

**ONLINE PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM**

*The Online Grocery Shopping (OGS) Trial*

*Chief Investigators:*

*Jason Wu, Bruce Neal, Cliona Ni Mhurchu, Adrian Cameron, Mark Huffman, Kathy Trieu and Fraser Taylor*

## **1. What is the research study about?**

Australians are increasingly shopping for groceries using supermarkets' online stores. However, we don't know much about how people are doing their shopping online and how they are using the information made available to them.

This research study will investigate grocery shopping behaviour and how purchasing choices may change depending on the information being presented. We will do this through a web-browser extension – the Online Grocery Shopping (OGS) extension. This has been designed to work with Woolworths' online store.

Once installed, the extension will run in the background of your web browser to enhance your shopping experience and provide us with important information on your shopping. While you may notice some minor changes to your shopping experience, it won't interfere with the ease of shopping that you're accustomed to.

If you consent to participate in this study and are eligible for participation, we will ask you to do your regular grocery shopping online via Woolworths for the duration of the study (approx. four months) and record your own blood pressure (at three time points) using a device that we will provide. You will also be asked to complete additional data collection procedures throughout the study, which will help the researchers evaluate the OGS extension – we explain all of these in greater detail below.

## **2. Who is conducting this research?**

The study is being carried out by the following researchers: Associate Professor Jason Wu, Professor Bruce Neal, Professor Cliona Mhurchu, Associate Professor Adrian Cameron, Associate Professor Mark Huffman, Dr Kathy Trieu and Mr Fraser Taylor at the George Institute for Global Health, Faculty of Medicine, University of New South Wales.

**Research Funder:** This research is being funded by the National Health and Medical Research Council Australia (APP1200105). The research team does not have any commercial ties, is not receiving in kind support, and nor are we supported in any way by Woolworths for the OGS Trial. We are developing the OGS web-browser extension independent of Woolworths.

## **3. Inclusion/Exclusion Criteria**

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part and that you meet certain eligibility criteria.

We will include people who:

- Are adults between 18 and 75 years of age.

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- Have a diagnosis by their clinician of high blood pressure or are currently taking a stable dose of blood pressure lowering medication, defined as no change to the dose in the past 6 months.
- Regularly shop and purchase most of their groceries online via Woolworths and plan to continue for the approx. 4 months duration of the study, OR Regularly shop and purchase most of their groceries online via a non-Woolworths retailer (e.g. Coles); but are willing to switch to shop at Woolworths online for the duration of the study.
- Use, or will use, a computer (laptop or desktop) to shop for their groceries online (i.e. not a mobile phone or tablet/iPad)
- Are assessed as demonstrating high salt purchasing behaviour
- Do not have another household member already participating in this trial
- Are the main person who shops for food and groceries in their household
- Have an upper arm circumference of less than 42cm (i.e. do not require an extra-large blood pressure cuff when measuring blood pressure)
- Successfully complete the run-in procedures, which will occur at the beginning of the study (explained in greater detail below)

We will exclude those who:

- Are less than 18 years of age or 75 years of age or older
- Are unable or unwilling to provide informed consent.
- Have an upper arm circumference of more than 42cm, i.e. require an extra-large blood pressure cuff when measuring blood pressure.
- Have one or more of the following advanced medical conditions:
  - Congestive heart failure (stage D)
  - Stage 4/advanced/metastatic cancer
  - Chronic kidney disease (CKD), Chronic Kidney failure (stage 4) and end-stage renal disease on dialysis (Stage 5)
  - Advanced liver disease, Cirrhosis, end-stage liver disease (ESLD)
  - Those with a life expectancy less than 1 year

#### **4. Do I have to take part in this research study?**

Participation in any research study is entirely voluntary. Even if you agree to participate, you can withdraw from the study at any time without any negative consequences. Before you decide to participate in or refuse to participate in this study, you can ask any member of our research team about the study. If you decide to withdraw from the study while the project is still going on, you should inform the investigator of your decision on email or by phone.

If you decide you want to take part in the research study, you will be asked to:

- Read the information in this document carefully (ask questions if necessary);

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- Confirm consent by reading and accepting the online consent form if you decide to participate in the study.

**5. What does participation in this research require, and are there any risks involved?**

In recognition of your commitment to the trial, you will be given \$50 worth of 'Woolworths Brand' eGift Card' grocery vouchers – \$25 for providing blood pressure measurements at the beginning of the study and \$25 for providing blood pressure measurements at the end of the study, which we will remind you about. If you are selected for and participate in a brief phone interview at the end of the trial period, where we will ask you for your thoughts on the web-browser extension, you will receive another \$25 shopping voucher (so \$75 in total). If you prefer, we can donate these vouchers to a charity on your behalf. You will also be able to keep the blood pressure monitors provided to you (valued at \$179).

If you decide to take part in the research study, and after providing informed consent, we will ask you to complete the following:

*Screening and baseline survey*

1. These are brief online forms that we will ask you to complete. They will include questions about you, your health and your household/family. This will help us assess your eligibility to participate. The surveys should take approximately twenty minutes to complete.
2. After completing these surveys, and if you are eligible to participate, you will be asked to download, install and activate the OGS web browser extension on your computer – please note that this extension must not be shared, but you can install the extension across multiple computers if you use different ones to shop for groceries online (the extension will only work on computers, not phones).

*Run-in period (4-5 weeks)*

3. After activating the extension, you will enter a "run-in" period of approximately 5 weeks, during which we will collect important information about your grocery purchases and further assess your eligibility to participate in the main phase of the study (which will run for 12 weeks).
4. We will ask you to continue to shop online as you normally would – please note that we require at least two completed shops during this period to help us assess your usual purchasing habits. Your purchases will be automatically recorded and sent to us by the extension.
5. After you complete two shops and we look at the data provided, we will send you a remote blood pressure monitor that you can operate at home and which will automatically send us your results. We will ask you to measure your own



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blood pressure two times (with a minute wait in between), twice a day (morning and evening, around the same time each day if possible) for three days in a row.

6. Once we receive your blood pressure measurements, you will progress to the main study period (12 weeks). We will also provide you with the first shopping voucher at this point.
7. During the run-in period, we will also send you a pathology request form and ask you to go to a local pathology centre to provide a urine sample.
8. We will also ask you to complete an online questionnaire about what you ate and drank over a 24 hour period (should take around thirty minutes).

*The main study period (12 weeks)*

9. You will be asked to continue using the OGS web-browser extension over the 12-week main trial period.
10. You will be randomly allocated to one of two groups and provided with different information/prompts depending on the group you have been assigned to, including some or all of:
  - a. Reminders to continue your regular online shopping and recording your blood pressure
  - b. Information on your purchases
  - c. Information on products available
11. Once the trial is complete, we will give you detailed information about what we tested and the findings.
12. We will ask you to provide blood pressure measurements, two times in a sitting twice a day for three days in a row, halfway through the main study period and again at the end of this period. We will send you the second shopping voucher once we receive the final lot of blood pressure results.
13. We will ask you to complete brief surveys, updating those you completed at baseline, halfway through the main study period and again at the end of this period. Though it is extremely unlikely that your participation in this study will cause new or worsen existing health issues, at these points you will also have the opportunity to let us know if you do experience any serious adverse events so we can follow-up with our trial clinician and refer you to your GP if required
14. We will also ask you, at the end of the main study period, to again provide a urine sample at a local pathology centre and complete the dietary recall questionnaire.
15. We may also ask you to participate in a phone interview at the end of the study. During this interview, we will ask you about your thoughts on the OGS web-browser extension and ways that it can be improved. This interview should take approximately 40 minutes. The interview will be audio-recorded and then transcribed by an independent transcriber. Any personally identifiable

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information will be removed. If you participate in this interview, we will provide you with another \$25 shopping voucher.

