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SALT-SWAP - Testing different approaches to help people reduce their salt intake

Submission date	Recruitment status	[X] Prospectively registered
27/03/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/02/2022	Circulatory System	

Plain English summary of protocol

Background and study aims
High blood pressure increases the risk of heart disease and stroke and is a major cause of ill-health in the UK. There is evidence that eating too much salt can increase your blood pressure. The recommended salt intake for adults is less than 6g/day, but the average adult in the UK eats 8.1g/day. The majority of the salt people eat comes from packaged or processed foods. For many high-salt products there is a similar, lower-salt alternative but it can be difficult for shoppers to quickly identify these alternatives. The aim of this study is to test a new program to help people with high blood pressure to reduce their salt intake, by helping them choose lower-salt products when supermarket shopping.

Who can participate?
Adults with high blood pressure who regularly shop in a supermarket and own a smartphone.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the program to help them lower their salt intake. This consists of advice from a healthcare professional about salt and its effect on blood pressure and instructions to download and use a smartphone app which suggests lower-salt alternatives when grocery shopping. Those in the second group receive an information leaflet which contains tips and tools to help reduce salt intake.

What are the possible benefits and risks of participating?
Participants may benefit from reducing their salt intake. There are no notable risks involved with participating.

Where is the study run from?
The study is being run by Nuffield Department of Primary Care Health Sciences, University of Oxford and takes place in GP practices in Oxfordshire and the Thames Valley (UK)

When is the study starting and how long is it expected to run for?
November 2016 to March 2019

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Ms Sarah Payne Riches
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(updated 07/09/2021, previously: sarah.payneriches@phc.ox.ac.uk)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33949

Study information

Scientific Title
Randomised controlled feasibility trial of a complex behavioural intervention to reduce salt intake among people with high blood pressure

Acronym
SALT-SWAP

Study objectives

The aim of this study is to test a new intervention to help people with high blood pressure to reduce their salt intake, by helping them choose lower-salt products when supermarket shopping.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central – Hampshire B REC, 17/03/2017, ref: 17/SC/0098
Major amendment 1: 20/12/2017
Major amendment 2: 21/06/2018,
Major amendment 3: 21/08/2018
Major amendment 4: 04/01/2019

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Hypertension

Interventions
Participants will be randomised to one of two groups using computer generated block randomisation.

Intervention: Participants will receive a behavioural intervention consisting of one session of brief dietary and motivational advice, to be delivered by a health care professional (HCP) in primary care. In addition, participants will receive ongoing support at the point of choice while shopping using a mobile phone application (app), which will suggest lower salt alternatives, enable self-monitoring and provide feedback on salt content of purchases. The brief advice session by the HCP will last approximately 20 minutes. The intervention period will be 6 weeks.

Control: Participants will receive an information and advice leaflet by post. This leaflet is produced by the British Heart Foundation and is called Cut Down on Salt and contains tips and tools to help reduce salt intake.

There will be one follow up assessment which will occur in the week following the 6 week intervention period. Baseline assessment measures will be repeated and all participants will be also be asked to complete a short post-intervention questionnaire to assess aspects of the intervention (or control) they received.

Intervention Type
Other

Primary outcome measure
Feasibility outcomes:
1. Study follow -up rate will be measured as the percentage of participants, in each arm of the study who attend the follow-up session within within 4 weeks from the end of the intervention period.
2. Intervention fidelity will be measured, on completion of delivery of all intervention advice sessions, as the mean percentage of pre-specified components of the intervention advice session which are delivered by the practice nurse(s). The fidelity with which the intervention was implemented will be tested by asking nurses to audio-record the consultation which is then compared against a checklist of the components required by the protocol.
3. Intervention usage (app usage) will be measured as the number of participants who use the app to scan products on at least one occasion by the end of month one of the intervention period

Secondary outcome measures
1. Salt content of purchased foods is measured as salt in g/100g of total product weight, assessed through scanning of purchased product bar-codes and linking to a food and nutrient information database during a baseline period of two weeks before the intervention and over the intervention period
2. Sodium intake is measured using a 24 hour urinary sodium test, at baseline and at the 6 week follow up appointment
3. Blood pressure is measured using an electronic BP monitor at baseline and at the 6 week follow up

