

## TITLE PAGE

### **A salt-reduction smartphone app supports lower-salt food purchases for people with cardiovascular disease: findings from the SaltSwitch randomised controlled trial**

Helen Eyles<sup>a,b</sup>, Rebecca McLean<sup>a</sup>, Bruce Neal<sup>c</sup>, Yannan Jiang<sup>a</sup>, Robert N Doughty<sup>d,e</sup>, Cliona Ni Mhurchu<sup>a</sup>

<sup>a</sup>National Institute for Health Innovation, University of Auckland, Private Bag 92019, Auckland 1142, New Zealand. Phone: +64 9 923 4658 Fax: +64 9 373 1710 Email: [h.eyles@auckland.ac.nz](mailto:h.eyles@auckland.ac.nz) (corresponding author and requests for reprints)

<sup>b</sup>Department of Epidemiology and Biostatistics, University of Auckland, Private Bag 92019, Auckland 1142, New Zealand

<sup>c</sup>George Institute for Global Health, University of Sydney, PO Box M201, 1 King Street, Newtown, Sydney, NSW 2042, Australia, Imperial College London, UK.

<sup>d</sup>Dept of Medicine, University of Auckland, Private Bag 92019, Auckland 1142, New Zealand

<sup>e</sup>Greenlane Cardiovascular Service, Auckland District Health Board, Auckland, New Zealand

**Previous presentations:** The study design and methods for this trial were presented at the International Society for Behavioral Nutrition and Physical Activity Annual Meeting in Edinburgh, Scotland, June 2015 and the Australasian Epidemiological Association conference in Auckland, New Zealand, October 2014

**Sources of support:** This work was supported by a Heart Foundation of New Zealand project grant (grant number 1560) and The University of Auckland School of Population Health Performance Based Research Funds. HE was funded by a New Zealand Heart Foundation Post-graduate Scholarship at the time of the trial, and RND by the Heart Foundation Chair of Heart Health.

**Word count:** 4,849 **Article type:** Full original research paper

## **ABSTRACT**

**Background:** SaltSwitch is an innovative smartphone application (app) that enables shoppers to scan the barcode of a packaged food and receive an immediate, interpretive, traffic light nutrition label on the screen, along with suggestions for lower-salt alternatives. Our aim was to determine the effectiveness of SaltSwitch to support people with cardiovascular disease (CVD) to make lower-salt food choices.

**Design:** Six-week, two-arm, parallel, randomised controlled trial in Auckland, New Zealand.

**Methods:** Sixty-six adults with diagnosed CVD (mean (SD) age, 64 (7) years) were randomised in a 1:1 ratio to either the SaltSwitch smartphone app or control (usual care). The primary outcome was the salt content of household packaged food purchases during the four-week intervention (g/MJ). Secondary outcomes were the saturated fat content (g/MJ), energy content (kJ/kg), and expenditure (\$) of household food purchases; systolic BP (mmHg), urinary sodium (mg), and use and acceptability of the SaltSwitch app.

**Results:** Thirty-three participants with CVD were allocated to the SaltSwitch intervention, and 33 to the control group. A significant reduction in mean household purchases of salt was observed (mean difference (95% confidence interval), -0.30 (-0.58 to -0.03) g/MJ), equating to a reduction of ~0.7 g of salt per person per day during the four-week intervention phase. There were no significant between-group differences in any secondary outcomes (all  $p > 0.05$ ).

**Conclusions:** The SaltSwitch smartphone app is effective in supporting people with CVD to make lower-salt food purchases. A larger trial with longer follow-up is warranted to determine effects on BP.

**Abstract word count:** 244

**Trial registration:** Australian New Zealand Clinical Trials Registry

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=365784&isReview=true>

ACTRN12614000206628

**Key words:** Cardiovascular diseases; Heart diseases; Salt; Sodium; Cellular phone; Smartphone; Telemedicine; Self-care; Secondary prevention

## **INTRODUCTION**

Effective interventions to reduce the incidence of CVD events are vital, especially for those who have suffered an event in the past(1). People with existing CVD are advised to eat a lower salt diet to reduce and control blood pressure (BP)(2, 3), yet global and national salt intakes are far above recommendations in most countries(4), and many find it hard to identify lower salt food choices(5). Cardiac rehabilitation programmes offer support to achieve lower salt diets, but uptake in most countries is poor, largely due to access issues(6).

Mobile technology may offer a potential solution. A growing body of evidence indicates mobile technology can support behaviour change(7, 8), yet robust evidence for the effectiveness of smartphone interventions is lacking(9). SaltSwitch is a feature of the free FoodSwitch smartphone app(10) which enables users to scan the barcode of a packaged food with their smartphone camera to receive an immediate, interpretive traffic light nutrition label on the screen, along with a list of lower salt alternatives to 'switch' to (Figure 1).

The primary aim of this study was to determine the short-term effectiveness of the SaltSwitch smartphone app in supporting people with CVD to make lower-salt food choices. Secondary aims were to determine the effectiveness of SaltSwitch in reducing the saturated fat content, energy content, and expenditure of household food purchases. Systolic BP (mmHg), urinary sodium (mg), and use and acceptability of the SaltSwitch app were also assessed.

## **METHODS**

### **Study design**

The SaltSwitch trial was a six-week, two-arm, parallel, randomized controlled trial. A two-week baseline data collection phase was followed by a four-week intervention phase.

The trial was conducted between June 2014 and July 2015 in Auckland, New Zealand. The study protocol was approved by the University of Auckland Human Ethics Committee (reference 010998) and published in 2014(11). All participants provided written, informed consent.

## **Participants**

The unit of randomisation for the trial was the person with CVD. However, the primary outcome was household food purchases. Therefore, where the person with CVD did not complete most of the grocery shopping, the main household shopper was also enrolled. The participant with CVD could be the same, or a different person to the main household shopper.

Participants with diagnosed CVD were aged 40 years or over. Cardiovascular disease was defined as having a diagnosed history of prior acute coronary syndrome [ACS], revascularization, or exertion angina. Participants with CVD could not have suffered a cardiac event (hospitalisation for ACS, coronary revascularization procedure, or stroke) in the past three months, been diagnosed with heart failure or severe valve disease, be on a physician supervised diet or unwilling to make dietary changes, or taking any medication that could lead to hyponatraemia or fluid retention (frusemide, regular non-steroidal anti-inflammatories (excluding aspirin), or regular prednisone use).

Main household shoppers had to own or have access to a smartphone (iPhone or Android) but could not be current users of the FoodSwitch smartphone app or be planning to use it during the following six weeks. Shoppers had to shop at the supermarket for household food at least once per week spending \$25 or more per household member, and return at least two till receipts for household food over the two-week baseline period. Where the main household shopper was different to the participant with CVD, they had to be at least 18 years of age. All participants were required to be resident at their usual address in Auckland, New Zealand for at least 39 of the 42 days of the six-week trial period.

## **Recruitment**

Recruitment took place over 11 months starting in June 2014. Recruitment methods and processes have been described in detail previously(11). Strategies included: advertisements placed in local supermarkets, hospital waiting rooms, healthcare organization newsletters, and Facebook; articles in local newspapers; invitations to participants in previous studies at the University of Auckland and members of a market research panel; and presentations at cardiac rehabilitation clinics.

## **Intervention**

The intervention group received the SaltSwitch smartphone app for four weeks. SaltSwitch enables users to make lower salt food choices by scanning the barcode of a packaged food using their smartphone camera to receive an immediate interpretive, traffic light nutrition label on screen, along with a list of lower-salt alternatives to 'switch' to (Figure 1).

Information regarding the algorithms used to assign traffic light labels and healthier alternatives in the SaltSwitch app has been reported previously(11) and is available on the FoodSwitch website(12). The SaltSwitch app is underpinned by a database of New Zealand packaged food and beverage products (~13,000 barcodes/unique products were included during the trial period)(12). The SaltSwitch app was not available to download from app stores in New Zealand prior to or during the study period.

Participants in the intervention group were emailed a link to download the SaltSwitch app to their smartphone and were provided with a telephone tutorial. Weekly reminder text messages were sent to intervention participants to encourage them to use the app when shopping for household food and beverages.

## **Control**

Those randomised to the control group continued to shop as normal and were able to access usual care cardiac rehabilitation services for people with CVD in New Zealand. On completion of the trial, control participants were provided with information about the FoodSwitch app and given the option to download it.

## **Outcomes and data collection**

### Study outcomes

The primary outcome was the salt content of household food purchases (g/MJ) during the 4-week intervention. Secondary outcomes were the saturated fat content (g/MJ), energy content (kJ/kg), and expenditure (\$) of household food purchases during the intervention. Systolic BP (mmHg), urinary sodium (mg), and use and acceptability of the SaltSwitch app were also assessed at the end of intervention. Post-hoc analyses were undertaken on the total fat (g/MJ), protein (g/MJ), and sugar content (g/MJ) of household food purchases, and purchases of key food groups known to be high in salt (Table 1).

## Data collection and outcome measurement

Detailed information on data collection and outcome measurements has been reported previously(11). Data collection took place over 13 months starting in June 2014. Briefly, till receipts for all household food purchased during the trial period were returned to researchers via the post in pre-paid envelopes, or at clinic visits. Two on-line questionnaires (baseline and end of intervention) were completed either by clicking on a link sent in an email, or during clinic visits. Participants received a \$NZ 20 petrol voucher following successful completion of each questionnaire. Clinical measures were collected at two visits (baseline and end of study) to The University of Auckland. Participants provided written, informed consent, and height, weight, and BP were measured. A urine sample for sodium analyses was also collected.

The primary outcome (salt content of household food purchases) and secondary outcomes related to shopping purchases (saturated fat content, energy content, and expenditure on food) were assessed by matching foods recorded on supermarket till receipts to a brand-specific food composition database from the SaltSwitch app (see Intervention section). Data on use and acceptability of the SaltSwitch app were collected via the on-line questionnaires, as previously described(11). Data on serious adverse events was collected at six weeks, regardless of potential causal relationship to the intervention.

## **Randomisation and blinding**

Registered participants were excluded from the study prior to randomisation if they did not spend at least \$25/household member per week on groceries/food, or returned fewer than two till receipts over the run-in (baseline) trial period.

Eligible participants were randomized at the end of baseline (week two) in a 1:1 ratio to receive either the SaltSwitch smartphone app or control (usual care). Computer generated randomisation lists were created by the study statistician (YJ) and sealed in individual opaque envelopes not accessible by the statistician or Investigators. Randomisation was stratified by the ethnic (Māori or non-Māori) and age group (40 to 59 years and 60+ years) of the participant with CVD, using variable block sizes of two and four. Due to the nature of the intervention, it was not possible to blind participants or outcome assessors.

## **Sample size and statistical analysis**

### Sample size

A total sample size of 300 participants with CVD (150 per group) was estimated to provide 80% power at 5% level of significance (two-sided) to detect a treatment difference of 0.07 g/MJ (~10%) of salt in household food purchases, between the two groups at the end of intervention, assuming a standard deviation of 0.22 g/MJ. The assumed difference was based on intervention effects achieved in the Dietary Approaches to Stop Hypertension (DASH) study(13). Further information is available in the study protocol(11).

### Statistical analysis

Statistical analyses were performed in SAS version 9.4 (SAS Institute Inc. Cary NC, USA). All statistical tests were two-sided at a 5% significance level. Baseline characteristics were summarised using descriptive statistics. Continuous variables were presented as mean and standard deviation (SD). Categorical variables were presented as frequencies and percentages.

Evaluation of the treatment effect was performed using the intention-to-treat principle with all participants analysed according to the group they were randomised to, regardless of whether they received the intervention. Missing outcome data were not imputed as it was difficult to make assumptions about the missingness of supermarket till receipt data. Analysis of covariance (ANCOVA) regression models were used to evaluate the main treatment effect on the primary outcome during intervention, adjusting for baseline, age and sex. Model-adjusted means and their difference between the two treatment groups were estimated and tested. A similar approach was used for other secondary outcomes measured at the end of the intervention period.

