Development and feasibility testing of an intervention to reduce salt intake in people with hypertension

Sarah Payne Riches
Linacre College

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Nuffield Department of Primary Care Health Sciences
University of Oxford

SUPERVISORS
Professor Susan Jebb
Dr Carmen Piernas
Professor Paul Aveyard

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Abstract

Reducing dietary salt intake plays an important role in the prevention and management of hypertension, yet the evidence for effective and scalable individual-level interventions is scarce. In this research I aimed to fill this gap by developing and testing an intervention to reduce salt intake in people with hypertension. Firstly, I investigated the impact of offering shoppers lower-salt alternatives when grocery shopping, in a randomised controlled trial using a simulated online supermarket platform. I found that shoppers were willing to swap to lower-salt alternatives, and that offering a wide range of products with greater reductions in salt (>20% less) significantly reduced the salt content of their shopping basket compared with offering alternatives which were more similar in nature and salt content (-0.09 g/100g, 95% C.I. -0.10 to -0.07 $p<0.001$). Secondary analysis showed that participants who had previously received advice to reduce their salt intake accepted more lower-salt swaps than those who had not. I then developed a primary care-led intervention, using a theoretical behaviour change framework, to motivate and support people with hypertension to reduce their salt intake, including an app to help them choose lower-salt food when grocery shopping. A feasibility randomised controlled trial showed that the intervention ('SaltSwap') could be delivered in routine primary care settings (intervention

fidelity 81% and high acceptability among healthcare professionals), it successfully engaged individuals with high blood pressure (the intervention session was attended by all participants randomised to the intervention group and the SaltSwap app was used by 87% of intervention participants in the first month and in 75% of shopping trips overall) and encouraged participants to swap to lower-salt alternatives for foods which typically contribute most to salt intake. An in-depth qualitative study demonstrated that SaltSwap improved participants' knowledge and motivation to reduce salt intake, and individuals engaged with the SaltSwap app in a meaningful way. Together these results suggest that offering shoppers lower-salt alternatives is a promising approach to reducing salt intake among people with hypertension and a future large-scale trial to test the effectiveness of the SaltSwap intervention for reducing blood pressure is warranted.

Word count: ~48,800 (main text)

Dedication

This thesis is dedicated to Rose and Barnaby for inspiring me every day and to Phil for supporting me to do my best and be the best I can, in all the ways that count.

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First and foremost, I'd like to acknowledge the unwavering, constructive and patient support from my supervisors, Professor Susan Jebb and Dr Carmen Piernas. I'd also like to thank Professor Paul Aveyard for his supervision in the early stages of my DPhil and for being a willing and valuable source of advice in the latter stages; Professor Mike Rayner, Dr James Sheppard and Professor Louise Locock, who helped me to design, manage and carry out this research and provided valuable insights and feedback; Dr Charlotte Albury for her support, input and constructive discussions about my qualitative research; Kerstin Frie, Lauren Bandy and Filippo Bianchi for being great friends, sounding boards and offering distraction when needed; Dr Constantinos Koshiaris for his help with statistics and coding; Dr Oliver Van Hecke for being a wonderful office buddy; my fellow DPhil students for tips, support and general bolstering when required; and Dr Gill Cowburn for tips on conducting think-aloud studies. I'd like to acknowledge those involved in helping me deliver this research including the Thames Valley Clinical Research Network, the Oxfordshire GP practices involved in my study and their wonderfully accommodating staff, the study participants, the PPI panel members who contributed so valuably to the intervention design and study materials, and The George Institute for Global Health who allowed me to use their product database. I also want to thank the women of the Oxford University Women's Boat Club for the opportunity to enter the crucible, to face the chance of failure and for reminding me of the privilege of being a student-athlete-mum.

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Statement of authorship

I declare that this work is my own, except where clearly indicated, completed under the supervision of Professor Susan Jebb, Dr Carmen Piernas and Professor Paul Aveyard and support of a wider supervisory panel, including Dr James Sheppard, Professor Mike Rayner and Professor Louise Locock (between Aug 2016 and Dec 2017). I led all aspects of the research including the design, conduct, analysis and write-up of all included studies. The SaltSwap app was created by a third-party developer (https://www.britishapps.co.uk/). I declare that no part of this thesis has been submitted for any other degree at this or any other university.

List of abbreviations used in this thesis

BCT	Behaviour change techniques
BCW	Behaviour Change Wheel
BI	Brief intervention
CVD	Cardiovascular disease (encompassing coronary heart disease, cerebrovascular disease, peripheral vascular disease, heart failure, rheumatic heart disease, congenital heart disease, and cardiomyopathies)
CHD	Coronary heart disease (also referred to as ischaemic heart disease)
DASH	Dietary Approaches to Stop Hypertension
GP	General practitioner
HCP	Healthcare professional
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PAR	Population attributable risk
RCT	Randomised controlled trial
SF	Saturated fat
SMBP	Self-monitoring of blood pressure
App	Smartphone application
TDF	Theoretical Domains Framework
TPB	Theory of planned behaviour
UK	United Kingdom
WHO	World Health Organisation

Terminology

Throughout this thesis, for consistency, I will primarily refer to ‘salt intake’ rather than ‘sodium intake’, unless it is not appropriate to convert figures from sodium. Where sodium is converted to salt, I will use the standard formula 1 g sodium = 2.5 g salt. Furthermore, I will typically use the term ‘high blood pressure’ throughout unless specifically referring to diagnosed hypertension, or where citing research or reports using the term hypertension.

Publications and presentations

Publications

Publications arising from this thesis:

Payne Riches, S. et al. (2019) 'Optimising swaps to reduce the salt content of food purchases in a virtual online supermarket: A randomised controlled trial.', Appetite. Elsevier, 133, pp. 378–386. doi: 10.1016/j.appet.2018.11.028. https://pubmed.ncbi.nlm.nih.gov/30502442/

Payne Riches S, Piernas C, Aveyard P, Sheppard JP, Rayner M, Jebb SA. The Salt Swap intervention to reduce salt intake in people with high blood pressure: protocol for a feasibility randomised controlled trial. Trials. 2019 Oct 11;20(1):584.

https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3691-y

Note: In addition, I co-authored a further publication as part of the background research:

Hartmann-Boyce J, Bianchi F, Piernas C, Payne Riches S, Frie K, Nourse R, et al. Grocery store interventions to change food purchasing behaviors: a systematic review of randomized controlled trials. Am J Clin Nutr [Internet]. 2018 Jun 1;107(6):1004–16. https://academic.oup.com/ajcn/article/107/6/1004/5032657

Presentations

UK Society for Behavioural Medicine conference, December 2018: Salt Swap: an intervention designed using the Behaviour Change Wheel to reduce salt intake in individuals with hypertension (*poster*)

Centre for Behaviour Change Digital Health conference March 2019 "APP + ADVICE': development of an intervention to reduce salt intake in people with high blood pressure using a theoretical behaviour change framework" (*oral*)

Public Health England conference September 2019: Salt Swap: A feasibility randomised controlled trial of a behavioural intervention to reduce salt intake among people with high blood pressure (*poster*)

British Heart Foundation Fellows meeting, September 2019. A feasibility randomised controlled trial of a behavioural intervention to reduce salt intake among people with high blood pressure (*poster*)

UK Society for Behavioural Medicine conference, January 2020: Salt Swap: A feasibility randomised controlled trial of a behavioural intervention to reduce salt intake among people with high blood pressure (*poster*)

Abstract accepted for oral presentation at ISBNPA 2020 Annual Meeting Salt-Swap: A feasibility randomised controlled trial and qualitative evaluation of a behavioural intervention to reduce salt intake among people with high blood pressure. (conference cancelled due to COVID19)

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Chapter 1. Dietary salt intake: an important risk factor for hypertension and cardiovascular disease

1. Overview

High dietary salt intake is a major risk factor for poor cardiovascular health (1). In my thesis, I will develop and test an approach to reduce salt intake in people with high blood pressure. In this introductory chapter, I will summarise the evidence supporting the need to reduce salt intake due to its effect on blood pressure and cardiovascular disease (CVD) and present an overview of the literature on related strategies and interventions to achieve this. I will identify specific gaps in the evidence-base and explain how my research will address these.

2. Literature review methods

Salt, and its relationship to blood pressure and CVD, has been investigated for decades, resulting in many hundreds of research papers. To summarise this vast literature, I have drawn primarily on published systematic reviews of the literature. I searched the Cochrane Database of Systematic Reviews and Ovid MEDLINE for published reviews (Appendix 1. Search strategies). I checked the reference lists of these reviews, to identify individual studies which contribute significantly to the evidence. For global disease mortality and morbidity data, I used published data from the Global Burden of Disease project (http://www.healthdata.org/gbd) which systematically quantifies global morbidity and mortality across World Health Organisation (WHO) member states (2); and available data from the WHO.

I conducted a further literature review investigating interventions for reducing dietary salt intake, focussing primarily on high-income settings with similar food-systems as the United

Kingdom (UK). This search was conducted using electronic databases (Cochrane Database of Systematic Reviews, MEDLINE and EMBASE) in July 2017 and updated in January 2020. Where the evidence-base on salt reduction interventions was sparse, I widened my search to include literature on interventions to address other dietary behaviours, such as fruit and vegetable consumption, saturated fat or energy intake, given the potential for these dietary change intervention approaches to be effective for salt reduction also. Interventions delivered in supermarket or grocery store settings were identified through a systematic review of randomised controlled trials (RCTs) of interventions to change food purchasing behaviour, of which I was a co-author (3); and several previous, related systematic reviews of point-of-purchase interventions for dietary behaviour change.

3. Epidemiology of cardiovascular disease and high blood pressure

3.1 Global and UK burden of cardiovascular disease

Cardiovascular disease is the leading cause of death worldwide (4) and the number of deaths from CVD increased by 21% in the decade from 2007-2017 (5). It is estimated that CVD accounted for nearly 18 million deaths worldwide in 2017, due mainly to ischaemic heart disease and stroke (together accounting for approximately 15 million deaths) (5). Other significant causes of global CVD mortality include hypertensive heart disease, cardiomyopathy and myocarditis, atrial fibrillation and aortic aneurysm (6).

In the UK, CVD accounts for 27% of all deaths (similar in men and women), just behind ‘all cancers’; the leading cause of death at 28% (7). There is a wide geographical disparity in CVD mortality with higher mortality rates in more deprived areas (8), exemplified by the

age-standardised death rate for coronary heart disease being more than two-fold higher in parts of Scotland (190/100,000) compared to parts of London (79/100,000) (9).

3.2 Global and UK burden of high blood pressure

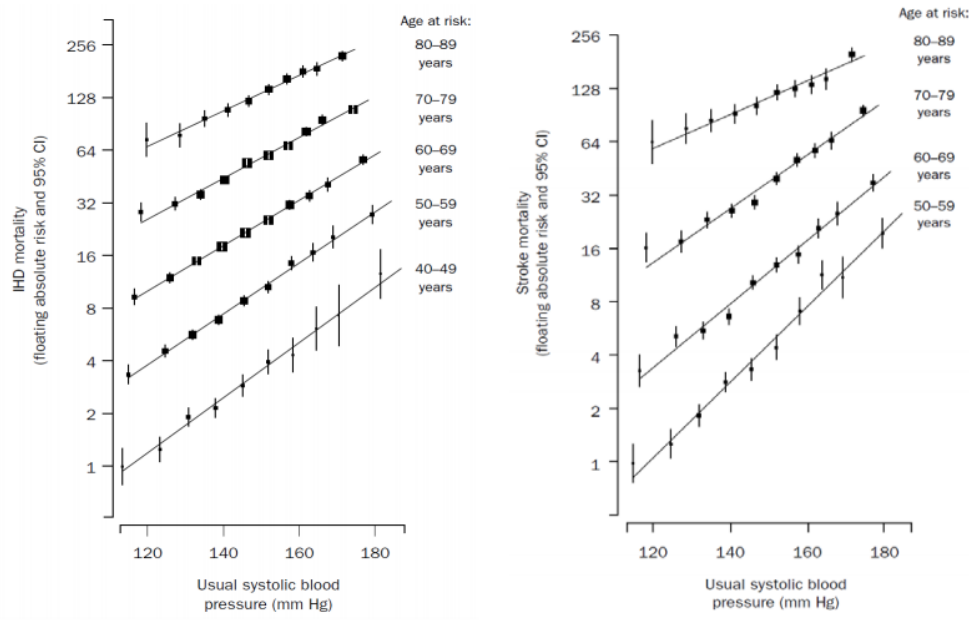
High blood pressure is arguably the most important modifiable risk factor for CVD (10) and the leading risk factor for early death and disability globally, higher than both smoking and overweight (11). There has been a 22.8% increase in the total number of deaths attributable to high blood pressure (defined as systolic blood pressure >115 mm Hg) between 2007 and 2017, to 10.4 million (11). These statistics demonstrate that this continues to be a substantial and growing problem.

In the UK, high blood pressure is the second biggest risk factor for premature death and disability after smoking (12), and the most prevalent long-term condition (13). National cross-sectional surveys show that a quarter of all adults in England have hypertension (13), with a prevalence in men of 28% and in women of 25% (7). There is a marked socioeconomic gradient, with people from the most deprived areas 30% more likely to have hypertension than those from the least deprived (13).

3.3 Association between blood pressure and cardiovascular disease

There is evidence of a clear dose-response relationship between blood pressure and CVD risk. An analysis of pooled individual-level data from 61 prospective observational studies (nearly 1 million participants) showed increases in the risk of both stroke and ischaemic heart disease mortality, with increased blood pressure (Figure 1.1) (14).

Figure 1.1. Dose-response relationship between systolic blood pressure and cardiovascular mortality, according to age. Reproduced with permission from (14) Copyright Massachusetts Medical Society.



Two meta-analyses of RCTs provide evidence that pharmacological interventions to reduce blood pressure reduce the risk of CVD proportionately (15,16). Ettehad et al. found a 20% reduction in the risk of CVD events was achieved for every 10 mm Hg reduction in systolic blood pressure (relative risk reductions 0.83 for coronary heart disease (CHD) and 0.73 for stroke); with similar reductions observed in trial participants with both high, and low, baseline blood pressure (16). Law and colleagues similarly reported a 22% reduction in CHD events for a 10 mm Hg reduction in systolic blood pressure (15).

3.4 Aetiology of high blood pressure

High blood pressure (and the development of primary hypertension[1]) is typically caused by a combination of biological and genetic factors including age, gender, ethnicity and family history; and 'environmental' (*modifiable*) factors including excess body weight, physical inactivity, smoking, excess alcohol consumption and dietary factors (including high salt intake) (17). Estimates of the risk of hypertension attributable to genetics or modifiable factors vary in the literature, in part due to the polygenetic nature of the genetic causes of hypertension and in part due to differences in prevalence of modifiable factors across populations (18,19). Estimates of the genetic contribution to hypertension range from 30-60%, with the remaining substantial proportion attributable to modifiable risk factors, or gene-environment interaction (19,20).

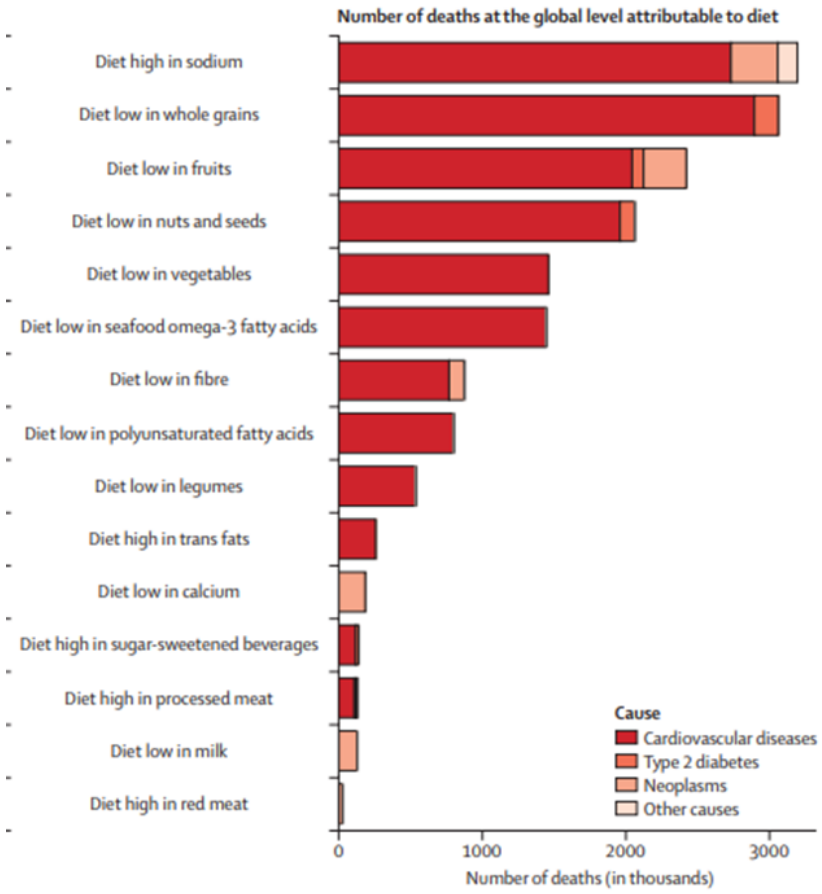
The prevention of primary hypertension, and non-pharmacological efforts to reduce blood pressure, typically focus on these modifiable factors (13,21), though their *relative* importance is debatable. One study assessed the relative contributions of several modifiable factors to the prevalence of hypertension in five western countries (Finland, Italy, the Netherlands, the UK and the USA), by calculating the population attributable risk percentage (PAR%) for each risk factor, based on meta-analyses of trial data (19). The PAR% considers both the estimated strength of the risk factor-blood pressure relationship and the risk factor prevalence in the population. The authors found that excess body weight (PAR% 11-25%), high salt intake (PAR% 9-17%), physical inactivity (PAR% 5-13%) and low potassium intake (PAR% 4-17%), were the most significant risk contributors to hypertension. In the UK specifically, a

[1] High blood pressure can also be caused by some underlying medical conditions and certain medications (termed 'secondary hypertension') which is outside the scope of this thesis.

high-salt diet (>5.5 g/day) and being overweight (BMI >25kg/m^2) were the biggest contributors, with PAR% of 13%. Though these figures are subject to assumptions in the underlying data, they provide some indication of the relative contributions from these risk factors.

In this thesis, I chose to focus on salt intake as the risk factor for intervention for two reasons. Firstly, because a high sodium diet is the largest dietary risk factor for global mortality, second only to lack of whole grains for CVD mortality; according to a global modelling study of the health effects of dietary risks (Figure 1.2) (1). Secondly, there is a relative lack of evidence for effective non-pharmacological interventions for reducing salt intake, compared with interventions for other CVD risk behaviours, e.g. weight loss.

Figure 1.2. Number of deaths and age-standardised mortality rate (per 100,000 population) attributable to individual dietary risks globally (195 countries) in 2017. Amended and reproduced from Afshin et al 2019 (1). Reproduction permitted under Creative Commons CC-BY.



4. The relationship between salt, blood pressure and CVD

4.1 Measurement of salt intake

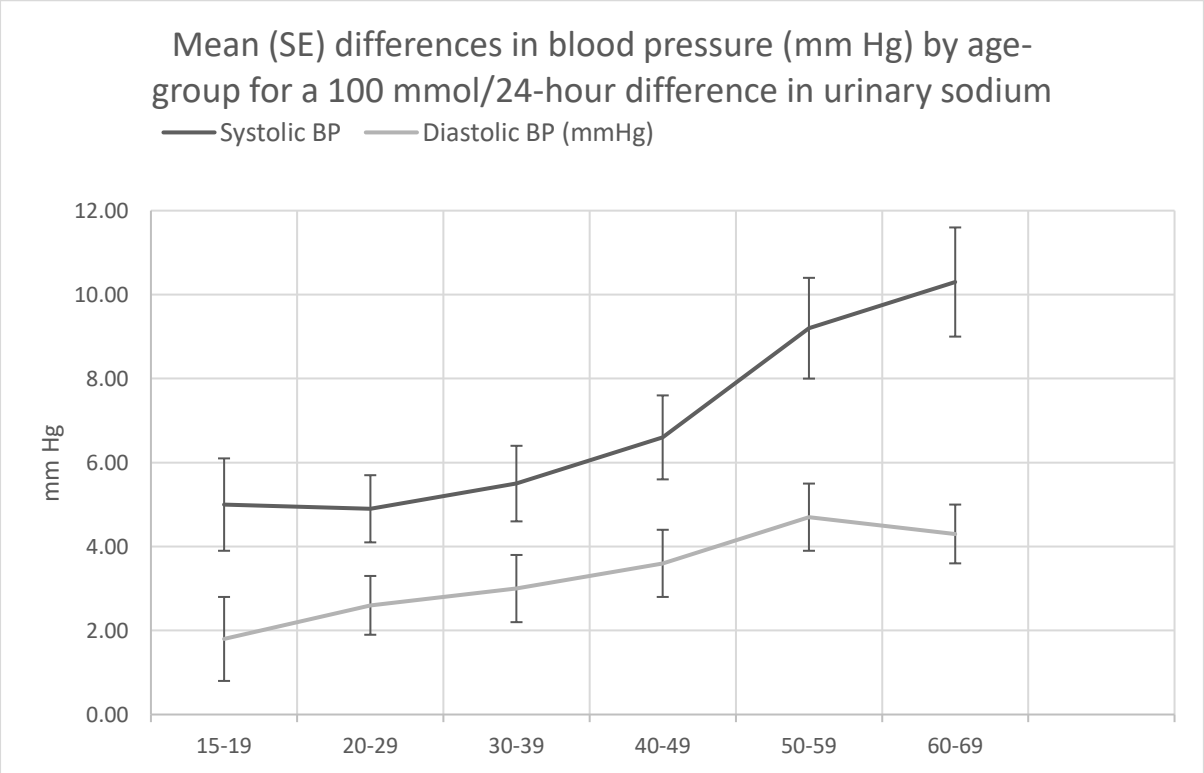
The most robust measurement of salt intake is via assessment of urinary sodium, a biomarker of sodium intake, using at least one 24-hour urine sample (22). Urinary sodium is a good biomarker of sodium intake because >90% of sodium ingested is excreted in the urine (23). Sodium is found in foods in several forms but much of our sodium intake is from sodium chloride (table salt), therefore sodium excretion can be converted to salt intake using a standardised formula. Day-to-day within-person variation in sodium excretion can be substantial due to differences in dietary intake and wider factors such as climate and physical activity. Therefore, to accurately assess an individual's sodium intake, multiple 24-hour urine samples are recommended; although for assessing population intakes, a single 24-hour sample is sufficient (24). Due to the high participant burden and other practical issues of 24-hour urine collection and analysis, studies often use alternatives methods to assess salt intake. Spot (or overnight) urine samples are frequently used to estimate 24-hour urinary sodium using mathematical formulae however, these are more open to random and systematic error than 24-hour collection (22). Other measures commonly reported include dietary assessment and purchase data. Dietary assessment surveys have a number of limitations, notably 1) the potential for inaccurate reporting by participants due to poor estimation or recall bias; 2) lack of inclusion of accurately measured salt added at the table or in cooking; and 3) lack of accurate and up-to-date food composition databases, leading to errors in sodium intake estimation (25). Data on the nutritional content of purchased foods using sales/purchase data is sometimes used to assess salt reduction interventions but is only a proxy for consumption. In my discussion of the literature, for transparency and to allow consideration of the

robustness of findings, I will state which methods have been used to assess salt intake where possible.

4.2 Salt intake and blood pressure

Systematic reviews of RCTs and prospective cohort studies have consistently shown a direct relationship between increased salt intake and increased blood pressure, typically stronger in those with existing hypertension (26–34). In an early observational study of this relationship in 1991, Law and colleagues analysed data from 47,000 study participants across 24 different communities globally and found a significant increase in blood pressure with higher salt intake – measured via 24-hour urinary sodium, varying by age (35) (Figure 1.3).

Figure 1.3. Mean (standard error) differences in systolic and diastolic blood pressure for a 100 mmol/24-hour difference in sodium intake according to age among different studies (35).



In the most recent meta-analysis of trials to date, Huang and colleagues reported an average reduction in systolic (-1.10 mm Hg, 95% CI 0.66 to 1.54) and diastolic (-0.33 mm Hg, 95% CI 0.04 to 0.63) blood pressure for each 50 mmol reduction in 24-hour sodium excretion (equivalent to 2.88g salt) (36). This positive association existed for people with and without hypertension, and across different ethnic groups. In a similar pattern to that reported by Law et al. in 1991, the magnitude of reduction in systolic blood pressure for a 50 mmol reduction in sodium excretion increased with increasing age, with greater baseline blood pressure and in those with existing hypertension (36).

A recent meta-analysis of RCTs also found differences in the effect of salt reduction by ethnicity and baseline blood pressure, reporting a greater mean reduction in systolic blood pressure in people of Asian ethnicity with hypertension (-7.75 mm Hg, 95% CI -11.44 to -4.07) compared to people of White ethnicity with hypertension (-5.51 mm Hg, 95% CI -6.45 to -4.57 mm Hg) and without hypertension (-1.09 mm Hg, 95% CI -1.63 to -0.56 mm Hg); concluding that there was either moderate or high-quality evidence for all results (29). The benefits of salt reduction persist even for those taking antihypertensive medication (14,32).

4.3 Salt intake and cardiovascular disease

Despite the strong associations of salt intake with blood pressure and a well-established causal link between high blood pressure and increased CVD morbidity and mortality, the direct relationship between salt intake and CVD is less conclusive, and the magnitude of impact on CVD mortality is estimated with less certainty. Randomised controlled trials of the relationship between salt intake and CVD are scarce as they present some methodological challenges. Many CVD events are required to robustly determine a significant relationship requiring large sample sizes to provide adequate power, and adherence to a controlled, low-

salt diet over a long study duration is challenging. Where such data exists, it supports an increased risk of CVD due to high salt intake. Data from the long-term follow-up (10-15-years) of seminal RCTs, show a reduction in CVD risk of between 25% and 32% for those in the sodium reduction group (average sodium intake <2.3g per day, equivalent to <6g salt) (37,38). Further trial evidence for the impact of salt intake on CVD comes from a cluster RCT conducted in veterans' retirement homes in Taiwan, which found a large and significant beneficial effect from reducing dietary sodium and increasing dietary potassium through switching to a low-sodium, potassium-enriched salt (49% sodium chloride, 49% potassium chloride, and 2% other additives) in the kitchens. The authors report an age-adjusted hazard ratio for CVD mortality of 0.59 (95% CI 0.37 to 0.95) for the intervention participants compared to the control, who continued to use standard sodium salt. The authors note that this effect could be related to reduced sodium intake, increased potassium intake, or a combination (39).

Several meta-analyses of cohort study data show a direct linear relationship between salt intake and CVD events and mortality (32,40,41). Poggio and colleagues conducted a meta-regression using data from 11 studies, finding that a 10 mmol/day increase in sodium intake was significantly associated with a 1% increase in the risk of CVD mortality (41). Sub-group analysis showed a slightly higher increased risk of CVD in women and for those over 50-years-old. Of the 11 studies included, four measured salt intake via 24-hour urinary sodium, with the remaining seven using dietary surveys. In a separate meta-analysis of 14 cohort studies, Aburto and colleagues reported an increased risk of stroke (risk ratio 1.24, 95% CI 1.08 to 1.43) and CHD mortality (risk ratio 1.32, 95% CI 1.13 to 1.53) (but not CHD events), associated with higher salt intake, though the categories of salt intake were not reported in this review and salt intake was measured using a variety of methods (32).

There is some controversy around the relationship between low salt intake and CVD with some authors reporting a J-shaped or U-shaped association, with increased risk of CVD at *both* high and low salt intakes. In a meta-analysis of data from four prospective cohort studies, Mente and colleagues reported that high salt intake (sodium excretion of >7 g/day; equivalent to 17.5g salt) increases the risk of CVD in those with hypertension compared to 'usual' sodium excretion of 4-5 g/day (10-12.5 g salt/day). However, low salt intake (sodium excretion <3 g/day; salt <7.5 g/day) increases the risk of CVD in those with *and* without hypertension (42). The authors explain this increased risk of CVD at low salt intakes as being due to other physiological responses to the low sodium intake, specifically an increase in renin and aldosterone (43), which are also involved in blood pressure homeostasis, and high levels of which have been independently associated with increased CVD events and mortality (42,44,45). An increased risk of CVD events with low sodium excretion was found in another meta-analysis of observational studies, though no stratification by hypertension status was reported (46). However, methodological limitations in these cohort study analyses include residual confounding, the potential for reverse causality; for example, caused by inclusion of those who develop CVD shortly after baseline (low salt intake occurs with low total dietary intake, frequently a by-product of existing ill-health) and inadequate sodium assessment methods (spot urine instead of single or repeat 24-hour urinary sodium excretion) (47,48).

In their recent review of the evidence, the European Salt Action Network concluded that studies indicating an association of low salt intake with increased CVD risk did not present an accurate association due to the methodological issues mentioned above, and the current recommendation of reducing population salt intake to <5g a day remains scientifically valid (48). From my consideration of the evidence, I concur there is so far a lack of persuasive

evidence from high-quality studies to strongly associate a low salt intake (<5 g/day) with increased CVD risk.

5. Dietary salt recommendations and current intakes

Major national and international guidelines recommend reducing salt intake to less than 5-6 g/day (2-3g of sodium) in adults (49–51). In 1994, the Committee on Medical Aspects of Food and Nutrition Policy first recommended a reduction in average salt intake in the UK to 6 g/day. In 2003, the Scientific Advisory Committee on Nutrition, responsible for advising the UK government on nutrition, confirmed that this recommendation was still valid with present evidence, while pointing out that 6 g/day is higher than nutritionally required and did not represent an ideal intake but an achievable population-level goal; and this recommendation still stands today.

A 2010 survey of salt intake in adults, across 187 countries using 24-hour urinary sodium and/or dietary assessment tools, reported that average salt intake in almost all nations included was above that recommended by the WHO guidelines; with a global mean intake at almost 10 g/day, though there were large degrees of uncertainty in some regions (52). The most recent published data in the UK reports mean adult salt intake (assessed by a single 24-hour urinary sodium sample) is 8.4 g/day; higher for men (9.2g) than for women (7.6g) with nearly 70% of adults consuming more salt than the recommended 6 g/day (53). Analyses of trends over time indicate that mean population salt intake decreased in the first decade of the 2000s; with estimates ranging from a 1.4 g/day reduction between the time-periods 2000-2001 and 2008-2011, assessed via 24-hour urinary sodium (54), to a 0.7 g/day reduction between 2003-2007, assessed using spot urine samples (55). However, there is no indication of more recent reductions (53). Furthermore, there are significant geographical and

socioeconomic variation in daily salt intake (assessed using 24-hour urinary sodium) with people in Scotland, those with the lowest educational attainment and those in lower occupational classes having a substantially higher salt intake than other groups (56).

5.1 Major contributors to dietary salt

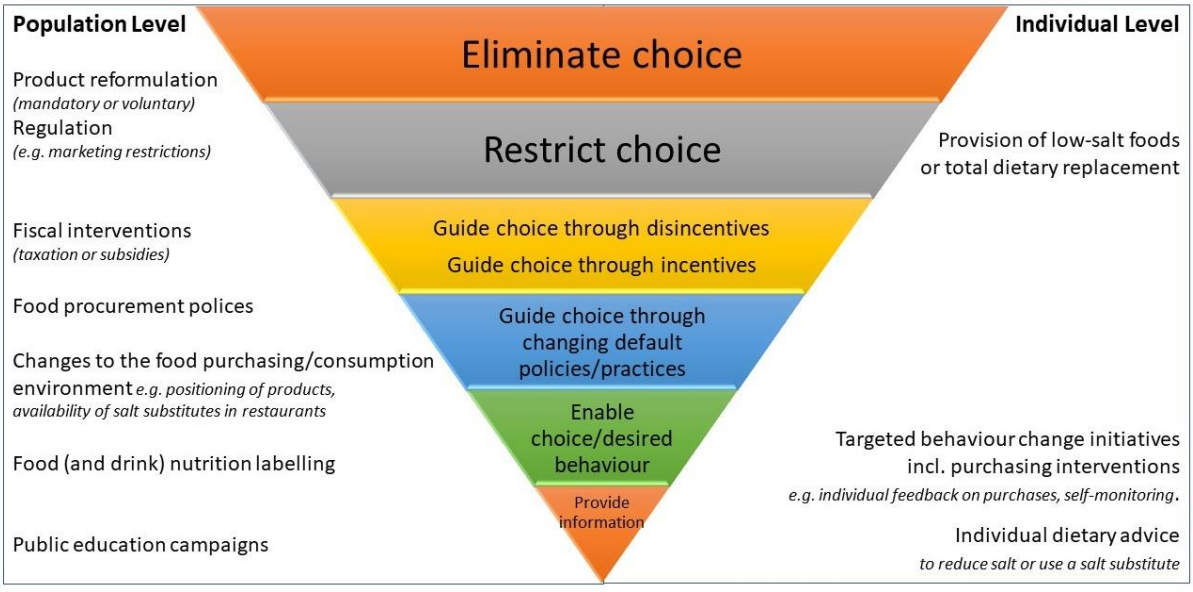
In the UK, as with other high-income countries, it is estimated that more than 75% of dietary salt intake comes from processed or packaged foods rather than from salt added in cooking or at the table (57–59). Salt is added to food during processing for preservation and to enhance flavour and texture (50). Two studies detailing the dietary sources of sodium in the UK, one using 24-hour dietary recall (57) and the other using consumer panel data (60) concur that the main contributors to dietary salt intake are: breads, cereals, meat (including meat products and processed meats), processed vegetables, some dairy products (such as cheese and milk), sauces and soups. The National Diet and Nutrition Survey in the UK lists the top contributors to salt intake among adults aged 16-64 years as bread (15%), other cereals (e.g. pasta, rice, pizza, pastries, biscuits) (14%) processed meats (sausages, bacon, ham meat pies & pastries) (11%) and cheese (5%) (61). The picture is similar in other developed countries, for example, studies carried out in Australia found that breads/bakery products, cereals, meats/meat products, dairy, sauces and spreads contribute the most to dietary salt (62,63).

6. The evidence for interventions to reduce salt intake

Approaches to salt reduction can be considered as either population-level (delivered to a wide, general audience) or individual-level approaches, often targeting those at higher risk of disease. Population-level salt reduction interventions usually address the environment (including the structural, policy, or social environment) and include public awareness campaigns, product reformulation, fiscal measures and regulatory approaches which might

influence the availability, price, promotion and access to salt, high-salt foods or salt substitutes. Individual-level interventions typically include educational interventions and support to change individual or household salt intake behaviours. These approaches to salt reduction can be considered using the 'Intervention Ladder' as described by the Nuffield Council on Bioethics in their seminal report in 2007, which grades interventions based on how intrusive or restrictive they are on personal freedoms (64). Population-level salt reduction approaches tend to be more restrictive on personal freedoms (therefore are likely to be less acceptable to the public) and require less personal agency (except for public awareness campaigns). In contrast, individual-level intervention approaches more commonly occupy the lower intervention rungs of 'enabling choice' or 'providing information'. Salt reduction interventions discussed in the literature (65–69), and how these relate to the Intervention Ladder, are shown in Figure 1.4.

Figure 1.4. Salt reduction intervention approaches and their relative position on the Nuffield Intervention Ladder.



One systematic review investigating the comparative effectiveness of salt reduction interventions concluded that interventions higher up the intervention ladder (e.g.

reformulation) are more effective at reducing average population salt intake than those lower down (e.g. nutrition labelling and dietary advice) (70). Although much of the data for these population interventions is from modelling or ecological studies. Cost-effectiveness analysis of various interventions indicates that the more restrictive population-level approaches, such as mandatory reformulation targets or taxes, are typically more cost-effective than less restrictive advice-based interventions. However, individual dietary counselling is still cost-effective (71) and is likely to be more palatable to policymakers and the general public than very restrictive approaches.

Over the remainder of this chapter, I will briefly discuss the implementation and evaluation of national salt reduction strategies, then summarise the available evidence for salt reduction interventions at both the population and individual level.

6.1 Population-level salt reduction interventions

A systematic review of global progress on salt reduction in 2015 identified 75 countries that had implemented population-wide strategies (68). These programmes tended to be multi-component, with strategies employing more than one of the interventions listed in Figure 1.4. The most commonly implemented population-level interventions were public education, followed by product reformulation (most commonly of bread) and nutrition labelling (68).

Further, a systematic review in 2016 assessing the *impact* of national strategies for salt reduction identified 15 countries with pre-and post-intervention data available (69). All countries delivered public information/education campaigns, 11 implemented reformulation, nine introduced procurement changes, eight labelling and only one (the UK) implemented restrictions on marketing. Fiscal interventions were not delivered in any of these 15 countries.

Five initiatives lacked variance estimates for the mean and were not included in the analysis of impact. Of the ten country-level strategies for which there was adequate data, five showed a decrease in average population salt intake per person, ranging from 1.15 g/day (Finland) to 0.35 g/day (Ireland). Two countries reported increases (0.8 g/day and 1.66 g/day) and three showed non-significant changes. In the two countries where increases were reported, the pre-intervention salt intake data was from several years prior to the start of the intervention, and the authors propose that population salt intake was likely to have gone up in this period before the interventions, potentially accounting for the apparent increase (69). Multi-component strategies, particularly those with structural elements (e.g. product reformulation) were found to be the most effective (69). Seven of the 15 countries assessed salt intake using 24-hour urine samples for at least one time point, and other countries used a mix of spot urine and dietary surveys. The authors graded all included evaluations as low-quality and at risk of bias due to confounding (studies were mainly pre-post, uncontrolled evaluations using cross-sectional survey data).

Studies evaluating the impact of national or regional salt reduction strategies on blood pressure are rare. However, one study evaluated changes in blood pressure and salt intake at the population-level, in response to the UK-wide salt reduction strategy between 2003-2011. Based on a cross-sectional population survey sample, the authors reported a 15% reduction in average salt intake (measured by 24-hour urine samples), and a parallel reduction in blood pressure of 3.0±0.33 mm Hg (systolic) and 1.4±0.20 mm Hg (diastolic) (72). This was an ecological study and other potential confounding factors were not controlled for.

A more recent study evaluated a comprehensive and wide-ranging regional salt reduction strategy in one Chinese province, implemented between 2011 and 2016 (73). The strategy

included food standards and regulation to promote salt reduction by caterers, supermarkets and manufacturers; a media campaign; education in schools; promotion of low-salt foods; salt substitutes; and provision of scaled salt-measurement spoons to households. The evaluation used a cross-sectional survey to measure 24-hour sodium excretion, potassium excretion and blood pressure, pre- and post-intervention, which showed a 25% reduction in sodium excretion and significant but modest reductions in blood pressure. Although the study design used was a before and after study, with no control, the authors report a range of outcomes to support the results; including an eight-fold increase in sales of low-sodium salt substitute in the region, not seen in other parts of China (73).

The national evaluations described above assess the impact of broad salt reduction strategies, most of which combine several population-level interventions. Here I will discuss the evidence for specific population-level interventions implemented most widely, namely reformulation, nutrition labelling and public education campaigns. There is little evidence, from modelling or real-world implementation, on the effect of procurement interventions. Modelling studies show that fiscal interventions could also be highly cost-effective (71) but such interventions have not, to my knowledge, been implemented in any country.

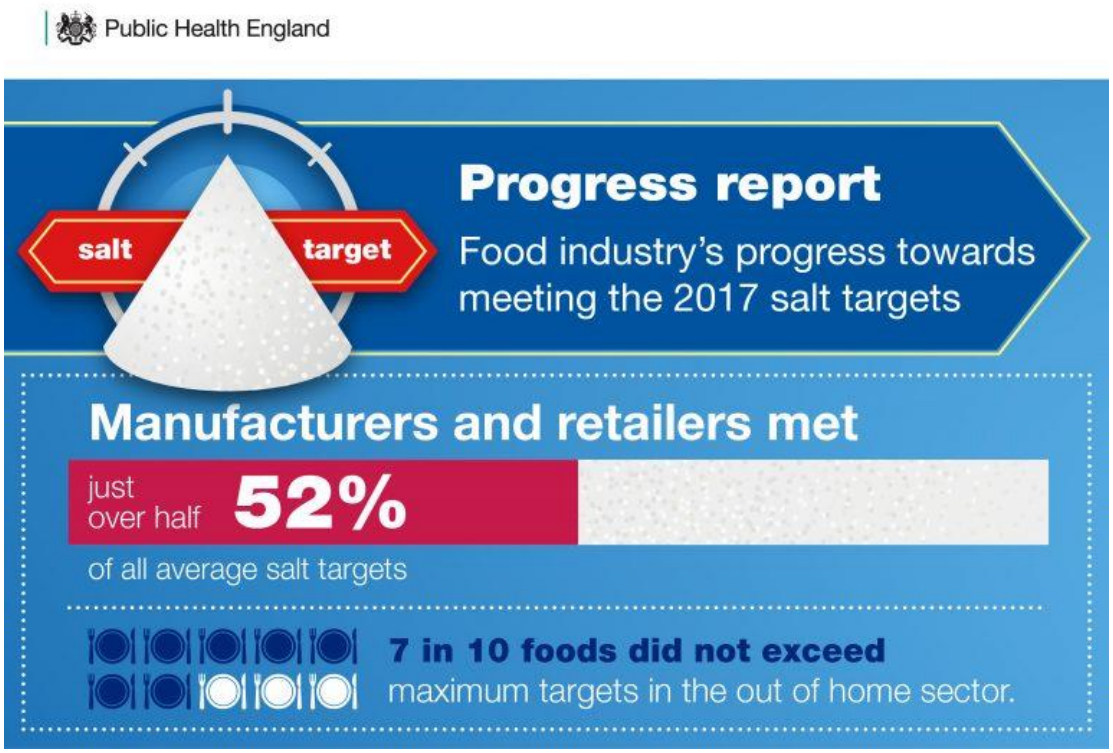
6.1.1 Reformulation

Reformulation is a core component of the WHO salt reduction package (74) and is particularly critical in contexts where the majority of salt intake comes from processed foods. The evidence for the potential effect on salt intake, of product reformulation to reduce the salt content in processed foods, comes largely from modelling studies which estimate that this approach would be effective and cost-effective (75–81). Reformulation has been implemented in the UK, New Zealand, Australia and several countries within Europe (69,82)

and the impact on population salt intake has been evaluated as part of wider national salt reduction strategies, as discussed on the previous section.

In the UK, the Scientific Advisory Committee on Nutrition specifically highlighted the need to reduce the salt content of processed foods (50) and in 2006, introduced a set of *voluntary* reformulation targets for a wide range of food groups, which have been revised over time to be more ambitious (83,84). Assessment of the impact of these targets indicates that they have helped to achieve substantial reductions in salt levels of many targeted foods (85–87). However, in many food categories, these targets have not been met, despite individual products in most food categories meeting the target (88) (Figure 1.5). In a more recent report the Scientific Advisory Committee on Nutrition introduced a recommendation to substitute 15-25% of sodium chloride in processed foods with potassium salts in order to improve progress towards national targets (89).

Figure 1.5. Infographic of progress against salt reduction targets in the UK (90). (Contains public sector information licensed under the Open Government Licence v3.0).



One study providing support for reformulation, is a community-level RCT in Iran which demonstrated that reducing the salt content of bread by 40% led to a significant reduction in both urinary sodium (using spot-urine) and blood pressure (91). Moreover, a systematic review and meta-analysis of consumer panel studies found that salt levels in products such as bread and processed meats can be reduced by between 40-70% without negatively affecting consumer acceptability (92).

6.1.2 Product nutrition labelling

Nutrition labelling is recommended by the WHO to reduce the risk of diet-related non-communicable diseases (49). However, evidence for the effectiveness of nutrition labelling in reducing purchase and consumption of key nutrients such as sodium is inconclusive. A systematic review and meta-analysis of research published in 2019, included studies in grocery stores, cafeterias, restaurants and lab settings. of which five studies reported the impact of nutrition labelling on the purchase of sodium in cafeterias and restaurants. These studies found an average reduction of 15% (95% CI 31.3% to 0.7%) in sodium purchased (93). This review also included an analysis of industry response to nutrition labelling in a small number of studies and reported significant reductions in the sodium content of products through reformulation (93). This underscores the potential indirect benefit of further product reformulation, stimulated by nutrition labelling; a potential benefit also raised by other authors (94,95).

Only a few studies have explored the effect of nutrition labels in a real-world grocery store setting. One study looking at the market share of sales of low-salt soup, found an increase in market share over ten-weeks with the introduction of low-sodium labelling, though the sample size was unclear and the outcome measure only an indicator of relative sales (96).

Two real-world studies investigated the effect of nutrition labels on the overall healthiness of purchased products but included sodium content as a secondary outcome. In these RCTs, the effect of 'interpretive' front-of-pack nutrition labels was compared to the standard back-of-pack nutrition information panel, in New Zealand and Australia. The authors found no significant difference in the sodium content of purchased foods (97,98). However, in one study the authors did note that the lack of effect was largely driven by low use of front-of-pack labels (97). In one other study on the effect of front-of-pack 'traffic light' labels (showing levels of fat, saturated fat, salt and sugar) in a real-world supermarket in the UK, the authors investigated overall 'healthiness' with products categorised as 'healthy' based on a composite score of nutrient content, but did not specifically investigate salt content (99). They found no change in the sales of healthy versus unhealthy products (ready meals and sandwiches) comparing pre- and post-intervention store sales data.

The lack of consistent findings in the evidence on the impact of nutrition labels may be explained by the setting, the types of labels used, foods studied and the study population. A review exploring the *use* of nutrition labels rather than their *effect on purchasing or consumption,* found that across studies, label use was above 50%, but there were differences in label use according to age, gender, income, eating habits and nutritional or dietary knowledge (100). Furthermore, several studies have found that consumers report using nutrition labels less for salt than for fat, sugar, or energy content (101–103). One review of nutrition label use suggested that although people report using nutrition labels, they do not necessarily engage with and process the nutritional content, possibly explaining the lack of effect seen in many studies (104).

6.1.3 Public education campaigns

Public education and awareness campaigns are one of the more commonly implemented population-level interventions, but there are few evaluations of these as stand-alone interventions, likely due to the difficulties measuring their impact. Three national strategies included in the review by McLaren et al. (69) involved education campaigns alone (in Japan, China, and Canada). China and Canada used 24-hour dietary recall surveys to assess salt reduction, with China showing a significant reduction in salt intake from 1991 to 2009 (16.76 g/day, 95% CI 16.56 to 16.97; to 11.94 g/day, 95% CI 11.79 to 12.09) and Canada showing an increased salt intake from 1972 to 2004 (6.11 g/day, 95% CI 5.74 to 6.28; to 7.77 g/day, 95% CI 7.69 to 7.85); with the note that pre-intervention data in Canada was captured some years before the intervention started. It was also noted by the authors of the evaluation in China that substantial changes occurred in China over this time including more urbanisation, an increase in refrigeration ownership and changes to food transportation, all of which may have reduced the use of salt as a preservative and driven the decrease in salt intake independent of the public information campaign (105); thus, highlighting the challenges of long-term ecological studies. Insufficient data was available to assess the effect of a public education campaign in Japan.

6.2 Individual-level salt reduction interventions.

Despite the implementation of a wide-ranging, population salt reduction strategy in the UK, the majority of the population (~70%) continues to consume more salt than recommended (53). This indicates a continued need for strategies targeting individuals, particularly those with hypertension or higher risk of CVD. This is a vision supported by policymakers through their recognition of the importance of personal behaviour change on diet, particularly prompted through individuals' regular contacts with healthcare providers (13). Although

pharmacological treatment is a staple in the management of diagnosed hypertension, poor adherence to antihypertensive medication can detract from the potential treatment benefit (106,107). Moreover, antihypertensive treatment comes with an increased risk of adverse events, a more significant issue among those with mild hypertension for whom the benefits of pharmacological treatment are less conclusive (108). These issues support the case for interventions on modifiable risk factors as a core part of the management and prevention of hypertension, more so, given the additive benefit of salt reduction even with pharmacological treatment. Hence, national guidelines on the management of primary hypertension include advice to reduce salt intake as a core recommendation (109).

In the following section, I discuss individual-level salt reduction approaches including those based primarily on dietary advice or behavioural support, those relying on other behaviour change techniques to alter dietary behaviour (e.g. feedback or self-monitoring), and mobile health interventions. I will also discuss the literature on grocery store and point-of-purchase interventions since food purchasing is a key antecedent of consumption and the major contribution of purchased foods to salt intake in the UK.

6.2.1 Dietary advice to reduce salt intake

Several systematic reviews have investigated the effect of providing individual-level dietary advice to reduce salt intake, blood pressure (27,28,30,110,111), and CVD (30,110,111). The evidence from these reviews indicates that advice-based interventions to reduce salt intake can result in small but significant reductions in blood pressure, ranging from -1.15 mm Hg to -4.14 mm Hg systolic blood pressure depending on the population group, but the most effective interventions tend to be intensive (and delivered by specialist staff). Hooper et al. found insufficient data to draw conclusions on the impact of salt reduction advice on CVD events (110). However, in later reviews, both Adler et al. and Rees et al. reported weak

evidence for the benefit of dietary advice to reduce salt in the prevention of CVD events and mortality (30,111).

In the earliest of these reviews, Hooper et al. (2004) included 11 studies; three in people with normal blood pressure, five in people with untreated hypertension and three in those with treated hypertension. They reported that the studies in those with normal blood pressure were all large and methodologically high-quality, graded as low risk of bias. All delivered intensive advice-based interventions by specialist staff (typically dieticians) and demonstrated a significant reduction in sodium excretion and blood pressure. The effect on systolic blood pressure was of the magnitude of 2.5 mm Hg at 6-12 months, attenuating over time but with a persisting, small reduction of 1.1 mm Hg at up to 1-5 years (110). This perhaps indicates the challenge of adhering to a low-salt diet over time or natural increases in blood pressure with age. Blood pressure reductions tended to be greater in those with existing hypertension.

Two seminal trials in this review were the Trials of Hypertension Prevention (I and II) and their long-term follow-up. These studies delivered an intensive salt reduction advice and behaviour change programme over ten weekly sessions covering: advice, goal setting, planning and social support (112–114). They found significant reductions in 24-hour urinary sodium excretion and blood pressure in the salt reduction intervention group compared to control. The risk of bias in these trials was considered low by the authors of the systematic reviews (110). A subsequent analysis of these study participants, with 10-15 years follow-up, found the risk of CVD events was 25% lower in the salt reduction groups (37).

Trials in individuals with untreated hypertension tended to be much smaller and some interventions were poorly described, making it difficult to draw any valid conclusions. Of the three trials in people with treated hypertension, the TONE study was a large RCT that investigated the effect of dietary sodium reduction on CVD and blood pressure in participants taking antihypertensive medication, who received intensive behavioural counselling (one individual session, then group sessions weekly for four-months, then bi-weekly for three-months) (115). The authors found significant reductions in 24-hour sodium excretion in the intervention group (equivalent to 2.3 g/day salt) at all follow-up points (to 30-months) and a significant reduction in systolic blood pressure (-2.0 mm Hg), compared to control. They also found that individuals in the intervention group were able to discontinue antihypertensive medication with a lower risk of adverse effects on blood pressure or CVD than control participants indicating an ability to maintain blood pressure control with a low-sodium diet (relative risk of the combined outcome of raised blood pressure at follow-up, CVD event, or restarting antihypertensive medication was 0.83 (95% CI 0.75 to 0.92) (115).

A later systematic review included five of the studies in the review by Hooper et al., plus three more recent studies which evaluated salt-substitution interventions (30). The authors concurred with the conclusions of Hooper et al. and added that advice to reduce salt intake reduced blood pressure in both those with normal and high blood pressure but resulted in greater reductions in those with existing hypertension (systolic blood pressure -4.14 mm Hg, 95% CI -5.84 to -2.43).

The most recent review, by Gay and colleagues (2016), focussed on all dietary interventions to reduce blood pressure, including the Mediterranean diet and the Dietary Approaches to Stop Hypertension (DASH) diet as well as low-sodium diets (28). It included the PREMIER

study, published after the review by Hooper et al., which assessed the impact of advice to follow a low-salt diet and a low-salt diet +DASH diet on blood pressure. Both were delivered as part of a broader lifestyle modification programme (116). The low-salt diet and the low-salt +DASH diet interventions were highly intensive, with participants receiving four individual and 14 group counselling sessions, use of food diaries and monitoring of physical activity and sodium intake. The authors reported a reduction in systolic blood pressure of around 4 mm Hg for both intervention diets (compared to control), with no significant difference between the interventions, and a significant reduction in 24-hour urinary sodium of 0.7 g/day (1.7 g salt) for the low-salt diet group compared to control (but not the low-salt +DASH). They also reported a greater reduction in both systolic and diastolic blood pressure in response to the intervention among those with hypertension compared to those without (116).

The success of interventions providing dietary advice may depend on the specialist knowledge, skills, status, role and training of the staff delivering the intervention. One systematic review which investigated the role of the key personnel delivering the intervention included 13 trials and showed that only those trials involving a dietician delivered a significant reduction in blood pressure (117). However, the results were confounded by the heterogeneity of intervention intensity. Only four studies did not include a dietician, and one of these studies assessed an intervention consisting of nothing more than a nurse sending participants weekly email reminders to reduce their salt intake (in addition to usual care delivered in both groups consisting of a one-hour lifestyle education programme and daily self-assessment) (118). In comparison, the studies including dieticians were typically intensive with some involving multiple counselling sessions (115,119). One provided a five-day intervention including practical cooking classes, plus four-days of follow-up support

(120). Another trial provided low-salt food for eight-weeks, selected by a dietician (121). These variations make it difficult to conclude whether the enhanced effectiveness solely reflected the skills of the provider or a more general effect of higher intensity or frequency of support.

Across the literature, there are vast differences in the intensity of dietary advice interventions to reduce salt intake. Although higher intensity interventions appear to be more effective, it is not an absolute predictor of outcome, and a comparison of several recent studies, one delivering intensive advice and two only light-touch, demonstrates that light-touch interventions can potentially have similarly sized effects to those delivering intensive behavioural support. The SPICE study delivered an intensive 20-week intervention including advice, cooking tips, monitoring of salt intake through food diaries and problem-solving. A decrease in 24-hour sodium excretion of nearly 1 g/day was demonstrated after 20-weeks (equivalent to 2.3 g/day salt), though blood pressure changes were not assessed (122). In contrast, Musso and colleagues (2018) reported on a low-intensity advice-based intervention delivered by a dietician in a single session, advising avoidance of specific high-salt foods and switching to salt-free bread (readily available in Italy, the study setting). This intervention reduced salt intake by a similar magnitude (~1 g/day sodium) and reduced both systolic and diastolic blood pressure (123). Finally, in a study of nutritionist delivered education to use one of two different nutrition labelling formats to choose lower-salt options (delivered in two 10-15-min sessions), participants significantly reduced their salt intake, measured via 24-hour urine sample at eight-weeks (baseline 7.9 g/day (SD 2.6); follow up 6.0 g/day (SD 3.0) in one labelling group), however, there was no control group for comparison (124). These seemingly contradictory results suggest that intervention intensity may not be such a strong predictor of the effect, and perhaps the nature of the intervention and the environmental context may be as important in determining whether an intervention will be successful.

The reviews and individual studies discussed above provide substantial evidence that providing advice to reduce salt intake can be effective at reducing intake and correspondingly blood pressure, particularly in people with high blood pressure, but that many characteristics of the intervention and delivery may affect its impact.

Interventions delivered in primary care settings

In the UK, adults routinely have their blood pressure assessed and monitored in primary care; and diagnosis and management of essential hypertension would typically be undertaken in primary care (125); making the primary care consultation the ideal setting to initiate salt reduction interventions. Despite comprehensive trial evidence for the benefit of dietary advice to reduce salt intake, there is little guidance on how to translate this into effective salt reduction interventions which clinicians can deliver in in primary care (126). Effective interventions described in the literature are typically delivered by nutrition or behavioural experts in specialist settings or involve provision of low-salt foods. A review of efficacious dietary counselling interventions for reducing salt intake, concluded that none of the included studies were feasible to deliver in primary care as they involved the provision of food, prepared meals, or intensive inpatient training sessions (127). Two subsequently published RCT studies in Finland, both including interventions delivered in primary care and covering multiple lifestyle factors for reducing blood pressure, appear feasible to deliver in primary care, however, neither reported a significant reduction in salt intake (128,129). Kastarinen and colleagues reported a significant reduction in blood pressure at both one- and two-year follow-ups, compared to a usual care control (-2.6 mm Hg, 95% CI -4.7 to -0.5 mm Hg), indicating that changes in other lifestyle factors were driving the reductions in blood pressure (128).

Despite this limited evidence for interventions for salt reduction delivered by generalist practitioners in primary care, interventions for other dietary behaviours have proven effective. A review and meta-analyses of RCTs showed increases in fruit and/or vegetable consumption; an increase in fibre consumption; and a decrease in total fat (130). Interventions varied in intensity and the personnel delivering the intervention (e.g. nurse, physician, nutritionist, health educator) but most involved at least one face-to-face session.

6.2.2 Other behaviour change strategies

Another strategy to reduce individuals' salt intake is to use established behaviour change approaches such as self-monitoring and feedback. A systematic review exploring the effect of self-regulatory interventions to address dietary behaviours, including only RCT studies that employed self-monitoring or tailored-feedback as stand-alone interventions, found that these interventions had a small but significant effect on dietary behaviour (131). However, the included studies were heterogeneous in results and bias was considered high in many (131). Only one included study assessed salt intake as the main outcome; finding that personalised dietary advice based on feedback on food intake significantly reduced salt consumption by −0.41 g/day (95% CI −0.71 to -0.10 p= 0.008) (assessed by food frequency questionnaires) compared to controls (132).

Two additional studies that focussed on salt reduction but were not included in the above review, due to publication date or trial design, employed self-monitoring as a stand-alone intervention. The first assessed a simple self-monitoring intervention whereby participants measured their overnight sodium excretion and plotted the result on a daily tracker for four-weeks (133). The control group did not measure their urinary sodium daily. No dietary advice was provided to either group. The authors found a significant reduction in 24-hour urinary

sodium excretion in the self-monitoring group (no significant reduction in the control group) but there was no significant between-group difference when adjusted for baseline values and no change in blood pressure. This lack of significant effect may be because self-regulation in the absence of any advice or other behaviour change techniques is insufficient to change behaviour. In addition, the study participants had normal blood pressure and, therefore, may have been less motivated to reduce their salt intake (133). In the other study, testing the feasibility of a diet tracking app which allowed users to record their dietary intake and receive feedback on salt intake (with comparison to reference intakes) to promote self-monitoring, the authors assessed change in salt intake over a three-month intervention period (using 24-hour dietary recall) (134). They reported a significant reduction in sodium post-intervention, however, there was no control group and the sample was small.

Monitoring and feedback on blood pressure could also be used to motivate individuals to reduce their salt intake. A systematic review of trials using home self-monitoring of blood pressure (SMBP) included eight studies which measured the impact of SMBP on lifestyle risk factors for hypertension (107). However, only one included study looked at the effect of SMBP on salt intake. In this RCT, salt intake was assessed via a questionnaire which asked whether participants added salt to their food, and there was no significant difference in the SMBP group compared to the control (no SMBP) group; although the intervention under investigation was an SMBP regime and did not include dietary advice (135).

Mobile app interventions

Mobile phone apps are ubiquitous, and many adults regularly use health apps. One published report describing results of a large representative survey in the UK reported that 23% of adults regularly use health apps, with 42% of these using them to encourage a healthy

lifestyle (136). A German survey showed that among older adults (>60-years) 16.5% used health apps at least once a week, not an insignificant number and indicating some appetite for use of health apps in an older population (137).

The potential benefits of utilising apps to deliver health interventions include the low relative cost of delivery and ability to deliver at scale compared to face to face interventions; the flexibility to allow tailoring to individuals; the ability to deliver an intervention with consistency; and the fact that individuals often have their device with them when they are undertaking the target behaviour which could make the intervention more salient. However, the evidence for effective health app interventions for reducing salt intake is scarce. The only published review of interventions employing a mobile phone to reduce salt intake included 11 studies, six RCTs and five quasi-experimental studies (138). However, only two of these studies focussed primarily on salt reduction, both of which assessed urinary sodium as an outcome using spot urine (139,140). Ipjian and Johnstone used the dietary monitoring and tracking app MyFitnessPal as a stand-alone intervention compared to a control group using a paper journal for dietary tracking, in a small pilot study (n=30). The authors found a significant decrease in urinary sodium in the app group (-0.8 g/24-hour, p=0.01) but not in the control group. In the other study, Eyles et al. investigated the use of an app as a stand-alone intervention to encourage adults with CVD to purchase lower-salt foods when grocery shopping (140). The authors reported a significant reduction in the total amount of salt in household food purchased (-0.30 g/MJ, 95% CI -0.58 to -0.03), though this did not translate into differences in urinary sodium or blood pressure (140).

A systematic review of the functionality of smartphone apps for managing hypertension included 107 apps, most of which focused on facilitating self-management of hypertension,

tracking blood pressure, providing general information on hypertension or improving medication adherence. Only three of the apps identified were capable of tracking salt intake. Eight included information on the DASH diet, but with no specific behavioural intervention to support reductions in intake beyond information provision (141). A review of the literature found no other published results for app-based salt reduction interventions, though research protocols indicate others are underway (142,143). Two small feasibility studies testing the appeal and potential use of smartphone apps for supporting healthy choices while grocery shopping, reported that apps were considered feasible and useful by most participants but no effectiveness data are available as yet (144–147). Although other apps to support salt reduction are freely available I am not aware of any published evaluations of the efficacy of these (148,149).

Despite this lack of evidence for app-based salt reduction interventions, there is some evidence for the benefit of this approach for other dietary behaviours. In one review of the efficacy of interventions that use apps to improve diet, physical activity and sedentary behaviour, 13 of the 27 included studies investigated dietary interventions using RCT or pre-post-experimental designs (150). These focussed mainly on fruit and vegetable intake, sugar-sweetened beverage intake and diet quality; just under half of which showed some significant effects. Another review looking at the effectiveness of app-based mobile interventions for improving nutrition behaviours included studies with weight loss or glycaemic control as outcomes and found a beneficial effect on these outcomes (151).

6.3 Point-of-sale and grocery shopping interventions

In a context where the majority of salt intake is derived from purchased processed foods, it is extremely difficult for individuals to reduce their salt intake sufficiently by adding less salt

when cooking, at the table, or swapping to a low-sodium salt substitute. Although reformulation can help reduce the salt in available foods, more targeted action may be required to encourage consumers to purchase lower-salt options. In the UK, most people still eat most of their meals at home (rather than at restaurants, cafes or from takeaways), purchasing the majority of their food for home consumption from supermarkets; takeaways still account for only a small proportion of household food expenditure (152,153). Supermarkets are therefore an important setting for food and nutrition choices. Point-of-choice salt reduction interventions in grocery stores include population-level interventions targeting all consumers (e.g. addressing the store environment), individual-level interventions (e.g. offering tailored feedback on purchases), and a combination of these approaches.

In a systematic review I co-authored of RCTs implemented in grocery stores to change the purchase or consumption of foods or nutrients, only one of the 35 studies focussed on salt reduction as the primary behaviour (3). This study evaluated an intervention that supplied grocery stores in rural villages with salt substitute and provided community health education on salt reduction, with some villages also receiving a price subsidy on salt substitute (154). The authors found that stocking salt substitute plus health education, increased the sales of salt substitute significantly; and the addition of the price subsidy increased sales even more compared to the control group (no intervention), with a similar pattern for reduction in 24-hour urinary sodium.

The conclusion of our systematic review was that grocery store interventions manipulating price or availability, and those suggesting swaps to healthier alternatives, are effective for changing food purchasing (3). Three other recent systematic reviews published between 2014 and 2016 also investigated grocery store interventions to encourage healthier food purchasing

(155–157), each with a slightly different focus. Across all reviews, included studies mainly targeted purchase of fruit and vegetables, or reduction in calories or fat, with only two studies looking specifically at salt. One study used shelf labelling, instore education material and a media campaign to highlight lower-sodium options for several food categories including frozen vegetable, tomato sauce and soft drinks, crackers, cereals, nuts/snacks, butter/margarine. The study showed a small significant increase in market share of sales for low-sodium products in three product categories over two-years compared to control stores, but not the others (158). The other was a study of the Baltimore Healthy Stores programme which aimed to increase the sale of ten 'healthier' options, one of which was low-salt crackers, by stocking and 'promoting' these items. The study showed no change in sales of low-salt crackers and little or no change across all promoted healthier products from baseline (though 'promotion' was not well defined) (159).

Despite the lack of evidence for salt reduction interventions at the point-of-sale, these systematic reviews of studies targeting healthier purchasing behaviour provide useful evidence to inform future salt reduction interventions. In a review of point-of-sale nutrition interventions (including mainly grocery stores, but also vending machines) Liberato and colleagues concluded that price incentives increased the purchase of healthy foods (155), as did a review focused on grocery store interventions to increase the healthiness of food purchases specifically to reduce obesity (157). The authors of this review also found evidence for the effectiveness of information provision (e.g. promotions, education, labelling), and easy access to and availability of healthy foods for increasing the healthiness of purchases. One other review of interventions to improve the nutritional content of purchases, which excluded price-based interventions, found that the higher quality RCT studies demonstrated positive changes in the healthiness of food purchases with availability, education and

promotion or placement of products in supermarkets, with shelf-labelling being particularly effective (156).

Though price interventions come out strongly across these reviews, the feasibility and sustainability of price-based interventions are questionable given price is controlled by retailers, government (through taxation), manufacturers and market forces; and that provision of vouchers or discounts may be unsustainable over the long term.

A promising approach evaluated in several previous studies is offering healthier alternatives in 'swap' interventions to encourage healthier food purchases, though there is a large degree of heterogeneity among these studies with regard to nutritional outcomes assessed, intervention approach and delivery setting (140,160–163) (Table 1.1). Only one supermarket-based swap study focussed on the salt content of purchased foods, investigating a smartphone app intervention (described above in mHealth interventions) (140). Of note, this was the only study of the five which included clinical outcome measures in addition to purchase outcomes, with no significant effect observed on salt intake or blood pressure despite changes in purchased salt content. Of the two other effective trials, one offered online grocery shoppers lower-saturated fat alternatives for commonly purchased products containing over 1% saturated fat (160). The authors found a significant reduction in the percent saturated fat as a percentage of basket weight, compared to the control group offered no intervention (0.66, 95% CI 0.48 to 0.84). The other delivered an intensive education and swaps intervention in grocery stores, using an early version of computer technology, and reported a reduction in the purchase of high-fat meat and high-fat dairy (163).

6.4 Gaps in the evidence to date

Despite comprehensive evidence for the effectiveness of dietary advice for reducing salt intake, particularly in people with hypertension, there is a lack of evidence for interventions that are feasible to deliver by staff in primary routine care, without specialist nutrition knowledge. In high-income countries such as the UK, where the majority of salt intake comes from processed and packaged foods, an important strategy to reduce population salt intake is to reduce the salt content of foods that people buy and consume. Product reformulation, though effective and cost-effective, requires a significant degree of political will and engagement with industry. A synergistic approach is to encourage and enable individuals to purchase lower-salt products when food shopping, as part of an individually targeted, salt reduction intervention; but there is a lack of evidence for how to successfully do so. Findings from studies aiming to improve the overall healthiness of food purchases indicate that strategies to encourage consumers to identify and choose healthier alternatives, through suggested swaps or shelf-labelling can be effective and could be feasible for reducing salt intake.

Table 1.1. Published studies of swap-based grocery shopping interventions to improve nutritional quality of purchased foods.

Study	Setting	Stated aim(s)	Intervention	Comparator	Primary outcome(s)	Other outcome(s)	Main results
Koutoukidis et al. 2019 (164)	UK, simulated online supermarket	Test the effectiveness of intervention conditions to reduce saturated fat (SF) content of purchases	Interventions:(a) offering lower-SF alternatives, (b) default ordering of products by SF content, (c) combination of swaps and ordering.	Control - no intervention	SF as percentage of total energy of shopping basket	Proportion of products with <1.5g SF; cost of basket; total energy, energy density sugar, and salt; % energy from SFA per swap; swap acceptance	Significant reduction in SF % in all three conditions compared to control. 14% of swaps accepted in intervention (a)
Eyles et al. 2017 (140)	New Zealand, physical supermarkets	Determine the effectiveness of an app to support people with CVD to make lower salt food choices	SaltSwitch smartphone app, which suggest lower-salt alternatives - for 4-weeks.	Control - no intervention. Usual care for CVD	Salt content of household food purchases (g/MJ)	SF content, energy content and expenditure on, purchased foods; blood pressure, urinary sodium, app use and acceptability.	Significant reduction in salt content of purchased foods. No change in urinary sodium or blood pressure. App use and acceptability high
Forwood et al. 2015 (162)	UK, simulated online supermarket	Evaluate the impact of offering lower energy-density products to online shoppers; and in different locations either imposed or consented.	Four intervention groups: consent swap at point of selection; consent swap at checkout; imposed swap at point of selection; imposed swap at checkout (one shopping trip)	Control - no intervention	Change in energy-density between the base food basket and purchased food basket (kJ/100 g)	Proportion of swaps accepted, location of swap offer, licensing effects; intervention acceptability	No difference in energy density between intervention and control; 25% of swaps accepted

Huang et al. 2006 (160)	Australia, commercial online supermarket	To evaluate the effect of offering tailored lower SF products to online shoppers	Automated advice that recommended specific switches from selected products high in SF to alternatives lower in SF while online shopping (median 3 shopping trips)	Control - general non-specific advice about how to eat a low SFA diet	Mean % SF (% of total grams of food purchased)	Cost of shopping basket goods (mean cost/100g)	Significant reduction in SF of 0.66% (0.48–0.84, $p<0.001$)
Ni Mhurchu et al. 2010 (161)	New Zealand, physical supermarkets	Assess the effect of price discounts and tailored nutrition education, separately and in combination, on supermarket food and nutrient purchases.	Three intervention arms: price discounts on healthier foods; tailored nutrition education promoting purchase of healthier foods; a combination of price discounts and tailored nutrition education, for 6-months	Control - no intervention	Change in % energy from SF in supermarket food purchases at 6-months	Change in % energy from SF at 12 months, change in other nutrients (e.g. sodium, sugar); change in quantity (weight) of healthier foods	No change in % energy from SF at 6 or 12 months; significant decr. in sodium at 6 months and incr. protein at 12-months
Winett et al. 1991 (163)	United States, a single physical supermarket	Evaluation of the NLS-1, an automated, interactive intervention to encouraging shoppers to buy lower fat and higher fibre foods.	Dietary information videos, feedback on intended purchases and suggested substitutes for high fat or low fibre foods, and goal setting for 7-8 weeks.	Control – no intervention	Purchases of 4 food groups (high fat meat; low/high fat dairy; high fibre grains & cereals)	Macronutrient purchases (% calories from fat; daily per capita fibre grams) and cost; purchase of fruit and vegetables.	Significant reduction in purchase of high fat meat & high fat dairy during intervention phase; reduction in % calories from fat; no increase in cost

6.5 Aims and objectives of this thesis

In my DPhil, I aim to address the evidence gaps identified in this chapter by investigating interventions to reduce salt intake in people with high blood pressure, which could be delivered at scale. Specifically, I will focus on changing people's purchasing behaviour when food shopping. I will explore the effect of suggesting lower-salt alternatives to people when they are grocery shopping and will use this knowledge to develop a salt reduction intervention for people with high blood pressure, to be delivered by non-specialist staff in a routine primary care setting. I will design the intervention using a theoretical behaviour change framework, following the principles of co- design. I will subsequently test this intervention using both quantitative and qualitative methods.

In my research I will:

a) Explore the acceptability and impact of offering supermarket shoppers lower-salt alternatives ('swaps'), tailored to their usual purchases in a virtual online supermarket study;
b) Conduct a behavioural analysis to identify the key aspects which need to be addressed in order to change people's grocery shopping behaviour; and use this, along with my findings on the acceptability of lower-salt swaps, to design an intervention suitable for delivery in primary care, to support individuals with high blood pressure to reduce their salt intake;
c) Assess the feasibility of this intervention and the trial design to evaluate its effect on blood pressure and salt intake; and
d) Explore the impact of the intervention on people's shopping behaviours and their experiences of trying to reduce their salt intake in a qualitative study.

Chapter 2. Offering swaps to reduce salt intake in an experimental online supermarket: a randomised controlled trial

1. Introduction and aims

In my introduction chapter, I discussed the evidence for supermarket-based interventions to reduce salt intake. Though there are few studies focussed on salt, a promising approach identified to change grocery purchasing behaviour to improve diet quality is to offer shoppers healthier alternatives at the point-of-purchase (3). Several previous studies have evaluated such 'swap' interventions to encourage healthier food purchases (Chapter 1, Table 1.1). One study that focussed on swapping to reduce salt intake, showed a promising effect on purchasing behaviour, though did not achieve a reduction in total salt intake and provided little evidence on the acceptance of swaps (140).

Among previously published studies of swap interventions, there is little evidence available on how the nature of the alternatives offered, particularly the magnitude of change and the similarity of the alternative products, influenced acceptability and hence the overall intervention effect. Where reported, the alternatives offered were either within the same brand (161) or the same narrow product category as original choices (140,162). This approach constrains the variety of alternatives offered and correspondingly the potential improvement in nutritional quality. One way to increase the impact of swap-based interventions is to increase the magnitude of difference in nutrient content for each swap offered. This could be achieved by offering alternatives that are less similar to the original ('out-of-category') rather than confining options to very similar ('within-category') products; for example, offering any type of cheese as an alternative to cheddar

cheese rather than offering only lower-salt cheddar cheese. However, the benefit could be attenuated if this decreased the acceptability of the swaps.

Rational choice theory and the economic concept of utility would suggest that offering lower-salt alternatives that are most similar to the original product would be most acceptable to consumers (165); offering products which are out-of-category i.e. not direct like-for-like alternatives, could potentially reduce utility. For example, offering sliced roast chicken as an alternative to sliced cooked ham (offering a substantially greater reduction in salt content than offering a lower-salt cooked ham), may reduce the utility if the consumer specifically wanted ham, but would not necessarily reduce utility if they simply wanted sliced cooked meat for a sandwich. A perceived reduction in utility might prompt consumers to offset the loss of utility against the expected health gain, potentially reducing the acceptability of such swaps and limiting salt reduction.

In addition, consumers often use heuristics to simplify decision-making, relying on experience, cues and 'rules of thumb' to make judgement decisions; rather than more systematic and reflective processes which require more cognitive effort (166,167). Offering consumers an out-of-category alternative may invoke this more effortful, reflective decision-making process causing consumers to disengage with the intervention thus limiting its impact. Furthermore, some authors have suggested that in familiar situations people tend to spend less time and effort choosing products and their 'choice-set' i.e. the range of items from which they will choose is narrower, compared to unfamiliar situations where they are more open to assessing a wider range of options (168). Routine grocery shopping is typically a familiar situation, where consumers may expect a

narrow choice set, hence out-of-category alternatives may be disregarded and lead to disengagement with an intervention.

From my review of the literature (above and in Chapter 1), I identified two areas where further research is needed to increase our understanding of the effectiveness of interventions to reduce salt intake by changing supermarket purchasing behaviour.

- The potential effect of offering reduced salt alternatives to grocery shoppers.
- The impact of offering grocery shoppers substantially lower-salt alternatives within a wider range of products, on acceptance of swaps and the overall impact on the total salt content of purchased foods.

Investigating these topics in a real-world online or physical supermarket would present logistical and contractual challenges as well as data sharing complexities, resulting in potential costs and delays. Accordingly, I decided to use an experimental shopping platform to test the impact of lower-salt swaps on the salt content of purchased foods and swap acceptance. This simulated online supermarket platform (OLS) allows rapid testing of interventions in a controlled environment which can be easily manipulated by researchers to provide tailored choices and feedback in response to people's shopping selections, and real-time changes to people's shopping basket at the point of selection or purchases. Greater control over the shopping task, than could be achieved in a real-world environment, also reduces between subject variability. The OLS allows the recruitment of large numbers of participants at a low-cost making it an ideal platform for testing intervention options ahead of field trials (162). Recruiting participants to an experimental study also provides greater opportunities to collect additional data to explore specific hypotheses such as how health motivations affect purchasing patterns which would not be possible in a real shopping environment. By closely mimicking a real-world online

shopping context, in terms of products and brands offered as well as the shopping process, the OLS provides a more realistic experience than a laboratory study or discrete choice experiment with the aim of providing a better predictor of behaviour in a real shopping scenario..

The aim was to test two different swap strategies; one which offered very similar alternatives with minimally less salt; and the other offering much lower-salt alternatives but including some 'out of category' products. I also aimed to explore specific participant characteristics associated with the acceptance of swaps. The results of this study will be used to inform the development of an intervention to encourage individuals with high blood pressure to choose lower-salt alternatives when grocery shopping in order to reduce their salt intake.

Note: a version of this chapter was published in the journal Appetite (103) (Appendix 2). This study was reported in accordance with Consolidated Standards of Reporting Trials guidelines (Appendix 3).

2. Methods

2.1 Study design

This two-arm randomised experiment used a simulated online supermarket which emulates a real online supermarket (www.woodssupermarket.co.uk). It contains a food database downloaded from a UK grocery retailer (Tesco.com API. February 2012) with ~11,000 products. Products are categorised into food groups and categories similar to real-world online supermarkets, for example, the food group 'dressings' contains categories: 'salad dressing' and 'mayonnaise & salad cream' (see Appendix 4 for further example groups

and categories). The database includes detailed nutrient information, downloaded from the retailer and supplemented with nutrient data provided by Kantar Worldpanel and the Medical Research Council Human Nutrition Research food and nutrient database. Salt content of foods is based on the sodium content (g) x 2.5. The website looks and functions like a real online supermarket website except that participants do not pay for the groceries and no goods are delivered. The development and testing of this online supermarket platform are detailed elsewhere (162). The study was conducted online between June and September 2017. Registered retrospectively on 5th February 2018 (ISRCTN91306993).

2.2 Participant and recruitment

Participants were recruited via two channels: a database of volunteers, primarily with diabetes, or heart disease, from across England but predominantly from Greater Manchester (www.researchforthefuture.org), targeted as a population likely to have a higher prevalence of hypertension (169); and a UK-wide panel from a market research agency (www.researchnow.co.uk). Participants were eligible if they were aged 18 or over with self-reported high blood pressure, spoke English, were responsible for at least some of their household grocery shopping and regularly shopped in a supermarket spending at least £25 per shop. People following a medically prescribed or restricted diet such as vegetarian, vegan, or gluten-free diets were not eligible, as these dietary restrictions may limit the acceptability of a wide range of alternatives. Individuals were invited to participate in the study via email and directed to an online eligibility screening questionnaire, participant information and consent form.

2.3 Randomisation and blinding

Eligible participants who consented were randomised on a one-to-one basis (in blocks of two) to one of two intervention arms and automatically directed to the online supermarket website. I used computerised random number generation and intervention allocation was concealed from researchers until after completion of the study and data collection. No control group was used as each participants' initial choice product was, in effect, their choice under control (usual) conditions. It was not possible to blind participants to the intervention.

2.4 Procedure

The experiment was delivered online, immediately following participant randomisation. Outcome data was collected automatically through the online supermarket website and exported for analysis. The website introduced the shopping task, provided instructions and a pre-determined shopping list of 12 items for the task (Figure 2.1). The list focused on foods which contribute substantially to the average daily salt intake: bread, cheese, bacon and ham, savoury sauces and soups (60,61), which individuals with high blood pressure would typically be advised to reduce consumption of (170); and foods with potential for swaps to a lower-salt alternative. The full shopping list included:

- Bacon or sausages for a cooked breakfast.
- Cold meat (e.g. for a sandwich or to go with a salad).
- Bread or rolls for lunch.
- Cheese or cheese spread for a sandwich.
- A pizza.
- Soup for a light meal.

- A 'ready meal' (e.g. a prepared meal).
- A savoury snack (e.g. a packet of crisps or nuts).
- Butter or spread (to use on toast or sandwiches).
- Dressing or mayonnaise for a salad.
- A box or bag of breakfast cereal.
- A packet of biscuits.

Participants were asked to ‘buy’ all the items on the list, but not to buy additional items. They were not limited to a set budget and were reminded that this was not a real supermarket and they would not be asked to spend their own money. Participants selected items from the list, added them to their online shopping basket and, where a lower-salt alternative existed, they were offered a swap. Swaps were offered at the point of selection, as opposed to at the checkout, as this has been shown to be more effective in a prior study (162). The percentage reduction in salt content and the price were displayed for each alternative offered. Participants completed the task once and were then asked to complete a short survey including questions on participant demographics; online shopping experience; blood pressure history; prior efforts to reduce salt; and their shopping habits (Appendix 5).

Figure 2.1. Woods instruction page.



2.5 Intervention piloting

I ran a small pilot between March and April 2017, recruiting colleagues, to test the wording of the website and instructions; the intervention procedures; and validate the shopping list. Pilot participants were asked to complete the shopping task using a study shopping list and specifically asked if they could find the products they wanted to easily, whether they used the search function or the drop-down menu to navigate the site, and how long the shopping task took them to complete. No swaps were offered in this pilot. The results of this pilot were used to refine the study procedures and instructions for participants.

2.6 Experimental conditions

The two experimental conditions were a lower-salt (LS) intervention and a much lower-salt (LS+MLS) intervention. In the LS, participants were offered alternative products from the same food group and category; containing between 5-20% less salt (g/100g) than the originally selected product, with product weight and price constrained to be between half and double the pack weight and price of the initially chosen product. Only one alternative product was displayed at a time, chosen at random from all available products matching the criteria. If there was more than one suitable product, participants had the option to be shown another, until they had exhausted all possible alternatives. If no alternatives meeting the criteria were available, no swap was offered. The product initially selected served as the control choice for each purchased item for each participant.

In the LS+MLS, participants were offered one alternative fulfilling the LS criteria (described above) and also one alternative product from the same food group, but not limited to the same category, with at least 21% less salt than the originally selected product (i.e. a much lower-salt (MLS) product). MLS alternatives had the same constraints on price and product weight as for LS alternatives. An example of the LS+MLS intervention would be: for an initial choice of ‘Brand A’ cheddar 400g (1.9 g/100g) from the group ‘cheese’ and category ‘cheddar cheese’, an LS alternative of ‘Brand B’ cheddar 350g (1.75 g/100g), or an MLS alternative of ‘Brand C’ double Gloucester cheese 250g (1.25 g/100g) from the group cheese and category ‘regional cheese’. Example screenshots of swaps offered in Woods online supermarket are shown in Figures 2.2a and 2.2b.

Figure 2.2a. Woods website screenshot of the swap pages – LS+MLS intervention.

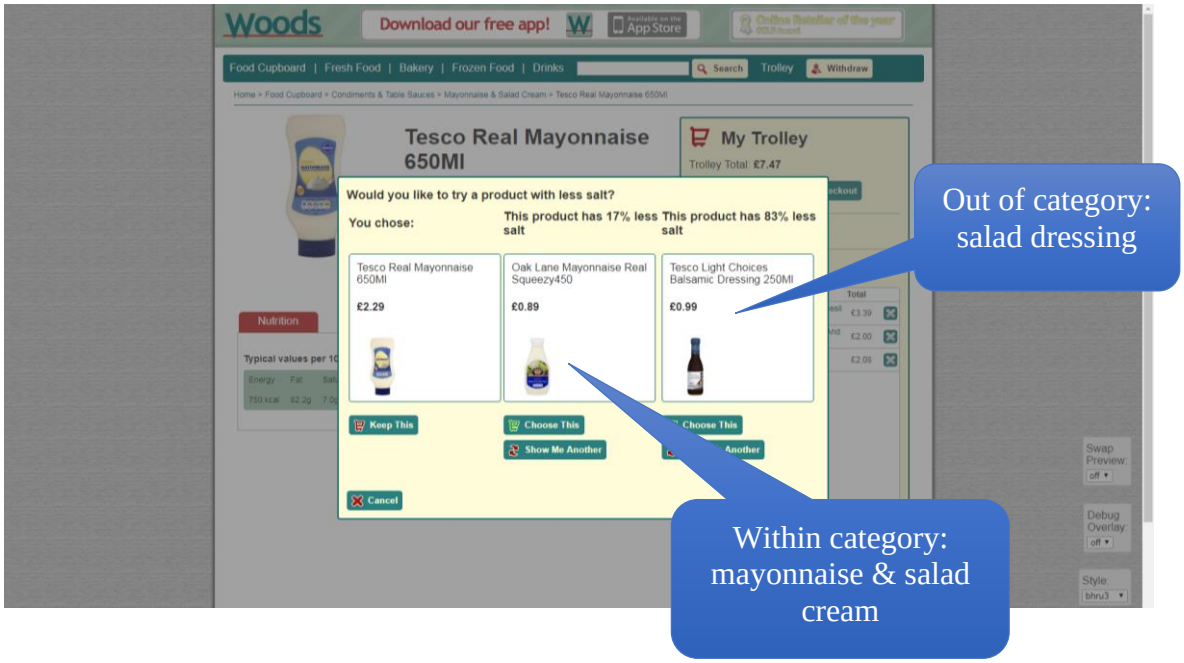


Figure 2.2b. Woods website screenshot of the swap pages – LS+MLS intervention.



2.7 Outcome measures

2.7.1 Primary outcome

The primary outcome was the mean difference in salt density (g/100g) between the 'initial basket' (the products chosen before any alternatives were offered) and the 'purchased basket' (the items in the basket at 'checkout'); weighted by the total weight (g) of food in the basket. The difference was also calculated as salt in g/MJ. Previous studies investigating the change in nutrient content in response to shopping interventions have used g/MJ as the primary outcome, as this accounts for variation in energy purchases. However, in this intervention, the intention was specifically to encourage a change to the salt content of purchased food, measured and displayed to participants as g/100g. I considered both options and concluded that it was more important that the primary outcome directly reflected the measure I was aiming to change.

2.7.2 Secondary outcomes

Secondary outcomes included the number of items for which a swap was offered and the number accepted; the proportion of offered swaps accepted per participant; the average salt reduction per accepted swap; and proportion of accepted swaps that were not within the same category (for the LS+MLS intervention only). I selected these outcomes to help better understand the processes and mechanisms underpinning the change, or lack of, in the salt content of the total basket, in order to inform the future development of swap-based interventions. I also assessed intervention acceptability (five-point scale) through a post-task questionnaire (Appendix 5). I calculated the sugar content, saturated fat content and cost of the initial and purchased shopping baskets (weighted for total purchased energy) to measure any spill-over effects. When salt is removed as part of a reformulation exercise other recipe changes may also be made to maintain palatability. Although there is

no evidence to indicate that lower salt products have more sugar, saturated fat or energy, I felt it was important to assess any possible adverse effects on other aspects of diet composition.

2.8 Sample size

Nine hundred participants (450 per group) were required to detect an absolute treatment difference of 0.04 g/MJ salt (change of ~5%) between intervention groups, with a common SD of 0.2 g/MJ to achieve 80% power at 5% significance level. This calculation is based on the mean salt content of a shopping basket from a previous supermarket purchasing study (mean 0.70 g/MJ (SD) 0.22) (161) and the ability to detect even a small difference between groups, both of which were delivering an active intervention. This intervention approach can reach a large number of people and the LS+MLS is no more costly or resource intensive than the LS intervention, therefore, even an incremental additional benefit is valuable.

2.9 Analysis

Statistical analysis was conducted as specified in the protocol, using STATA version 14.1 (171). I analysed the primary outcome using linear regression with significance evaluated at p-value<0.05, having first tested the assumptions of linear regression, including linearity (using a scatter plot), normality of residuals and homoscedasticity. I present both the unadjusted effect and adjusted, after taking into account hypothesised explanatory covariates. These include participants' rating of price, health, habits, and family food preferences as important factors influencing grocery shopping decisions and baseline salt content of the shopping basket. I hypothesised that the variables relating to the use of

nutrition labels or previous advice to reduce salt intake may be correlated with the variable related to health being an important factor in decision making when supermarket shopping. I tested these correlations and investigated associations between them using logistic regression. The result was that I used only the variable related to health as an important factor in decision making in the final regression models. I also hypothesised that education and household income may be predictors of swap acceptance and that these may be mediated by the importance of price in decision-making. I used the "four-step method" for mediation analysis (172) to test this and found no mediation effect. I, therefore, only included the variable related to price as an important factor in decision–making, in the final regression model.

For the secondary outcomes, I used Poisson regression to estimate the differences in the number of swaps offered and accepted, reporting the Incidence Rate Ratio (IRR) and 95% confidence interval; and linear regression to estimate the difference in the average proportion of swaps accepted per participant and the average salt reduction per accepted swap. I conducted exploratory observational analyses, using linear regression adjusted for the intervention group only, to investigate associations between salt reduction from the initial to purchased baskets and participants' use of nutrition labels, history of dietary salt advice, and the importance of price and health in their purchasing decisions. I also explored the association between intervention acceptability (an ordinal variable) and salt reduction achieved, using linear regression, adjusted only for the intervention group.

2.10 Ethics

Approval for the study was given by the University of Oxford on the 20th January 2017 (R42142/RE001). All participants were shown a detailed participant information sheet and subsequently confirmed their consent.

2.11 Patient and public involvement

I contacted members of an existing public and patient engagement panel for feedback on participant facing materials, including the consent form and the participant information sheet. I used The Writer readability checker (http://www.thewriter.com/what-we-think/readability-checker/) to ensure the participant facing materials were of a suitable reading level.

3. Results

3.1 Participants

Of the 5309 participants screened for eligibility, 2021 were randomised. Eligibility data were not captured during the online recruitment process for data privacy reasons therefore, no data were available on the reasons for ineligibility or demographic data on those not eligible. Of those eligible, 79 participants (4%) did not provide baseline data, 801 (40%) started but did not complete the shopping task and a further 193 (9.5%) completed the shopping task but did not adhere to the task instructions (defined as selecting fewer than three items from the list provided) and were excluded from the analysis. Numbers who were excluded were similar across intervention groups (see Figure 2.3). In total, 947 participants completed the task and were included in the analysis. Most participants (96%)

had used online shopping websites, and 44% had used online grocery shopping, in the past year. Family likes/dislikes (84%), price (74%) and health (44%) were reported as the strongest drivers of food choice.

Baseline characteristics are shown in Table 2.1. Data on the baseline characteristics of the 193 participants, who were excluded due to not adhering to the instructions, show that 25-44-year olds, men, and those on high income were over-represented in this excluded group (Appendix 6). No data was available describing characteristics of those who did not complete the shopping task.

3.2 Primary outcome

There was a significant reduction in the salt content of the purchased basket compared to the initial basket in both intervention groups: LS -0.04 g/100g (95% CI -0.04 to -0.03, $p<0.001$); LS+MLS -0.13 g/100g (95% CI -0.14 to -0.11, $p<0.001$). There was a significantly greater reduction in the LS+MLS group compared to the LS group (-0.09 g/100g, 95% CI -0.10 to -0.07, $p<0.001$) (Table 2.2). This equates to a reduction in salt between the purchased and initial baskets of -4% for the LS group, -13% for the LS+MLS group, and a between-group difference of -9% (Table 2.2). Though there was some degree of heteroscedasticity, this appeared to be driven by one outlier and otherwise, the assumptions for the use of linear regression were broadly met. Sensitivity analysis showed that removing this outlier made no material difference to the results, so all data was included. There was a significant reduction in both groups in salt content relative to the total energy of the purchased basket (g/MJ), with a significant between-group difference of -0.07g/MJ (95% CI -0.09 to -0.06, $p<0.001$), equivalent to an -8% between-group difference (Table 2.2).

Figure 2.3. Consort diagram reproduced from Payne Riches et al. 2019. (103)

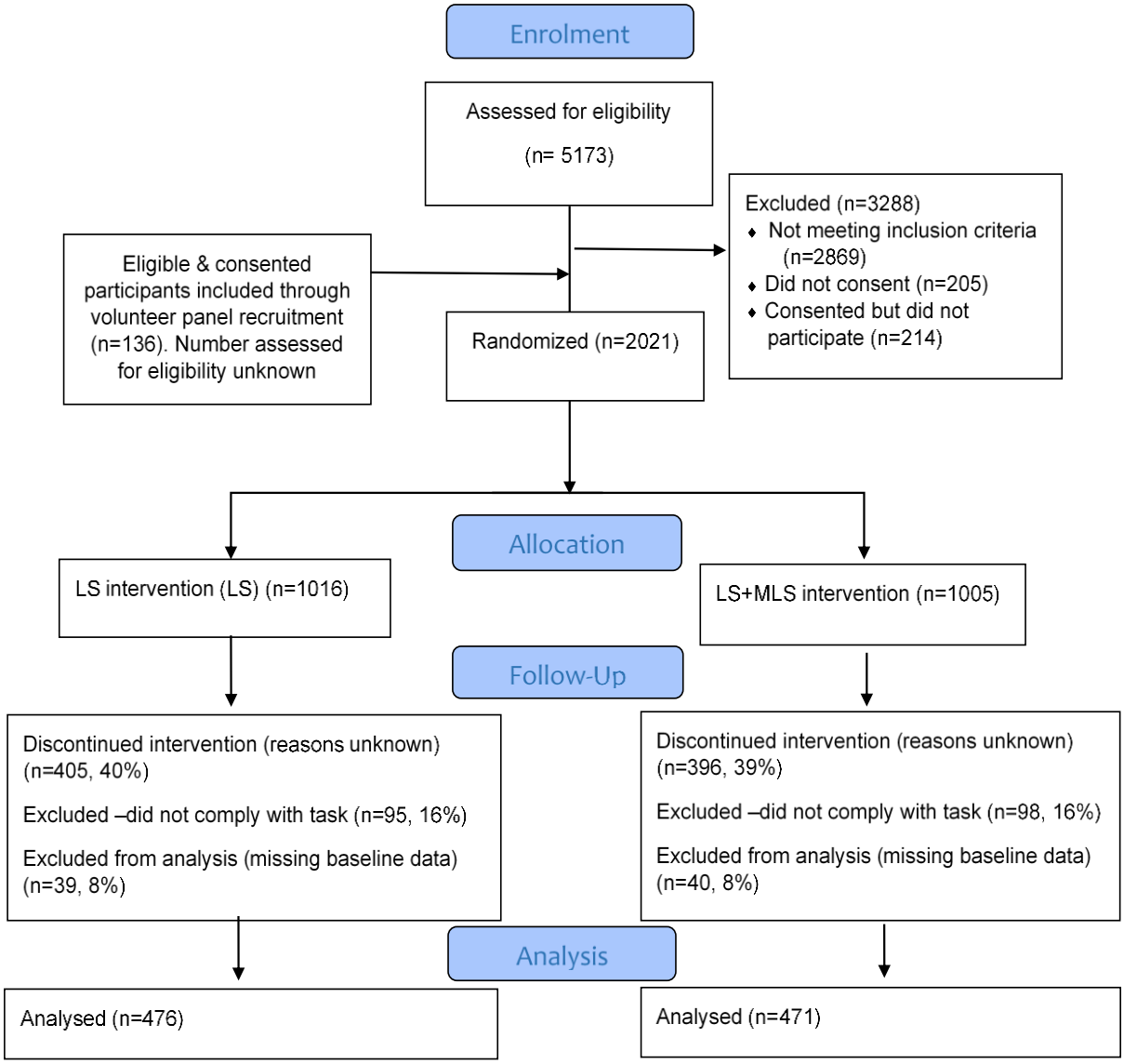


Table 2.1. Baseline characteristics of participants.

Characteristics	**LS group, N (%)** n=476	**LS+MLS group, N (%)** n=471	**Total, N (%)** n=947
Age			
18-24	2 (1)	3 (1)	5 (1)
25-34	19 (4)	9 (2)	28 (3)
35-44	26 (5)	25 (5)	51 (5)
45-54	73 (15)	88 (19)	161 (17)
55-64	169 (36)	150 (32)	319 (34)
65 or older	187 (39)	196 (42)	383 (40)
Sex (n, %)			
Male	274 (58)	276 (59)	550 (58)
Female	202 (42)	195 (41)	397 (42)
Household income (total household income before tax)			
Below £15, 500	84 (18)	88 (19)	172 (18)
Between £15, 600 and £25,000	106 (22)	118 (25)	224 (24)
Between £26,000 and £35,000	102 (21)	98 (21)	200 (21)
Between £36,000 and £50,000	106 (22)	81 (17)	187 (20)
£51,000 or above	78 (16)	86 (18)	164 (17)
Highest educational level			
None	24 (5)	35 (7)	59 (6)
Up to 4 GCSE's	70 (15)	79 (17)	149 (16)
5 or more GCSE's or 1 A-level	66 (14)	66 (14)	132 (14)
2 or more A-levels	94 (20)	95 (20)	189 (20)
Bachelor's degree	144 (30)	129 (27)	273 (29)
Post-Graduate degree or qualification	78 (16)	67 (14)	145 (15)
Online shopping experience (groceries)			
Never or not in the last year	274 (58)	258 (55)	532 (56)
1-3 times in the last year	69 (15)	74 (16)	143 (15)
4-11 times in the last year	66 (14)	67 (14)	133 (14)
1-3 per month	43 (9)	44(9)	87 (9)
Once per week or more often.	24 (5)	28 (6)	52 (5)
Online shopping experience (non-food)			
Never or not in the last year	15 (3)	25 (5)	40 (4)
1-3 times in the last year	73 (15)	71 (15)	144 (15)
4-11 times in the last year	221 (46)	194 (41)	415 (44)
1-3 per month	138 (29)	133 (28)	271 (29)
Once per week or more often	29 (6)	48 (10)	77 (8)
Has a household member who has been diagnosed with high blood pressure? (n, % Yes)	124 (30)	130 (31)	254 (31)

Previously advised by health professional to reduce their salt intake (n, % Yes)	190 (40)	195 (41)	385 (41)
A household member has been advised to reduce their salt intake (n, % Yes)	57 (14)	76 (18)	133 (16)
Previously tried to reduce their salt intake (n, % Yes)	322 (68)	327 (69)	649 (69)
A household member has previously tried to reduce their salt intake (n, % Yes)	167 (42)	177 (43)	344 (42)
How often participant looks at nutrition labels for salt			
At least sometimes	329 (69)	298 (63)	627 (66)
Never or rarely	147 (31)	173 (37)	320 (34)
Drivers of shopping choices (n, % Yes)			
Family likes/dislikes	392 (85)	386 (84)	778 (84)
Price	338 (73)	350 (76)	688 (74)
Health	206 (44)	185 (40)	391 (42)
Special/offers	145 (30)	175 (38)	320 (35)
Habits	70 (15)	54 (11)	124 (13)
Convenience	51 (11)	62 (13)	113 (12)
Appearance (of products)	54 (12)	54 (12)	108 (12)
Animal welfare	50 (11)	54 (12)	104 (11)
Organic	20 (4)	9 (2)	29 (3)
Special Diet	17 (4)	8 (2)	25 (3)

Table 2.2. Change in salt density, total salt and total food weight between the initial and purchased shopping baskets for each intervention group (using independent t-tests) and the effect of the intervention groups on these changes.

	LS (n=476)	**LS+MLS (n=471)**	**Difference between groups LS+MLS v LS**	***p*-value**	**Difference between groups LS+MLS v LS**	***p*-value**
	Difference purchased-initial (95% C.I)	Difference purchased-initial (95% C.I)	unadjusted (95% C.I)		adjusted ** (95% C.I)	
Total basket salt density (g/100g)	-0.04 (-0.04, -0.03)*	-0.13 (-0.14, -0.11)*	-0.09 (-0.10, -0.07)	<0.001	-0.09 (-0.11, -0.08)	<0.001
% difference	-3.76 (-4.19, -3.32)*	-12.65 (-13.90, -11.39)*	-8.89 (-10.22, -7.56)	<0.001	-8.94 (-10.27, -7.62)	<0.001
Total basket salt content (g/MJ)	-0.04 (-0.05, -0.04)*	-0.11 (-0.13, -.10)*	-0.07 (-0.09, -0.05)	<0.001	-0.07 (-0.09, -0.06)	<0.001
% difference	-4.45 (-5.17, -3.73)*	-12.25 (-13.58, -10.92)*	-7.80 (-9.30, -6.29)	<0.001	-8.04 (-9.53, -6.55)	<0.001
Total salt (g)	-2.93 (-3.43, -2.43)*	-7.97 (-8.78, -7.17)*	-5.04 (-5.99, -4.10)	<0.001	-5.17 (-6.10, -4.23)	<0.001
Total food weight (kg)	-0.07 (-0.10, -0.04)*	-0.21 (-0.27, -0.16)*	-0.15 (-0.20, -0.08)	<0.001	-0.15 (-0.21, -0.09)	<0.001

* Significant at $p<0.05$

**Calculated using linear regression adjusted for: health considered important; price considered important; shopping habits considered important; family likes/dislikes considered important; and baseline shopping basket salt content.

3.3 Secondary outcomes

3.3.1 Purchases

The mean number of products added to the purchased basket was 17 (SD 12), weighing 7.1 kg (SD 6.5), with 54.4 g salt (SD 48.5), and a salt content of 0.92 g/100g (SD 0.53). There was no difference between groups in the total number of items bought and no difference between groups in the salt density (g/100g), in the initial shopping basket. There was a significant reduction in both total salt content (g) and total product weight (kg) in the purchased shopping basket within each intervention group; and a significant between-group difference for both total salt (-5.2, 95% CI -6.1 to -4.2, $p<0.001$) and total weight (-0.15, 95% CI -0.21 to -0.09, $p<0.001$) (Table 2.2).

There were small changes in saturated fat and sugar in the purchased basket for both groups, with a significant between-group difference of -0.08 g/MJ (95% CI -0.16 to -0.01, $p=0.023$) for saturated fat; and 0.12 g/MJ (95% CI 0.00 to 0.25, $p=0.043$) for sugar (Table 2.3). There was a small decrease in the cost of the basket in both groups, but no between-group difference (Table 2.3). There was a significantly larger decrease in total energy in the purchased basket compared to the initial basket in the LS+MLS group compared to the LS group (-1.71MJ, 95% CI -2.54 to -0.89, $p<0.001$).

3.3.2 Acceptance of swaps

Swaps accepted as a proportion of those offered was the same in both groups (Figure 2.4). However, the LS+MLS group were offered 15.7 swaps compared with 8.4 in the LS group (IRR 1.86, 95% CI 1.79 to 1.93, $p<0.001$), and accepted a significantly higher number of offered swaps; 4.39 compared to 2.69 in the LS group (IRR 1.64, 95% CI 1.53 to 1.76, $p<0.001$). In the LS+MLS group, 68% of accepted swaps were MLS swaps. Of the swaps

accepted, 30% in the LS+MLS group were from a different category and 70% from the same category. The mean salt reduction per swap accepted in the LS+MLS group was more than double that of the LS group (Figure 2.4, Table 2.4).

3.3.3 Predictors of swap acceptance

In an exploratory analysis among all participants, those who rated health as an important consideration when grocery shopping accepted 13% more swaps (95% CI 10% to 17%, $p<0.001$) than participants who did not view this as a priority. These participants also reduced the salt in their purchased basket by an additional -0.03 g/100g (95% CI -0.05 to -0.02, $p<0.001$), equivalent to a 3% greater reduction in salt (Table 2.5). There was no difference in average salt reduction per swap. Similarly, participants who reported previously being advised to reduce their salt intake (or who had a household member who had been so advised) and those who reported they regularly used nutrition labels for salt content accepted more swaps and reduced the salt in their purchased basket more than those who had not. There was no significant association between the importance attached to price and any of the outcomes.

3.3.4 Intervention acceptability

More than two-thirds (70%) of all participants ‘strongly’ or ‘somewhat’ agreed that this type of swap intervention is something they would like to see when they do their usual shopping; only 7% somewhat or strongly disagreed. Increasing acceptability of the intervention was associated with a greater reduction in salt in the total shopping basket; -0.04 g/100g greater reduction in salt with each increasing category of acceptance (95% CI -0.05 to -0.03, $p<0.001$).

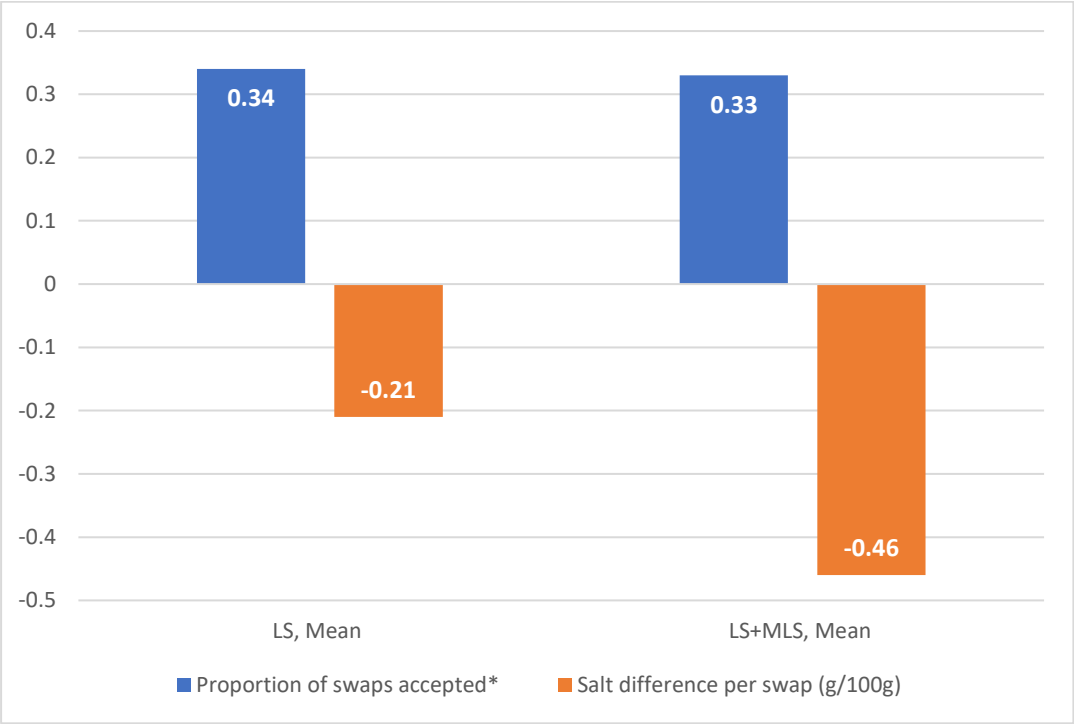
Table 2.3. Change in nutritional composition and cost between the initial and purchased baskets.

	LS (n=476)	LS+MLS (n=471)	LS+MLS compared to LS			
	Difference purchased-initial (95% CI)	Difference purchased-initial (95% CI)	Mean (95% CI) (unadjusted)	*p*-value	Mean (95% CI) (adjusted **)	*p*-value
Total basket sugar (g/MJ)	-0.07 (-0.13, -0.01)*	0.05 (-0.06, 0.16)	0.12 (0.00, 0.24)	0.0459	0.12 (0.00, 0.25)	0.043
Total basket saturated fat (g/MJ)	0.03 (-0.02, 0.07)	-0.06 (-0.11, 0.00)	-0.08 (0.01, 0.16)	0.0244	-0.08 (-0.16, -0.01)	0.023
Total basket energy (MJ)	-0.37 (-0.86, 0.13)	-2.10 (-2.75, -1.44)*	-1.73 (-2.55, -0.91)	<0.001	-1.71 (-2.54, -0.89)	<0.001
Total basket cost (£/MJ)	-0.01 (-0.02, -0.01)*	-0.01 (-0.01, 0.00)	0.01 (-0.00, 0.02)	0.1186	0.01 (-0.00, 0.01)	0.142

* significant at $p<0.05$

**Calculated using linear regression adjusted for: health considered important; price considered important; shopping habits considered important; family likes/dislikes considered important; and baseline shopping basket salt content.

Figure 2.4. Impact of the intervention on the acceptance of swaps and the salt reduction (g/100g) per swap.



*proportion of swaps accepted calculated as the number of swaps accepted out of those offered per participant.

Table 2.4. Between group difference on the acceptance of swaps and magnitude of salt reduction.

	Difference LS+MLS v LS (95% C.I) unadjusted	***p*-value**	**Difference LS+MLS v LS** (95% C.I)**	***p*-value**
Average proportion of swaps accepted per participant*	-0.01 (-0.04, 0.03)	0.622	-0.00 (-0.04, 0.03)	0.785
Salt difference per swap (g/100g)	-0.25 (-0.29, -0.21)	<0.001	-0.25 (-0.29, -0.21)	<0.001

*Calculated as the number of swaps accepted out of those offered per participant
**Calculated using linear regression adjusted for: health considered important; price considered important; shopping habits considered important; family likes/dislikes considered important; and baseline shopping basket salt content.

Table 2.5. The impact of health or price being considered important, use of nutrition labels, and salt reduction advice, with salt reduction and swap outcomes†.

	Beta (95% C.I)							
	Health important	*p*-value	Advised to reduce salt	*p*-value	Use of nutrition labels	*p*-value	Price important	*p*-value
Salt reduction (g/100g) (n=924)	-0.03 (-0.05, -0.02)	<0.001	-0.03 (-0.04, -0.01)	<0.001	-0.02 (-0.04, -0.01)	0.004	0.00 (-0.02, 0.02)	0.872
Proportion of swaps accepted (n=923)	0.13 (0.10, 0.17)	<0.001	0.06 (0.03, 0.10)	<0.001	0.10 (0.06, 0.13)	<0.001	0.01 (-0.03, 0.05)	0.662
Average salt reduction per swap (g/100g) (n=811)	0.01 (-0.03, 0.05)	0.579	-0.03 (-0.07, 0.00)	0.062	-0.01 (-0.05, 0.03)	0.628	0.00 (-0.04, 0.04)	0.883

† Beta (95% CI) from linear regression models adjusted for intervention group. Each covariate (e.g. health important) are modelled as dummy variables (yes vs no) in separate models with "no" being the comparator.

4. Discussion

4.1 Main findings

Offering shoppers with high blood pressure lower-salt alternatives was acceptable and reduced the salt content of purchased foods significantly. Offering shoppers alternative products with at least 21% less salt, including out-of-category items, lowered the salt content of their total shopping basket by 9% more than offering within-category alternatives with minimal (≤20%) salt reduction alone. The proportion of swaps accepted in each group was similar but, in the LS+MLS group, two-thirds of the accepted swaps were much lower in salt than the initial product; leading to a two-fold greater reduction in salt per swap accepted.

Offering alternative products chosen from a wider selection of foods increases the potential for offering larger reductions in salt content, however, I hypothesised that it may negatively influence acceptability by increasing the cognitive complexity of the decision-making process. However, this hypothesis was not upheld. The results of this study suggest that despite the potentially higher cognitive effort required in decision-making when offered out-of-category swaps, this did not adversely affect the acceptability of swaps and resulted in greater salt reduction overall. In 30% of LS+MLS swaps, the accepted alternative was from a different product category to the original item, suggesting that out-of-category swaps are acceptable. Field trials might, therefore, want to test the more varied LS+MLS strategy in interventions to encourage swaps in real supermarket environments, rather than limiting alternatives to within a narrow product range.

Across both intervention groups, greater salt reduction was associated with previous advice to reduce salt, perception of health as an important factor in food choice and regular use of nutrition labels. This suggests that the benefits of swap-based interventions could be enhanced by complementary interventions that increase intrinsic motivation. As postulated in self-determination theory, intrinsic motivation can be influenced by an individual's perceived competence at a behaviour, perceived autonomy with respect to a behaviour and relatedness (173,174). Increasing belief in the importance and benefits of salt reduction and strengthening an individual's self-identification as someone who places importance on health and is capable of making healthy food choices could strengthen their perceived competence and perceived autonomy. Understanding factors that increase acceptance of swaps is crucial. Here, 33% of swaps offered were accepted, whereas previous studies have reported lower swap acceptance rates. One study using a similar experimental online supermarket platform to investigate the effect of offering lower-saturated fat alternatives, found 14% of swaps were accepted, leading to an 8% relative reduction in the percentage energy from saturated fat in the total purchased basket compared to no intervention (164). Forwood et al. reported an acceptance rate closer to what I found here, at 25%, reporting that participants who accepted swaps had a lower-energy density in their total purchased shopping basket (162). Overall however, 50% of participants accepted no swaps. In the only published real-world study to my knowledge, the authors did not report the swap acceptance rate (160).

The reasons for these differences in the swap acceptance rate are unclear. The shopping list items across the experimental online supermarket studies discussed above were similar, with a mix of core foods and discretionary items, therefore, it is unlikely that differences in swap acceptance were due to list items. However, participants in my study were offered more swaps (15.7 in the LS+MLS group and 8.4 in the LS group) compared to only seven swaps in

one trial (164) and four swaps in the other trial (162). This may be explained by how the algorithm identified potential alternatives or the degree of variation in salt content across products compared to saturated fat or energy. Another explanation of the higher acceptance rate may be the nature of lower-salt alternatives compared to lower-saturated fat or lower-energy density alternatives, particularly how this affects the potential utility of suggested alternatives. These unexplained discrepancies in swap acceptance rate, and the importance of this as a predictor of intervention effect, suggest that more research is required to understand strategies to increase swap acceptance. Other salt related behaviours not captured here, such as habitual addition of salt to food or in cooking, may also impact swap acceptance and could be explored in future research.

4.2 Strengths and limitations

This study used a randomised experimental design with a large sample size, sufficient to detect a difference of at least 5% in salt between groups. The OLS provided a well-controlled environment in which swaps could be offered across a large, representative selection of products. Variability in the shopping basket between participants was limited using a shopping list, focused on high-salt foods which also provided sufficient opportunity for swaps. The outcome measure was objectively recorded and not reliant on self-report. Although this was a simulated supermarket experiment, it closely mimicked real-life online shopping, using a database of products from a large UK grocery retailer ensuring participants were presented with an array of familiar products to increase the likelihood that users engage with the task in a realistic manner.

This study has some limitations. The task was not completed by 40% of randomised participants, and a further 9.5% were excluded for not adhering to the task, though this was

evenly balanced across both intervention groups. Although comparable to a previous study (162) and to 'success rates' more generally for online shopping tasks (175), the low completion rate could introduce a degree of non-response bias and impact generalisability. A review of reviews of online behaviour change interventions found the average completion rate for internet-delivered interventions is approximately 50%, suggesting this is a problem more generally for internet-delivered interventions (176). Participant characteristics were collected at the end of the experiment in order to limit the barriers to starting the task and therefore, no data is available on non-completers. Furthermore, randomisation occurred before any baseline or demographic data was collected therefore imputation of missing outcome data for participants who were randomised but did not complete the study, was not possible. Typically, those who did not complete the task discontinued very early (having selected one item or less). There were some differences in baseline characteristics of those who completed the task but did not adhere to the instructions, suggesting there is a degree of sampling bias which may affect generalisability. It is possible that participants with more time to engage with the study completed it accurately and those who did not adhere to the task were not motivated to engage in a meaningful way. In a future study of similar design, I would capture baseline data at the beginning of the shopping experiment and randomise people only after completing this step to ensure that differences in characteristics of those who complete the task or not, could be properly examined. This may also help to ensure a more motivated group of participants were randomised, improving the task completion rate.

The study population were representative of a typical population of people with hypertension in terms of age and gender, with the majority over age 55 years and slightly more men than women. An advantage of the study and outcome assessment being online was that I could use an online recruitment approach. I chose to use a market research panel to recruit participants

as it enabled rapid recruitment of a large number of participants over a short time period, following an initial slow uptake in recruitment through the volunteer database recruitment., The majority (94%) of participants recruited were recruited via the research panel and there were no differences in age, gender, income, or education level between those recruited via each channel. Those recruited via the volunteer database would be expected to have a higher prevalence of diabetes, respiratory conditions, or heart disease than research panel members, although I did not record diagnosis of these conditions. However, the number of participants recruited through this route was small and therefore, it is unlikely any sampling bias would affect the results. Participants in this study all had self-reported hypertension, which potentially increases their intrinsic motivation to reduce their salt intake.

While this simulated environment allows efficient testing of interventions, the external validity is unknown. Shoppers do not pay for their goods nor take delivery of them and their choices may represent their intentions or stated preferences rather than their true purchasing behaviour. The alternatives offered were chosen automatically and at random from all items matching the swap criteria, and in some cases may not have provided sufficiently appropriate or desirable swaps. The hypothesised increase in cognitive effort involved in assessing the out-of-category swaps in the LS+MLS intervention did not result in lower acceptability in this OLS study, but it is possible that in a real-life environment this may have more of an impact.

4.3 Implications for practice

Overall, the LS+MLS intervention resulted in a 13% reduction in salt content of the shopping basket from the initially selected items. If this percentage reduction was carried through to individual-level daily salt intake, it would result in a decrease of 1 g/day, based on the

average adult salt intake in the UK of 8.4 g/day. This would be sufficient for individuals with hypertension to make a meaningful step towards achieving the recommended salt intake of less than 6 g/day. To put this reduction in context, average daily salt intake among adults in the UK decreased 1.4 g/day over a ten-year period from 2001-2011 (177) due to population-level interventions such as national media campaigns to raise public awareness and product reformulation.

The online supermarket shopping environment can be easily manipulated to provide tailored choices and feedback in response to people's shopping selections, and real-time changes to people's shopping basket at the point of selection or purchase; presenting a distinct opportunity for changing food purchasing behaviour to reduce salt intake. In the UK, online grocery shopping is increasing and is forecast to account for 10% of all grocery shopping in the next five-years. Already, 45% of adults, including 35% of those 45-years-old and over, do at least some of their grocery shopping online (178). Some retailers in the UK have already implemented similar swap functions in commercial online grocery shopping sites (179,180), suggesting there is commercial willingness to implement this behavioural strategy. This study confirms the acceptability of this approach by shoppers.

This type of intervention is less easy to implement in physical grocery stores, though technologies which enable consumers to scan food products to purchase items could be adapted to identify lower-salt or other healthier alternatives while shopping in-store (148,181,182) opening up broader application of this research into physical grocery stores.

5. Conclusions

Offering lower-salt alternatives to individuals with high blood pressure when grocery shopping has the potential to reduce the overall salt content of their shopping. Offering alternatives with greater reductions in salt is acceptable to shoppers and leads to significantly greater reductions in the salt content of their shopping basket than offering only swaps to very similar products with small reductions in salt. Offering lower-salt alternatives which are from a wider range of products, rather than limited to the same brand or food subcategory does not negatively impact acceptability. This research adds to the evidence-base on offering healthier food alternatives as a mechanism to improve the nutritional composition of people's grocery shopping baskets and will inform the design of an intervention to encourage people with high blood pressure to reduce their salt intake by purchasing fewer high-salt foods.

Chapter 3. Design of an intervention to reduce salt intake in people with hypertension

1. Background

In the UK, most of the salt consumed comes from processed and packaged foods rather than table salt or salt used in cooking (57). Therefore, helping people to avoid high-salt foods or eat them less frequently, and to swap to lower-salt alternatives for foods eaten regularly, is an important component of reducing salt intake. In Chapter 1, I highlighted the potential for instore interventions to increase the healthiness of purchased foods by changing people purchasing behaviours. Food choice and purchasing behaviours are complex, dynamic, and driven by a far wider range of factors than simple physiological needs; with food choice made more complex by the vast array of foods available in the modern world, the so-called 'tyranny of choice' (183). Interventions to influence this complex behaviour must consider the factors driving food choice behaviour and aim to address these (184).

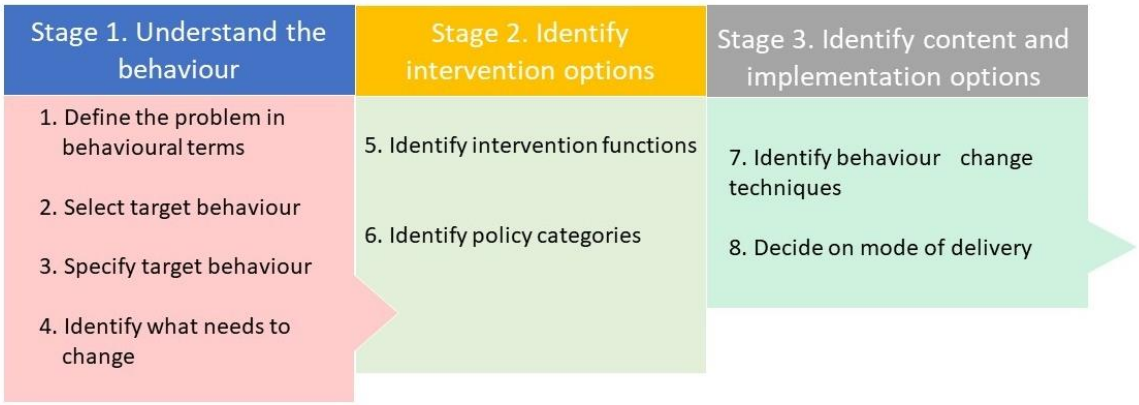
Best practice guidance recommends that the development of behaviour change interventions is supported by existing evidence and underpinned by a sound theoretical basis (185,186). There are a plethora of behaviour change theories available to draw on (187); which can make intervention development overwhelming and often specific theories are too narrowly focused to cover all influences on the behaviour. The need for a 'supra-model' to guide design, implementation and evaluation of complex behaviour change interventions was recognised by Michie and colleagues, leading to the development of the Behaviour Change Wheel (BCW) (188). The BCW approach begins by defining the problem in behavioural terms, identifying and specifying the target behaviour, and then guides intervention design through a comprehensive behavioural analysis and specification of the intervention content.

The BCW has been used to design interventions across a range of healthcare behaviours (189–191). In this chapter, I will describe how I used the BCW to design an innovative, brief intervention to reduce salt intake in people with hypertension. I will summarise the literature informing the behavioural analysis and describe the resulting intervention. Finally, I will describe how my theoretical approach to the intervention design informed subsequent evaluation planning.

2. The BCW framework

The BCW approach, as described by Michie and colleagues, follows three key stages, encompassing eight steps (192) (Figure 3.1).

Figure 3.1. The stages and steps of the Behaviour Change Wheel.



Using the BCW starts with a detailed analysis of the target behaviour, drawing on existing literature and stakeholder views. It centres on the COM-B model, which proposes that to change an individuals' behaviour, it is necessary to change at least one of these three elements: *Capability* (physical and psychological); *Opportunity* (physical and social); or *Motivation* (reflective and automatic), to perform the desired behaviour (or competing behaviours). Each of these components of COM-B can be considered in more detail, using the domains from the Theoretical Domains Framework (TDF) (193), which identifies 14

domains of behavioural influence, and facilitates assessment of the “barriers and enablers” to change the target behaviour (194).

An important principle in the development of health behaviour change interventions is the use of a participatory or co-design approach, involving the intended end-users in the design and development of the intervention, and the BCW lends itself to this approach. The aim of such a participatory approach is to ensure interventions are usable, engaging and persuasive for the target population. The core principles of user-design include that it is participatory, there is shared decision making, cooperation and mutual exchange of information, and it empowers participants due to shared decision making (195). As part of the initial scoping for this research, I involved several members of a local Public and Patient Involvement (PPI) panel to help develop the research questions and proposal. In the intervention development phase, I built on this by convening a user co-design panel, consisting of members of the public with self-reported high blood pressure; the target audience for this intervention. Individuals were recruited via a pre-existing database of volunteers and via advertisements in primary healthcare practices (GP practices) in Oxford. This panel helped me to better understand what people with high blood pressure believed were important aspects of capability, opportunity and motivation to reduce salt intake; and informed the intervention content, mode of delivery and the key questions for intervention evaluation. Panel members also reviewed the final intervention design and conducted initial pilot testing. I met the co-design panel as a group at two time-points, and with each member individually once. Meetings were held at the University of Oxford Nuffield Department of Primary Care Health Sciences and I facilitated these group sessions. Examples of some of the co-design group discussion points are in Appendix 7. I also undertook one-to-one, formative interviews with two primary care practice nurses from one of the practices where I planned to initially trial

the intervention. This was a convenience sample of the healthcare professionals (HCPs) typically responsible for delivering health promotion activities, including dietary advice.

3. Application of the Behaviour Change Wheel

The steps included in the three stages of the BCW are described below.

3.1 Stage 1. Understanding the behaviour

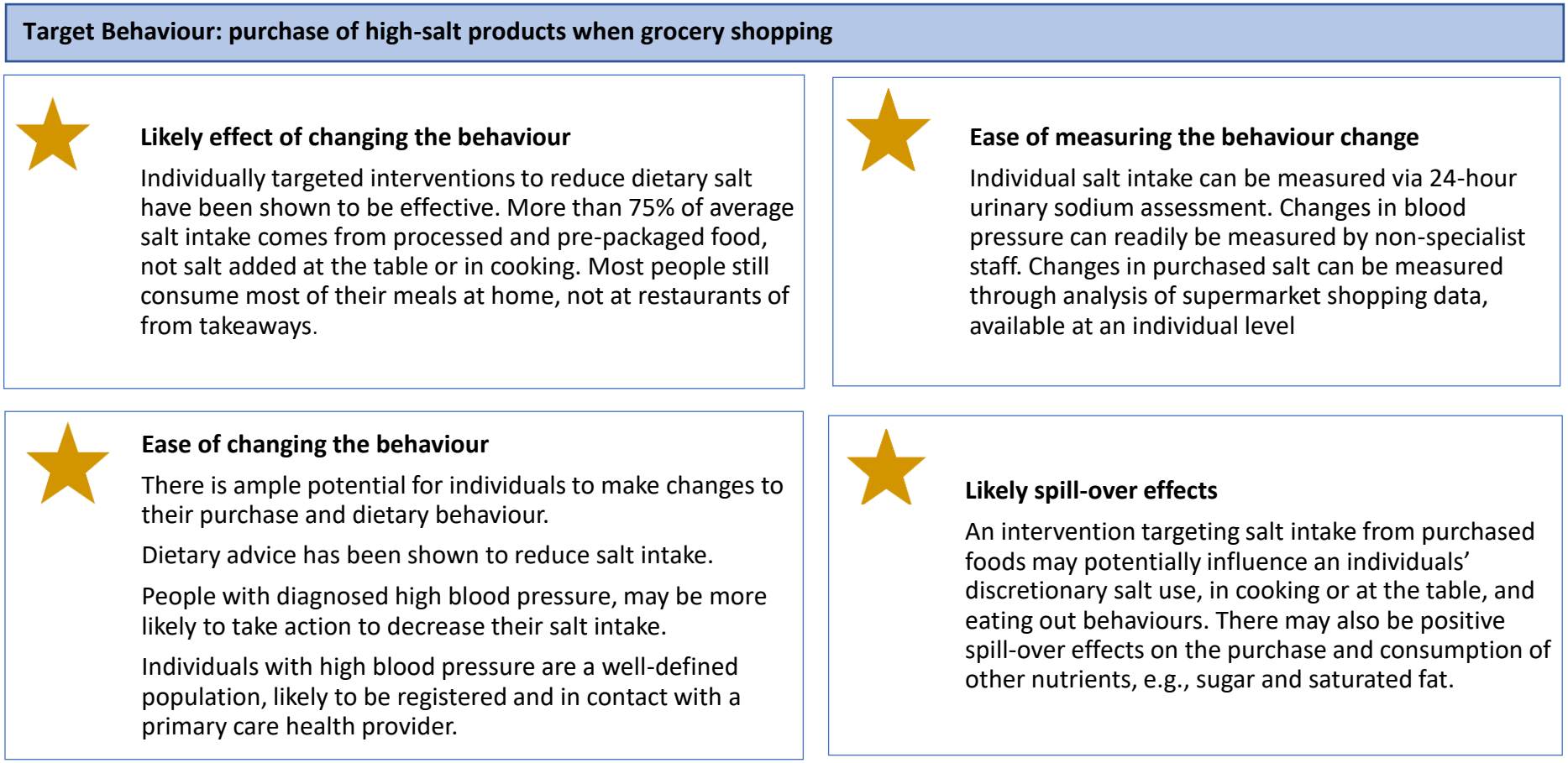
Steps 1-4: Define the problem, specify the target behaviour and undertake an analysis of the factors influencing that behaviour.

The problem I identified, in behavioural terms, is that approximately 70% of adults in the UK eat more than the recommended 6 g/day of salt, leading to increased risk of high blood pressure and cardiovascular disease. There are a multitude of behaviours that could influence an individual's salt intake and are potential targets for intervention (Figure 3.2). I considered these potential behaviours against the BCW criteria for choosing a target behaviour (Figure 3.3), along with the epidemiological data about the sources of salt in the UK diet and the evidence on interventions to reduce salt intake, and identified the most appropriate target behaviour for this intervention as: *the purchase of high-salt foods by individuals when grocery shopping*. Figure 3.3 shows how this target behaviour meets the criteria in the BCW framework.

Figure 3.2. Behavioural systems map for an individual's salt reduction.



Figure 3.3. Criteria for choosing the target behaviour.



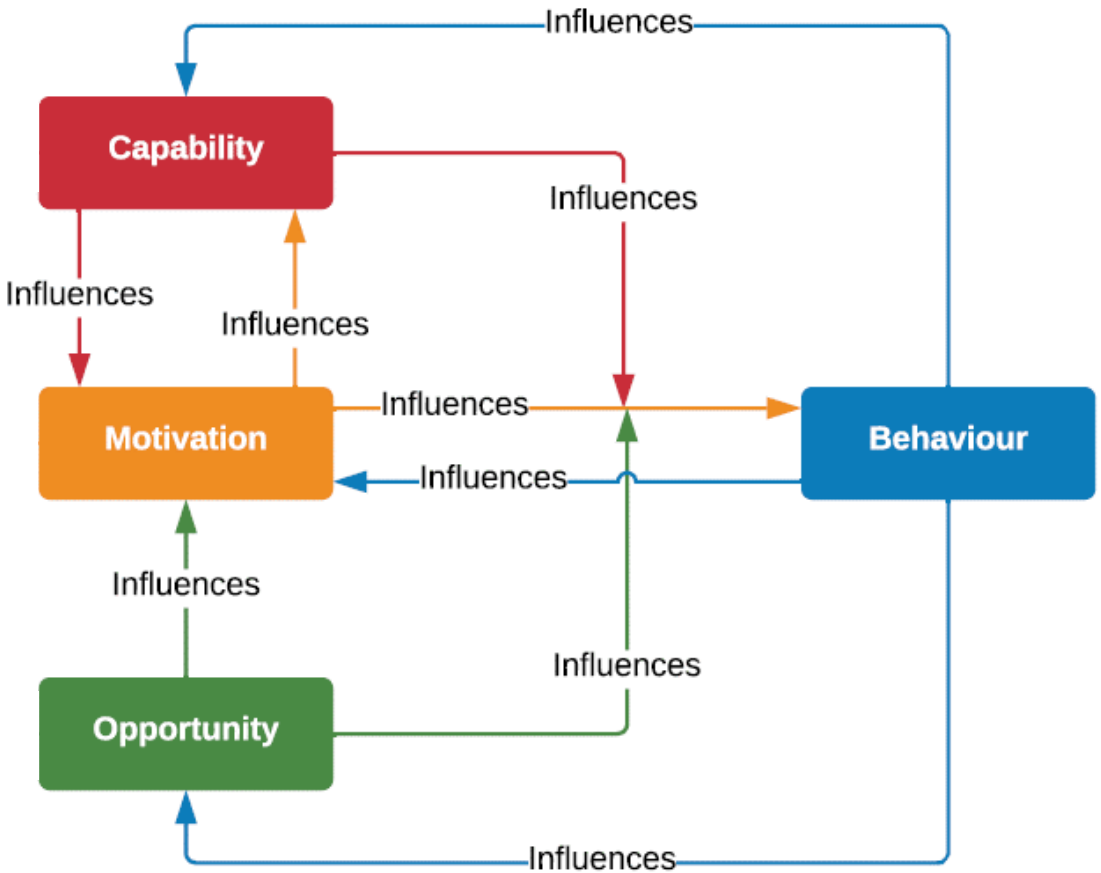
Next, I specified the details of behaviour; whose behaviour, where the behaviour occurs, and when, what needs to be done differently, how often and with whom in order to facilitate detailed analysis of the influences on the behaviour (Figure 3.4).

Figure 3.4. Specifying the target behaviour.



Having specified the behaviour, I conducted a behavioural analysis using the COM-B model. This involved assessment of capability (C), opportunity (O) and motivation (M) to identify which aspects need to change to enable people to reduce their purchase of high-salt foods. As shown in Figure 3.5, the separate aspects of COM-B interact, rather than applying a unidirectional influence. For the desired behaviour to occur, capability, motivation, and opportunity all need to be 'activated'. I further considered each aspect of COM-B using the TDF.

Figure 3.5. COM-B including directional interactions and influences (196).



3.1.1 Capability

Capability includes physical and psychological aspects. There is no apparent need to address *physical* capability because most shoppers have the physical skills and capacity to choose lower-salt foods. However, several aspects within *psychological* capability are relevant. Psychological capability comprises four domains from the TDF: knowledge; cognitive and interpersonal skills; memory, attention, and decision-making; and behavioural regulation (193). Knowledge might encompass; 1) knowledge of how much salt is too much; 2) the most common sources of salt; 3) knowledge about the health consequences of high salt intake and the benefits of reducing it; and 4) knowledge of personal salt intake. A systematic review of the quantitative literature (mainly survey data) on the knowledge, attitudes and behaviours around salt intake specifically in high-income countries, found that few individuals are aware of the recommended level of salt intake (197). Two qualitative studies, in New Zealand (198) and the UK (102), found similar results. One large global survey covering nearly 7000 participants over eight countries, found that only 13% of respondents could correctly state the recommended salt intake (55% did not know, and 32% were incorrect) (58).

Some survey-studies in high-income countries have shown that people are largely aware that most of their salt intake is from processed foods (58,199,200), though one also found that participants were still unable to recognise certain foods as being high in salt (e.g. processed cheese) (200). In one qualitative study in a high-income setting where most salt is from processed food, participants were unaware of the major sources of dietary salt (198). The importance of this knowledge was highlighted by a survey-based study showing that people who had a greater knowledge of the common sources of salt showed an increased willingness to purchase lower-salt foods (201).

Knowledge of the benefits to be gained from reducing salt intake along with an understanding of personal salt intake may boost motivation to reduce salt. The literature suggests that people are aware that too much salt is not good for their health, but many do not believe that reducing their salt intake will improve their health (58,198). One study reported that although most respondents (88%) knew that salt was a risk factor for high blood pressure, only 46% of respondents thought that their health would improve with reducing salt intake (101). This may be due to the age of people surveyed; 56% were under 45-years-old and hypertension is more prevalent in older adults (202). Or, it may be because people are unaware of how much salt is 'hidden' in foods, therefore, they underestimate their own salt intake (101). One study compared how people perceived their personal salt intake (i.e. too low, satisfactory, too high) to their estimated salt intake, calculated via a food frequency questionnaire, and found that participants typically underestimated their own salt intake (58). In two separate studies in Australia, conducted eight-years apart, authors found that the majority of participants (56% in one study and 66% in the other) thought their salt intake was at or below the recommended level, despite the average salt-intake in Australia being 50% higher than recommended (101,199). Together, this evidence suggests that the recommended intake of salt, foods that are major contributors to salt intake, and information about personal intake are particular aspects of knowledge that should be addressed in a salt reduction intervention to encourage people to buy lower-salt foods.

Other domains of psychological capability include skills; memory, attention and decision-making; and behavioural regulation. There is some evidence to suggest that people lack the skills to adequately interpret and use nutrition labelling, in particular, to compare the nutrient content between products (100,101,198), which could impact their ability to choose lower-

salt foods. Though not explicit in the literature, cooking skills to adapt to using less salt in cooking may conceivably play a role in salt reduction also.

