolicBP<99 mm Hg

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. 160 mm Hg<SystolicBP<135mm Hg and 99 mm Hg<DiastolicBP<85 mm Hg.
2. Individuals with CVD, diabetes or fasting blood glucose concentration > 7.0mmol/L, asthma, or

thyroid conditions
3. Subjects with eating disorders, high habitual intake of wholegrain food (> 7 portions per weeks) or taking regular medication or supplements known to affect any dependant variable measured
4. Pregnant women
5. Individuals with bowel disorders (Crohn's, IBS, coeliac)

Date of first enrolment
01/08/2017

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Aberdeen
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Sponsor information

Organisation
University of Aberdeen

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name

Scottish Government (Rural and Environmental Science and Analytical Services)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Frank Thies, f.thies@abdn.ac.uk.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes