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Participant Information Sheet

STUDY TITLE:	SALTS (Salt ALTernatives Study) A randomised controlled trial to determine the effects of a 12-week dietary salt reduction intervention (SaltSwitch app + dietary salt substitute) on systolic blood pressure in adults with high blood pressure.
FUNDED BY:	Health Research Council (18/672)
LEAD INVESTIGATORS:	Dr Helen Eyles Professor Cliona Ni Mhurchu Professor Bruce Neal Dr Lisa Te Morenga
LEAD INSTITUTION:	University of Auckland
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Kia ora, Talofa lava, Kia Orana, Malo e lelei, Fakaalofa lahi atu, Malo Ni, Ni Sa Bula Vinaka, Namaste, Mauri, Ia Orana, Fakatalofa atu, Aloha, Halo olaketa

We invite you to take part in a research study called **SALTS**. The study wants to find out what effect a 12-week dietary salt reduction programme has on participants who have high blood pressure. The salt reduction programme includes a smartphone app called SaltSwitch and a salt replacement product to use in place of regular table salt.

Whether you choose to take part or not is up to you. This information sheet is designed to give you all the information required to make an informed decision.

Who is coordinating the study?

The study is being coordinated by the National Institute for Health Innovation (NIHI) at The University of Auckland. The lead researcher is Dr Helen Eyles and Co-Investigators are Professor Cliona Ni Mhurchu, Professor Bruce Neal, and Dr Lisa Te Morenga.

About the study

From May 2019 to November 2020, we plan to recruit 326 people who have a blood pressure reading higher than 140 /85mmHg). Participants will be referred by a Health Professional (doctor, nurse or pharmacist) at a GP practice or pharmacy, or they may be referred by one of our research assistants in a shopping mall, events, through social media, or at another venue or by completing a market research survey.

If you decide to take part in the study, you will be randomly allocated (like the toss of a coin) to one of the following two study conditions: an intervention or control condition. The table below shows what it means when you are allocated to one of these conditions:

	Intervention condition	Control condition
What will I receive in this condition?	• Intervention App to use when grocery shopping in store or online • Study App with videos and study reminders • Study salt • Blood pressure monitor that will connect to your wi fi and will automatically send your blood pressure readings back to us as well as showing you the reading on the screen. • At the end of the study you will receive a summary of your blood pressure measures, information on how to keep using the Intervention App and where to buy the study salt	• Study App with healthy eating information, videos and study reminders • Blood pressure monitor that will connect to your wi fi and will automatically send your blood pressure readings back to us as well as showing you the reading on the screen. • At the end of the study you will receive a summary of your blood pressure measures, information on how to download the Intervention App and details on where to buy the study salt
How long will I be in the study for?	2 weeks baseline (pre study) 12 weeks study period	2 weeks baseline (pre study) 12 weeks study period

What does the Intervention App do?

The Intervention App will help you to make lower salt food choices. The app allows you to scan the barcode of a packaged food and receive a traffic light nutrition label on-screen alongside suggestions for lower salt alternatives. You can also directly compare the salt content of different food products.

What does the Study App do?

The Study App will host the questionnaires you will be required to complete at baseline and at the end of the study. It will also send you notifications to remind you about different requirements throughout the study and have tutorial videos to help you. You will also use this app to scan the barcodes of packaged food you have purchased at different time points in the study. This will help us to see if there was a change in food purchased from the beginning of the study to the end. At the end of the study you will be able to view your blood pressure results over the duration of the study.

What is the study salt?

The study salt is a special type of salt which is used in place of regular table salt - it is much lower in sodium and higher in potassium but has a similar taste and flavor. Therefore, it can lower blood pressure without requiring the user to change the amount of 'salt' they usually use. The product is safe unless you eat a very large quantity (more than 50g/day) or have serious problems with your kidneys. It is also safe to be used for your whānau (family), so long as they do not have any conditions which mean they should not change the amount of salt they currently eat. If you have any concerns, we suggest you check with your doctor first.

Who can take part in this study?

You can take part in this study if you:

- Are able to read and understand English
- Are aged 18 years or older
- Own a Smartphone (iPhone or Android)
- Have a blood pressure reading greater than 140/85mmHg (either systolic (top number) or diastolic (bottom number) must be higher
- Are willing to help with household grocery shopping during the study in store or online (the main household shopper, if that's not you, will not take part in the study)
- Are willing and able to make small changes to your diet
- Have not been diagnosed with heart failure
- Have not had a heart event in the past six months (hospitalization for a heart attack, coronary artery revascularization (CABG or stenting), stroke, or heart failure
- Do not currently use a dietary salt substitute or the FoodSwitch smartphone app

Where will the study be undertaken?

The study will be undertaken in Auckland but may also be expanded to other locations in the North Island. All information will be delivered and collected through your phone or computer. There is no need to attend face-to-face visits however there will be an option to meet with a research assistant face to face during study set up if required. You will need to either visit the grocery store to do your food shopping each week and take your phone with you or do your shopping online and scan barcodes when you receive your shopping and then choose healthier options next time you shop online.

What will I be asked to do?

You may be asked to join the study by your doctor, nurse or pharmacist if your blood pressure has been taken and shown to be high, one of our study research assistants may have approached you in a shopping mall, or you may have contacted us directly after seeing our study in a social media campaign, advert or sent your details in a survey. Our study research assistants will support you through the study and help you with any queries. If you decide to take part, we will ask you to follow these steps:

P1: Referral and Screening	• Have your blood pressure, weight and height measured by a pharmacist, doctor, nurse or research assistant. If you find out about the study via social media we will tell you where to go to get these measurements done or support you to take these measurements at home or through one of our clinics *(this will take approx. 5-10 mins).* • If you meet the inclusion criteria a referral form with your details will be sent to us • Our research assistant will call you to go through some screening questions and explain the study. You can also ask questions *(this will take approx. 10 mins).* • If you are eligible, the research assistant will send you details to download the Study App and provide you with a unique study code to login to the app on your smartphone.
P2: Baseline (2 weeks)	• You will need to complete the following in your app: 1. Consent form 2. Baseline questionnaire (asking questions about your health and diet) 3. Watch a tutorial about what is required during the study *(The above will take approx. 15 mins).* • The research assistant will post out a pack with your blood pressure monitor and urine collection equipment.

P2: Baseline (2 weeks) *(Continued)*	• You will be required to scan the barcodes of all packaged foods and drinks using the study app (scanned over 2 weeks). • In the second week of baseline you will be required to take your blood pressure morning and night every day with the blood pressure monitor supplied (the monitor will automatically send your results to us), and take a small urine sample using the equipment provided (you will courier it back to us in courier bag provided). • Urine samples will be collected in a test tube which will be labelled with your unique study code and frozen (for a maximum of 10 months) until analysis at University of Otago laboratories. You will be asked to freeze your test tube of urine before sending it by courier to study staff – this is to protect the sample from degrading. If you do not wish to use your freezer you may use a freezer pack in a bucket to keep your sample cool, or courier it as soon as possible instead. Any left-over urine will be disposed of immediately following analysis by incineration in standard Bio Waste containers. • Notifications in the study app will remind you when and what you need to do at each stage.
P3: During the study (12 weeks)	• Once all the baseline requirements above are completed you will be randomly allocated to either the intervention or control group. • If you are allocated to the intervention group you will be asked to download the Intervention App on your phone and use it help you make food choices when grocery shopping (instore or online). The research assistant will post out the study salt to you and you should use it how you normally would. • If you are allocated to the control group you should use regular table salt how you normally would. • At week 6 you will need to take your blood pressure again every morning and night for a whole week. • During weeks 11&12 you will be required to scan barcodes of all of your packaged food and drink purchases. • During week 12 you will need to collect and send back your final urine sample. • During week 12 you will also need to take your blood pressure in the morning and at night. • At the end of the 12 weeks the Study App will prompt you to complete a follow up questionnaire *(approx. 10 mins).* • Once you have completed the questionnaire you will receive information about your blood pressure results over the duration of the study, how to download the Intervention App if you did not receive it during the study, and how to access the salt we used. • Notifications in the study app will remind you when and what you need to do at each stage.