**What will happen at each point in the study:**

Activity	Screening and baseline	Run-in period	Main trial period (week 6)	Main trial period (week 12)
Informed consent	X			
Screening survey	X			
Baseline survey	X			
Physical activity survey	X		X	X
Medications survey	X		X	X
Shop for groceries online via Woolworths using OGS extension		X	X	X
Dietary recall questionnaire		X		X
Urine sample		X		X
Blood pressure measurements		X*	X	X*
Serious adverse events			X	X
Telephone interview				X*

\* \$25 shopping vouchers provided at these points when measurements are complete. Only a subset of study participants will be selected to participate in the telephone interview at the end of the study.

Measurement of blood pressure using study monitor should be very safe and research staff will provide clear instructions on how to do so in accordance with best practice for home blood pressure measurement. If you experience any discomfort or have questions about how to conduct the home blood pressure assessment, you can contact the research staff at any time.

**6. What are the possible benefits to participation?**

The aim of this study is to test the effects of providing different information to people shopping for their groceries online. The direct benefits to the trial participants will be limited but we hope to use information from this research to develop new ways to help consumers choose products in line with their health and nutrition needs.

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If the tool proves to be successful, we will seek Therapeutic Goods Administration registration of this intervention as a medical device and seek to market the OGS web-browser extension to food retailers, health insurers, directly to consumers, or a combination thereof for scaling to help more people when shopping online.

**7. What will happen to information about me?**

By providing your informed consent you are providing your permission for the research team to collect and use information about you for the research study.

The research team will store the data collected from you for this research project for:

- A minimum of 15 years after the publication of research results.

The information about you will be stored confidentially as follows:

- In a re-identifiable format where any identifiers such as your name, address, date of birth will be replaced with a unique code.
- Information collected from you in an electronic format and backed up using password protected local hard drives and secure servers at the George Institute for Global Health Sydney office. You may request access to the information collected and stored by the research team at any time.
- Only research team members directly involved in this project will have access to your data. In addition, a third-party blood pressure monitor supplier will be given your name, address and phone number to arrange delivery of a blood pressure monitor to you.
- All personal information will be handled in accordance with section 95A of the Privacy Act 1988

**8. How and when will I find out what the results of the research study are?**

The research team intend to publish and report the results of the research. All information will be published in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

**9. What if I want to withdraw from the research study?**

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document and email it, or you can ring the research team and tell them you no longer

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want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or the George Institute for Global Health. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the [UNSW Privacy Management Plan](#).

**10. What should I do if I have further questions about my involvement in the research study?**

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the research team directly:

**Research Team Contact**

<b>Name</b>	OGS Research Team
<b>Telephone</b>	+61 2 8052 4319/ +61 2 8052 4757
<b>Email</b>	OGS@georgeinstitute.org.au

**What if I have a complaint or any concerns about the research study?**

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

**Complaints Contact**

<b>Position</b>	Human Research Ethics Coordinator
<b>Telephone</b>	+ 61 2 9385 6222
<b>Email</b>	<a href="mailto:humanethics@unsw.edu.au">humanethics@unsw.edu.au</a>
<b>HC Reference Number</b>	<a href="#">HC Number 200970</a>

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## Consent Form – Participant providing own consent

### Declaration by the participant

By checking the I agree/start questionnaire option below:

- I understand I am being asked to provide consent to participate in this research study;
- I have read the Participant Information Sheet, or it has been provided to me in a language that I understand;
- I provide my consent for the information collected about me to be used for the purpose of this research study only.
- I understand that if necessary, I can ask questions and the research team will respond to my questions.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- I understand that the results of the research will be made available on the George Institute for Global Health website.
- I understand that I can download a copy of this consent form from [\[INSERT weblink/web address\]](#)
- I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.
- I am providing my contact details to allow the research team to send me reimbursement.

**Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**Email Address:** \_\_\_\_\_

**Submit consent**



The George Institute  
for Global Health



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**Form for Withdrawal of Participation**

I wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales George Institute for Global Health. We will not collect additional information from you after you have withdrawn from the study.

I am withdrawing my consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me which I have provided for the purpose of this research.

**Participant Name**

Name of Participant (please type)	
Date	

**Submit withdrawal of  
consent**