

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

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| Submission date 27/03/2017 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 05/04/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 25/02/2022 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

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
sarahpayne001@yahoo.com
(updated 07/09/2021, previously: sarah.payneriches@phc.ox.ac.uk)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Nuffield Department of Primary Care Health Sciences

University of Oxford

Radcliffe Observatory Quarter

Woodstock Road

Oxford

United Kingdom

OX2 6GG

Sponsor information

Organisation

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

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? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| Results article | | 21/10/2021 | 25/02/2022 | Yes | No |
| Protocol article | protocol | 11/10/2019 | 14/10/2019 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |