



PARTICIPANT INFORMATION SHEET

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

We'd like to invite you to take part in a research study funded by the British Heart Foundation and conducted by the University of Oxford. In this study we aim to test different ways to help people reduce the amount of salt they eat by encouraging and supporting them to buy lower salt products when shopping for food. This is important because reducing the salt in our diet has been shown to reduce blood pressure and this reduces the chance of heart disease and stroke.

Why have I been invited?

You have been invited because we are looking for people between the age of 18 and 80 with high blood pressure (or who have recently had a high blood pressure reading) who are responsible for some of their household grocery shopping. Your GP has searched in their records to see who might be eligible based on recent blood pressure measurements. The University of Oxford did not have access to any of your personal or medical information.

Do I have to take part?

No. Taking part is entirely voluntary. You can ask questions about the study before deciding whether or not to participate. Taking part in the study will not affect the usual care you receive from your GP. If you do agree to participate, you may withdraw yourself and your data from the study at any time, without giving a reason and without penalty, by advising the researchers of this decision. Withdrawing from the study will not affect your clinical care.

What will happen to me if I decide to take part?

All participants will attend a baseline study visit for data collection. They will then be randomly allocated into one of two groups. Neither you nor your nurse or the research team can choose which group you will be in. However both groups will receive an intervention to help them reduce the amount of salt in their diet. One group will receive a booklet in the post with detailed information and tips for reducing salt and identifying lower salt alternatives for some common high salt foods. The other group will attend an appointment with a healthcare professional at their local GP practice who will provide advice to reduce salt and instructions on how to use a mobile phone app to provide further assistance when shopping. All participants will need to attend a follow up study visit. We will ask you to send us your grocery shopping receipts and scan barcodes of the products you buy during the study (and for a 2-week period beforehand) so that we can calculate the amount of salt in your shopping. We will also analyse samples of your urine, which you will be asked to collect at home, to assess the level of salt in it (this is a good way of measuring the amount of salt you actually eat). The accompanying chart gives more detail of what is involved.

What should I consider?

To be able to take part in the study, we need to confirm that you currently have high blood pressure, or a recent high reading (this will be determined by your most recent blood pressure measures in your GP records) and if you are currently taking medication for your blood pressure, you are on a

stable dose. You also need to have a mobile phone capable of downloading apps (i.e. a smartphone – android or iOS).

If you agree to take part in the study we would expect you to:

- Follow your allocated intervention to the best of your ability
- Collect two 24 hour urine samples and deliver them to your GP practice
- Complete the questionnaires we provide
- Record your grocery shopping purchases in an app, by scanning the barcode, for a 2 week baseline period and during the study
- Attend two appointments with the study team; and, depending on which group you are assigned to, one appointment with the healthcare professional
- Allow a member of our research team to accompany you on one your grocery shopping trips and interview you afterwards about the shopping trip and your grocery shopping habits in general. This may include the researcher taking photos or very short video footage of products you consider during your shopping.

Taking part in this study will not affect any other treatment you are receiving. You may continue to take your regular medication or other prescribed or over-the-counter medicines during the study.

Are there any possible benefits or disadvantages from taking part?

Everybody who takes part will benefit by receiving information about how to reduce their blood pressure. In addition, everyone will have their urinary salt excretion measured, an indicator of how much salt they consume. This knowledge can provide helpful feedback on your salt intake. The dietary advice we provide as part of the intervention is consistent with UK dietary recommendations. The questionnaires you will be asked to complete do not cover topics usually considered sensitive, therefore we do not anticipate that they will cause distress.

Will I be reimbursed for taking part?

To compensate you for any costs or inconvenience in attending appointments related to the study, you will be offered a £10 gift card after submitting your baseline study measures and being randomised to a study group. You will also be offered a further £10 gift voucher when you attend the final study appointment. You will be offered a further £20 gift card for submitting all shopping data during the study. Those who are asked to take part in the accompanied shop will also receive an additional £10 gift card.

Will my taking part in the study be kept confidential?

Any information that is collected about you during the course of the research will be kept strictly confidential and stored securely. We will use codes to avoid identification of participants with their names. Your mobile phone number will be held by the text message network provider. This is needed in order to send you reminder messages for study appointments. This information will be held by the network provider until the end of your involvement in the study. They will have no other identifying information about you.