An important concept in behaviour change is that of self-regulation. The process of self-regulation is the underpinning tenet of both self-regulation and control theory (203,204). In summary, these theories postulate that behaviour towards a goal is driven by a cycle of behaviour, self-monitoring of outcome, assessment against the goal and redirection of behaviour(s) towards goal attainment. Self-monitoring, and feedback necessary to enable this, are recognised as important components in dietary behaviour change (205,206). In the context of developing an intervention to reduce the purchase of high-salt foods and overall salt intake, this highlights the need for feedback and self-monitoring mechanisms, as there are currently few easily accessible ways of receiving accurate feedback on salt intake such as there are for weight or blood pressure for example. I found one study which investigated the impact of providing individualised feedback on sodium intake (calculated from an online sodium calculator (https://www.projectbiglife.ca/)); as well as comparison to the recommended intake; on knowledge, attitudes and intentions towards salt intake. This study found that feedback changed respondents *intended* behaviours (e.g. use of table salt, purchase of packaged foods, eating out), assessed by a validated questionnaire, though no assessment of actual intake was reported (207).

In addition, implementing change also requires utilisation of planning techniques such as implementation intentions or action plans (208) which can increase the effectiveness of interventions to change dietary behaviours (209,210). Though I found no specific evidence for a lack of behavioural regulation being an issue in achieving a lower-salt diet, the evidence

clearly suggests that it is helpful to have strategies to transform intentions into behaviour change.

3.1.2 Opportunity

Opportunity encompasses both physical and social opportunity. Physical opportunity includes the environmental context and resources for individuals to reduce their purchase of high-salt foods such as the availability of lower-salt options; a way of easily identifying lower-salt options when shopping; and an environment which encourages or enables shoppers to choose lower-salt options e.g. through pricing, promotion, or placement. In the UK, lower-salt options exist for many foods which contribute substantially to salt intake (e.g., bread, ham), and in some of these food categories, there is a wide variety of salt content which creates opportunities to swap to lower-salt options (87,88).

The introduction of a simple traffic light format for front-of-pack nutrition labels in the UK may have increased the opportunity for individuals to identify lower-salt foods, however, not all products have these front-of-pack labels. One study specifically investigating the use of low-salt nutrition labels reported that participants found it time-consuming to identify lower-salt alternatives (124). This provides some evidence for the need to enhance the 'opportunity' for people to identify lower-salt options. In the online supermarket study in Chapter 2, lower-salt options were promoted to customers as active prompts in response to the selection of high-salt foods. The results of the study suggest that such prompts can encourage shoppers to change their purchasing behaviour (103).

Whether people have the social opportunity to reduce their purchase of high-salt foods is unclear. Part of social opportunity is the social norms which exist around a specific behaviour. Social norms are "implicit codes of conduct that provide a guide to appropriate

action" i.e. what we perceive other people to do, or to approve of (211). There is evidence that social norms influence food choices (212), though the literature on social norms for salt consumption or purchase is not extensive. One online survey of 1030 people in Denmark found that social norms influenced peoples' *intention* to reduce their salt intake but this study did not investigate purchase or consumption (201). A study in the UK among first-generation Bangladeshi patients with chronic kidney disease, found perceived social norms around use of salt to be a barrier to reducing salt, though it is unclear if this is specific to this population (213). Both studies support the idea that social norms may influence salt reduction behaviour and therefore, should be considered when developing an intervention.

Another element of social opportunity is social support which could be from friends, family, health professionals, or other individuals trying to change their dietary salt intake. While social support has been identified as a key component to encourage dietary behaviour change (214), the evidence for the need for social support to achieve a low-salt diet is primarily drawn from the literature on people with heart failure, who are already unwell and possibly have different support needs (215,216).

3.1.3 Motivation

In the COM-B model, motivation comprises reflective and automatic motivation. Reflective motivation is the 'conscious' process whereby we stop to think and consider a behaviour, before engaging in it. Reflective motivation drives our intention to behave in a certain way and is influenced by beliefs about what is good and bad behaviour, the consequences of the behaviour and individual self-efficacy (192). This aligns with the Theory of Planned Behaviour, which states that intention to perform a behaviour is influenced by social norms, attitude and perceived behavioural control (i.e. how much do we think we can control this behaviour); the strength of intention to engage in a behaviour directly influences the

likelihood of a person doing so (217). Based on these theoretical constructs, for individuals to reduce their purchase of high-salt foods, they need to believe it is beneficial to them, that they can make this change and it is a socially accepted behaviour.

Several studies provide support for this theory, having found that people who believe salt reduction is important, and those with hypertension (who may perceive a greater personal benefit) are more likely to take action to reduce their salt intake than their peers (101,200,218,219). Further, in the online supermarket study presented in Chapter 2, I found that people who rated health as an important consideration in food purchasing decisions, reported regular use of nutrition labels; or who had previously been advised to reduce their salt intake, accepted more lower-salt swaps offered (103). Together this evidence suggests that boosting peoples' beliefs about the need to change and the benefits of salt reduction are likely to be important aspects in encouraging behaviour change, and that people with existing hypertension may be a more intrinsically motivated target audience.

Automatic motivation is the processes involving emotional reactions, reflex states and habits (192). Despite the influence of price and other marketing factors on shoppers' conscious decision making, much of shoppers' purchasing behaviour is still habitual and automatic. Shoppers often rely on heuristics, where most product information is ignored and they focus on a few key cues such as the appearance of objects, familiar pictures, shapes, sizes, logos, and brands (220,221). Given this automatic factor in purchasing decision, there may be a need to disrupt this habitual behaviour in a salt reduction intervention, to encourage a more information-processing approach, allowing reflective motivation to drive shoppers' buying choices.

3.1.4 Input from the co-design panel

The themes drawn from the literature around psychological capability were broadly reflected in discussion with the co-design panel. Though panel members were aware of the high salt content of many processed foods, they were not aware of the benefits of reducing their salt intake. In addition, they reported difficulty in identifying lower-salt options, particularly understanding the nutrition information available on packaging. They were also supportive of actions to make it easier to identify lower-salt options. The responses could generally be grouped into three areas: knowledge of how salt affects blood pressure; the need for help to identify lower-salt products; and other ways to help reduce salt intake (Table 3.1).

Table 3.1 Themes from the co-design panel.

Theme	Example quotes
Knowledge of how salt affects blood pressure	*"Visual representation of what happens when you have too much salt i.e. how does it actually cause a raise in blood pressure" Panel participant 02, female, focus group 1* *"More sharp messages [are required]" Panel participant 03, female, focus group 1* *"Make it meaningful, what is the impact on health…" Panel participant 01, male, focus group 2*
Help identifying lower-salt foods	*"…if there was a way to identify the options which are no-salt or lower-salt" Panel participant 03, female, focus group 1* *"…processed foods are what matters so help choosing processed foods would be good" Panel participant 01, male, focus group 1* *"…if there is low salt option, I would buy it happily" Panel participant 02, female, focus group 1* *"…info on what you could substitute, examples of alternatives when cooking (spices, etc), things to avoid." Panel participant 02, female, focus group 1*

	"Highlight how much salt is in unexpected things…for example bread, cheese" Panel participant 02, female, focus group 2
Help to reduce salt intake	*"if supermarkets could be involved to improve choice, have separate aisle for low-salt foods in the way they have a 'free from' section or a section for foreign foods." Panel participant 03, female, focus group 1* *"need to involve the supermarket to change the environment and also incentives to supermarket to do this so they can get something back… people are busy and need something quick, to make their lives easier and improve their health" Panel participant 01, male, focus group 1* *"Supermarkets should do all this work of identifying high-salt food" Panel participant 04, male, focus group 1* *"Also, availability and more choice would help, having more lower-salt products, that your supermarket stocks lower-salt options" Panel participant 02, female, focus group 1* *"How much salt is 6g – visual of this?" Panel participant 03, female, focus group 2* *"Make a commitment on the app…for example a goal" Panel participant 05, female focus group 2*

3.1.5 Input from healthcare professionals

Two practice nurses provided input from their experiences of discussing lifestyle risk factors with people with high blood pressure, including their experience of barriers and facilitators for patients to reduce their salt intake. Example statements included:

"…Patients are incentivised by measurable things"

"Patients are good at recognising what they could work on"

"Patients often know what they should be doing so sometimes giving them a choice of ways to reduce their blood pressure is good"

"People are motivated to not want to be on medication"

"People say they don't cook with salt…or they are aware they have too much salt" "they do know that they have lots of ready meals so too much salt, but some are willing to change…"

3.1.6 The behavioural diagnosis

Based on the COM-B analysis, I concluded that to reduce individuals' purchase of high-salt foods, changes are required to the aspects of psychological capability, physical opportunity, social opportunity, reflective and automatic motivation (Table 3.2). There is insufficient evidence to determine which of these aspects are the most important in driving change to purchasing of high salt foods but I would propose that changing one of these alone would not be enough. It is certainly well recognised that providing information is not enough to change health behaviour (222). For reducing salt intake, there is a greater quantity of evidence describing deficiencies in specific areas of knowledge (e.g. how much is too much salt? What are the key contributors to salt intake) and opportunity (time and effort to identify lower salt foods) but this may be due to biases inherent in methods of data collection? Therefore, all identified aspects were treated as important in designing the intervention and the impact on behaviour was considered as part of the subsequent qualitative evaluation.

3.2 Stage 2. Identifying intervention options

Step 5. Identify the intervention functions Step 6. Identify policy categories.

Intervention functions are the "means by which an intervention can change behaviour" and can be mapped to the COM-B components (192). I considered the nine intervention functions set out in the BCW approach, to determine the suitability of each function to address the components of COM-B and domains of the TDF, most needing to change in order to impact my chosen target behaviour. I assessed suitability using the APEASE criteria of affordability,

practicability, effectiveness, acceptability, safety and equity (of access, opportunity and delivery) (Table 3.3) and concluded that the intervention functions best suited to deliver this intervention were *education, persuasion* and *enablement*.

I then considered which policy categories would be suitable to support the chosen intervention functions, also using the APEASE criteria (Table 3.4). I selected service provision as the primary policy option as it can readily deliver all the selected intervention functions.

Table 3.2. COM-B components, TDF domains and what needs to change to reduce individuals' purchase of high-salt foods.

COM-B component	TDF domain(s)	What needs to change for the target behaviour to occur?
Physical Capability	Physical Skills	No changes required.
Psychological capability	Knowledge Cognitive & interpersonal skills Memory, attention & decision making Behavioural regulation	Increase knowledge about why to reduce salt; the health consequences of high salt intake and the benefits of reducing it; knowledge of how much salt is recommended; what the most common sources of salt in the diet are; and how to identify high-salt foods and lower-salt alternatives. Knowledge and understanding of their personal salt intake. Improve skills for using nutrition information on packs Improving decision-making between alternative products Enhance self-monitoring of progress towards goals e.g. facilitate feedback and encourage action planning to achieve a pre-selected goal.
Physical opportunity	Environmental contextual & resources	Changes to the environmental context to make lower-salt options more easily identifiable
Social opportunity	Social influences	Improve family support for lowering salt intake Manipulation and communication of social norms towards purchase of lower-salt products
Reflective motivation	Goals Intentions Beliefs about consequences Optimism Beliefs about capabilities Professional/social role & identity	Increase intention to reduce salt intake, particularly through purchasing lower-salt alternatives, and fewer high-salt products Persuade people that reducing their salt intake really could improve their health and blood pressure Increase peoples' belief in their capability to reduce their salt intake Encourage and facilitate goal setting to reduce salt intake Encourage people to see eating a low-salt diet as part of their identity as someone who lives a healthy lifestyle
Automatic motivation	Reinforcement Emotion	Disrupt automatic purchases of 'habitual' products

Table 3.3. Intervention functions and how they might address 'what needs to change' to reduce purchase of high-salt foods.

Intervention function	Example for reducing purchase of high-salt foods	APEASE assessment
Education	Provide education on the health benefits of reducing salt and how to reduce salt intake	**Suitable** Meets the criteria of affordability, practicability, acceptability and safety and there is evidence for effectiveness. Consideration needs to be given to deliver equitably.
Persuasion	Persuade people that it is beneficial for their health, and that it is effective and achievable	**Suitable** Meets the criteria of affordability, practicability, acceptability and safety. Evidence for effectiveness is less clear as persuasion often combined with education/awareness. Consideration needs to be given to deliver equitably.
Incentivisation	Provide social or financial rewards for choosing lower-salt products	**Not suitable** Not practicable and no clear evidence of effectiveness.
Coercion	Create a punishment for purchase of high-salt foods	**Not suitable** Unlikely to be acceptable to individuals
Training	Training in selection of lower-salt options, skills to form and maintain new habits, and interpersonal skills to overcome any barriers to purchasing lower-salt options.	**Not suitable** Not affordable or practicable to deliver this degree of skills training widely. Otherwise meets the criteria of safety effectiveness, safety.
Restriction	Restrict access to high-salt products in stores	**Not suitable** No available options for applying restrictions so not practicable
Environmental restructuring	Use choice architecture approaches to move all high-salt products to less accessible placements and the reverse of low salt products. Place low salt options, clearly signposted, next to all high-salt alternatives	**Not suitable** Not practicable as requires change to behaviour of others (retailers or government)
Modelling	Demonstrate examples of individuals choosing lower-salt options when grocery shopping	**Not suitable** Not practicable and no evidence of effectiveness
Enablement	Making it easier for people to identify high-salt products and lower-salt alternatives	**Suitable** Meets the criteria of affordability, practicability, acceptability and safety and there is evidence for effectiveness. Consideration needs to be given to deliver equitably

Table 3.4 APEASE assessment of policy categories.

Policy category	APEASE assessment
Communications/marketing	Suitable but questionable effectiveness or practicability
Guidelines	Suitable but question effectiveness
Fiscal measures	Not practicable
Regulation	Not practicable
Legislation	Not practicable
Environmental/social planning	Not practicable
Service provision	Possible

3.3 Stage 3. Identify content and implementation options

Steps 7. Identify the behaviour change techniques Step 8. Identify mode of delivery

I specified the intervention content using behaviour change techniques (BCTs) drawn from a published taxonomy of 93 techniques (223). The BCTs are the "active ingredients" of an intervention; the components designed to change behaviour (188). Specifying the content using an established taxonomy enables robust reporting of the intervention design, facilitates intervention fidelity assessment and evaluation of the mechanisms by which the intervention effects behaviour change (223). I reviewed the full taxonomy of 93 BCTs to identify potential techniques that could be used to address the COM-B components identified in the behavioural analysis: psychological capability, physical and social opportunity, reflective and automatic motivation. To identify and prioritise BCTs to include, I referred to the literature for evidence of the effectiveness of, or rationale for use, and I also drew on input from the co-design panel. Although national guidance on the development of behaviour change interventions recommends choosing BCTs for which there is evidence of effectiveness (224), reporting of BCTs used in behaviour change interventions and evaluation of their effectiveness, is still relatively limited in the literature. Reasonable evidence of effectiveness is available only for those BCTs most

frequently used. Techniques which have been shown to be effective in changing behaviour in a variety of settings include: goal setting, action planning, feedback, and monitoring (224). For dietary behaviours in particular, there is evidence of effectiveness for techniques of self-monitoring (131,206,214,225,226) goal setting (206), social support (214,226) and tailored feedback (131). In addition, a multi-country qualitative study by Newson and colleagues explored the preferred communication source for people to hear about the impact of salt and health, and found that people prefer to hear this from the medical community, e.g. doctors or dieticians (58), giving rationale for the use of the BCT 'credible source'. Where I found insufficient evidence as to the effect of techniques, I included BCTs with a plausible rationale for use which could reasonably be delivered through the chosen intervention functions.

The final step of the BCW is to determine how best to deliver each of the intervention functions and BCTs, e.g. whether to deliver the intervention at an individual level, group, or community level; and whether to deliver it face-to-face or remotely. I discussed proposed approaches to deliver the intervention content with the co-design panel and in interviews with HCPs, and I used the APEASE criteria to inform this step. To accommodate the selected BCTs, and to deliver the intervention at the point where purchasing decisions are routinely made, i.e. in grocery stores, I chose a combined approach of face-to-face and via a mobile app, at an individual level. The HCPs indicated that delivering targeted advice would be something within their usual job role and skill set, and that with adequate training, they would feel comfortable demonstrating how to use an app to their patients. The selected BCTs included in the intervention, and the mode of delivery are outlined in Table 3.5.

Table 3.5. BCTs delivered through the intervention to reduce individuals purchase of high-salt foods, and the selected mode of delivery.

BCT	Definition	Delivered in SaltSwap	Mode of Delivery
1.1 Goal Setting	Set or agree on a goal defined in terms of the behaviour to be achieved	Set a goal to make swap a set number of products to lower-salt alternatives	Face-to-face App
1.2 Problem Solving	Analyse, or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators	Discuss the individuals' perceived barriers to swapping to lower-salt alternatives and how to overcome these.	Face-to-face
1.4 Action planning	Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive)	Complete an action plan detailing which products to find alternatives for (each week), and where and when they will do this.	Face-to-face
2.2 Feedback on Behaviour	Monitor and provide informative or evaluative feedback on performance of the behaviour	Feedback provided on the number of swaps to lower-salt alternatives accepted each shopping trip, in relation to their goal	App
2.3 Self-monitoring of behaviour	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy	Show the number of swaps made, and what they were, for each shopping trip	App
2.4 Self-monitoring of outcome of behaviour	Establish a method for the person to monitor and record the outcome(s) of their behaviour as part of a behaviour change strategy	Show the percentage reduction in salt achieved through the swaps made, for each shopping trip	App
2.7 Feedback on Outcome of Behaviour	Monitor and provide feedback on the outcome of performance of the behaviour	Provide feedback on the percentage salt reduction achieved through swaps made, for each shopping trip	App
4.1 Instruction to perform behaviour	Advise or agree on how to perform the behaviour	Show the person how to identify lower-salt options, using the app and product nutrition labelling and also explain other ways to reduce salt intake	Face-to-face

5.1 Information about health consequences	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	Explain the effect of reducing salt intake on blood pressure and risk of CVD	Face-to-face
7.1 Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance	Use of the SaltSwap app as an environmental stimulus to look for salt content of products or for products labelled 'reduced-salt'. The traffic light labels in the app will also be prompts to change to a lower-salt product	App
8.2 Behaviour substitution	Prompt substitution of the unwanted behaviour with a wanted or neutral behaviour	Provide suggested alternatives to high-salt products	App
9.1 Credible source	Present verbal or visual communication from a credible source in favour of or against the behaviour	Salt reduction advice presented by a trained healthcare professional. Include references to evidence in the scientific literature to support the benefits of salt reduction.	Face-to-face
11.3 Conserving mental resources	Advise on ways of minimising demands on mental resources to facilitate behaviour change	Use of the app to make it easier to identify lower-salt alternatives, as the best alternative is shown	App
12.5 Adding objects to the environment	Add objects to the environment in order to facilitate performance of the behaviour	Via the app, add traffic light nutrient labels and suggested lower-salt alternatives, into the shopping environment to aid identification of lower-salt products	App
13.1 Identification of self as a role model	Inform that one's own behaviour may be an example to others	Encourage the person to share their successes in finding lower-salt options with their friends and family	App
15.1 Verbal persuasion about capability	Tell the person that they can successfully perform the wanted behaviour, arguing against self-doubts and asserting that they can and will succeed.	Discuss the person's capability to swap to lower-salt alternatives and stick with them. Demonstrate that they can successfully reduce their salt intake without giving up all their favourite foods.	Face-to-face

4. The intervention

Taking the results from this detailed intervention design approach using the BCW, I set out the key intervention objectives (Figure 3.6). The resulting intervention, SaltSwap, consists of a single face-to-face session with a healthcare professional, to provide education, advice and behaviour change support; and use of a smartphone app to help identify high-salt foods and lower-salt alternatives when grocery shopping. The nature of salt consumption in the UK is such that number of core foods contribute substantially to salt intake (57,60,61). Across these core foods, there is a wide variation in the salt content (88) providing opportunity to reduce salt by a moderate degree by switching to a product with less salt over several commonly consumed products. Further, as demonstrated in the OLS study in Chapter 2, encouraging larger magnitude reductions in salt, by offering out of category foods, can result in greater total salt reduction overall. If successful, this approach of offering moderate changes over a number of purchases has the potential to provide a larger cumulative reduction in total intake, without individuals needing to sacrifice certain foods entirely, which may limit the sustainability of behaviour change.

Figure 3.6. Intervention objectives.

Key intervention objectives

1. To inform people of the common sources of salt dietary salt and the recommended maximum daily intake.
2. To persuade people that reducing their salt intake is beneficial for reducing blood pressure, that they may be consuming more salt than is recommended and that reducing their salt intake is achievable.
3. To optimise behavioural change by maximising behavioural regulation.
4. To enable people to identify lower-salt options when supermarket shopping.
5. To motivate people to make lower-salt food choices.

4.1 Brief advice

The advice session serves to increase knowledge among the target population about the health impacts of high-salt intake, sources of salt, and the recommended daily limit; to persuade and motivate individuals to decrease their salt intake, and; to initiate the behaviour change process by working with individuals to set goals and make an action plan to reduce their salt intake. The advice session covers all elements of salt reduction, including discretionary salt use and eating out, but focuses primarily on reducing purchases of high-salt foods when grocery shopping. The session also introduces the SaltSwap app.

The content of the brief-advice session is as follows:

- The impact of salt on health, and blood pressure in particular.
- The health benefits of salt reduction.
- Recommended salt intake.
- Advice for cutting salt intake.
- Examples of lower-salt alternatives.
- A set of activities including:
    - Identifying personalised targets for change.
    - Problem-solving and overcoming barriers.
    - Salt reduction goal setting.
    - Self-assessment of capability.
    - Action planning to reduce salt intake.
- Introducing and downloading the SaltSwap app.

The advice session is supported by the SaltSwap booklet (Appendix 8), which sets out detailed information, visually highlighting key facts. The session is delivered by a trained HCP, who would typically deliver brief, dietary advice in primary care. HCPs receive one-

hour of in-person training to deliver the intervention (and the related trial procedures) and are provided with online, video-based training materials for later reference. These materials cover the rationale and theory behind the intervention, the detailed content of the intervention and materials demonstrating use of the app.

4.2 SaltSwap app

Before undertaking to develop an app, I systematically reviewed the app market (the App Store and Google Play Store) to determine if any existing apps contained the functionality required to deliver the intervention objectives (Appendix 9). Lack of a suitable, available app indicated it was necessary to develop a bespoke app to deliver this intervention.

The SaltSwap app allows users to scan product barcodes to view the nutrient content of products and suggests similar but lower-salt alternatives (Figure 3.7). Nutrition information is provided in a clear and consistent traffic light format, as recommended by UK guidelines (227). Alternative products, which are at least 10% lower in salt, are presented in order of the magnitude of salt reduction with the lowest-salt alternatives listed first. There are no restrictions on pack size, price, other nutrient or energy content of suggested alternatives.

Individuals can set goals within the app (‘make one swap’, up to ‘make five or more swaps’), following the goal-setting activity in the advice session. They can record swaps (i.e. where the lower-salt alternative was accepted) in the app. At the end of each shopping trip, the app provides feedback on achievement of swap goals and the percentage reduction in salt content achieved through making these swaps (calculated as the percentage reduction in salt content in g/100g for each product, averaged across all products swapped) (Figure 3.8). The app also provides a history of previous shopping trips including the number of swaps made in each

trip, listing specific products swapped and the salt reduction in each swap. Each swap can also be shared through social media, email, or messaging apps to enable users to tell their friends and family about the products they have swapped (Figure 3.8). The SaltSwap app functions and how these relate to the BCTs is shown in Figure 3.9.

To enable evaluation of changes to food purchases, the app enables users to record all items purchased, by scanning the product barcode or typing product information manually into the app.

Figure 3.7. SaltSwap screenshots.

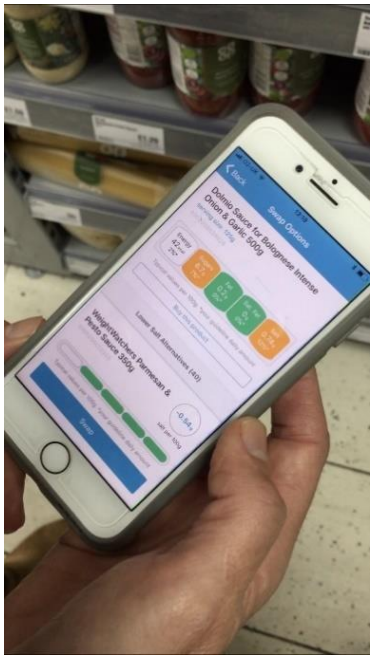




Figure 3.8. SaltSwap feedback, previous shops and 'share' screens.

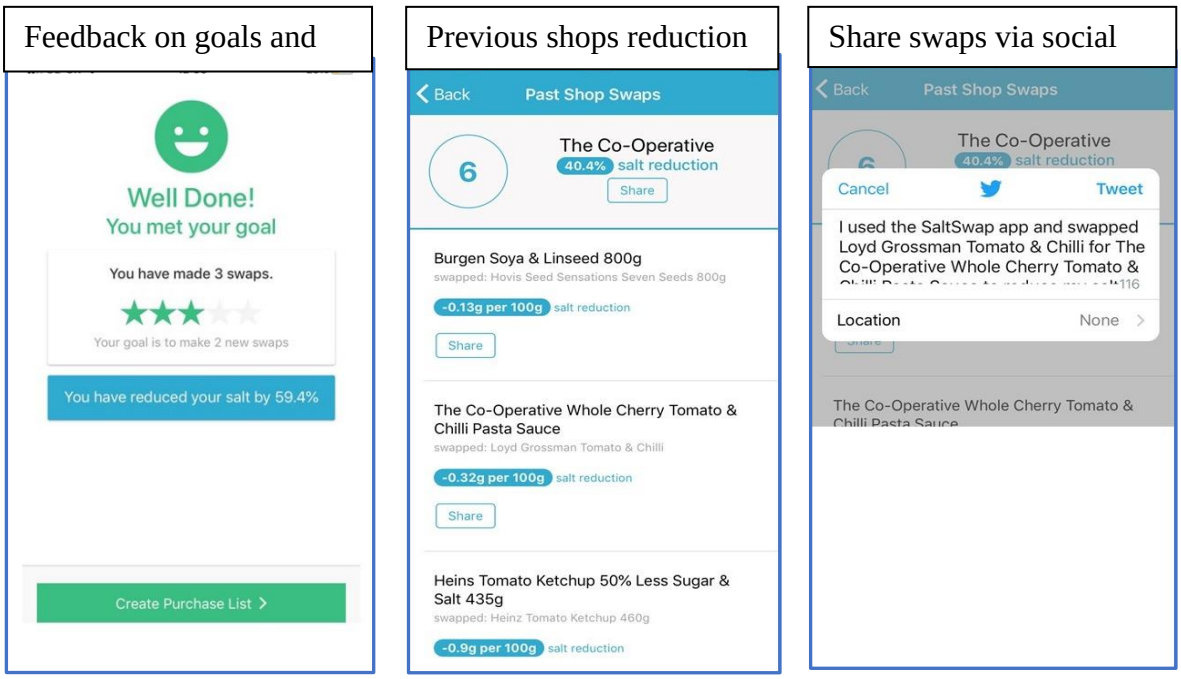
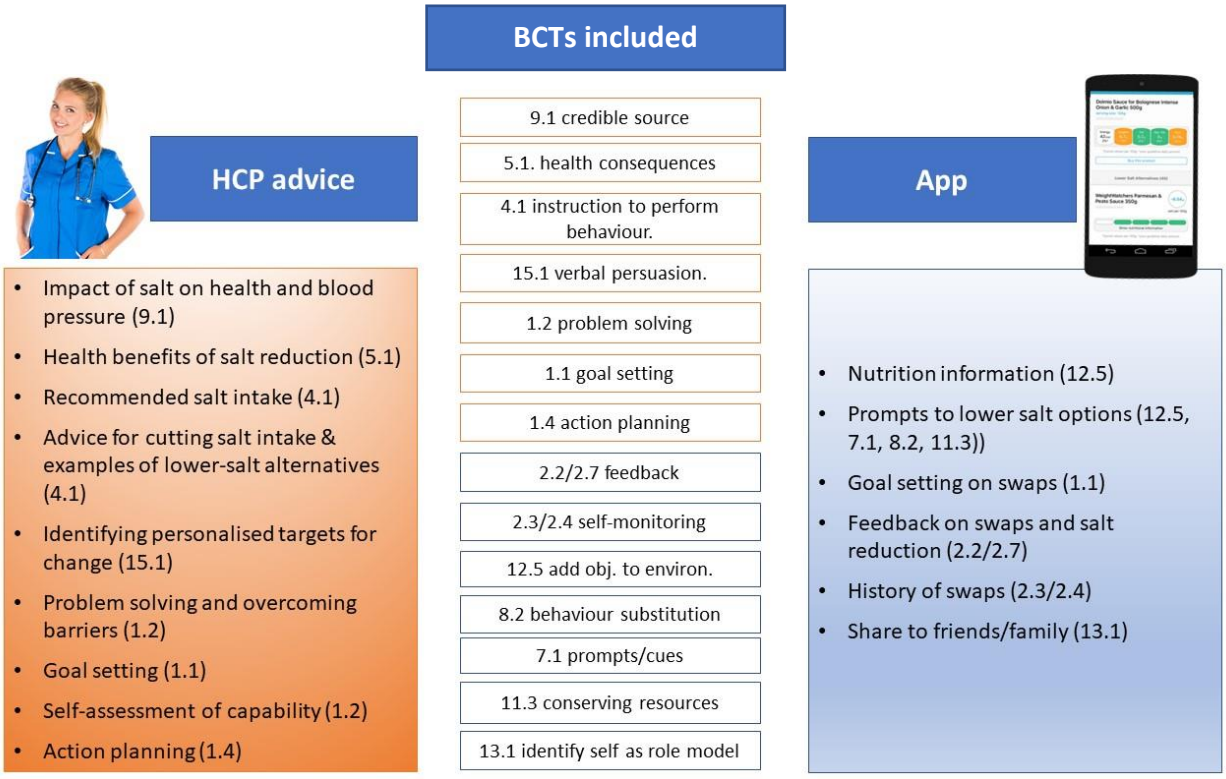


Figure 3.9. The SaltSwap intervention components and related BCTs.



4.2.1 App database development

The SaltSwap app is underpinned by a database of products available in UK grocery stores, with detailed nutrient data. This database was sourced from two key sources: a commercial organisation that collates product and nutrient data for several UK retail supermarkets (Asda, Sainsbury's and Tesco) (https://www.brandview.com/); and The George Institute of Global Health (https://www.georgeinstitute.org.au/) who have created a food and nutrient database of products, primarily crowd-sourced, from UK supermarkets including Tesco, Sainsbury's, Morrison's, Lidl, Aldi, Iceland, Waitrose, The Co-operative, and Marks & Spencer's.

The SaltSwap database contains 95,290 unique products. All products in the app database are categorised according to a defined schema of product group (i.e. a wider selection of products) and category (i.e. from a narrower subset of products). Product categorisation utilised the product categories of the source databases and these were mapped to the new schema. An example product group and associated categories is group*: breakfast cereals;* categories*: hot cereals, ready-to-eat cereals, muesli & granola and breakfast cereal variety packs.* Appendix 10, Table 4 shows other examples. Suggested alternatives are drawn from the same group (the first ten results presented) followed by alternatives which match the same product group and category. Offering alternatives from the wider product group increases the variety of lower-salt products available and increases the potential magnitude of salt reduction through accepting a swap (see Appendix 10, Table 5 for an example).

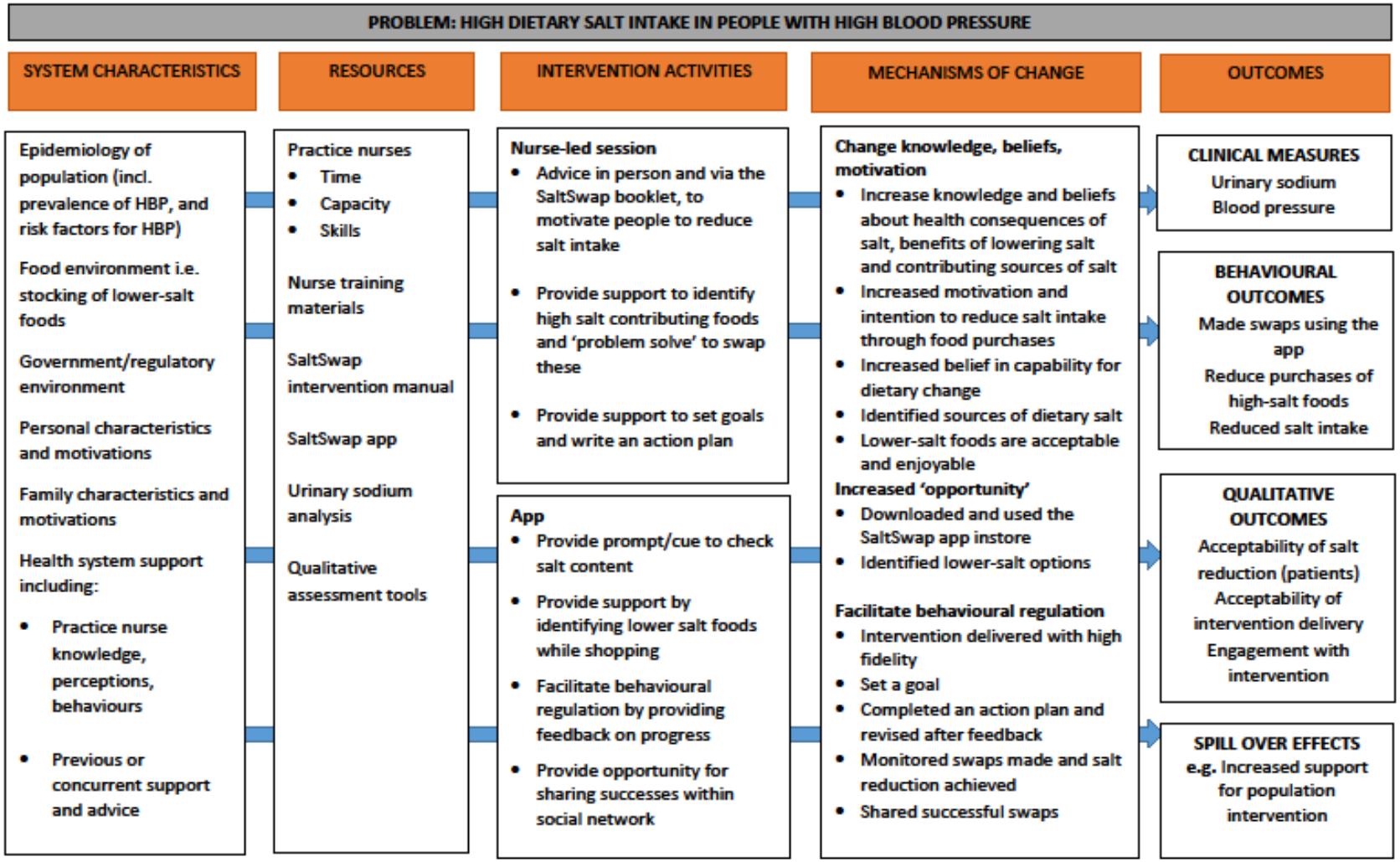
5. Evaluation design

Evaluation design should be considered in the early phases of developing interventions (228). The BCW approach facilitates evaluation, design and planning through the transparent and systematic specification of the intervention content as BCTs and identification of the

hypothesized mechanisms of change. Lack of clarity around the mechanisms through which digital behaviour-change interventions influence behaviour is recognised as a particular issue when creating and evaluating digital interventions for health behaviours (229). To help overcome this issue, I used a logic model to systematically consider and visually present the relationships between planned intervention activities and the intended outcomes, explicitly identifying the proposed mechanisms by which these activities will generate the desired behaviour change, i.e. a causal pathway (Figure 3.10) (230,231). These mechanisms of impact can be linked directly back to the BCTs identified earlier in the intervention design process. For example, BCT 5.1. "information about health consequences", links directly to the mechanism of impact statement "increase knowledge and beliefs about health consequences of salt". The logic model was developed iteratively throughout the intervention development process, in conjunction with my supervisors. The outcomes and intervention activities were informed by the co-design focus groups.

The initial evaluation of this intervention will be a feasibility and process evaluation. This will assess fidelity of intervention delivery, use of and engagement with the intervention, engagement with specific intervention components (and the underlying BCTs), and barriers and facilitators related to the intervention. I will employ quantitative and qualitative methods to inform iterative future development of the intervention. The intervention development, content and evaluation were reported in accordance with the WIDER recommendations for reporting of behaviour change interventions (232).

Figure 3.10. Logic model for encouraging people to reduce purchases of high-salt foods.



6. Discussion

6.1 Summary of findings

The aim of this research was to design an intervention to reduce salt intake among people with high blood pressure, using an established behaviour change framework. The resulting intervention combines digital and face-to-face components using the intervention functions of education, persuasion, and enablement to enhance key aspects of capability, motivation and opportunity identified in the behavioural analysis. The intervention targets the purchase of high-salt foods when supermarket shopping and encourages individuals to swap to lower-salt alternatives for the key foods which contribute most to their dietary salt intake, and to limit their purchase and consumption of high-salt foods. Altogether 16 BCTs are included, largely drawn from the BCT taxonomy groups 'goals and planning' and 'feedback and monitoring'; both of which have significant evidence to support their effectiveness in dietary behaviour change (224,225). SaltSwap is a multi-component intervention; the app enables delivery of BCTs which could not easily be delivered through a single face-to-face session (e.g. tailored advice, feedback on the outcome of behaviour), and the HCP advice session provides verbal persuasion and problem-solving, which could less easily be delivered by a stand-alone app intervention. Moreover, the face-to-face advice session provides support to participants to start using the app, which in an older population with likely lower app-use, may be a key element in achieving app use. The behavioural analysis and specification of BCTs informed a logic model to map the hypothesised causal pathway of the intervention and choose outcome measures for future evaluation.

6.2 Strengths

I found the BCW to be a systematic and comprehensive approach to developing a behaviour change intervention which encouraged intervention development in line with best-practice recommendations, i.e. that interventions are based on evidence of effectiveness, developed through co-production, have a theoretical grounding, and use techniques proven to be effective for changing behaviour (224). I considered using other theoretically informed intervention design frameworks here such as Intervention Mapping (233) and the Causal Model (228). Intervention mapping is an early pre-cursor to the BCW, specifically intended for developing health education programmes but provides little guidance on the choice of specific behavioural theories, being a more 'expert-led' approach, a key limitation for use by non-psychologist intervention designers. While both Intervention Mapping and The Casual Model have similarities to the BCW, I felt that neither provides the structured framework for considering behavioural influences, and the link from these to the specific intervention content, that the BCW does.

Though guidance recommends behaviour change intervention design should have a sound theoretical basis, the evidence that interventions based on theory are more effective is somewhat inconsistent (206). A review of 11 systematic reviews of the use of theory in behaviour change intervention development, across a range of behaviours from diet to cancer screening, concluded that interventions based on theory were more effective overall than those not (234). Similarly, a review specifically investigating digital interventions for health behaviour change concluded that greater use of theory and using a greater number of BCTs both led to increased effect sizes (235). Yet, one review of interventions to improve diet quality, found that interventions targeting fruit and vegetable consumption had larger effects if they were theoretically based, whilst there was no beneficial effect of using theory for

interventions targeting fat intake or serum cholesterol (130). Some authors have attempted to rationalise this mixed picture, proposing that it may be poor choice or application of theory that leads to lack of effect (187). It is also possible that lack of intervention effect is due to ineffectual delivery of intervention components rather than interventions being ineffective (130). Further, effective interventions may be designed by subject matter specialists, without explicit reference to theory, but with an implicit understanding of the target behaviour drawn from experience in the field. This was demonstrated in a study to reduce salt intake in China. The authors, who have published widely in the field, developed an educational behaviour change intervention with no reported reference to theory (236), yet it significantly reduced salt intake in children and adult family members (237). Using the BCW as the theoretical framework for this intervention enhanced my understanding of the behaviour-guided use of relevant theory and enabled clear specification of the intervention content which will support future evaluation of intervention fidelity.

Using an iterative co-design approach and involving HCPs who would ultimately deliver the intervention brought several benefits. For example, the co-design panel brought to light the need to enable people to identify lower-salt options when shopping, a view not raised in the literature. They also highlighted to me that not all smartphone users knew how to use their phone to scan product barcodes. This informed the development of the training materials, to ensure this functionality was adequately demonstrated. Interviews with HCPs provided assurance that the proposed intervention approach would likely be acceptable to HCPs and feasible to deliver.

A key strength of the intervention development was the specification of content using the BCT taxonomy. This enabled me to link concepts from the behavioural analysis to specific

features of my intervention and enable comprehensive and transparent reporting of intervention content in a future trial, the lack of which is a common problem in synthesising current literature on behavioural interventions (238,239). Use of the BCT taxonomy helped evaluation planning by informing the logic model of how and why the intervention is expected to change behaviour. Several examples from the literature highlight the benefit of measuring hypothesised mechanisms of impact in addition to primary outcomes. One study used the Theory of Planned Behaviour (TPB) to inform the development of educational materials on salt reduction for people at risk of high blood pressure, specifying key TPB constructs thought to be important in driving salt reduction. They found significant changes in all measured TPB constructs in the intervention group compared to control, as well as the primary endpoint of a significant reduction in salt intake (24-hour urinary sodium) providing a clear rationale for the impact of the intervention (240). In another example, the authors assessed a web-based educational salt-reduction intervention for children, applying social cognitive theory and using the BCT taxonomy to inform intervention content (241). This intervention showed no significant reduction in salt intake but did improve salt-related knowledge and attitudes which were hypothesised to drive overall salt reduction, providing some evidence to the impact of the intervention.

6.3 Limitations

The BCW was a practical and useful framework to develop a theory-based intervention, however, the framework leaves some gaps between the behavioural analysis, intervention content, and the final delivery. It did not go so far as to discuss the ‘how’ of delivery. For example, the BCT ‘information about health consequences’ could be delivered using the same mode, i.e. face-to-face delivery to individuals, but in different ways based on other attributes of the delivery such as the use of positive or negative framing (242). Similarly, the

BCT ‘feedback on outcome of behaviour’ could be considered in terms of how this feedback is framed but also based on how it could be affected by priming and salience; two of the key influences on behaviour as set out in the MINDSPACE framework (243). However, in comparison to other frameworks such as the Intervention Mapping approach (233), the BCW relies less on expert consensus therefore is a go-to tool for non-specialists in behaviour change. Applying the BCW approach was time-consuming, largely due to time invested in undertaking a rigorous behavioural analysis, including the use of evidence to support key decisions, involvement of a co-design panel and HCP interviews. Further, the BCW requires some comprehensive training to do it justice and maximise the benefit gained from taking a theoretically informed approach. I expect both these limitations would also apply to the use of any theoretically informed, user-centred design.

The resulting intervention design has some limitations also. The design does not easily allow identification of which BCTs are contributing the most to any effect. A modular approach, as used in some other health behaviour change apps, would allow for this (244). However, the SaltSwap app is delivered as a singular unit (app or no app) *and* as part of a multi-component intervention, rather than a purely digital intervention, therefore, practicalities may limit the use of a modular approach for testing. This is an area for future development and research should the intervention produce the desired effect on salt intake.

The SaltSwap intervention includes the use of a smartphone app among those with high blood pressure, who are typically older adults (202). Smartphone (i.e. mobile phones capable of using apps) use in the UK is ubiquitous and has grown dramatically; a 2019 report found that most adults in the UK use a smartphone phone (84%), and this is true for all age groups; including 93% of 35-54-year olds and 64% of those aged 55 and over (245). However, even

as ownership increases, it is important to recognise and try to address important age-related barriers to the effective use of smartphone apps. Wildenbos and colleagues (2018) summarise the main barriers as being cognitive and motivational barriers, physical barriers such as diminished eyesight, or impaired fine motor skills due to other medical conditions, and perceptual barriers which might increase the risk of errors when using mobile apps (246). This is not a reason to abandon mobile health apps for older adults, it provides rationale for age-appropriate, and well-considered user-centred design, which I have endeavoured to do here.

7. Conclusions and next steps

Using an established theoretical behaviour change framework, the BCW, I was able to develop a multi-component intervention aimed at reducing salt intake in people with high blood pressure, drawing on the published literature and taking a user-centred approach. I found the BCW to be a suitable tool for non-specialists; and it helped me to specify the intervention content in a transparent and robust manner, and plan a subsequent evaluation taking into account the hypothesized mechanisms of impact. Following this detailed intervention development and evaluation design, I developed a trial protocol to assess the impact of this intervention using a mixture of quantitative and qualitative methods. This evaluation will provide further feedback on the usefulness of this approach and is described in chapters 5 and 6.

Chapter 4. A feasibility randomised controlled trial of the SaltSwap intervention

1. Introduction

Cardiovascular disease (CVD) is the leading cause of premature mortality worldwide (4). One of the most significant risk factors for CVD is hypertension (14), a highly prevalent condition which affects a quarter of the adult population in the UK (13). A high-salt diet leads to increased blood pressure and risk of CVD, therefore reducing dietary salt intake is a key pillar of CVD prevention and the management and prevention of hypertension. Yet, adults in the UK consume on average 40% more salt than recommended by national dietary guidelines (53), with the majority of this derived from processed foods rather than salt added in cooking or at the table (57); and there has been no significant change in average population intake since 2009 (53).

In the UK, the routine assessment and management of hypertension is carried out in primary care. Guidelines exhort HCPs to provide advice to encourage individuals with hypertension to reduce their salt intake (109). Yet, despite good evidence for the effectiveness of interventions centred around dietary advice and acquisition of skills to maintain a low-salt diet (110), there are few effective interventions suitable for delivery in the primary care setting, by staff without specialist nutrition or behaviour change knowledge (127). In the previous chapter, I described the development of the SaltSwap intervention, a behaviourally informed intervention designed to be delivered in a routine primary care setting, to help people with hypertension reduce their salt intake. In brief, the intervention comprises a single, one-to-one advice and behavioural support session delivered by a practice nurse (or other HCP) to educate and motivate individuals to reduce their salt intake; in conjunction with a

smartphone app to help individuals identify lower-salt products when grocery shopping, to facilitate goal setting and to provide feedback on salt reduction in purchased foods.

In this chapter, I describe the initial feasibility evaluation of the SaltSwap intervention. I hypothesised that the SaltSwap intervention will reduce household purchases of high-salt foods, leading to reduced daily salt intake and blood pressure. A definitive trial to show whether this intervention can achieve sustained dietary behaviour change resulting in lower blood pressure would need to be large and expensive. Before this is justified, it is important to assess the feasibility of the intervention and to ensure that the research methods run as expected, in accordance with the Medical Research Council guidance on developing and evaluating complex interventions (186). In particular, I aimed to investigate whether primary care nurses (or healthcare assistants) can deliver this intervention as intended and whether participants use the intervention app. Although there is ubiquitous use of mobile phone apps for many aspects of modern-day living, the target population for this intervention is primarily older adults, whose use of mobile health apps is not so widespread (137) and who may experience unique usability issues (246), therefore usability testing is critical.

The intervention evaluation was based on a logic model to ensure that outcomes include not only the primary endpoints but measures of intermediary outcomes representing the causal pathway. Outcome measures for any future trial of effectiveness include blood pressure, salt intake and the salt content of purchased foods. I used 24-hour urinary sodium analysis to objectively assess salt intake, regarded as the gold standard method of assessment (22). This places a high burden on participants which may lead to loss to follow-up or incomplete outcomes. To collect purchase data and assess the salt content of purchased foods, I used a bespoke app, which has not previously been tested. Therefore, an additional aspect of this

trial was to assess the reliability and accuracy of this app as an outcome measurement tool, and the willingness of participants to complete 24-hour urine collections.

2. Aims & objectives

The overarching aim of this study was to test the feasibility of the intervention and trial design; therefore, the primary objective was to assess the criteria for progression to a full trial. Other objectives included:

- To examine the effectiveness of the intervention to reduce salt intake, salt purchased in household grocery shopping and blood pressure, after six-weeks (also to inform sample size calculations for a future trial).
- To examine the mechanisms of the impact of the intervention, and further feasibility outcomes through a range of process measures.

3. Methods

3.1 Trial design and setting

This feasibility study was an individually randomised, parallel, two-arm, controlled trial. A two-week baseline period was followed by randomisation, intervention delivery and then a six-week intervention period with a single follow-up visit. Participants were recruited through five GP practices in Oxfordshire, United Kingdom. The trial protocol was registered with an international trial registry on 5/04/2017 (trial registration**:** ISRCTN 20910962) and published in the journal Trials (Appendix 11). This study was reporting in accordance with the Consolidated Standards of Reporting Trials guidelines for feasibility trials (Appendix 12) (247).

3.2 Study roles and responsibilities

As the primary researcher, I undertook all study initiation and set-up activities, training for GP practice staff, trial management activities, the majority of the participant-facing study visits, and data collection and analysis. Nurses from the Thames Valley Clinical Research Network conducted three baseline visits and five follow-up visits on my behalf.

3.3 Recruitment

GP practices searched the electronic health records of registered patients to find people who met the demographic and clinical inclusion criteria. Prior to the invitation letters being sent, a general practitioner (GP) screened the search results to ensure that all those identified were medically appropriate to participate in the trial and met the clinical inclusion and exclusion criteria. The GP practice sent potential participants an invitation letter, asking them to contact the research team if they were interested in participating. The letter included a link to the participant information sheet.

3.4 Eligibility criteria

3.4.1 Inclusion Criteria

- Most recent systolic blood pressure reading (in the past two-years) above 130 mm Hg if patient is currently prescribed antihypertensive medication, or above 140 mm Hg if not prescribed medication.
- If on pharmacological treatment for hypertension, the participant had been prescribed a stable dose for at least six-weeks before beginning the study.
- Willing and able to give informed consent for participation in the study.
- Aged between 18- and 80-years.

- Responsible for at least some of their household grocery shopping (assessed as spending at least £25 at least once a fortnight in a supermarket, excluding online supermarket shopping).
- Own a smartphone (android or iOS) and willing to use an app for healthy eating.
- Express a desire for support to improve the nutritional quality of their diet to reduce their CVD risk.

3.4.2 Exclusion criteria

- Already on a clinician supervised diet or a restricted diet (e.g. vegan, gluten-free).
- Currently using, or have experience of using, the FoodSwitch or SaltSwitch apps.
- Unable to read and understand the instructions provided in English.
- Have secondary, previous accelerated, or malignant hypertension documented in electronic patient record.
- Currently being assessed for a diagnosis of hypertension.
- Currently on any medication that may lead to hyponatraemia or fluid retention.
- Existing or recent cardiovascular conditions: heart attack or stroke within the last three-months, heart failure of grade II New York Heart Association and more severe or prolonged QT syndrome, angina, arrhythmia, or atrial fibrillation.
- Currently participating in another research study that may interfere with the demands of the current study.
- Patients that the GP judges not suitable for, or able to meet the demands of the study, or unlikely to comply with study procedures as stated in the protocol.
- Planning to be away from home for more than two consecutive weeks during the six-week intervention period.

3.5 Screening and informed consent

Participants who were interested in taking part contacted me directly by phone or email. I assessed eligibility based on the full inclusion and exclusion criteria, verbally provided information as described in the participant information sheet and answered any questions about participation in the study. Those who were eligible were booked into an initial face-to-face baseline visit. When the participant attended the baseline visit, they were provided verbal and written information about the trial and written informed consent was sought.

3.6 Randomisation

I used computer-generated randomisation, stratified by GP practice with block randomisation (blocks of six), to allocate participants in a two-to-one ratio (intervention: control). A researcher not involved in taking consent or measuring study outcomes, generated the random number sequence, using an online random sequence generator (www.sealedenvelope.com). When a participant completed and submitted the baseline data, I requested a new allocation from this researcher, who assigned the participant according to the allocation sequence. This ensured the allocation was concealed from any researcher responsible for recording study outcome data until the intervention was assigned. Participants were unaware of the treatment allocation prior to consent.

3.7 Blinding

Due to the nature of the intervention and trial resources, it was not possible to blind participants, clinicians delivering the intervention, or outcome assessors, to the treatment group. The main trial outcomes were progression criteria which were unlikely to be influenced by knowledge of treatment allocation. Intervention effectiveness measures

comparing trial arms, which would be used as the primary outcome in a future RCT, were objectively measured and not subject to interpretation by researchers. Thus, limiting the effect that researcher knowledge of the treatment group could have on outcomes.

3.8 Intervention and comparator

3.8.1 Intervention

The SaltSwap intervention aimed to reduce salt intake by educating participants about the importance of salt reduction, how they can reduce their salt intake, and providing motivation to do this. It encouraged them to swap to lower-salt alternatives when grocery shopping and provided tools to help them do this. The intervention comprised behavioural advice and support provided by an HCP in primary care, and the SaltSwap app to use when grocery shopping. The intervention content and development are described in detail in Chapter 3. All other clinical care was continued as usual.

I trained designated HCPs from each practice (typically practice nurses or healthcare assistants) to deliver the intervention and to complete relevant study procedures, including the intervention checklist. The intervention was designed to be delivered by a HCP in a single 20-30-minute visit at the GP surgery. The HCP training video(s) can be viewed as MP4 files in the supplementary materials:

Video 1. SaltSwap intervention training

Video 2. SaltSwap app training

3.8.2 Comparator (control arm)

The control arm received generic salt reduction advice, intended to be equivalent to usual care. Participants randomised to the control arm received a postal copy of the publicly

available British Heart Foundation Cut Down on Salt booklet (170) or its successor; Taking Control of Salt (248). On completion of their follow-up visit, control participants were given the SaltSwap booklet and were shown how to download the SaltSwap app, although this was not known to them until the end of this visit. All other clinical care was continued as usual.

3.9 Data collection

3.9.1 Baseline assessment

At the baseline assessment visit, following consent, a researcher undertook a detailed assessment including measures of height, weight and blood pressure; recorded relevant medication history and medications; and recorded demographic information and details of the participants' shopping behaviour via a non-validated questionnaire (Appendix 13). At the end of the baseline visit, participants were taught how to use a restricted version of the SaltSwap mobile phone app (allowing only recording of purchased items with no nutrition information offered) to record their grocery shopping throughout the study (Appendix 14). They were also asked to collect their grocery shopping receipts throughout the study. They were provided with a stamped, self-addressed, envelope labelled with their participant ID, to return these receipts; which were scanned and stored electronically with originals kept in a locked cupboard in a secure, access-controlled room.

Following the baseline visit, participants collected baseline data over a two-week period including a single 24-hour urine sample, shopping till receipts, and data on grocery shopping purchases, recorded in the app. Participants who returned no data or partial baseline data were prompted, by phone or email, to return all requested data. Participants were randomised once all baseline data were returned and only those who provided this data were randomised.

3.9.2 Intervention visit

Participants randomised to the intervention arm attended one visit with a HCP. This session was audio-recorded to assess fidelity of intervention delivery. Healthcare professionals completed a paper-based checklist to prompt them to deliver all aspects of the intervention and to record if these were delivered.

3.9.3 Follow-up assessment

All participants were invited to attend one follow-up assessment six-weeks after the intervention visit or being sent the information leaflet, in the case of the control group. During this follow-up visit, a researcher measured blood pressure and documented any changes to relevant medical history and medications. Participants were asked to complete a questionnaire about the intervention (or control leaflet) (Appendix 15). Participants were asked to bring their grocery shopping receipts for the past six-weeks to the follow-up visit (or return by pre-paid post) and to provide a second 24-hour urine sample, at this appointment or within a week. In accordance with the protocol, participants were contacted by phone or email to arrange follow-up visits and sent text messages to remind them of their upcoming appointment.

3.10 Outcomes

3.10.1 Primary outcomes

The primary objective of the trial was to determine whether to progress to a larger trial to assess the effect of the intervention on blood pressure. The following criteria were used to assess whether to progress with minimal amendments to trial procedures (level one) or with substantial amendments to trial procedures (level two, threshold in brackets):

1. That at least 65% of participants attend the follow-up session (40%).

2. HCPs deliver at least four of the six essential intervention elements during the advice session (three of the six essential elements).
3. At least 50% of participants use the SaltSwap app to scan products (for nutritional information or swaps) on at least one occasion in the first month (40%).

If level two criteria were not met, I would not consider it feasible to continue to a larger trial with this trial design as follow-up would be too low to adequately asses the effect, or intervention fidelity too poor to be considered the cause of changes in outcomes. Progression criteria were set based on confidence intervals around a required threshold (see section 3.12 sample size).

3.10.2 Secondary outcomes

These outcomes would be effectiveness outcomes in a future trial and will be used to inform sample size estimates:

1. Change in salt intake from baseline to follow-up measured through analysis of 24-hour urinary sodium excretion.
2. Change in blood pressure (systolic and diastolic) from baseline to follow-up.
3. Change in salt content of food purchases measured as salt in g/100 grams (and g/MJ) in the shopping basket; assessed through analysis of nutrient composition of all purchased products over the final two-weeks of the intervention period compared with the two-week baseline period.

3.10.3 Process outcomes

1. Recruitment rates: the total recruited; the number invited, eligible, and consented; the number completed all baseline assessments; the number randomised; and time to recruit.

2. Participants' use of the SaltSwap app and perceived acceptability: frequency of use, number of products scanned per user, frequency of swaps presented and accepted, use of specific goal-setting function, and participant-reported acceptability.
3. Acceptability of intervention delivery: the perspective of the HCPs responsible for delivering the intervention, captured via interviews exploring barriers and facilitators to delivering the brief intervention, and their confidence and belief in their capability to support people to make dietary changes.
4. Feasibility of data collection: willingness of participants to submit 24-hour urine samples; and completeness of shopping purchase data recorded in the app (including completeness of nutrient data of purchased foods).
5. Evidence of contamination: use of the SaltSwap app by the control group.
6. Changes in participants' self-reported knowledge about the effects of salt on health, use of nutrition labels for salt, and dietary salt behaviours including use of salt in cooking or at the table as well as consumption of high-salt foods.

3.11 Measures

3.11.1 Participant characteristics and clinical measures

Relevant medical history, current medications, and last recorded clinic blood pressure were reported by participants and verified against the participant's electronic clinic record. Height was measured in centimetres using a stadiometer and weight measured in kilograms on calibrated scales. Participant demographics and shopping behaviours were collected via an investigator-designed questionnaire at the baseline visit.

3.11.2 Primary outcome measures

- Follow-up attendance: visit data was recorded in the study database by the researcher conducting the assessment.
- SaltSwap app use: measured through app data logs recorded automatically for each participant. App logs were accessed via a secure password-protected administration system and user-logs were downloaded for each user. Users were identified by the unique email address they entered when registering to use the app. App logs were stored using participant ID as identifiers.
- Intervention fidelity: intervention sessions were audio-recorded by the HCP. I assessed all recorded sessions using an assessment framework based on the checklist of essential intervention components. An independent researcher co-assessed the first five of these (20%). We discussed any discrepancies in our interpretation of the assessment framework before I assessed the remaining sessions using the refined assessment framework.

3.11.3 Secondary outcome measures

Salt intake

Salt intake was estimated based by 24-hour urinary sodium excretion, using a single 24-hour sample taken on any week or weekend day. At the baseline appointment, participants were given two 3-litre standard laboratory collection containers, one to use at baseline and a second for the follow-up urine sample and asked to return the urine sample to their GP practice. Participants were reminded, when booking their follow-up visit, to complete the second urine sample and bring it on the day of the follow-up visit or within seven-days. Sample containers were labelled according to standard requirements of the laboratory. The collection procedure was discussed in the baseline assessment visit to allow participants to

ask any questions and standardised written instructions were given to participants (Appendix 16). Urine sample analysis was undertaken by the biochemistry laboratory at Oxford University Hospitals NHS Foundation Trust and reported directly to the requesting GP, following usual clinical procedures. Sodium excretion was reported as mmol/L, mmol/24-hours; and total volume (L) of the urine sample was reported. Sodium excretion was converted to salt intake using the standard equation: 17.1 mmol of sodium = 1g salt and assumes all of the sodium was derived from salt (249).

Blood Pressure

Systolic and diastolic blood pressure were measured at baseline and follow-up visits, following a standard protocol and using a validated digital OMRON blood pressure monitor. Participants were positioned in accordance with the British Hypertension Society guidance (250). Three blood pressure readings (mm Hg) were taken with one-minute between readings. The average of the second and third readings were used. If any reading resulted in an error, an additional reading was taken to ensure three valid measurements. Participants with a systolic blood pressure above 160 mm Hg were advised to discuss this with their GP (and where possible to take home readings if they had access to a home blood pressure monitor); and readings were reported directly to the named lead GP for the study, as agreed with the practice before recruitment.

Salt content of purchased foods

The salt content of household purchased foods was assessed via the SaltSwap app (using the restricted version in the control group). Participants were asked to use the app to record all food or drink items purchased (apart from fresh fruit and vegetables) during the baseline and intervention periods. The app is linked to a database containing the nutritional composition of foods. Participants could scan products that had a barcode or enter data manually on the

product name, pack size, and quantity if there was no barcode present or the barcode was not registered in the app database. Salt content of the shopping basket (g/100g) was calculated for each participant for the two-week baseline period and for the final two-weeks of the intervention period, using the total salt in grams of all purchased items, divided by the total weight/volume of products purchased.

3.11.4 Process measures

SaltSwap app use and acceptability

App use was measured through automatic app logs as described above in section 3.11.2 and through a non-validated questionnaire at the follow-up visit via a question on frequency of use (always, most of the time, occasionally, never). This questionnaire also assessed how helpful participants found the SaltSwap intervention (advice session and SaltSwap app) or control leaflet (1-5 scale from very unhelpful to very helpful); and for the intervention group, specific reasons why it was considered helpful or unhelpful, and app acceptability, based on perceived future usage ("would you be interested in using a free app like the SaltSwap app if it was publicly available?").

Healthcare professional perceived acceptability

Healthcare professionals responsible for delivering the intervention were interviewed using semi-structured interviews, once they had delivered all intervention sessions. These interviews were audio-recorded (following informed consent from the HCP) and transcribed by an independent transcriber. I interviewed all five of the HCPs and analysed the data using thematic analysis, using NVivo software (251). The aims of the interviews were to understand any barriers to delivery of the intervention and to gather HCP perceptions of participant engagement with the intervention. Key areas for discussion included:

- How the HCP felt about delivering the intervention session.

- How the HCP perceived the intervention was received by participants.
- Barriers and facilitators to delivering the intervention session.

Feasibility of outcome assessment

Feasibility of 24-hour urinary sodium collection was assessed as the number of completed 24-hour urine samples returned at baseline and follow-up out of all participants who attended the follow-up visit. The feasibility of data collection on the salt content of household food purchases was assessed using data from the purchase scanning app for the baseline two-week period, in a subset of 20 participants. Data from till receipts were used to supplement app recorded shopping data. I calculated the proportion of total products purchased (based on till receipts) which were also recorded in the app. I also calculated the proportion of products recorded manually in the app out of all those recorded in the app. Participants were asked to manually enter the name, pack size and quantity, for any purchased items where the barcode was not recognised by the app. Products entered manually were not linked to nutrient composition data, therefore, could not contribute to the secondary outcome of purchase salt content.

Other process measures

The follow-up questionnaire collected data on changes in knowledge, attitudes and behaviours related to dietary-salt intake, and whether any other forms of support (e.g. apps, tools, advice, or contact with health professionals) were used throughout the study (Appendix 15).

3.12 Sample size

This study was a feasibility study and was not powered to detect any significant intervention effects. However, I calculated the sample size that would be sufficient to estimate progression outcomes within acceptably narrow confidence intervals to enable robust testing of the trial methods. For the trial to be considered feasible, 80% follow-up attendance and fidelity of intervention delivery would need to be achieved, therefore, allowing for a 95% confidence interval around this point estimate I set the minimum criteria for progression at 65% (80% +/- 12%; 95% CI 68 to 92). For app use, a minimum of 70% was required, therefore, I set the minimum progression criteria at 50% based on the confidence interval around this estimate (70% +/-18%; 95% CI 52 to 88).

3.13 Statistical analysis

Baseline characteristics were summarised using descriptive statistics, by trial arm. Descriptive statistics were reported with 95% confidence intervals. Statistical analyses were conducted using STATA IC 16.0 (252). Progression criteria analysis used data from all randomised participants. Secondary outcomes were analysed on an intention-to-treat basis, i.e. all participants were analysed according to the group to which they were randomly allocated, using complete case analysis; missing data was not imputed for urinary sodium or blood pressure. Before calculation of the salt content of purchased foods, missing data on product weight/volume were imputed where possible, otherwise, products were excluded. Items categorised as fresh fruit and vegetables, alcohol, or household non-food items, and those without a recorded salt content were excluded from the analysis.

I used linear regression models to calculate differences in means at follow-up between the intervention and control groups, with 95% confidence intervals; adjusted for baseline values of the dependant variable and recruitment site. I also examined the sensitivity of the results to confounding due to differences in baseline characteristics which were plausible confounders and imbalanced between groups; and due to obvious outliers, testing the model fit using likelihood ratio tests. I tested the assumptions of linear regression, specifically homoscedasticity, and normality of the distribution of residuals. Where these assumptions were not met, I applied the Wilcoxon rank-sum test to assess the outcomes, presenting results from both analyses. I also described the proportion of participants who showed a reduction in salt intake and purchased salt and assessed any differences in this proportion by trial group, using t-tests for proportions.

Process measures used all data available, regardless of whether participants completed the trial or withdrew and were reported using descriptive statistics with 95% confidence intervals. Continuous variables were reported as mean and SD unless the use of median and interquartile range were indicated; categorical variables were reported as frequencies and percentages.

3.14 Adverse events

All serious adverse events were reported during the trial. Participants were asked about adverse events at follow-up, or at the point of withdrawal from the trial. In accordance with the protocol, only related, unexpected, serious adverse events were reported to the Research Ethics Committee. Relatedness was determined by the lead GP for the site (as documented in the site file) where the adverse event was reported.

3.15 Public and patient involvement

The trial intervention was co-designed with members of the public who had a diagnosis of hypertension, described in Chapter 3. Participant facing materials, including the consent form and participant information sheet, were reviewed by members of an existing PPI panel and amendments made according to their feedback.

I assessed the reading age of all materials for participants using The Writer Readability Checker **(**http://www.thewriter.com/what-we-think/readability-checker/**)** to ensure they were written at an appropriate reading level for the public.

3.16 Data management

The trial was run in accordance with Good Clinical Practice guidelines (253) and access to data was restricted to appropriately trained members of the research team and host organisation as necessary for audit and regulatory purposes. Data was kept in accordance with the Data Protection Act, 1998 and confidentiality was maintained at all times.

Data was entered directly into a secure online database using the REDcap electronic data capture tools (254), hosted at the University of Oxford. The database incorporated an electronic case report form, using a unique participant ID. The database includes data validation checks, and prior to database lock, I reviewed the full dataset to ensure all queries had been resolved and the dataset was complete. All participant identifiable data, linked to the participant via their unique ID, was kept separately from anonymised research data in a password-protected file. Audio recordings were only stored with participant ID in a password-protected file on secure University of Oxford servers. Transfer of audio-recorded data, and transcripts of this data, was via the University of Oxford data-sharing platform.

3.17 Trial management committee

A trial management committee was established, including members of the supervisory panel convened for this DPhil research who also acted as senior co-investigators on the trial, along with two members of the public. I was responsible for project coordination, with oversight from the senior co-investigators. All investigators were trained in Good Clinical Practice and took appropriate actions to safeguard participants and the quality of the trial. Due to the short duration of the trial, lack of active collection of adverse event data or stopping rules, it was agreed by the trial management committee that a trial steering group or data monitoring committee were not necessary.

3.18 Ethical approval

This study was reviewed and approved on the 17/03/2017 (reference number 17/SC/0098) by the South Central - Hampshire B Research Ethics Committee and the Health Research Authority. Appropriate approvals were sought for any protocol amendments or new documents. Approved amended versions of the protocol and study documents were communicated to live recruitment sites via the study site file.

4. Results

4.1 Recruitment

Participants were recruited between October 2018 and April 2019. Of the 2028 patients invited, 107 registered for the study and completed screening (5.3% of the invited participants) and 50 participants were enrolled (Figure 4.1). Further details of the feasibility of recruitment are described under the results heading *process measures*.

4.2 Participant characteristics

Participants had a mean (SD) age of 65 (11) years and the majority reported a diagnosis of hypertension (74%) (Table 4.1). Only 14% of all participants had previously been advised by an HCP to reduce their salt intake, though 54% of the intervention group and 69% of the controls reported they had previously attempted to reduce their salt intake.

4.3 Primary outcomes

Level-one progression criteria were met (Table 4.2). Of the two randomised participants who did not attend follow up; one withdrew due to difficulty using the study app and one suffered an exacerbation of an unrelated health problem. Of the intervention sessions that were adequately recorded (n=25, 81%), all included at least four of the six essential elements. All six elements were delivered in 21 (84%) of these sessions. The element most commonly not delivered was action planning (n=3).

Figure 4.1. Consort diagram.

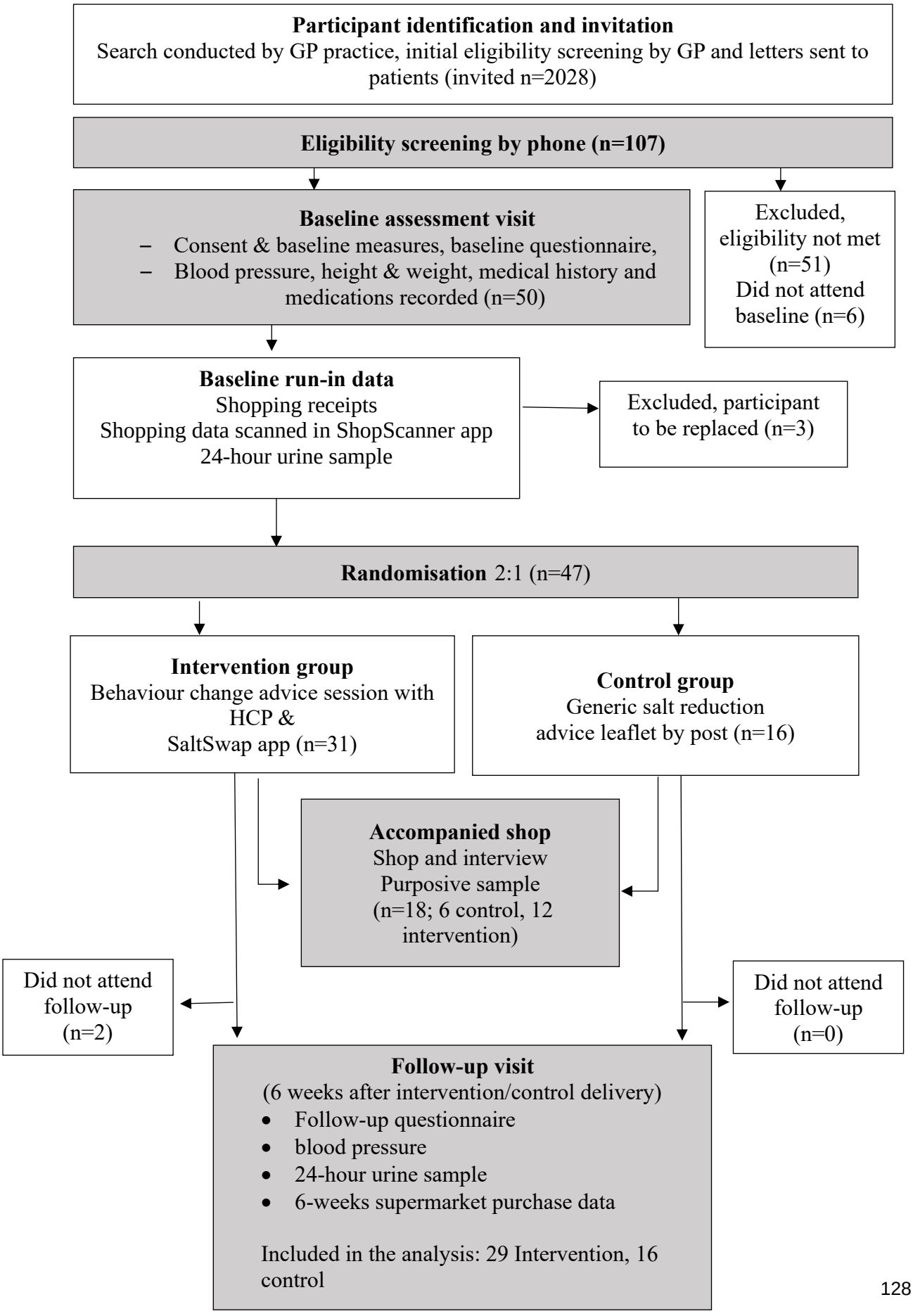


Table 4.1. Baseline characteristics of randomised study participants.

Baseline characteristics of randomised participants Mean (SD) unless otherwise specified	**Control (n=16)**	**Intervention (n=31)**	**Total (n=47)**
Age (years)	67 (7)	64 (12)	65 (11)
Sex (% female)	63	65	64
BMI (kg/m^2)	29 (5)	29 (6)	29 (6)
Blood pressure (mm Hg)			
Systolic	137 (15)	134 (16)	135 (15)
Diastolic	80 (8)	81 (10)	81 (9)
Estimated daily salt intake[a] (grams)	6.8 (2.7)	6.5 (3.9)	6.6 (3.5)
Smoking, n (%)			
Current	0 (0)	1 (3)	1 (2)
Ex-smoker	7 (44)	11 (35)	18 (38)
Never	9 (56)	19 (61)	28 (60)
Ethnic group, n (%)			
White	15 (94)	29 (94)	44 (94)
Asian or Asian British	0 (0)	1 (3)	1 (2)
Black of Black British	0 (0)	0 (0)	0 (0)
Mixed / Other/Chinese	1 (6)	1 (3)	2 (4)
Education, n (%)			
No formal qualifications	4 (25)	0 (0)	4 (9)
Secondary education	6 (38)	10 (32)	16 (34)
Higher education	6 (38)	21 (68)	27 (57)
Household size, median (IQR)	2 (2-2)	2 (1-2)	2 (2-2)
Weekly grocery shopping >£25/trip			
≥ Once a week	5 (31)	12 (39)	17 (36)
Once a week	9 (56)	15 (48)	24 (51)
Once a fortnight	2 (13)	3 (10)	5 (11)
Once a month	0 (0)	0 (0)	0 (0)
< Once a month	0 (0)	1 (3)	1 (2)
Factors influencing grocery shopping decisions n (%)[b]			
Price	6 (38)	20 (65)	26 (55)
Appearance	0 (0)	5 (16)	5 (11)
Taste	13 (81)	20 (65)	33 (70)
Habits	5 (31)	7 (23)	12 (26)
Health	9 (56)	17 (55)	26 (55)
Convenience	1 (6)	5 (16)	6 (13)
Special offers	7 (44)	8 (26)	15 (32)
Organic	2 (13)	3 (10)	5 (11)
Special diet	2 (13)	2 (6)	4 (9)
Other	4 (25)	6 (19)	10 (21)

Frequency of using nutrition labels, n (%)			
Salt	10 (63)	14 (45)	24 (51)
Sugar	14 (88)	20 (65)	34 (72)
Fat (total or saturated)	13 (81)	21 (68)	34 (72)
Energy (calories)	13 (81)	21 (68)	34 (72)
Been advised by HCP to reduce their salt intake, n (%)	2 (13)	4 (14)	6 (14)
Previously tried to reduce salt intake, n (%)	11(69)	15 (54)	26 (59)
Knowledge of the effect of salt on blood pressure? n (%)[c]			
Yes	8 (50)	11 (35)	19 (40)
No	1 (6)	7 (23)	8 (17)
Don't know	7 (44)	13 (42)	20 (43)
Eating breakfast out, median (IQR)	0 (0-0.5)	0 (0-0)	0 (0-0)
Eating lunch out, median (IQR)	0 (0-1)	1 (0-2)	1 (0-1)
Eating dinner out, median (IQR)	1 (0-1)	0.5 (0-1)	1 (0-1)
Relevant Health history, n (%)			
CVD	0 (0)	4 (13)	4 (9)
Diagnosed Hypertension	14 (88)	21 (68)	35 (74)
Diabetes	4/16	3 (10)	7 (15)
AF	0 (0)	0 (0)	0 (0)
CKD	0 (0)	1 (3)	1 (2)
Peripheral Vascular Disease	1 (7)	1 (3)	2 (4)
Other (related to CVD)	5 (31)	5 (16)	10 (21)
Anti-hypertensive medication n (%)	12 (75)	19 (61)	30 (64)

[a] Converted from 24-hour urinary sodium excretion
[b] Participants were asked to choose the top three factors
[c] Participants were asked "Do you think the amount of salt you eat affects your blood pressure?"

4.4 Secondary outcomes

The assumptions of linear regression were broadly met for salt intake and diastolic blood pressure outcomes. Similar tests indicated that for the outcomes of systolic blood pressure and purchased salt, these assumptions were less clearly met, therefore, as specified in the protocol, I also analysed and reported these outcomes using the non-parametric Wilcoxon rank-sum test for between-group differences.

4.4.1 Salt intake

Salt intake decreased in both groups, though not significantly (intervention -0.2g/day, 95% CI -1.4 to 0.90; control -1.0 g/day, 95% CI -2.4 to 0.4) (Table 4.3, Figure 4.2). There was no significant between-group difference in a model adjusted only for salt intake at baseline and GP practice. Level of education and hypertension status were potential confounders which, due to chance, appeared imbalanced despite randomisation. Therefore, in a second model I adjusted for participants' level of education (no formal education, secondary education, or higher education) and whether participants were diagnosed with hypertension (binary), to assess model fit. Model fit was improved with the addition of education but not hypertension status therefore, this variable was not included in the final model. The between-group difference in the final multi-adjusted model showed a greater mean reduction in the intervention group of -0.40g (95% CI -2.33 to 1.53) but this was not statistically significant (Table 4.3).

In the intervention group, 50% (14/28) of the participants reduced their salt intake from baseline to follow-up (mean reduction -2.44 g/day, 95% CI -8.71 to -0.20) compared to 66% (10/15) of the control group (mean reduction-2.42 g/day, 95% CI -6.76 to -0.08). The difference in these percentages was not significant.

Table 4.2. Follow-up rates, intervention fidelity and use of the SaltSwap app in the SaltSwap feasibility trial.

Progression criteria, N (%) unless otherwise specified	Total (n=47)	Control (n=16)	SaltSwap (n=31)
Follow-up rate			
Number of participants measured at follow-up	45 (96)	16 (100)	29 (94)
Fidelity of the intervention (advice) session			
Number of intervention advice sessions where at least four out of six of the essential intervention elements are delivered[a]	Not applicable	Not applicable	25 (81)
Use of the SaltSwap app			
Number of participants who use SaltSwap to scan products on at least one occasion by the end of month one	Not applicable	Not applicable	27 (87)

[a] Audio-recordings for assessment of intervention fidelity were available for 25 of the 31 advice sessions delivered.

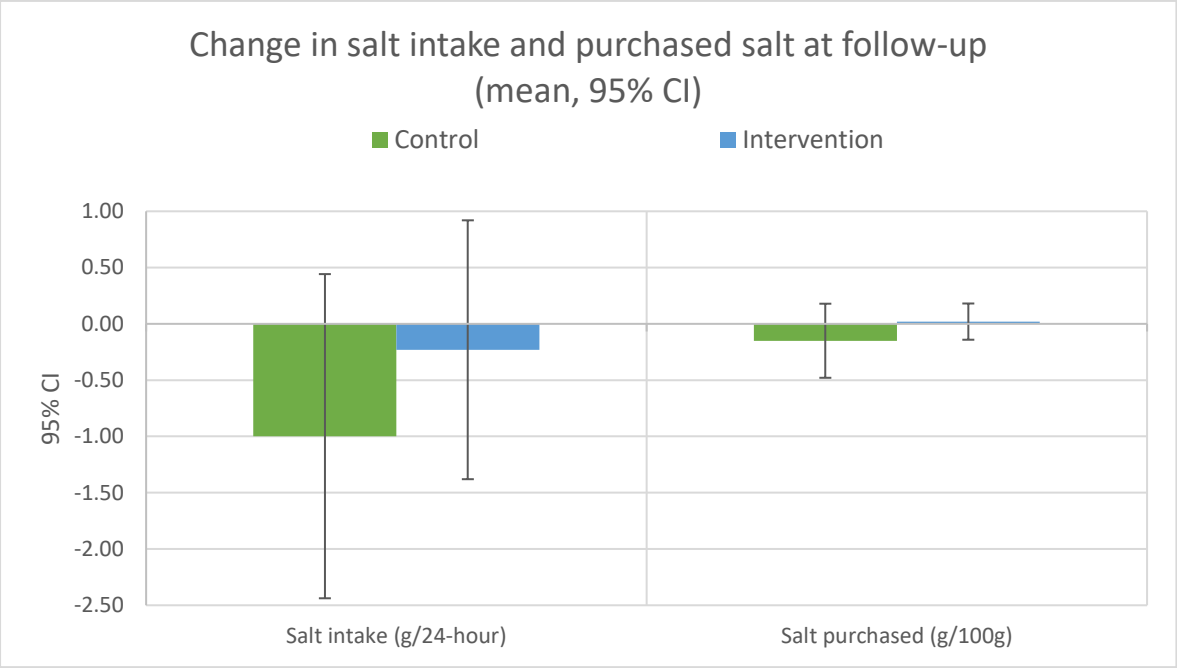
Table 4.3. Effects of the SaltSwap intervention and control booklet on changes in mean salt intake and blood pressure from baseline and estimates of between group differences.

	Baseline values Mean (SD)		**Mean change (95% CI)**		**Mean between group difference model 1*(95% CI)**	**Mean between group difference model 2[a] (95% CI)**
	Control	SaltSwap	Control	SaltSwap	SaltSwap vs Control	SaltSwap vs Control
	(n=16)	(n=31)	(n=15)	(n=28)	(n=43)	(n=43)
Salt intake (g/day)	6.8 (2.7)	6.5 (3.9)	-1.0 (-2.4, 0.4)	-0.2 (-1.4, 0.9)	0.3 (-1.4, 2.1)	-0.4 (-2.3, 1.5)
Blood pressure (BP)	(n=16)	(n=31)	(n=16)	(n=29)	(n=45)	(n=45)
Systolic BP (mm Hg)	137.3 (14.8)	134.2 (15.8)	-1.1 (-6.7, 4.4)	-1.0 (-5.5, 3.6)	0.5 (-6.6, 7.6)	-0.4 (-8.2, 7.4)
Diastolic BP (mm Hg)	79.7 (8.0)	81.2 (10.2)	2.3 (-2.7, 7.2)	-1.0 (-4.3, 2.2)	-1.37 (-6.03, 3.28)	-3.04 (-8.04, 1.96)

*Model 1. Regression adjusted for baseline values and GP practice only

[a] Model 2. Regression analysis adjusted for baseline values, GP practice, and level of education

Figure 4.2. Change in salt intake and purchased salt at follow-up (mean, 95% CI).



4.4.2 Blood pressure

There was a non-significant reduction in systolic blood pressure in both the intervention (mean -0.98, 95% CI -5.54 to 3.58) and the control (mean -1.13, 95% CI -6.66 to 4.41) group with no significant between-group difference when adjusted for baseline blood pressure and GP practice, or when other potential confounders were added (Table 4.3). Results of the Wilcoxon rank-sum test indicated no significant between-group difference in the change in systolic blood pressure. Diastolic blood pressure decreased in the intervention group but not the control group; however, these changes were not significant and there was no between-group difference in the adjusted model(s). I tested the models for blood pressure outcomes taking into account whether participants were taking antihypertensive medication, but the model fit was not improved and the result not materially different.

4.4.3 Purchased salt

Baseline and follow-up data on purchased products were available for 37 of the 47 participants (79%); 75% of control and 80% of intervention participants. The analysis

included all purchased items recorded in the app(s). The number of products purchased was slightly lower at follow-up in both groups and missing data were comparable between groups (Table 4.4). A linear regression model showed no significant reduction in the salt content of purchased foods in either group or between-group difference (Table 4.5, Figure 4.2). Results of the Wilcoxon rank-sum test also concurred. When two participants who appeared to be outliers, due to buying five or fewer products in the follow-up period, were removed from the analysis, the results did not materially differ. In the intervention group, 72% of all participants reduced the salt content of purchased foods (mean -0.15g/100 (SD 0.13)) compared to 66% of the control group (mean -0.4g/100g (SD 0.27)), with no significant difference in proportions between groups detected. There were non-significant reductions in expenditure on food for both groups with no significant between-group difference (Table 4.5).

Table 4.4. Number of products purchased and recorded in the app, and missing data (lack of data on salt content).

Purchased salt data	**Control**	**SaltSwap**	**Total**
Total products purchased, baseline (m, SD)	60 (29)	56 (35)	57 (32)
Missing data (%)	*40%*	*37%*	*38%*
Total products purchased, follow-up (m, SD)	45 (32)	29 (20)	34 (25)
Missing data (%)	*40%*	*34%*	*36%*

Table 4.5. Effects of the SaltSwap intervention and control booklet on changes in the salt content of household food purchases from baseline to follow-up and between group differences.

	Baseline values Mean (SD)		Mean change, follow-up-baseline (95% CI)		Between group difference (95% CI)*
	Control	SaltSwap	Control	SaltSwap	SaltSwap vs Control
Purchased salt (g/100g)	0.76 (0.47) (n=12)	0.50 (0.24) (n=25)	-0.15 (-0.45, 0.16)	0.02 (-0.13, 0.18)	-0.04 (-0.36, 0.28)
Average expenditure (£) (Baseline 2 weeks to the last 2 weeks of the intervention period)	168.4 (84.5) (n=16)	143.8 (84.7) (n=28)	-38.8 (-84.6, 7.0)	-27.5 (-70.2, 15.1)	-11.3 (-75.8, 53.2)

*regression adjusted for baseline purchased salt and GP practice

4.5 Process measures

4.5.1 Recruitment

Of the 107 patients who registered for the study and completed screening, 51 did not meet the inclusion criteria and six did not attend the baseline assessment visit. The main reasons people did not meet the inclusion criteria were not owning a smartphone (n=29); not responsible for household grocery shopping (n=7); or they were away during the study period (n=6). Of the 50 eligible participants who attended the baseline visit and provided consent, three did not provide data for the baseline period, therefore, were not randomised. Of the 47 participants randomised, 16 were allocated to the control arm and 31 to the intervention arm. The mean time from letters being sent to completion of all baseline visits per practice was 7.4-weeks (range 6 to 12-weeks). All intervention participants attended the intervention session, on average 12-days after randomisation (range 1-29-days).

4.5.2 Acceptability of intervention delivery among healthcare professionals

Healthcare professionals described the SaltSwap intervention as something that was within their role and skillset, comparing it to typical health promotion work. They felt confident and capable of delivering it, especially with the training provided. One HCP noted that, although were comfortable with it, offering the app as part of the intervention may not appeal to all practitioners and some would find this out of their comfort zone.

> *"It's a little bit of health promotion really. We have the kind of background or, you know, knowledge of what we're doing and why we're doing it…So, definitely, I enjoyed it because I like health promotion bit of talking to patients" (Practice nurse, site 3)*

> *"I don't think it would appeal to everybody as in like I am quite tech; I love tech and, you know, everything…so, I suppose for me I found it really interesting, and it fitted my role, but I know for a fact that my colleague over the way would be like, 'Haven't got a clue what you're doing.'" (Healthcare assistant, site 4)*

Some commented that they felt uncertain or worried before delivering the intervention but once they had delivered one or two, they felt confident and enjoyed delivering it.

> *"Well, generally I really enjoyed it actually. Yeh, I mean it was a bit nerve-wracking, to begin with, you know, thinking, 'Ooh, they might ask something that I don't know the answer to.' But I feel yeah, I feel reasonably confident." (Practice nurse, site 2)*

Healthcare professionals reported that the SaltSwap booklet helped them to deliver the advice sessions and provided them with new knowledge as well as their patients. They thought that the level was appropriate, participants engaged in the discussion and the behavioural components were useful.

> *"So, especially the goal setting and things like that; that was well received I felt…whenever we sort of look at behaviour change we're always trying to do things like smart goals….so, I think writing it down and getting the patient to actually say what they think they can do and writing it down...it kind of commits the patient to thinking, 'Actually, I could do this; it's not as hard as I think,' etc." (Practice nurse, site 1)*

Although HCPs broadly felt the time provided for the intervention in the study was enough, some HCPs noted that it might be challenging to implement this in routine primary care due to time limitations.

> *"Time is another thing. I probably wouldn't be discussing in most of the consultations that I have because you're just so focused on the task in hand…Because that's general practice that... and yeh, the restricted timeframes that you have really." (Practice nurse, site 2)*

The main barriers raised were technical issues experienced with the app component of the intervention. HCPs reported that some participants were unable to download the app during the session due to password or internet issues, so they were uncertain whether the participant successfully downloaded it at home and were able to use it. It was noted that use of apps is not uncommon, for managing a variety of health issues.

> *"Because for me it just felt a bit... yeah, as I said, it felt a bit incomplete to send people away not having that on their phone, like they've done sort of three-quarters of their job really and sending them home to fumble through" (Practice nurse, site 2)*

"But I do think that a lot of things nowadays, it is easy to sort of track on your phone or monitor things. People show me all the time their sleeps and…all sorts of things on their phone" (Healthcare assistant, site 4)

4.5.3 SaltSwap app use and intervention acceptability (intervention participants)

During the six-week intervention period, participants used the SaltSwap app to check the nutrition content of products and/or find alternative products during a mean of 7.7 (SD 5.6) shopping trips (75% of all recorded trips) and scanned a mean 39 (SD 35) products to find alternatives. The mean total number of swaps recorded in the app per participant was 3.1 (SD 3.2). The median salt reduction per swap accepted was -0.6g/100g (IQR -0.2g/100g to -1.2g/100g). The top food categories in which swaps were accepted were bread, cheese, and processed meats, accounting for 29% of all swaps recorded.

Of the 45 who completed follow-up, 44 completed the follow-up questionnaire (28 intervention, 16 control). Twelve participants (43%) rated the SaltSwap app as helpful or very helpful and 19 (70%) reported they would use the app if it were freely available. Among those who reported they would not be interested in using an app like this (or were unsure), reasons included not being able to find alternatives on the shelf, alternatives suggested not being suitable or enticing, or the app not recognising product barcodes. One participant reported:

"I wouldn't use the app but think it would be good to make it publicly available…Did manage to discover which products were low in salt and started using the labels more…learnt a lot about products that are high in salt which I wasn't aware of…have made some good swaps…" Participant 0501, female, 74yrs

Twenty participants (71%) described the HCP advice session as helpful or very helpful (compared to 63% of control participants who similarly rated the control booklet). Eighty-nine percent reported that this advice session motivated them to shop for products with lower salt; 79% agreed it motivated them to try to reduce their salt intake; and 57% agreed it helped

them to understand more about the importance of salt for blood pressure control. Factors considered unhelpful about the intervention session were that it was too short and basic (13%), too general to motivate them (13%), or not relevant to them (10%). No one reported that they did not understand the content.

4.5.4 Feasibility of data collection

Baseline 24-hour urine samples were collected for all 47 randomised participants. Follow-up urine samples were collected for 43 participants out of 45 (96%) who attended the follow-up assessment and 91% of all participants.

Participants recorded data in the study app for 97% of shopping trips recorded by receipt. In these shopping visits, most purchased products were recorded in the app, with only 3.6% of all purchased products (as documented on receipts) not recorded. A mean of 77 items (SD 49) were purchased per participant over the two-week baseline period. Out of a total of 1,548 products recorded in the app over this baseline period, 649 were recorded manually (42%), slightly higher in the control compared to intervention group (Table 4.6). Analysis of product categories for manually entered products showed that nearly half of these products were fresh fruit, fresh vegetables, alcohol or non-grocery items and would be excluded from the analysis of the salt content of purchased foods. The remaining 359 products (23% of products purchased) were foods that would be included in the analysis if nutrient content data was available (therefore are categorised as ‘missing data’).

4.5.5 Knowledge, dietary salt behaviours and use of nutrition labels

Knowledge

In the intervention group, 93% of participants reported that they "somewhat agree" or "strongly agree" that the study improved their knowledge of salt and health, compared to 81% in the control.

Use of nutrition labels

At baseline 45% of intervention participants and 63% of control participants reported checking nutrition labels for the salt content of foods at least sometimes, less than for other nutrients; this improved substantially in both groups during the study. Twenty-two (79%) intervention participants reported an increase in use of nutrition labels for salt and 81% of control participants. At follow-up, 100% of participants in both groups reported using nutrition labels for salt at least sometimes, with 75% of intervention participants and 69% of control, reporting use of them often or always.

Dietary salt behaviours

Specific dietary salt behaviours reported in the study included:

- Swaps made to lower-salt foods (intervention 82%; control 50%).
- High-salt foods eaten less frequently (or smaller portions) (intervention 68%; control 69%).
- Reduced salt use in cooking (intervention 54%; control 56%).
- Reduced use of table salt (intervention 25%; control 31%).

Table 4.6. Process outcomes.

N (%), unless otherwise specified	Total (n=47)	Control (n=16)	SaltSwap (n=31)
Recruitment rates			
Number of participants invited	2028	-	-
Number of participants consented & enrolled	50	-	-
Number of participants randomised	47	16 (34)	31 (66)
Intervention acceptability			
Number of intervention participants who rate the nurse support as helpful or very helpful	-	-	20 (71%) (n=28)
Number of intervention participants who rate the SaltSwap app as helpful or very helpful	-	-	12 (43%)
Number of intervention participants who would use a free app like this	-	-	19 (70%) (n=27)
Use of the SaltSwap app			
Number of times the app is used throughout intervention period (i.e. number of shopping trips where it is used to scan products to identify swaps) (mean, (SD), % of all trips)	-	-	8 (6), 75%
Number of products scanned (for swap), total (mean (SD))	-	-	39 (35)
Number of swaps accepted through the app, total (mean (SD))	-	-	3 (3)
Number of participants who set a goal in the app	-	-	27 (93)
Feasibility of data collection			
Number of randomised participants who provide a urine sample at follow-up	43 (91)	15 (94)	28 (90)
Number of till receipts submitted per participant, total during the baseline and intervention periods (Median (IQR))	Baseline 5 (3-7) Intervention 11 (8-17)	4 (3-8) 11 (7-17)	5 (3-7) 11 (8-17)
Number of shops recorded in the app(s) per participant, total during the baseline and intervention periods (Median (IQR))	Baseline 4 (3-7) Intervention 9 (6-16)	4 (3-8) 8 (5-17.5)	5 (3-7) 10 (7-13)

Products recorded manually in the app during baseline two weeks (% of total recorded products)	42% (n=20)	54% (n=7)	35% (n=13)
Adherence to protocol			
Number of participants allocated to intervention arm, who attend the session	-	-	31 (100)
Time between randomisation and intervention session (mean number of days)	-	-	12 days
Contamination			
Number of participants allocated to control, who access the SaltSwap app	-	0	-
Knowledge and behaviour change			n=28
Number of participants who increased their use of nutrition labels for salt	35 (74)	13 (81)	22 (79)
Number of people who reported somewhat or strongly agree the study has improved their knowledge of salt & health	39 (83)	13 (81)	26 (93)

4.6 Contamination

I found no record in the app logs of use of the unrestricted SaltSwap app by control participants and no one reported using it when asked about other forms of support used during the study.

4.7 Serious adverse events

One serious adverse event was reported during the study. The lead GP for the practice concluded that this adverse event (hospitalisation for unrelated existing illness) was unrelated to the study. No further action was taken. The participant did not continue in the study or attend follow-up.

5. Discussion

5.1 Summary of findings

The criteria for progression to a full trial were met to a high level, with high follow-up, fidelity of intervention delivery and use of the intervention app; indicating that the SaltSwap intervention can be delivered by non-specialist staff in primary care and is acceptable to individuals with high blood pressure. The trial procedures to evaluate the effect of the intervention on salt intake and blood pressure were shown to be robust. However, the low response rate to the trial invitation, and the resulting 'health-conscious' and likely highly motivated sample recruited, provides some concern for the feasibility of recruited a sufficiently larger representative to test effectiveness in a future trial and modification to the procedures would be required. The secondary outcomes provided no clear indication of whether the intervention is effective for reducing salt purchased, salt intake, or blood pressure

compared to the control, though the high rates of follow-up and completion of 24-hour urinary sodium samples in a free-living, healthy population provide reassurance that a larger trial using these study procedures would be feasible.

Process measures demonstrated high engagement with the SaltSwap app to identify lower-salt options. Swaps recorded in the app were predominantly in the food categories of bread, cheese and processed meats; foods which contribute most to total daily salt intake (accounting for 34%) among those aged 65-74-years (61), suggesting the intervention successfully targeted the main sources of dietary salt. Furthermore, process measures assessing specific targets of the intervention indicated that it increased participants knowledge of salt and health, their use of salt information on nutrition labels, and led to beneficial behaviour changes: swapping to lower-salt foods, reducing their frequency of consumption of high-salt foods, and reducing salt use in cooking. These behaviours are hypothesised to be on the causal pathway for effectiveness of the intervention.

5.2 Strengths

This study was a randomised controlled trial which employed a wide range of outcome measures to investigate a novel behaviour change intervention to reduce salt intake. The detailed evaluation included clinical endpoints and behavioural outcomes, as well as process outcomes to explore the hypothesised mechanisms of impact and enable a greater understanding of how the intervention influences behaviour. High fidelity of the advice session delivered by HCPs provides assurance that with just one training session, and clear reference materials, the content of the intervention can be delivered as intended; by non-specialists in primary care. Interviews with HCPs delivering the intervention supported this view. This trial successfully engaged a population of adults with an average age of 64-years,

with a mobile app-based intervention with few usability issues raised; demonstrating the feasibility of delivering app-based health behaviour change interventions to older adults.

This study used objective measures to assess primary and secondary outcomes. Such measures were less prone to the adverse effects of response bias than self-report. Outcome data on the salt content of purchased foods was captured through the app. Studies investigating interventions to change the nutritional content of purchased foods commonly rely on estimates drawn from till receipts of purchased foods, or from retailer store data. However, receipt data is frequently not specific enough to accurately assess the product nutrient content and gaining access to retailer sales data is challenging (and data is often aggregated for privacy). The innovative app I developed and used here to collect purchase data demonstrated it has potential utility as an efficient alternative to these methods.

5.3 Limitations

A key aim of the SaltSwap app was to enable participants to more easily identify lower-salt options; providing salient and tailored information on product salt content and lower-salt alternatives at the point of choice. A major limitation of this study was the poor product coverage in the app database. If products were not recognised by the app, this intervention objective was not adequately delivered. Furthermore, this study relied on the app database to assess the nutritional content of purchased products. A high proportion of products with no associated nutrient information limited the accuracy of assessment of the salt content of foods purchased, though in this feasibility study the impact was minimal as the study was not powered to detect differences in this secondary outcome. Moreover, I would expect nutrient data to be 'missing completely at random' (MCAR) therefore this would not materially bias the results (255). Participants willingly used the app for recording purchases; therefore, I

expect that improvements in the coverage of products in the app database would enable improved data collection, providing a useful tool to assess nutrient composition of purchased foods in future trials.

Although the study did not aim to detect significant changes in salt intake and blood pressure, my choice of comparator was a limitation. The control group was intended to reflect 'usual care' but in fact delivered a more active intervention. At baseline, only 14% of participants reported having received advice to reduce salt. Sending written information about the benefits of salt reduction for those with high blood pressure, and the importance of reducing salt in purchased foods, led to a reduction (albeit nonsignificant) in salt intake and systolic blood pressure in control participants. Moreover, given this group had specifically opted into a trial of salt reduction, they were likely to be more motivated to change than their peers; and these materials may have increased the salience of general population advice on salt reduction, also prompting behavioural changes. The increase in use of nutrition labels in the control group is a possible indicator of this, as I did not expect to see such a large magnitude increase in label use from the control leaflet alone. This also prompts consideration of whether a stand-alone brief advice intervention could deliver significant benefits alone.

The response rate in this study was low, at only 5%. For comparison, a recent feasibility study investigating weight loss using similar recruitment methods, achieved a 15% response rate (256). This comparatively low response rate may indicate that there is less interest among potential participants in reducing salt intake than other dietary goals such as weight loss, or potentially less appetite to undertake a trial involving a mobile phone app. Smart phone ownership is lower among adults aged over 55 at 64%, than in younger age groups. Although this is increasing over time, use of health apps is still significantly lower in older

adults and this may present a barrier to the SaltSwap intervention. The low response rate may also indicate that only highly motivated or 'health-conscious' individuals are willing to engage with an intervention of this nature, requiring high levels of personal agency. A similar trial investigating an intervention providing dietary advice in primary care, alongside grocery shopping support, reported an equally low response rate (3%) (257). This may be explained by an eligibility requirement that participants shopped mainly at a specified retailer, but it may also support the idea that dietary behaviour change interventions (other than weight loss) are less appealing to the public. Although recruitment was timely, the primary concern is that a low response rate could have an impact on the generalisability of results in this study and the potential to successfully recruit a more representative population in a future trial. A low response rate could also impact future potential of the intervention if used in routine practice however, it is a measure of interest in participating in a trial (with the additional trial measures and visits required and with an unproven intervention) rather than acceptability of the intervention in a real-world setting.

Furthermore, the study population was self-selected – drawn solely from Oxfordshire, a county with lower deprivation than many others; and recruiting practices were located in areas of comparatively low deprivation (258). As such the study population were possibly not representative of the wider population in terms of socioeconomic status, a factor known to influence salt intake and adherence to wider dietary guidelines (259–261). The study participants were also predominantly of White or White British ethnicity. Sodium intake varies across ethnic groups (262,263), and culture is a major determinant of food choice and consumption (263,264), therefore I would expect that cultural differences would influence how people engage with, or respond to the SaltSwap intervention. There is emerging evidence of the need to adapt health behaviour change interventions for ethnic minorities and

tools to do so (265,266). However, the literature on differential impacts of salt reduction interventions on minority ethnic groups is sparse and there is a lack of evidence for barriers and facilitators for dietary behaviour change in general among minority ethnic groups to adequately inform intervention adaption (267). Further research is much needed on the effect of interventions for promoting healthy diet (not limited to salt intake) for minority ethnic groups in the UK, specifically the evidence on the eating habits, food purchasing behaviour, and drivers for dietary patterns, (268). An important consideration for any future trial of the SaltSwap intervention is recruitment of greater representation of people from minority ethnic groups.