## **RESULTS**

### **Recruitment**

Four hundred and sixty three participants registered for the study, of which 205 (44%) did not meet inclusion criteria, 149 (32%) declined to participate on hearing more about the study, and 43 (9%) were excluded for other reasons, such as failing to complete baseline

questionnaires (Figure 2). The main reason participants did not meet the inclusion criteria is that they did not have diagnosed CVD (most had high BP only), and/or own a smartphone. The main reason eligible participants declined to participate was lack of interest in taking part in a smartphone intervention. A total of 66 participants with diagnosed CVD were included in the trial, of which 33 were randomised to the SaltSwitch app intervention group and 33 to the control group. The trial was stopped before the projected 300 participants with CVD were recruited due to recruitment rates being much slower than predicted, and funding for extending the trial further could not be obtained.

### **Baseline characteristics of households and participants**

At baseline there were 66 participants with diagnosed CVD (33 in each group) and 12 participants who were enrolled in the study as main household shoppers only (seven in the control group and five in the intervention group).

Participants with CVD had a mean (SD) age of 64 (7) years, were predominantly male (n=55; 83%), had a mean BMI of 29 (4) kg/m<sup>2</sup>, mean systolic BP of 132 (15) mmHg, and a mean 24-hour urinary sodium excretion content of 3,465 (828) mg. The majority were New Zealand European (n=55; 88%). Characteristics of participants with CVD were similar between groups (Table 1).

At the household level, most had an annual income of >\$NZ 50,000 (n= 48; 68% of those who answered), lower than the median household income in New Zealand (\$73,500 in 2013(14)). The average household size was 2 (1) people. Fourteen of the 66 households (21%) had at least one member with diabetes, and 27 (41%) had members with other medical conditions affecting the type of household food purchased. Similar numbers of shoppers used nutrition labels often or every time when shopping for food (n=31; 47%) versus those who only occasionally or never used nutrition labels (n=35; 53%). The only major difference observed between groups was for baseline household food expenditure (\$NZ162 per week in the control group and \$102 per week in the SaltSwitch intervention group; Table 1).

### **Till receipt return, product purchases and household expenditure**

Overall, participants returned on average 4.3 till receipts during the two-week baseline period and 7.2 receipts during the four week follow up period. The average till receipt return rate was lower in the SaltSwitch intervention compared with the control group at both baseline and intervention (3.8 and 6.4, versus 4.9 and 8.0, respectively). The total number of products purchased over the baseline period was also lower in the SaltSwitch group compared with the control group at baseline (n=47 (27) and 72 (40), respectively) and



intervention (n=90 (51) and 115 (64), respectively). Of the 64 participants who completed the follow up survey, the majority reported returning all or most till receipts for household food or beverages purchased during the four week intervention period (n= 31/32 and 29/32 for the intervention and control groups, respectively).

Participants spent on average \$129.90 (SD, \$84.50) per week on household groceries during the baseline period and \$119.40 (78.2) per week during follow-up, for a mean (SD) household size of 2 (1). Participants in the control group spent more per week than those in the intervention group (mean (SD); \$162 (94) and \$102 (65)).

### **Till receipt matching**

Overall, 1,964 food and beverage products (units) were purchased over the baseline period and 3,807 over the intervention period (1,234 and 2,336 unique barcodes, respectively). Ninety percent (5,225/5,771) of total purchased products on till receipts could be matched with an identical product in the SaltSwitch app food and nutrient database. The majority of the remaining 10% (n=546) belonged to the following five food groups: non-alcoholic beverages (n=135), alcohol (n=62), coffee and tea (n=35), meat and meat products (n=34), and fruit and vegetables (n=31).

### **Serious adverse events**

One serious adverse event was reported during the study period but was deemed unrelated to the intervention (onset of chest discomfort while exercising resulting in angioplasty).