At the end of the study, video recordings will be destroyed and only anonymised written copies will be stored. Study data will be stored for 3 years after the end of the study and then destroyed.

Grocery shopping data collected through the mobile phone app during the course of the study will be held securely by a third party (the app developer) and transferred securely to the University of Oxford research team for analysis. Members of the University of Oxford and/or the NHS Research and Development Office may be given access to data for the purpose of monitoring and/or audit of

the study to ensure that the research is complying with applicable regulations. These staff are bound by the same duty of confidentiality as the researchers and those providing clinical care.

Will my GP be informed of my participation?

We do not expect any side effects of taking part in this study, but your GP will be notified of your participation and will receive copies of your urinary sodium test results during the study. If we happen to identify anything which causes medical concern, such as a blood pressure reading higher than expected, we will, with your consent, contact your GP. Your participation in the study will not affect any other care you receive from your GP.

What will happen if I don't want to carry on with the study?

Your participation is voluntary. If you no longer want to take part in the research you can withdraw at any time without giving a reason. Your future medical care will not be affected. You can withdraw from the study but keep in contact with us to let us know about your progress. Information collected may still be used. Any stored samples that can still be identified as yours will be destroyed if you wish.

What will happen to the samples I give?

The urine samples will be analysed to measure how much salt you eat. These results will be sent to the research team and, with your consent, to your GP. After this, the samples will be destroyed and will not be used for other purposes.

What will happen to the results of this study?

The overall study results may be presented at scientific meetings or published in a scientific journal. This research will also contribute to a doctoral thesis at the University of Oxford. You will be not identified in the presentations and publications. We will send you a summary of the study results and also your personal results.

Funding Sources and collaborators

This study is funded by the British Heart Foundation, a UK registered charity. We developed the intervention for this study in collaboration with the George Institute of Global Health and Consensus Action on Salt & Health (CASH).

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Ms Sarah Payne Riches on 01865 617195 or email sarah.payneriches@phc.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrig@admin.ox.ac.uk.

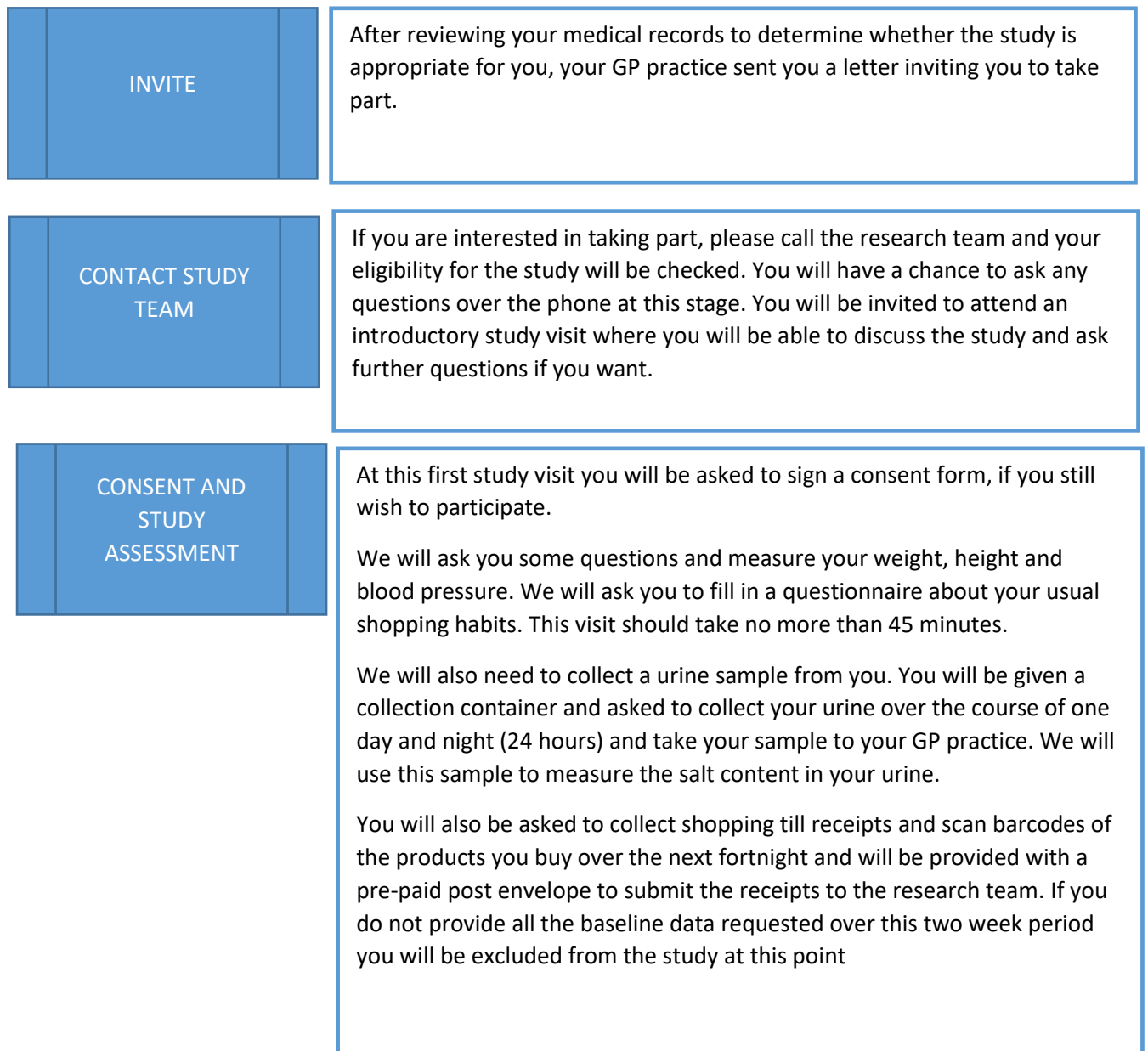
If you have any complaints or queries regarding the care you receive as an NHS patient, you can contact Patient Services for Oxfordshire Clinical Commissioning Group at patient.services@oxfordshireccg.nhs.uk or phone 0800 052 6088. Patient Services is unable to provide information about this research study.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This particular study was reviewed and approved on the 17th March 2017 (reference number 17/SC/0098) by the NHS national Research Ethics