Overall study start date
08/11/2016

Completion date
05/07/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/02/2019:
1. Participants' most recent systolic blood pressure reading in the past 2 years is above 130 mmHg if they are currently taking anti-hypertensive medication or above 140 mmHg (if non-medicated)
2. If on pharmacological treatment for hypertension, participant has been prescribed a stable dose for at least the past 6 weeks.
3. Participant is willing and able to give informed consent for participation in the study

4. Male or female, aged between 18 and 80 years
5. English speaking
6. Who regularly shop in a supermarket (excluding online supermarkets), spending at least £25 at least once a fortnight
7. Own a smartphone (android or iOS) and express interest in using an app for healthy eating
8. Who express a desire for support to improve the nutritional quality of their diet to reduce their CVD risk

Previous inclusion criteria:
1. Participants' most recent blood pressure reading in the past 2 years is 140/90 mmHg or higher (taken in clinic, with or without subsequent ambulatory blood pressure monitoring daytime average or home blood pressure monitoring average blood pressure of 135/85 mmHg or higher)
2. Not currently taking hypertension medication
3. Participant is willing and able to give informed consent for participation in the study
4. Male or Female, aged between 18 and 80 years
5. English speaking
6. Who regularly shop in a supermarket (excluding online supermarkets), spending at least £25 at least once a fortnight
7. Own a smartphone (android or iOS)
8. Who express a desire for support to improve the nutritional quality of their diet to reduce their CVD risk

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
50

Key exclusion criteria
Current exclusion criteria as of 15/02/2019:
1. Already on a clinician supervised diet or a restricted diet
2. Unwilling to make dietary changes
3. Are currently using or have used the Foodswitch or Saltswitch apps previously
4. Unable to read and understand the instructions provided in English
5. Participants with secondary, previous accelerated or malignant hypertension as defined by read code
6. Currently being assessed for diagnosis of hypertension
7. Currently on any medication that may lead to hyponatraemia or fluid retention
8. Existing or recent cardiovascular conditions: heart attack or stroke within the last 3 months,

heart failure of grade II New York Heart Association and more severe, or prolonged QT syndrome, angina, arrhythmia or atrial fibrillation
9. Currently participating in another study
10. Patients that the GP judges not able to meet the demands of the study or unlikely to comply with study procedures as stated in the protocol
11. They are planning on going away from home for more than 2 consecutive weeks during the 6 week intervention period

Previous exclusion criteria:
1. Already on a clinician supervised diet or a restricted diet
2. Unwilling to make dietary changes
3. Are currently using or have used the Foodswitch or Saltswitch apps previously
4. Unable to read and understand the instructions provided in English
5. Currently on blood pressure lowering medication
6. Currently on any medication that may lead to hyponatraemia or fluid retention
7. Existing or recent cardiovascular conditions: heart attack or stroke within the last 3 months, heart failure of grade II New York Heart Association and more severe, or prolonged QT syndrome, angina, arrhythmia or atrial fibrillation.
8. Currently participating in another study (including follow-up)
9. Patients that the GP judges not able to meet the demands of the study or unlikely to comply with study procedures as stated in the protocol
10. They are planning on going away from home (holiday or other) for more than 4 consecutive days during the 6 week intervention period

Date of first enrolment
20/09/2018

Date of final enrolment
01/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Department of Primary Care Health Sciences
University of Oxford
Radcliffe Observatory Quarter
Woodstock Road
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Sponsor information

Organisation
University of Oxford

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. Study results will be communicated to study participants and members of the public involved in the research through email newsletters and press releases targeted to the specific audience
2. Planned publication of study results in academic peer-reviewed journals and through presentations at relevant conferences

Intention to publish date
17/04/2021

Individual participant data (IPD) sharing plan
The data will be in a non-publically available repository (University of Oxford).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/10/2019	14/10/2019	Yes	No
Results article		21/10/2021	25/02/2022	Yes	No
HRA research summary			28/06/2023	No	No