### **Primary end-point salt**

Participants using the SaltSwitch smartphone app purchased significantly less salt (adjusted mean (95% CI); 0.7 (0.52 to 0.88) g/MJ) over the four-week intervention period compared with those assigned to control (adjusted mean (95% CI); 1.00 (0.80 to 1.20) g/MJ; group difference (95% CI) -0.30 (-0.58 to -0.03) g/MJ, p=0.03) (Table 2).

### **Other nutrient outcomes**

There were no significant differences between intervention and control groups for other nutrient outcomes assessed i.e. energy density, total fat, saturated fat, protein, or total sugar (Table 2).

### **Systolic blood pressure**

Systolic BP at follow up in the intervention group was mean (95% CI) 129 (125 to 133) mmHg. The corresponding value for participants in the control group was 131 (127 to 135)

mmHg. The mean difference (95% CI) between groups was not statistically significant (-1.7 (-7.4 to 3.9) mmHg;  $p=0.54$ ).

### **Urinary sodium**

Urinary sodium excretion at follow up was mean (95% CI) 3,534 (3,347 to 3,720) mg/day. The corresponding value in the control group was 3,545 (3,358 to 3,731) mg/day. The mean difference (95% CI) between groups was not significant (-10.6 (-278 to 256) mg/day;  $p=0.94$ ).

### **Household food expenditure**

Average weekly household food expenditure (adjusted) in the intervention group was mean (95% CI) \$NZ 117.93 (95.49 to 140.37). Corresponding expenditure for the control group was \$NZ 130.01 (105.38 to 154.65). The mean (95%) difference in expenditure between groups was not significant (\$NZ -12.08 (-46.98 to 22.82);  $p=0.49$ ) (Table 2).

### **Use and acceptability of the SaltSwitch smartphone app**

Of the 30 participants who responded to the question, 87% ( $n=26$ ) reported using the SaltSwitch app while shopping for household food during the intervention period. Usage was similar across each of the four weeks, with the majority of shoppers reporting that they used the app all or most times they shopped (percentages for each of the four weeks were: 60%, 75%, 60%, 70%, respectively).

Of the 24 participants who responded to the question, 18 (75%) reported finding the SaltSwitch app very easy to use, and a further four found it somewhat easy to use. One shopper found the app neither difficult nor easy to use, and the remaining shopper found it difficult. However, all 24 shoppers found that the SaltSwitch smartphone app was a good way to help shoppers to make lower salt food purchases.

## **DISCUSSION**

### **Principal findings**

This study has shown that the SaltSwitch app had a significant impact on reducing household purchases of salt from packaged foods. The SaltSwitch app was well-used and accepted by the intervention group.

## **The meaning of study findings**

Based on an average of 131 MJ of total energy purchased for each household over the trial period, the 0.3 g/MJ reduction in salt purchases equates to a reduction of ~0.7g per person per day. This is ~30% of the reduction reported in the DASH study (2.3 g salt per day)(13). However, the absolute drop in salt purchases observed in the SaltSwitch trial would likely have been larger should all participants have returned all till receipts. Overall, missing till receipts resulted in (reported) total energy purchases being much lower than expected, especially over the intervention period i.e. 2,335kJ per person per day, or 25% of expected (excluding food waste) when compared with the median energy intake in the most recent 2008/09 New Zealand Adult Nutrition Survey (9,158kJ for men aged 51 to 70 years)(15). Although till receipts are not a perfect proxy for dietary intakes(16, 17), these estimations suggest the magnitude of salt reduction seen in the SaltSwitch trial is likely underestimated.

Compared with the DASH study, we also observed a similar sized but non-significant reduction in BP (mean difference -1.7 mmHg,  $p=0.54$  compared with 2.1 mmHg,  $p<0.001$ , respectively). The current study was not powered for this outcome, and it is further removed from the intervention, which aimed to reduce household purchases of salt. Nonetheless, the results indicate a larger study to determine the effects of SaltSwitch on BP may be warranted.

## **Strengths and weaknesses of the study**

The main strengths of this study include that it is one of few randomised controlled trials of a smartphone app or mHealth dietary intervention in a clinical population(7, 8). The trial was conducted in a real world setting with high follow-up rates and objective outcome measures. In addition, the match rate between till receipt purchases and food composition information was high (90%), resulting in the majority of available food purchasing data being used to assess effects of the intervention on the primary outcome.

Nonetheless, there were limitations, including the fact that recruitment rates were not met and the study was underpowered based on the initial power calculation. However, the large effect size observed (0.3g/MJ compared with 0.07g/MJ in the sample size calculation) means it is unlikely the result is a false positive.

In addition, a proportion of till receipt data were missing, with ~25% of participants reporting that they did not return all receipts for household food and beverages purchased during the intervention period. Further, the till receipt return rates and product purchase numbers were lower in the SaltSwitch group compared with the intervention group. The distribution of expenditure on household food was much wider in the control group and included one

participant with particularly high expenditure (\$421 at baseline and \$462 during intervention). However, one household in the control group also failed to return any till receipts. Nonetheless, the relative outcome measures (g/MJ of salt rather than total salt purchased) mean the groups are still comparable and the missing and unequal till receipt return rates were unlikely to significantly impacted results.

Finally, generalisability may be limited because the initial response rate was low, with 149/463 (32%) of eligible participants declining to participate. The main reason was lack of interest in using a smartphone app. This self-selection bias is a common problem with intervention studies and could reflect the older age of this population group. However, the RCT study design and objective outcome measures mean internal validity for the trial was high, and the study findings robust.

### **Comparison with similar studies**

Limited research is available on the efficacy of smartphone interventions to improve self-management of cardiovascular outcomes(18). However, the modest findings of the SaltSwitch trial align with results of recent systematic literature reviews in the area. A 2015 review of the impact of mHealth for chronic disease management (n=107 studies for patients with diabetes, CVD, and lung diseases) found high patient acceptability, usability, and feasibility for mHealth interventions, but only 16/27 included trials (39%) showed significant between-group improvements(19). Another 2015 review (n=51 trials) of the potential benefit of digital health interventions on CVD outcomes and risk factors found digital interventions significantly reduced CVD outcomes, body weight, and BMI, but not BP (compared with usual care)(20). A protocol has been published to undertake a formal systematic review and meta-analysis of text-message based interventions for the prevention of CVD(21); as the field of smartphone trials in CVD prevention and treatment grows, such a review will be important to determine the effects of smartphone apps.

### **Implications for consumers, clinicians, and policy makers**

The findings of the SaltSwitch trial suggest that the app has potential to help people with CVD make lower-salt food purchases. The SaltSwitch app is currently available to download in several countries (New Zealand, Australia, and the United Kingdom), and could be used as a tool for consumers and clinicians globally, the latter of whom could include the app in traditional CVD rehabilitation education sessions as a secondary prevention measure. The proportion of the global adult population with high BP is much higher than the proportion with CVD(22) and is likely to be younger and possibly more amenable to a smartphone intervention. Therefore, SaltSwitch might be better suited to primary rather than secondary prevention of CVD.

## Unanswered questions and future research

The findings of the SaltSwitch trial add further data to the modest evidence base for mHealth interventions in clinical populations(7, 8, 19, 20, 23). Despite positive effects on the primary outcome (household purchases of salt from packaged foods), there were no statistically significant impacts on secondary outcomes, including other nutrients or food groups purchased, household expenditure, urinary sodium excretion, or systolic BP. However, given that the SaltSwitch trial was underpowered, a larger, longer-term RCT is warranted to measure the effect clinically important CVD risk factors such as BP.

**Acknowledgements:** SaltSwitch research assistants: Gareth Cogan, Luke Gemming, Rita George, Linda Lay, Carolyn McNabb, and Rachel Sullivan; and SaltSwitch research nurses: Mandy Fish, Mariska Terbals, and Melinda Copley.

**Declaration of conflicting interests:** The authors declare that there is no conflict of interest.

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## **Figure Legends**

### **Figure 1: SaltSwitch Smartphone Application**