Committee and the Health Research Authority. If you want to discuss the study in more detail or to participate in the study please contact us on: 01865 617195 or email: saltswap@phc.ox.ac.uk.

Thank you very much for taking the time to read this information sheet.

Figure 1. Study Participation flow chart



INTERVENTION ALLOCATION & DELIVERY

After this two week period of data collection you will be randomly allocated to one of the two study groups. The group you will be assigned to is down to chance. Neither you nor the study team will know what group you will be allocated to in advance and you will not be able to choose your group. If you are allocated to the group with the brief advice session, you will be booked in for an appointment with a healthcare professional at the study centre or your GP practice. This appointment will take approx. 20 mins. If you are allocated to the information group you will be sent a booklet by post.

DATA COLLECTION

During the next 6 weeks you will be asked to collect your grocery shopping receipts and submit them to the research team using pre-paid envelopes that we will provide you with. You will also be asked to scan barcodes of the products you buy using a free mobile phone app.

ACCOMPANIED SHOP

At one point in the study we may ask to accompany you on a shopping trip in your usual supermarket and afterwards, conduct an interview with you, about that shopping trip, at your home or our office as you wish. The purpose of this is to observe how you shop and to understand ways in which the intervention has influenced your shopping, or not. This is called a think-aloud study and we will ask you to speak your thoughts out loud to yourself as you do your shopping. We will give you some advice on how to do this and suggest you practice this at home beforehand. We will observe and we may take some video or photo footage during this shopping trip to remind us of things we want to discuss in the interview afterwards.

FINAL STUDY ASSESSMENT

At the end of the 6 week study period we will ask you to attend one follow-up assessment session at your GP Practice where we will repeat the measurements we took at the first study visit. We will ask you to bring your second urine sample to this visit. This visit should take no more than 30 minutes and will be the final study visit. The result of your urine sample may be recorded in your notes at your GP practice, if you consent to this.

PRIVACY NOTICE

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The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for three years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting us on: 01865 617195 or email: saltswap@phc.ox.ac.uk.

The study app will collect information from you for this research study in accordance with our instructions.

The University of Oxford will collect information about you for this research study from your GP surgery. This information will include your name, NHS number, urinary sodium analysis and relevant health information, which is regarded as a special category of information. We will use this information to determine your eligibility for the study and for study outcomes.