Protocol for a novel sodium and blood pressure reduction intervention targeting online grocery shoppers with hypertension – the SaltSwitch Online Grocery Shopping (OGS) randomised trial

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ABSTRACT

Background

High dietary sodium intake is a leading cause of hypertension. A major source of dietary sodium is salt added to processed food products available in retail food environments. The fast-growing online grocery shopping setting provides new opportunities for salt reduction interventions that support consumers in choosing healthier options.

Methods

The SaltSwitch Online Grocery Shopping randomised controlled trial is investigating the feasibility, acceptability, and effectiveness of a novel intervention for lowering salt consumption and blood pressure amongst people with hypertension who shop for groceries online. The intervention is based on a bespoke web browser extension that interfaces with a major retailer's online store to highlight and interpret product sodium content and suggest similar but lower-sodium alternatives.

The primary outcome of interest is change in mean systolic blood pressure between individuals randomised (1:1) to the intervention and control (usual online shopping) arms at 12 weeks. Secondary outcomes are diastolic blood pressure, spot urinary sodium and sodium:potassium ratio, sodium purchases, and dietary intake. Intervention implementation and lessons for future uptake will be assessed using a mixed methods process evaluation.

Participants with hypertension who shop online for groceries and exhibit high sodium purchasing behaviour are being recruited across Australia. A target sample size of 1,966 provides 80% power (two-sided alpha = 0.05) to detect a 2 mmHg difference in systolic blood pressure between groups, assuming a 15 mmHg standard deviation, after allowing for a 10% dropout rate.

Discussion

This trial will provide evidence on an innovative intervention to potentially reduce salt intake and blood pressure in people with hypertension. The intervention caters to individual preferences by encouraging sustainable switches to similar but lower-salt products. If effective, the intervention will be readily scalable at low cost by interfacing with existing online retail environments.

BACKGROUND

Hypertension affects over 1.2 billion people around the world [1], with high systolic blood pressure contributing to 10.8 million premature deaths in 2019 [2] and causing considerable disease-related economic burden [3-5]. Around the world, fewer than half of those with hypertension receive treatment and less than one-quarter have their hypertension controlled [1]. Excess dietary sodium consumption is a leading cause of hypertension [6]. Accordingly, reducing dietary salt (sodium chloride, the major source of sodium) intake is strongly recommended for the prevention and management of high blood pressure [7, 8]. Population-level interventions to reduce salt intake are promoted by the World Health Organization (WHO) to be some of the most cost-effective strategies to reduce the burden of non-communicable diseases [9]. However, salt intake remains too high globally, with most populations around the world exceeding the maximum intake of 5 g salt (or 2 g of sodium) per day recommended by the WHO [10, 11].

In many high-income countries such as Australia, most dietary salt is consumed from highly processed foods such as bread and other cereal products, convenience products, and processed meats [12]. Such products are also an increasing source of dietary salt intake in low- and middle-income countries as food systems transition to a Western-style diet [13, 14].

There is great variability in salt levels amongst otherwise comparable packaged food products [15-18], indicating the potential for consumers to select similar but lower-salt products. Information on salt content is typically available on product packaging in the form of detailed numeric information, with prior research suggesting many consumers find this format challenging to understand and interpret [19, 20].

Growing evidence suggests that providing consumers with easy-to-understand, interpretive nutrition information to facilitate product comparisons [21-23], particularly at point-of-sale [24], and actively "nudging" them towards individual product-level *switches* to healthier foods [25-28] can improve consumer purchases. These approaches may therefore be useful for reducing intake of nutrients of concern such as salt. This may be particularly true amongst people with hypertension, as there is some

evidence that people who are aware that they are hypertensive are more likely to follow salt reduction recommendations [29-32].

An important food retail environment for interventions to improve consumer purchases and dietary patterns is online grocery shopping, which comprises around a quarter of food retail sales in some countries [33] and is growing rapidly, especially since the COVID-19 pandemic and its associated restrictions [33].

Here, we describe the protocol for a randomised controlled trial (RCT) to investigate the feasibility, acceptability, and effectiveness of a novel intervention for lowering salt consumption and, in turn, blood pressure amongst individuals with hypertension who shop for their groceries online. The primary aim of this trial is to compare the effect of the SaltSwitch Online Grocery Shopping (OGS) intervention versus usual online shopping on change in mean systolic blood pressure levels at 12 weeks. Secondary outcomes of interest are changes in diastolic blood pressure, sodium content of food purchases, spot urinary sodium concentration and sodium:potassium ratio, and dietary intake. Acceptability, preferences, and lessons for implementation of the OGS intervention will also be assessed using a mixed methods process evaluation.

METHODS

Funding sources

This study is supported by an Australian Government Medical Research Future Fund Cardiovascular Health Grant (MRF1200105). The chief investigators take full responsibility for all aspects of the study. No external source has had or will have any input into trial design, conduct, analysis, or reporting. The authors are solely responsible for the drafting and editing of this paper and its final contents.

Study design

The aims of the SaltSwitch OGS study will be investigated using a two-arm, parallel-design, individual participant RCT (**Figure 1**). After informed consent is provided and initial screening, participants enter a 4- to 5-week run-in period during which eligibility is further assessed and demographic and baseline outcomes data are collected. Once participants successfully complete the run-in period, they are centrally randomised using a computer-generated sequence to either the intervention (online shopping using OGS platform) or control (usual online shopping) arm in a 1:1 ratio and enter the main trial for a period of 12 weeks. Follow-up data collection on primary and secondary outcomes takes place at weeks 6 and 12. A sub-sample of participants allocated to the intervention will also be purposively selected to participate in the process evaluation following trial completion.

The trial received ethics approval from the University of New South Wales Human Research Ethics Committee (HC200970) and was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621000642886).

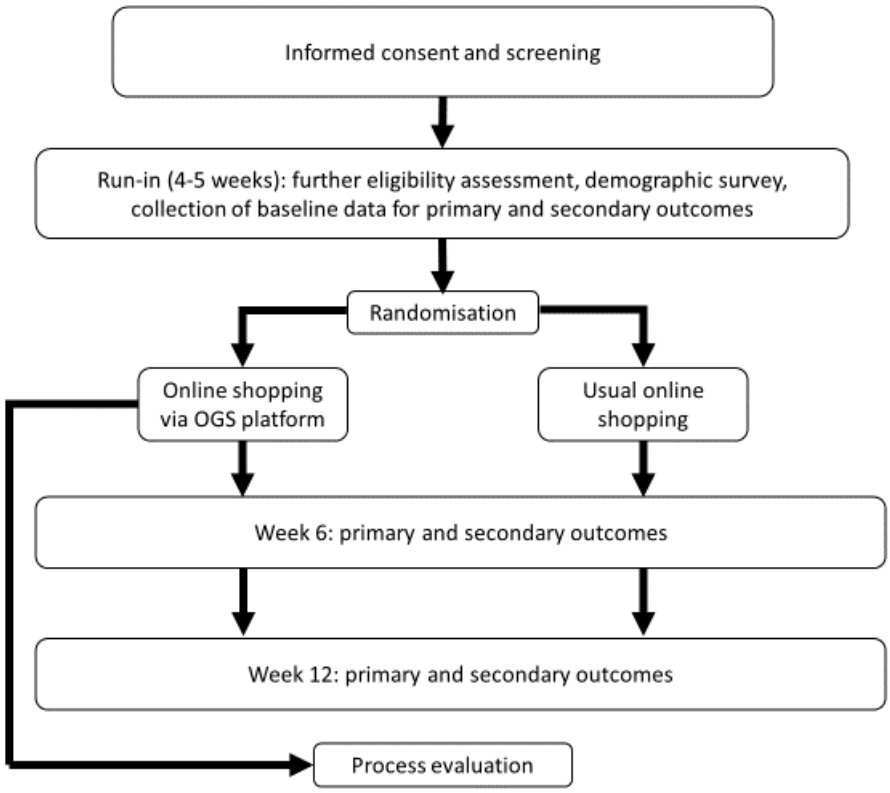

Figure 1. Trial schema

Hypothesis

We are testing a primary null hypothesis of no difference in the change in mean systolic blood pressure between participants in the intervention (the OGS intervention) and control (usual online shopping) groups at 12 weeks.

Participants

The trial is designed to select participants who will benefit the most from the intervention, in terms of both reducing salt purchases and blood pressure.

Inclusion criteria

As salt reduction has a greater blood pressure lowering effect amongst those with hypertension [34, 35], eligibility is restricted to those who self-report a clinician diagnosis of current hypertension and/or that they are currently taking a stable dose of blood pressure lowering medication, defined as no change to dose in the past 6 months. The latter requirement is to mitigate against the potential impact that a recent change may have on the primary outcome.

Participants must intend to shop for most of their groceries online using a computer for the duration of the study. This intention must be self-declared during screening but is also assessed through the run-

in period, during which participants must complete at least two shopping events (successful placement of an online order) through the OGS extension and purchase at least 500 g of food per person in their household per day (approximately 33rd percentile of volume of foods purchased from supermarkets, based on unpublished analyses of NielsenIQ Homescan data, a nationally representative household shopping panel of ~10,000 Australian households).

Participants must also be assessed by study investigators as exhibiting high salt purchasing behaviour, evaluated through an analysis of purchases during the run-in period. High salt purchasing behaviour is defined as purchasing at least one product from five or more of the 36 food categories (approximately one third of all food categories) that have the highest average sodium content or contribute the most to sodium intake in Australia [36], excluding those which typically contain only natural sodium, e.g. milk (unpublished analyses by study investigators using NielsenIQ Homescan data).

Exclusion criteria

Individuals are excluded if they do not live in Australia, are not between 18 and 75 years of age, have another household member already participating in the trial, are not the main person who shops for food in their household, do not intend to shop online using a computer, or have one or more specified advanced medical conditions: heart failure (stage D); stage 4/advanced metastatic cancer; chronic kidney disease (stage 4) and end-stage renal disease on dialysis (stage 5); advanced liver disease including cirrhosis and end-stage liver disease; or a life expectancy of less than one year. Participants must also not have an upper arm circumference greater than 48 cm as cuffs larger than this are unavailable for the blood pressure monitors used in this study.

Recruitment

Participants are recruited from across Australia, with procedures informed by those used in prior nutrition labelling interventions [37, 38]. We are drawing upon multiple study promotion strategies and potential sources of participants, including:

- Advertising on social media, search aggregators such as Google, and other web pages
- Databases/registers of potential participants (e.g. market research panels such as Join Us (www.joinus.org.au) and TrialFacts (www.trialfacts.com)
- Outreach to relevant clinics/clinicians seeking assistance with promoting the trial

Incentives

In recognition of their commitment to the trial, and to support retention and the provision of data on the primary outcome of interest, participants will be provided with up to AUD75 worth of grocery vouchers. The first $25 voucher will be available for providing baseline blood pressure measurements, with a second $25 voucher delivered after blood pressure measurements are provided at week 12. If a participant joins the process evaluation at the end of the trial they will receive an additional $25 shopping voucher. Participants will be offered the option to have these vouchers donated to a charity on their behalf. Participants will also keep the home blood pressure monitors provided.

Intervention and control

Intervention group

The intervention is based on a custom-developed web browser extension that modifies the user interface of a retailer's online store.

Participants allocated to the intervention group after randomisation experience the OGS web browser extension in the intervention mode. In this mode, when a participant selects a product the extension reads the on-screen product information and communicates with the Australian FoodSwitch database [39] (a large and regularly updated database of packaged products, discussed in greater detail below) to access product nutritional data and search for healthier alternatives in the same product category. Healthier products are defined as those with a better overall nutrient profile according to the Health Star Rating system (the government endorsed interpretive front-of-pack labelling system that summarises the overall healthiness of products based on their ingredient and nutrient composition [40]) *and* lower sodium content than the initial product selected by the participant.

The FoodSwitch database then returns information to the OGS extension, which displays an on-screen pop-up that highlights the sodium content of the original product. If any healthier products have been identified, the extension simultaneously searches the retailer's web store for the identified products to check if they are currently in stock at the relevant outlet. If available, the pop-up then immediately lists these similar but healthier and lower sodium alternatives in ascending order of sodium content, including links to allow participants to add these products to their shopping cart (**Figure 2**). During testing of the intervention, healthier and lower sodium options were available for 90.5% of products, indicating the feasibility of the intervention to support consumers in identifying healthier alternatives.

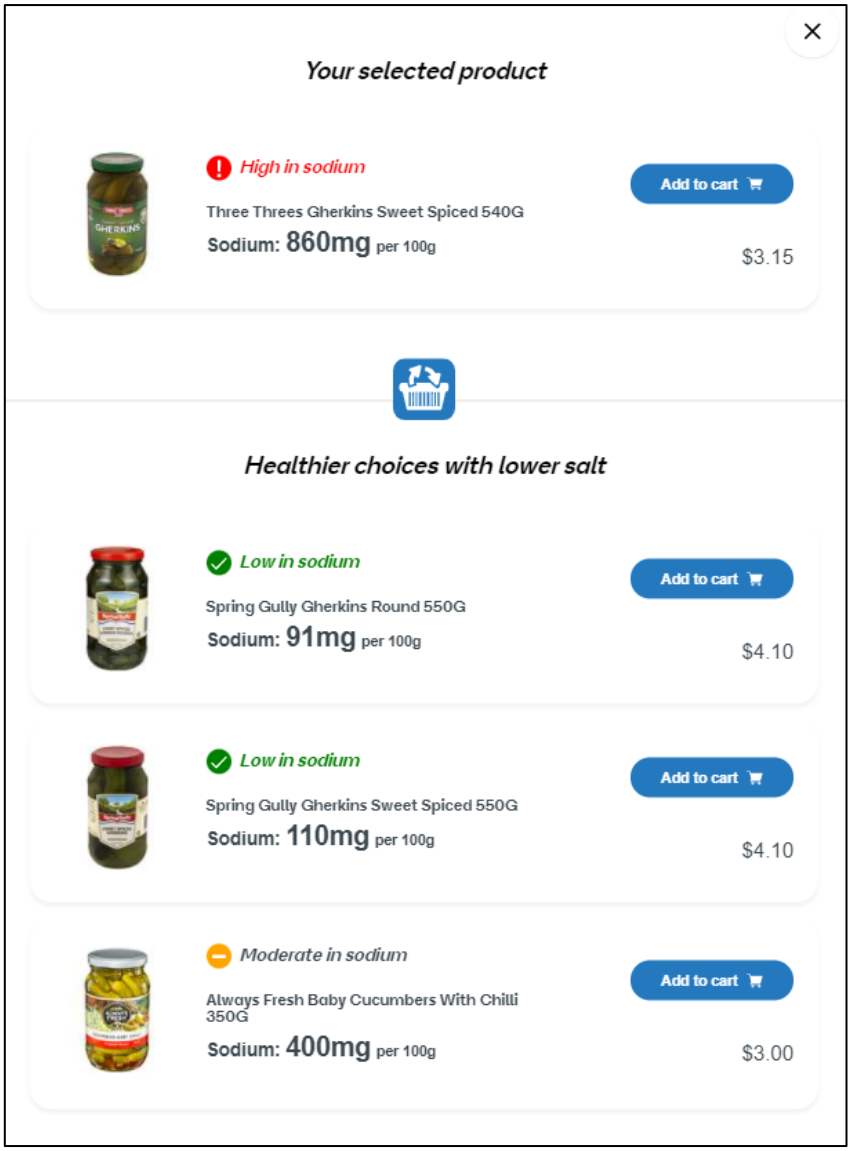

Figure 2. Example of OGS extension pop-up

Information on sodium content is colour-coded and interpreted to assist with decision-making. The FoodSwitch database assigns this according to the United Kingdom's traffic light front-of-pack labelling system [41] (**Table 1**). In Australia, a product is eligible to display a "low salt/sodium" claim if it contains ≤120 mg sodium per 100 g or mL [42], which aligns with the UK threshold for a green traffic light; however, no further guidance exists in the Australia New Zealand Food Standards Code to demarcate "moderate" and "high" content.

The UK system also includes product serving size in the calculation of some traffic light labels. As the sodium information highlighted on the OGS pop-up is presented solely on a per 100 g or mL basis, this additional step may present ostensibly contradictory outcomes where a product lower in sodium

per 100 g or mL may receive a worse label than a similar product with higher sodium content per 100 g or mL but a smaller serving size. Given the wide variation in (manufacturer-determined) serving sizes reported on packaged products in Australia [43-45], the additional serving size calculation in the UK traffic light system was not implemented for the OGS intervention to minimise the potential for confusion [46, 47].

Table 1. Interpretive sodium labels applied in OGS intervention, adapted from UK front-of-pack nutrition labelling system [41]

Label	Foods (per 100 g)	Beverages (per 100 mL)
Low in sodium	≤120mg sodium	≤120mg
Moderate in sodium	>120mg to ≤600mg sodium	>120mg to ≤300mg sodium
High in sodium	>600mg sodium	>300mg sodium

Should a high-sodium product be selected and all identified and available alternatives also contain high levels of sodium (e.g. salty snacks or processed meats), participants will be advised by the pop-up that the entire product category is high in sodium and that the purchase of any item within that category should be reconsidered.

Other display options are possible:

1) If no healthier alternatives are identified or available and the original product is low in sodium, the pop-up displays the original selection and a message that a low sodium option has already been selected.
2) If no healthier alternatives are identified or available and the original product contains a high or moderate level of sodium, the pop-up displays original selection and message that no healthier options are currently available.
3) If no matching product can be found in the FoodSwitch database no pop-up is displayed.

Figure 3 details the full interaction pathways between the OGS extension, the FoodSwitch database, and the user interface. The web browser extension has been optimised to ensure minimal time lag between a participant selecting a product and the pop-up being displayed (95% within 1 second,

maximum time-lag 2 seconds). It also automatically records product selections, alternatives displayed, any switches, and the full final list of groceries purchased.

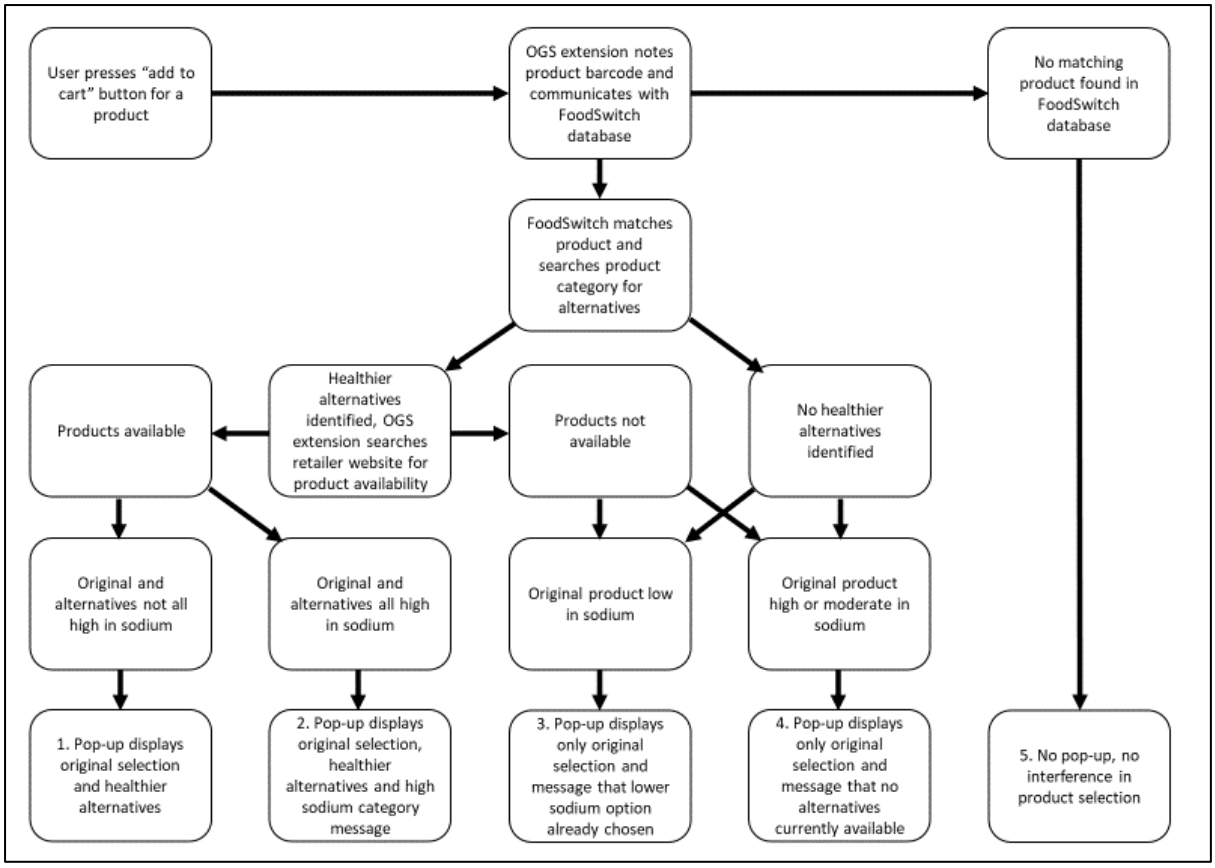

Figure 3. OGS extension (intervention mode) flow chart.

In addition, participants assigned to the intervention group receive fortnightly advice by email to complement the functions of the extension. These messages, reviewed by an Accredited Practising Dietitian with expertise in salt reduction efforts in Australia, provide key information on and encourage healthy behaviours that will assist in controlling blood pressure. They cover topics including the relationship between salt and sodium, the effect of sodium on blood pressure, interpreting food labels, reducing sodium intake in different settings, and other relevant lifestyle modifications.

Controls

Participants in the run-in period and those randomised to the control group experience the control mode of the OGS extension. In this mode, the extension records grocery purchases for the purposes of assessing eligibility during run-in and capturing data on secondary outcomes but does not modify the retailer's website or interfere with the usual shopping process in any other way. Participants will not be

provided with any additional educational material. All participants will receive the same incentives and regular reminders to support retention/follow-up.

Due to the nature of the intervention, participants randomised to the intervention group cannot be blinded. All participant-facing recruitment and general trial material has been designed to avoid referring to the mechanisms and intentions of the intervention to avoid potential contamination amongst the control group.

Product data

The Australian FoodSwitch database is a large food composition database which contains data for >90,000 individual packaged products. Detailed information on data collection and processing for FoodSwitch is available elsewhere [39].

We are drawing upon a subset of the FoodSwitch database for this study, with a bespoke web-scraping approach allowing automated and more frequent collection of data. This directly captures product data such as nutrition information, barcodes, prices and package size from product pages on retailers' online stores. The web-scraping is performed at least quarterly to ensure that changes to product ranges are captured. As product ranges and availability may differ across the country, the data collection also applies a range of metropolitan and regional postcodes drawn from each Australian state and territory as reference locations to ensure a more complete range of products is captured. All data are sent to a trained research team for further processing and both automated and manual quality checks.

Based on previous analyses of NielsenIQ Homescan data [36, 48], FoodSwitch contains ~90% of the total quantity of packaged food products typically purchased by Australian households. The quarterly updates improve this match rate, with an estimated 95% of the total volume of household purchases now available.

Study procedures

All data will be collected remotely with the goal of reducing participant burden, minimising loss to follow-up and missing data, and reducing trial costs. Remote data collection also allows for continued participant recruitment and engagement during COVID-19 outbreaks and associated restrictions. Table 2 provides an overview of trial activities and data collection.

Table 2. Study activities

Activity	Run-in period/baseline	Main trial period (week 6)	Main trial period (week 12)	Process evaluation (post-week 12)
Demographic survey	X			
Physical activity survey	X	X	X	
Medication use survey	X	X	X	
Online groceries purchases*	X	X	X	
Blood pressure measurements*	X	X	X	
Dietary recall questionnaire	X		X	
Urine sample	X		X	
Telephone interview				X

* Data are continuously collected, with prompts sent during run-in and at weeks 6 and 12.

Consent and screening

A detailed participant information sheet is provided to people expressing an interest in the study, with sufficient time provided thereafter for questions to be answered by study investigators. Informed consent is then obtained via an online form. Following this, potential participants complete an online screening survey to assess eligibility criteria related to intention to shop online, blood pressure, other medical conditions, household participation and shopping, and arm circumference.

Run-in period

Potential participants then progress to the run-in period (four to five weeks in duration) for additional eligibility assessment and collection of baseline data. Participants complete the demographic survey and baseline physical activity, weight and medications surveys. After this, they are provided with instructions to download and install the OGS extension, which will operate in control mode. In the run-in period, participants are asked to continue with their usual online grocery purchasing habits. Participants are also provided with a pathology request to assess sodium, creatinine, and potassium levels in a spot urine sample and a link to the dietary recall questionnaire.

If a participant completes at least two online shopping events within 4 weeks and is assessed as meeting the product volume and salt purchasing behaviour criteria based upon the data provided, a blood pressure monitor is sent to them. The receipt of blood pressure readings is taken as completion of run-in procedures. Neither the dietary recall survey nor urine sample (as secondary outcomes) are mandatory to advance to the main trial period.

Main trial period

Following successful completion of the run-in procedures, participants are randomised using a computer-generated sequence to either the control group or the intervention group in a 1:1 ratio, stratified by age (⩽50 years, >50 years), sex (male, female) and baseline blood pressure medication use (yes, no). The random allocation sequence was generated by a blinded statistician, independently of both support staff who recruit and manage participants and study investigators. Randomisation triggers the OGS extension to switch to the appropriate delivery mode (control or intervention).

The main trial period runs for 12 weeks, during which all participants are asked to continue with their usual frequency and volume of online shopping. Both groups are prompted to measure blood pressure at weeks 6 and 12, though the study allows participants to use the provided monitors as often as they like, which can also increase statistical power for both the primary and some secondary outcomes. Participants are also asked to complete physical activity, weight and medication surveys at weeks 6 and 12, provide a urine sample at week 12 and complete the dietary recall questionnaire at week 12. Participants are sent regular reminder emails/text messages, with additional follow up if required.

Process evaluation

A process evaluation will assess the acceptability and usability of the OGS intervention, factors influencing the adoption and effect of the intervention, and how the intervention was implemented and used in practice. Understanding these indicators is critical to inform improvements to uptake, the sustainability of the intervention, and scaling-up to different contexts.

This process evaluation adopts a mixed methods approach, following the guidance provided by the United Kingdom Medical Research Council on process evaluations of complex interventions [49]. Routinely-collected data (e.g. number of online shopping events, frequency of product switches) captured by the web browser extension will be triangulated with responses from in-depth interviews with participants at the end of the intervention.

Participants assigned to the intervention group remain eligible for the process evaluation regardless of whether they completed some, all or none of the data collection procedures during the main trial period. Only those who have withdrawn consent to participate will be excluded from the selection

process for this phase of the study. Initially, all eligible participants will be invited to participate in an effort to collect data that may inform updates to trial procedures (e.g. improved participant management), as well as to inductively develop further interview questions and initial codes for analyses. Following this, we will seek maximum variability sampling by recruiting participants assigned to the intervention group, stratified by age, sex, shopping activity (consistent online shopping, sporadic online shopping) and use of the OGS extension (no alternatives selected, alternatives selected).

Two trained researchers will conduct semi-structured interviews by telephone, following an interview guide designed specifically to capture participant's views on perceived usability, acceptability, benefits, and challenges of the OGS web browser extension, investigate whether the extension was used as intended, and explore external factors that influence implementation and outcomes. Product cost is likely to be a relevant consideration for participants [50], and the importance of prices in shaping preferences and purchases will also be explored qualitatively through the process evaluation.

Outcomes ascertainment

Primary outcome: mean systolic blood pressure

Participants are provided with an iHealth® FEEL BP5 or NEO BP5S Wireless Blood Pressure Monitor. This model has been validated against the European Society of Hypertension International Protocol for assessment of blood pressure in adults [51], is listed as a "preferred device" by STRIDE BP [52] and is approved for use in Australia by the Therapeutic Goods Administration. This device allows participants to take their own blood pressure measurements at home, with readings both displayed to participants and automatically sent electronically to study investigators.

Participants receive detailed information on how to set up and use the monitor, including an on-demand video walkthrough. They are also guided in best practice for home blood pressure monitoring [53]. During the run-in period and at weeks 6 and 12 of the main trial period, participants are asked to take their blood pressure measurements two times (one minute apart) twice a day (morning and evening) for three consecutive days. Should individual abnormal readings (>180 or <80 mmHg systolic blood pressure or >110 or < 50 mmHg diastolic blood pressure [53]) be returned, participants are contacted to evaluate their clinical condition and confirm the appropriate use of the monitor.

The provision of home blood pressure monitors to participants may lead to behavioural changes and a blood pressure-lowering effect independent of the intervention. However, as the monitors are provided to both the intervention and control groups we expect that any such changes will be comparable between the randomised groups, with any effect of the OGS intervention itself additive to the effect of the home blood pressure monitoring [54].

Secondary outcomes:

Secondary outcomes include:

1) Mean difference in diastolic blood pressure between the intervention and control groups at 12 weeks. Data collected as per primary outcome of interest.
2) Mean difference in the change of spot urinary sodium excretion from baseline to 12 weeks, expressed as grams of salt per day. Pathology testing forms are sent to participants to provide a spot urine sample at their nearest Approved Pathology Collection Centre, with results returned directly to study investigators. The concentration of sodium, creatinine, and potassium in these samples will be determined using standard laboratory methods. Standard equations for spot urine samples will be used to estimate differences in mean daily salt intake between groups and over time [55].
3) Mean difference in the change of spot urinary sodium:potassium ratio from baseline to 12 weeks. Sodium:potassium ratio has shown a greater association with blood pressure amongst people with hypertension than sodium or potassium alone [56]. Data collected as above.
4) Mean difference in the change of average and total level of sodium purchased from foods and beverages from baseline to 12 weeks, expressed as mg/kJ. We will assess the impact of the intervention on purchases of sodium through product order data automatically captured by the OGS extension, matched to the FoodSwitch database.
5) Mean change in self-reported diet from baseline to 12 weeks, assessed using a Dietary Approaches to Stop Hypertension (DASH) diet scoring method [57]. A single 24-hour diet recall administered at baseline and follow-up is the recommended method for assessment of the effect of a dietary intervention [58]. As such, to evaluate changes in food and nutrient consumption in our study, at baseline and week 12 a 24-hour dietary recall online questionnaire is administered

using the Australian Automated Self-Administered (ASA) 24-hour Dietary Assessment Tool (ASA24-Australia), which has been developed and validated for use in Australia [59]. Dietary data collected using this method are comparable to interviewer-administered 24-hour recalls [60, 61].

Exploratory outcomes:

Exploratory outcomes include: 1) rate of hypertension control (defined as systolic blood pressure <130 mmHg and diastolic blood pressure <80 mmHg) at 12 weeks, with data collected as per primary analysis; and 2) change in blood pressure-lowering medication use at 12 weeks, as reported by participants via secure online forms.

Safety

Given the very low likelihood that the OGS intervention will cause or contribute to any adverse outcomes, a full data and safety monitoring committee has been deemed unnecessary by the OGS trial Steering Committee. Instead, a practicing cardiologist has been appointed as an independent safety monitor.

As noted above, in the first instance participants returning individual abnormal blood pressure readings will be contacted to confirm that the appropriate processes for set-up and measurement at home have been followed. Should further abnormal results be returned, the independent safety monitor will review participant data and advise next steps, including referral to their usual general practitioner. Abnormal results from urine samples will also be reviewed and follow-up actions advised by the safety monitor.

Participants are also asked to report serious adverse events, including, but not limited to, life-threatening events, intercurrent or prolongation of hospitalisation, persistent or significant disability or incapacity, congenital anomaly or birth defect, and presentation for acute medical care. As we have information on participants' emergency contacts we are also able to monitor the (unlikely) outcome of death during the study period.

Sample size

We plan to randomise a total of 1,966 participants. Assuming up to 10% dropout by the 12-week follow-up time point, we anticipate an analytic sample size of 1,768 participants (1:1 allocation). This dropout rate is realistic yet conservative, given a prior SaltSwitch pilot study had no dropouts over a 4-

week period (n = 66) [62]. For primary outcome analyses, the target sample size will provide 80% power to detect a 2 mmHg or greater difference in systolic blood pressure between the intervention and comparator arms, assuming a two-sided 5% level of significance and a 15 mmHg standard deviation in systolic blood pressure in both arms. The magnitude of estimated effect is based on a systematic review and meta-analysis of the dose-response effect of salt reduction on blood pressure [34], with a 1g reduction in daily salt intake associated with a 2 mmHg reduction in systolic blood pressure in hypertensive patients; this would represent an 11.3% reduction in the usual daily salt intake for people with hypertension in Australia [63]. Though we plan to assess primary and major secondary outcomes via mixed models, sample size calculations were based on an independent two-sample t-test, which is considered conservative.

The process evaluation phase of the study will involve participants from the intervention group only. The final sample size will be based on when saturation is reached regarding opinions on the feasibility, acceptability, and implementation fidelity of the OGS intervention, however is unlikely to exceed 50 participants.

Data management and analysis

The primary analysis will be performed on an intention-to-treat principle (all-randomised, all-analysed). A per-protocol analysis will also be conducted to either exclude non-compliant participants or include non-compliant participants from the intervention group in the control group.

To assess the primary outcome of difference in mean systolic blood pressure between the intervention and control groups at 12 weeks, we will use mixed models with a random effect at the participant level to account for the repeat blood pressure measurements per participant over time. Fixed effect covariates will include: group (intervention, control), time point, interaction between group and time point, and baseline systolic blood pressure. We will also evaluate the relevance of including an interaction between baseline systolic blood pressure and time point. Sensitivity analyses including additional covariates may be conducted if there is a substantial imbalance in covariates between the randomised groups.

Analysis of diastolic blood pressure will follow the same statistical approaches as for systolic blood pressure. For other secondary and exploratory outcomes, Pearson's Chi-squared tests or Fisher's exact

methods will be used to evaluate the differences between randomised groups. Base case analyses will be based on complete case records, but we will assess the possibility of using multiple imputation (for outcomes and/or covariates) according to missing data mechanisms/patterns.

A two-sided alpha=0.05 will be used to indicate statistical significance, without adjustment for multiple testing. Subgroup analyses will be conducted for age (⩽50 years, >50 years), sex (male, female), baseline blood pressure medication use (yes, no), household income (≤$41,599, $42,600-$103,999, ≥$104,000) and education (primary, secondary, trade/vocational, university/postgraduate).

Interview data will be audiotaped, transcribed, and anonymised by an independent company, then coded and analysed using a combination of inductive and deductive content analysis with NVivo software.

Data monitoring and cleaning will be performed concurrently with participant recruitment. By conducting real-time monitoring, we will ensure high-quality and timely completion of data collection, data cleaning, and database lock. All data analysts and study investigators will be blinded to allocation.

DISCUSSION

Unhealthy diets are major drivers of disease burden globally, with excess salt intake a leading dietary risk factor for cardiovascular diseases. Individual-based education and clinical counselling to influence overall dietary patterns has limited effectiveness, is resource intensive, and has limited reach [63, 64]. New scalable strategies which address unhealthy food environments and support informed, easy decision-making are required to help improve population diets.

Online grocery shopping is increasingly common and offers an innovative platform for nutritional intervention. The setting offers opportunities for interventions based on interpretive nutrition labelling and nudging consumers to change products. Such an approach should be familiar to consumers since retailers already regularly present and promote a wide range of alternative products when shopping online, and product switches are highly feasible and often easier online than in-store since it can be done at a click of a button. However, the effectiveness of such interventions in real-world online supermarkets is largely untested.

The OGS web browser extension is a simple online platform that can highlight relevant product information and facilitate immediate product comparisons. Several elements of the display (colour coding, interpretive labelling, warnings) have previously been found to help consumers improve the healthiness of food purchases [65]. In addition, an intervention at the point of product selection [24], allowing for easy switching of products, may prove particularly effective. The potential of the intervention is augmented through the additional educational/behavioural advice provided, even in the short-term [66]; however, a limitation to this aspect of the intervention, which primarily aims to improve knowledge around the relationships between sodium/salt, cardiovascular disease and supermarket purchases, is that it does not attempt to address many broader aspects of food literacy.

This study will be the first large-scale RCT to examine the effect of an online grocery shopping intervention on blood pressure, mediated through reduced dietary salt consumption of foods purchased. The personalised approach caters to individual preferences, with the aim of encouraging sustainable uptake and engagement. Additional potential benefits of the intervention include ease of use, safety and low cost.

The potential equity impacts of the OGS intervention are currently uncertain. The extent to which interventions that aim to facilitate healthier behaviours through improved structural conditions while still allowing for individual agency affect equity is contested [50, 67, 68]. While our intervention addresses some barriers to achieving healthier dietary patterns (e.g. low health/nutrition literacy, time and physical constraints), it does not consider others (e.g. price) which may be influential in determining the effectiveness of the intervention amongst different groups [50]. For people with lower health or nutrition literacy the intervention supports capacity to understand and use sodium information through the clear, simple and immediate provision of sodium information and identification of healthier alternative products. In addition, one recent study of the effect of nudges on purchases in a real-world online supermarket found that the provision of additional information on products by itself led to more healthy purchases amongst people living in more socioeconomically disadvantaged areas, without a considerable impact on expenditure [69].

However, the uptake of online grocery shopping by different groups and the relative cost of similar but lower sodium products in Australia are unknown. We will explore the equity impacts of this intervention throughout the trial, while participant-level factors affecting implementation and outcomes will be investigated through the process evaluation.

This trial builds upon a 2017 pilot study evaluating the effect of an in-store SaltSwitch intervention in New Zealand [62, 70], which saw a reduction of ~0.7 g of salt per person per day over the four-week trial period. Findings also suggested a trend towards a blood pressure and urinary sodium lowering effect, although the result was not statistically significant as the trial was not powered to detect an effect on these secondary outcomes. Purchase and barcode scanning data also indicated high levels of participant engagement. This preliminary work to establish the feasibility of the SaltSwitch intervention informs the current study. The move to an online setting is driven not only by the growth of online shopping but also by feedback from participants that in-store switches can be challenging where alternative products are not readily available or presented.

The SaltSwitch pilot demonstrated the potential of the intervention [62, 70], while other studies have established that the mechanism for the intervention is feasible [37] and that trials can be successfully administered remotely [38, 71]. Our study design will leverage the scale and growth of online grocery

shopping for rapid recruitment and will use modern tools for self-collection/self-assessment to increase trial efficiency and decrease trial costs.

The findings of our trial will provide high-quality evidence on the clinical implications of a new digital health intervention that could be used therapeutically by patients with hypertension based upon, or even independent from, physician and allied health care worker prescription. If effective, then the intervention will be readily scalable as it simply requires a patient to download the OGS web browser extension, meaning it could be efficiently delivered to a large number of people as a stand-alone or complementary tool.

The OGS intervention therefore has the potential to have a modest but important effect on blood pressure control and prevention of cardiovascular disease for people with hypertension. Recruitment for the SaltSwitch OGS trial began mid-2021 and is expected to continue until mid-2023; it is currently anticipated that results will be available by early 2024.

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CNM was lead investigator of a study to test a shelf placement intervention on sales of healthier and less healthy products in supermarket stores. The study was funded by the Health Research Council of New Zealand. The supermarket partner did not provide any monetary funding for the study but did provide in-kind support (in the form of staff time for co-design, planogram development, extraction of sales data, in-store shelf alterations, interviews and access to six stores for product audits and shopper surveys). The supermarket partner had no role in the data collection and analysis or decision to publish. MDH has pending patents for combination therapy for the treatment of heart failure. AJC and CNM are academic partners on a healthy supermarket intervention trial that includes Australian local government and supermarket retail (IGA) collaborators, with funding from the NHMRC, the Victorian Health Promotion Foundation (VicHealth) and Deakin University. BN, through The George Institute for Global Health, has received research grants and funding for commissioned research from multiple government and industry sources involved in delivering the food supply. The George Institute for Global Health has a patent, license, and has received investment funding with intent to commercialise fixed-dose combination therapy through its social enterprise business, George Medicines.

Data sharing statement

Deidentified participant data that underlie any results reported by study investigators, as well as study documents such as data dictionaries, information and consent forms, case report forms and statistical code, may be shared after contacting study investigators, subject to relevant policies of the host organisation.

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