Will it cost me anything to be in the study?

No, the app is free of charge.

Will I be paid?

Participants who complete the study will be able to keep their blood pressure monitor and will be eligible to enter a draw to win one of five $100 grocery vouchers. To enter the draw, you must indicate your interest on the consent form and complete and return your final urine sample. Winners will be contacted by phone and email at the end of the study (estimated date March 2021). If no response is received within 14 days of notification, another winner will be drawn at random.

What are the possible benefits?

High dietary salt intake is strongly linked to high blood pressure. This study is examining the effects of using a special salt substitute and smartphone app to help reduce blood pressure. If effective, the study may help you to lower your blood pressure which will reduce your risk of developing cardiovascular disease. It may also have a positive effect on your whānau health if they benefit from eating healthier options during the study. You may also benefit from receiving a blood pressure monitor and being able to monitor your own blood pressure from home.

What are the possible risks?

As we are only collecting information on blood pressure and urinary sodium, it is unlikely that there will be any risks for you with this study. However, if we observe your blood pressure to be particularly high, we will advise you to visit your GP to get this checked. There is also a very small chance that you are taking an ACE inhibitor drug to lower your blood pressure you could end up with too much potassium in your body. However, the chance is very small, associated only with very high intakes of potassium, and very unlikely to occur if you use the study salt in moderation, as you would use normal table salt. If you are taking an ACE inhibitor drug you may wish to advise your GP if you decide to take part in the study. The amount of urine collected will not be sufficient to make any conclusion about health, and we will not complete any tests outside of urinary sodium and potassium levels. In the unlikely event you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

What are my rights during the study?

Your participation in this study is your choice. If you choose not to take part in this study you will not be affected in any way. You can pull out at any time from the study and this will not affect your future healthcare or your relationship with the University of Auckland. This Participant Information Sheet will help you decide if you would like to take part. The study research assistants can also give you further support and answer any questions you may have. Before you decide you may want to talk about the study with other people, such as whānau, friends, or healthcare providers. If you decide you wish to take part you will need to give us your permission. This will be done through the app in an electronic consent form.

Will the information about me be kept confidential?

All information that you provide will remain strictly confidential. We need to collect personal details such as your name and contact information to communicate with you throughout the study. This information will be stored separately from any other personal data we collect like your ethnicity, age or any health information. No material that could personally identify you will be used in any reports on this study. All information collected during the study will be stored securely by the National Institute for Health Innovation, The University of Auckland for 10 years. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act, 1994. If you wish, we can also send you a summary of the results.

Follow-up

We may also want to see if any changes you made during the study have a positive influence on your health in the long-term. Therefore, we may want to contact you up to two years after the study is complete. We will only do this if you give us your consent to do so (in the consent form in the app). If you decide not to give consent, you can still be part of this study.

Who do I contact for more information?

If you have any questions or concerns about the study at any stage, you can contact:

Research Assistant:
Shistata Shrestha
Email: salts@auckland.ac.nz
Tel: 027 264 3689

Primary Investigator:
Helen Eyles
Email: h.eyles@auckland.ac.nz
Tel: 09 923 4659

Māori Co Investigator:
Lisa Te Morenga (Ngapuhi, Ngāti Whātua, Te Rarawa)
Email: lisa.temorenga@vuw.ac.nz
Phone: 04-463-4757

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:
Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

The study has ethical approval from the Health and Disability Committees (18/NTB/239)