

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

<b>Submission date</b> 27/03/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/04/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/02/2022	<b>Condition category</b> 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**  
Ms Sarah Payne Riches

**ORCID ID**  
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**Contact details**  
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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

Oxford

United Kingdom

OX2 6GG

## Sponsor information

**Organisation**

University of Oxford

**Sponsor details**

Clinical Trials and Research Governance Joint Research Office

Block 60

Churchill Hospital

Headington

Oxford

England

United Kingdom

OX3 7LE

+44 1865 289300

ctrq@admin.ox.ac.uk

**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?
<a href="#">Protocol article</a>	protocol	11/10/2019	14/10/2019	Yes	No
<a href="#">Results article</a>		21/10/2021	25/02/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No