A further limitation which may affect the generalisability of the results to a wider hypertensive population was the low salt intake at baseline (6.6 g/day), much lower than the population average for the UK (8.4 g/day); for both men (8.9 vs 9.2 g/day) and women (5.3 vs 7.6 g/day). Participants, therefore, had less capacity to benefit from the intervention. The lower than average salt intake may be because participants had previously tried to reduce their salt intake (69% control and 54% of the intervention group) or were more 'health-conscious', though no measure of this was taken at baseline. Average blood pressure at baseline was 135.3 mm Hg systolic and 80.7 mm Hg diastolic, with only 64% of participants on antihypertensive medication and 74% diagnosed with hypertension. This suggests that study participants may have had only mildly elevated blood pressure; the typical threshold for classification of 'mild hypertension' being systolic blood pressure 140-159 mm Hg, DBP 90-99 mm Hg (109,269).

The study duration was appropriate for a feasibility trial; being sufficiently long enough to detect reductions in blood pressure due to reduced salt intake (31), whilst minimising the

participant burden of collecting supermarket shopping data and reducing loss to follow-up. However, a six-week trial period would not be long enough to determine if the intervention leads to sustained behaviour change and longer-term reduction in blood pressure. A future trial may benefit from assessing clinical outcomes over a longer duration, but it is possible that a longer study duration would negatively impact participants' adherence to data collection. There was some indication of a waning of engagement with the app over the six-week period with fewer recorded purchases in the app during the follow-up two-weeks compared to baseline (for both groups) suggesting purchase data may be more reliable over a short time frame.

The sample size of 50 is slightly smaller than typical for feasibility trials, which according to one audit have a median of 36 per arm (270), however, it was calculated using an accepted approach based on confidence intervals around an estimated proportion (271). The sample here provided ample data on all outcomes to determine the feasibility of the intervention and trial design. A larger sample may have provided narrower confidence intervals around the secondary outcomes but would have been prohibitively time- and resource-intensive while adding limited value to the primary outcomes. Despite randomisation, there was an imbalance between groups in the proportion of participants diagnosed with hypertension. Although this could be adjusted for in the analysis, and in a larger trial is less likely to occur, a future trial might consider randomisation stratified by hypertension diagnosis.

Participants were not blind to the intervention allocation, which may have led to a degree of response bias in the self-reported behavioural outcomes, though these were not primary outcomes. Moreover, as the sole researcher and outcome assessor, I was not blind to intervention allocation. The proposed primary outcome of a larger future trial would be

objectively measured outcomes - urinary sodium excretion and blood pressure so the potential for bias is limited.

A further potential bias in this study is measurement reactivity bias, also known as the Hawthorne effect, whereby participants change their behaviour (notably the behaviour being measured) because they know they are being monitored (272,273). Measurement of salt intake via 24-hour urinary sodium is not typically monitored in primary care yet there are few other ways for individuals to accurately assess their salt intake. Most study participants were interested to learn their salt intake during or after the study and it is likely that the knowledge of assessment of their urine sample influenced their salt intake behaviour, if only on collection days. The reduction in salt intake among the control participants, who received only generic advice and were not expected to change their salt intake, provides some indication of this measurement reactivity in action. Measurement reactivity is a greater concern when one group is measured more frequently (or differently) to the other (273) which was not the case here, but it can bias results towards the null.

5.4 Contribution to the literature

Only a few studies have investigated how to effectively change people's grocery shopping behaviour specifically to reduce their salt intake or the acceptability of such an approach. (140,154,159). One study investigating an app-based intervention similar to the SaltSwap intervention (described previously in Chapter 1), demonstrated a significant reduction in the salt content of household food purchases in a real-world shopping environment (-0.30 g/MJ p=0.03), but no significant impact on overall salt intake (measured via spot urine) or blood pressure compared to usual care (140). However, baseline salt intake in the study participants was much higher than among participants in this trial at 8.7g (83% of participants were men,

who typically have a higher salt intake than women) and the study population were individuals with diagnosed CVD who may have been more motivated to make dietary changes than those with uncomplicated high blood pressure as recruited here. In addition, the outcome data on purchased salt was more complete than in my study.

The results of my study provide valuable insight into the acceptance of lower-salt foods and the nature of swaps made. I demonstrated that the SaltSwap intervention successfully encouraged participants to swap to lower-salt foods, with an average reduction per swap of -0.6 g/100g, and targeted the purchase of high-salt foods; the top categories of foods which participants swapped for lower-salt alternatives (cheese, bread, processed meats) aligned with those which contribute most to daily salt intake in the UK (60,249). Results of the online supermarket study in Chapter 2, showed a similar magnitude salt reduction per swap (-0.46 g/100g in the most intensive swap intervention group), however, in the online study this was combined with a high swap acceptance of 33%; leading to a significant overall reduction in salt content of purchased foods of -0.11g/MJ (95% CI -0.13 to -0.10). In this feasibility study, the swap acceptance rate was not recorded, however, I would expect swap acceptance to be higher in the online supermarket study because it included a more comprehensive database of products from which to offer alternatives, and the online environment provides more immediate alternatives compared to instore alternatives, which may not be in the same location or in stock.

Use of the SaltSwap app in 75% of all shopping trips during the study provides evidence that apps of this kind are an acceptable tool for this population group. Previous studies of mobile health apps to change shopping behaviour towards healthier purchasing (not salt specifically), have also shown that apps are acceptable and can achieve high engagement among

participants (146,147). Consistent with my findings, a feasibility evaluation of another app which provides nutrition information (as a composite 'health' score) and shows healthier alternatives, found the app increased participants health-related knowledge and their self-efficacy, though purchasing data was not collected to assess overall efficacy (146). The authors also reported that app-users who were actively planning to change their behaviour, or were developing their motivation (according to stages of the Trans-Theoretical Model), benefited more from the nutrition education provided in the app than other app-users (146). This supports the role of the HCP advice in the SaltSwap intervention, to generate this motivation, as a precursor to use of the app.

The literature indicates that salt reduction advice and support can generate *moderate* reductions in blood pressure in people with hypertension. For example, a meta-analysis of RCTs reported reductions in systolic (5.0 mm Hg) and diastolic blood pressure (2.7 mm Hg) due to a sizeable reduction in salt intake (-4.6 g/day) (274). One other RCT showed a low-salt diet resulted in a modest salt reduction of 1.7 g/day and a corresponding reduction in systolic blood pressure of 3.7 mm Hg, among participants with high blood pressure (116). Based on the results of previous studies, I would expect the SaltSwap intervention to generate a reduction within a similar range (1-2 g/day). To put this into context, the reductions achieved through *optimal* treatment with various antihypertensive drug classes (ACE inhibitors, ARBs and Alpha-blockers) is approximately -8 mm Hg systolic, and -5 mm Hg diastolic blood pressure (275–277). Moreover, the benefits of salt reduction can be additive to the benefit of antihypertensive medication (32). Although the estimated effect size for salt intake with this intervention is small, since it could be delivered at scale through routine care there is potential to generate a meaningful impact on blood pressure. Though is it premature to extrapolate cost-savings from the SaltSwap intervention, individual counselling interventions,

delivered by specialist dieticians and involving more counselling time then the SaltSwap intervention have been shown to be cost effective based on expected reductions in salt intake of 0.5 g/day (71). The SaltSwap intervention, requiring less specialist resource and less time and included one-off app development costs, would therefore be cost-effective if it delivers at least a 0.5 g/day reduction in salt intake. Furthermore, at a public health level, even a reduction of 1 g/day would be equivalent to the reduction seen as a result of product reformulation over a decade and achieve nearly half the decrease in salt intake needed for the average adult to reach the recommended maximum daily intake.

5.5 Next steps

In section 5.3 I highlighted several limitations in the intervention, and I would make specific recommendations to improve the intervention and evaluation before a large-scale trial to assess the effect of the SaltSwap intervention on blood pressure. Crucially, the SaltSwap app requires a more comprehensive, frequently updated, and well-categorised database of products to ensure that users can be offered lower-salt options for most commonly purchased products; particularly across products known to contribute substantially to salt intake. This would also improve the capability to accurately record purchased products and swaps offered and accepted using the app.

I would also recommend some minor changes to the trial procedures. To improve the generalisability, a future trial should consider recruitment sites based on markers of deprivation and include strategies to recruit a more ethnically diverse sample. In this trial, I chose recruitment sites for convenience given I was the sole researcher conducting the trial, but this ought not to be a limitation in a future trial. Current evidence recommends that to give a true estimate of an individual's salt intake collection of a minimum of three, 24-hour

samples on non-consecutive days is needed (24). This would provide an estimate of intake less open to error due to day-to-day variation in sodium excretion and variation due to daily salt consumption. Although this could be a consideration for a future trial, it would undoubtedly impact recruitment and retention of participants. Given the primary outcome of a future trial would be changes in blood pressure, with sodium excretion and purchased salt as intermediary outcomes, I am not convinced the benefit of a more accurate measurement of sodium excretion would outweigh any negative impact on recruitment and retention. To improve the validity of the measurement of sodium excretion, without such a burden on participants, completeness of urine samples using para-aminobenzoic acid should be considered in a future trial (22).

To better evaluate the hypothesized mechanisms of the impact of the intervention, I would recommend more rigorous assessment of the knowledge, motivation, intentions, and self-efficacy (using validated tools) of participants to determine the part these play in any intervention effect and potentially allow for analysis of any mediating effects. The low average baseline urinary sodium excretion in this study sample provided little room to demonstrate improvement. In a future trial consideration could be given to planning a secondary, stratified analysis to explore the intervention effect at different baseline salt intakes (e.g. high, moderate, low), or excluding those with low baseline salt intake. Similarly, recruiting only those with diagnosed hypertension would provide a sample with greater capacity to reduce their blood pressure. Furthermore, given the unexpected reductions in salt intake and systolic blood pressure (and reported increases in behaviours such as use of nutrition labels) in the control group who received advice alone, a future trial may want to explore the separate effects of targeted advice from an HCP alone, versus advice in combination with the SaltSwap app.

Though no between-group differences were found in this study, the standard error of the mean change in salt intake (g/day) in the intervention group can be used to estimate the necessary sample size for a definitive trial. Based on these data, a sample size of 143 per group would be required to detect a difference in salt intake of at least 1 g/day between the control and intervention groups with an adequate degree of confidence. However, the primary outcome of a future trial would be the change in blood pressure and to detect a change in systolic blood pressure of at least 3 mm Hg, 260 per group would be required. This is a larger reduction than demonstrated here but I would expect that changes to the intervention and trial processes, described above, would be capable of delivering this change.

6. Conclusions

This study indicates that a next-stage trial to assess the impact of the SaltSwap intervention on blood pressure would be feasible but important learnings from this feasibility study need to be considered for a future trial. Specifically, these include the need to make improvements to the app database to ensure current limitations are overcome and increase its potential effectiveness, and evaluation of the revised app, as well as modifications to the trial procedures to encourage recruitment of a more representative sample with greater capacity to benefit.

Chapter 5. Salt reduction: A qualitative think-aloud study

1. Introduction

In the previous chapter, I reported the results of an RCT to investigate the feasibility of the SaltSwap intervention. The main trial outcomes provided evidence that the intervention was feasible to deliver in primary care and acceptable to individuals with high blood pressure. The trial provided some evidence that participants used the SaltSwap app; that the intervention improved overall knowledge about salt and health; and it influenced salt intake behaviours such as use of nutrition labels. However, the trial outcomes provided little detail about *how* the intervention affected salt intake, its influence on knowledge, intentions or motivation to reduce salt intake, or any barriers that might limit the effectiveness of the intervention. The intervention logic model in Chapter 3 (section 5) illustrated how the intervention might work, via mechanisms of impact, to create behaviour change and reduce salt intake. Investigating the hypothesised pathways of impact is important in understanding why the intervention works– as it might have different effects in different contexts – or why it does not work, in order to identify improvements (231). This requires a more in-depth evaluation.

Understanding the barriers and facilitators for salt reduction, and key factors that shape purchasing decisions, among people who have received advice to reduce their salt intake, could also provide some explanation as to why the intervention did or did not lead to salt reduction, informing future intervention design. A number of studies have explored the key influences on food purchasing decisions; with factors such as health, price, freshness, and brand familiarity coming through as most salient (198,201,278,279). One author concluded

that shoppers had to "juggle and trade-off a myriad of different considerations during their purchasing decisions" (280), indicating a complex and effortful decision-making environment. To my knowledge, no published studies have explored in detail the factors influencing shopping decisions following advice to reduce dietary salt intake.

2. Aims and objectives

This study aimed to investigate the impact of the SaltSwap intervention on salt reduction practices, especially shopping behaviours; and explore the impact of both the intervention and generic dietary advice on the salient factors shaping participants' purchasing decisions. The key objectives were to:

1. Explore the impact of the SaltSwap intervention on real-world shopping behaviours.
2. Understand participants' experiences of trying to reduce their salt intake.
3. Explore the factors influencing participant's supermarket shopping behaviours and how these affect their decision-making, in the context of advice to reduce salt intake.

3. Methods

3.1 Study design

I used an interpretive qualitative methodology (281) to explore the shopping behaviours of people in the SaltSwap trial, applying a relativist ontological approach, as described by Greene (282). A relativist ontological stance posits that "our knowledge about a given social phenomenon is contextual, interactive, multiplistic and phenomenological" (282). One evaluator's understandings about the experiences and impacts of a given social program will

be different from another evaluator's understandings of the same program, because such understandings are constructed by each inquirer's unique interactions with others in that context" (282). This is the alternative to a realist approach which implies that there is only one independent reality, an approach taken more commonly in ethnographic research for example. The relativist approach embraces the subjective nature of qualitative evaluation and the interplay between the evaluator and that being evaluated. Although a think-aloud study is observational, it also places the researcher in the context, and along with the semi-structured interviews, creates an interplay between researcher and the subject/intervention under investigation.

I chose a qualitative approach to address the research aims as it allows an in-depth investigation of the impact of the SaltSwap intervention on the decision-making process, answering the questions of 'how' and 'why' phenomena occur (283). I used participant observation and the think-aloud method during accompanied supermarket shopping trips; complemented with semi-structured interviews conducted face-to-face immediately after the shopping trips, to build the most comprehensive narrative.

In determining the most appropriate data collection methods, I considered the distinction between *naturally occurring* data such as observational data, i.e. 'the enactment of social behaviour in its own social setting'; and *generated* data, i.e. 'the recounting or re-telling of experiences, beliefs, or other phenomenon' (284). As shopping behaviours may be instinctive, habitual, or sub-conscious, and need to be understood in the real-world context, participant observation was particularly appropriate here. The think-aloud method attempts to access and record participants' inner speech, the 'transformation of thought processes into words' (Charters, 2003). It is a common tool to assess the usability of web-based tools (286). It has also been widely used in the design and evaluation of digital interventions; (287,288)

and to explore consumers' food purchasing behaviours (289,290) and use of nutrition labels (291,292). Combining this observational method with generated data, captured through semi-structured interviews following the shopping trip, enabled me to elicit further detail on the beliefs, perceptions and shopping behaviours of participants relating to salt reduction and influences on their shopping choices more broadly.

3.2 Recruitment

Participants were recruited from those participating in the SaltSwap feasibility trial. A sub-sample of this group were selected to participate in the think-aloud shopping study. Participants were selected at two time-points in the trial intervention period, weeks two to three and after week five (but before the follow-up assessment). I hypothesised that the effect of the intervention (or control advice) may wane over time and I wanted to explore shopping behaviours early in the intervention period. However, I was aware that the accompanied shopping trip may influence the participants to such a degree that it becomes an intervention component. To balance these factors, I planned to conduct half of the interviews towards the end of the intervention period. Participants were offered a £10 gift card as an incentive for their participation.

3.3 Sampling strategy

I employed non-probability sampling as my aim was to achieve an 'informationally representative' sample, not one which was statistically representative of the population (284). I initially used a purposive sampling strategy based on key participant characteristics which I identified as representatively important. I also considered the richness of data each case would generate. Information-rich cases, described by Patton as "those from which one can learn a great deal about issues of central importance to the purpose of the research" (293),

were actively sought as they allowed me to generate as much data as possible within the resource constraints of the study. I had to adapt this to a more convenience sampling approach (284) due to participant availability to participate in the accompanied shopping trip. I included both intervention and control participants as both had relevant experiences to address the study objectives. The key characteristics on which I based my sampling frame, and whether ideal targets for these were achieved, are shown in Table 5.1.

Table 5.1. Characteristics for purposive sampling, the target and whether this was achieved.

Key sampling characteristics	Target	Achieved
Group allocation (intervention or control)	66% Intervention	✓
Timing of the accompanied shop within the intervention period (weeks from intervention)	50% at week 2-3	33% at week 2-3
Gender	At least 40% male	39% male
Recruitment site	Fair spread across sites	✓

3.4 Sample size

The pre-determined sample size was guided by the relative homogeneity of the study population, the small number of selection criteria, and use of single interviews instead of focus groups; all of which indicate that a smaller sample size would be sufficient (284). Also, as I was the sole researcher doing the data collection, and the accompanied shopping trips had to occur within the six-week intervention period, the sample size was limited to a pragmatic and achievable size. As the study progressed, I applied Malterud and colleagues' model of information power to inform the required sample size (294). This model sets out five items to consider when determining the information power achieved (Table 5.2). Using the concept of information power throughout the data collection, I determined that 18 was a sufficiently large sample.

3.5 Public and patient involvement

Participant-facing materials were reviewed by the co-design panel recruited for the SaltSwap feasibility trial in which this qualitative study was nested.

Table 5.2. The constructs of information power applied to this study.

Information power considerations	Impact on my sample size
1. Whether the study aim is broad or narrow	I had a narrow and well-specified study aim indicated a smaller sample required.
2. The specificity of the sample	I recruited a highly specific sample, chosen from within a larger trial with specific eligibility criteria therefore a smaller sample would suffice.
3. Use of established theory	There was an established behaviour change theory underpinning the intervention and guiding the topics I was aiming to explore.
4. Quality of dialogue	Despite my relative inexperience in conducting qualitative interviews, previous training in interview skills helped to strengthen the quality of the dialogue. My in-depth knowledge of the study topic area, and previous interaction with the participants as part of the wider study engendering confidence and familiarity between researcher and participant, increased the information power requiring fewer participants.
5. Case or cross-case analysis	I applied a cross-case analysis thereby requiring relatively more participants to achieve enough information power.

3.6 Data collection

Accompanied shopping trips were conducted in the participants' store of choice, usually where they regularly shop. I accompanied the participant for the duration of their shopping trip. Participants received oral instructions before beginning the think-aloud shopping trip (Appendix 17). Participants were encouraged to speak freely, saying whatever came into their

head as they carried out their shopping. They were assured there was no right or wrong answer. Before starting their shopping, I asked the participant to practise thinking-aloud by considering purchasing a non-food or drink item in the store (e.g. a pair of socks). Throughout the accompanied shopping trip, I used prompts such as 'tell me what you are thinking' to encourage the participant to think-aloud if they were silent for period. I occasionally took photographs of the products being considered by participants.

Post-shopping interviews were conducted at in-store cafés or, in one case, at the participant's home immediately after the shopping trip. The interview topic guide (Appendix 18) was developed with input from two experienced qualitative researchers. Topic areas focused on specific elements targeted by the SaltSwap intervention, to explore theoretical aspects of participants' shopping behaviours while also eliciting their perceptions and beliefs around salt, health and influences on grocery purchases. Questions were slightly different for participants in the control group due to the nature of their experience in the study. The topic guide was not formally piloted, but I iteratively developed it as I conducted more interviews, to explore topics raised in earlier interviews.

Written informed consent for the think-aloud study was gained as part of the SaltSwap trial. The date and participant ID number were recorded to identify the study session. Audio recordings of the think-aloud sessions and interviews were uploaded and saved securely on the University of Oxford server, with participant ID as the identifier.

3.7 Data Analysis

I used thematic analysis to synthesise and interpret the data. Thematic analysis is a systematic approach which allows the development of a coding framework based on *a priori* themes (a

deductive approach) as well as the generation of additional codes derived from the data (an inductive approach) and focuses on generating meaning *across* a dataset. I applied Braun and Clarke's six-phase approach to thematic analysis, with some minor adaptations (295) (Table 5.3). I used Nvivo 12 (251) for data storage, coding, and management. I chose not to differentiate between data captured during the think-aloud session or the interview because I considered the interviews an extension of the think-aloud rather than a separate data collection activity. I did, however, identify where data was captured only through observation during the think-aloud, i.e. observer notes and photographs, though this was infrequent.

3.7.1 Theoretical constructs

The intervention under investigation in this study was developed using the Behaviour Change Wheel (Chapter 3). The theoretical constructs included in this model, and their influence on the desired behaviour change were used to facilitate interpretation of the data. For example, when interpreting the data on the salient influences on food purchasing decisions, I considered influencing factors as part of motivation (automatic and reflective) to choose lower-salt foods. These theoretical constructs were mapped to 'mechanisms of impact' in a logic model in Chapter 3.

Table 5.3. Thematic analysis approach adapted from Braun and Clarke.

Thematic analysis steps	Description
Familiarisation	I listened to the audiotapes of the think-aloud sessions and interviews and read through the written transcripts before beginning the analysis.
Create a coding framework	I created an initial set of codes based on topics purposefully explored in interviews and those that developed from the data in my initial read through. I typically used codes that were close to the content of the data, in language and meaning but also used some interpretative codes to adequately capture phenomena.
Apply and refine the coding framework	I applied these codes to relevant passages of the transcript and dual-coded data where appropriate. I described each code in detail to ensure codes were well defined and consistently applied. This was an iterative process with creating the coding framework as additional codes developed and others were refined to form a working framework for the analysis
Reapply the coding framework	To ensure the coding framework was applied consistently, I completed a second round of coding using the final iteration of the coding framework.
Summarise the data	I employed the One Sheet of Paper thematic method described by Ziebland & McPherson (296) to identify broad topics across cases, constructing themes and grouping these together into categories.
Review and revise the themes	Moving codes from one theme to another or redefining codes and themes to create the best representation of the data, and clearly defining them. At this point I also referred to my research objectives, to relate themes to these objectives.
Interpret the data	I integrated theoretical constructs and other literature, drawing connections between themes and exploring similarities or differences between cases and drawing out relevant quotes to illustrate key concepts. I aimed to present a fair representation of the data, not solely based on the frequency of reporting of similar views but with the aim of presenting the full breadth of views or experiences reported.

3.8 Quality and validity

Data quality was enhanced through the detailed description of codes and through a second coding iteration to apply the fined coding framework (Appendix 19). Furthermore, the coding framework was discussed with my supervisors who have substantial experience in nutritional research and an experienced qualitative researcher before coding and after the first iteration. Example transcripts were reviewed and discussed, together with the developing coding framework, to determine how these could be grouped into themes. I recorded all iterations of the coding framework, as well as documenting reasons for amendments.

Validity is an important consideration during data analysis and is 'the extent to which conclusions drawn from research provide an accurate description of what happened or a correct explanation of what happens and why' (297). To enhance validity, I monitored and recorded the decisions made during analysis to ensure consistent interpretation and enable reflection on the implications of these decisions on the reported outcomes (298,299). I sought out similarities and differences across accounts to ensure different perspectives were represented and included verbatim quotes of participant responses to support the constructs and findings reported in results (298). I followed the Standards for Reporting Qualitative research (SRQR) from the equator network, to ensure complete and transparent reporting of this study (300). Throughout the research process, I considered aspects of reflexivity and how these might impact the validity of the data. My own personal characteristics, position, relatedness to the research, and beliefs are likely to have affected the data collection, analysis and interpretation. I was conscious of this and took deliberate steps to mitigate this impact such as focussing on positive and critical aspects, taking care not to reinforce my own beliefs through ad-hoc comments to participants, and documenting the rationale for my interpretation of data.

3.9 Ethics

This study was reviewed and approved on the 17/03/2017 (reference number 17/SC/0098) by the South Central - Hampshire B Research Ethics Committee and the Health Research Authority.

4. Results

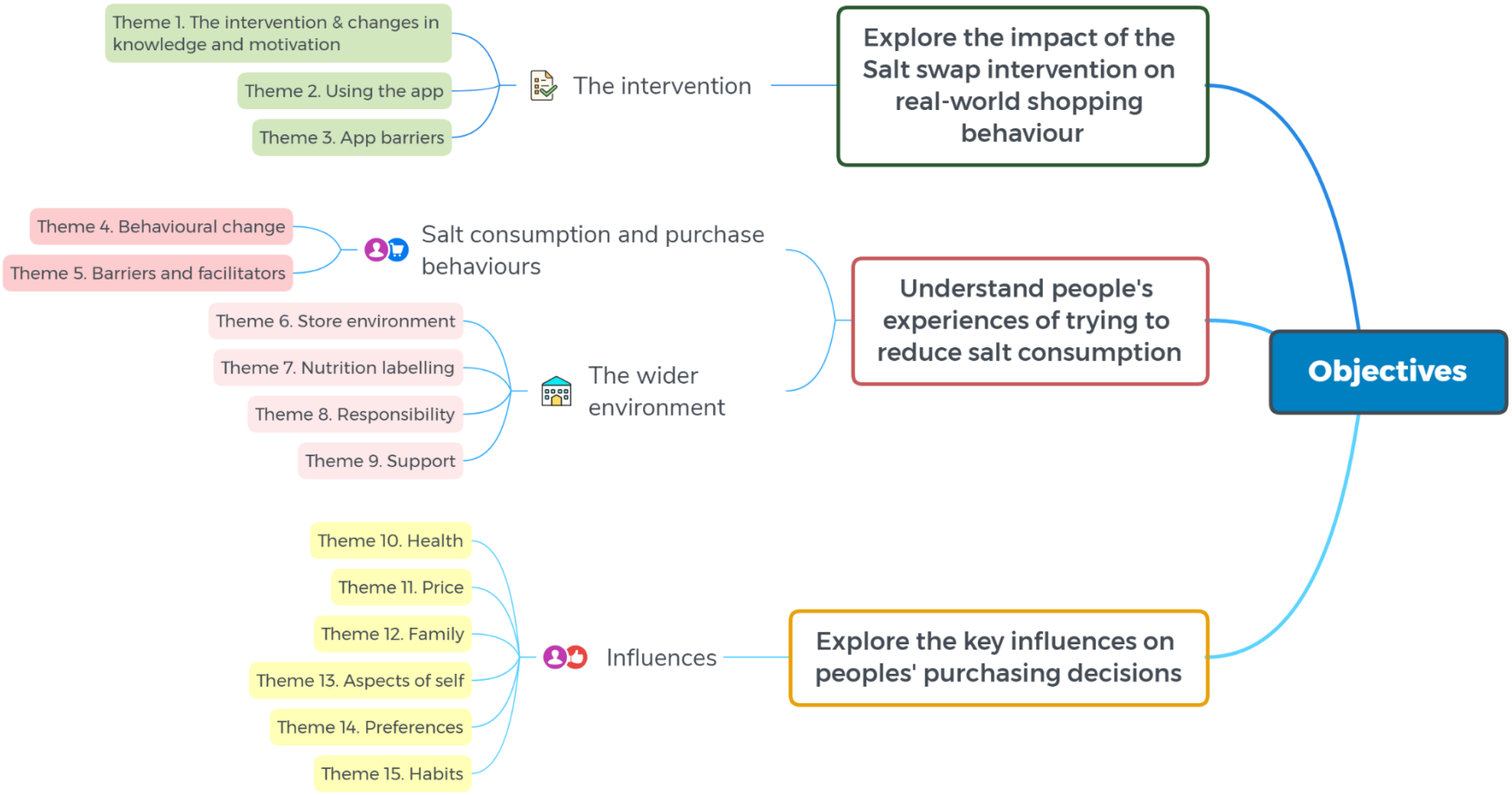
4.1 Participants

I invited 22 of the 50 participants enrolled in the SaltSwap trial to participate in this think-aloud study; of which one declined, one did not reply, and I was unable to find a mutually convenient date with two participants. Six participants had received the generic salt-reduction advice booklet as part of the control group and 12 had received the SaltSwap intervention. Shopping trips were conducted between October 2018 and May 2019, typically in large supermarkets. Shopping trips varied in duration from 5-44-minutes and interviews 12-40-minutes, with an average combined duration of data collection of 49-minutes per person. One intervention participant was interviewed but did not complete the think-aloud shopping trip due to time constraints on the day. Most participants shopped with a list, and meal planning or stocking up on necessities was a big factor in the shopping habits with most participants buying ingredients to prepare a meal rather than pre-prepared food. Participant characteristics are shown in Table 5.4.

4.2 Thematic analysis

Findings from the thematic analysis are summarised in key themes, grouped together as categories relating directly to the study objectives (Figure 5.1).

Figure 5.1. Map of themes and study objectives.



Themes one to three explore the impact of the SaltSwap intervention, therefore, includes only data from the 12 intervention participants. All other themes include data from both intervention and control participants. All names (of people and places) have been changed to protect participant confidentiality. A detailed description of the themes with additional example quotes to illustrate or exemplify findings is in Appendix 20. The frequency of coded excerpts from the raw transcripts under each theme, indicating the relative volume of data captured, is depicted in Appendix 21. To aid my interpretation of the data, here I considered how each of the emerging themes addressed the mechanisms of impact detailed in the evaluation logic model in Chapter 3 (Figure 5.2).

Figure 5.2. Hypothesised mechanisms of impact related to qualitative themes.

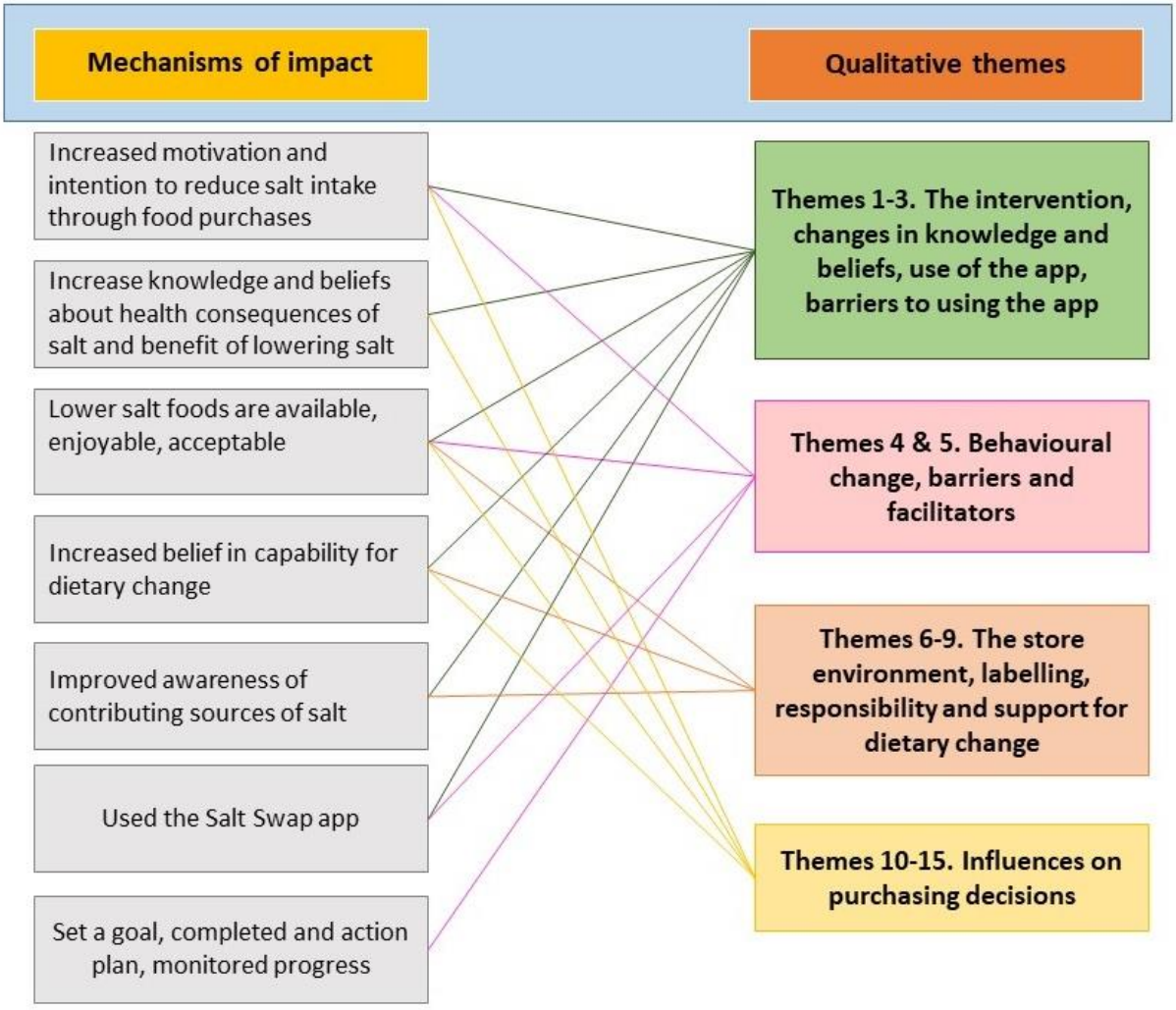


Table 5.4. Characteristics of think-aloud participants (n=18).

ID	Age (yrs.)	Gender	Ethnicity	Study group	Diagnosed hypertension	Household size	Shop frequency	Think-aloud (week)	Total duration (min)
0108	69	Female	White British	Control	Yes	2	More than once a week	4th	60
0205	68	Female	White British	Intervention	Yes	2	Once a week	3rd	40
0206	64	Male	White British	Intervention	Yes	3	More than once a week	2nd	70
0207	58	Male	White British	Intervention	No	3	Once a week	2nd	63
0210	79	Female	White British	Control	Yes	2	More than once a week	4th	46
0215	60	Male	White other	Control	Yes	2	Once a week	3rd	21
0218	76	Female	Prefer not to say	Intervention	Yes	1	More than once a week	3rd	37
0309	71	Male	White British	Intervention	Yes	1	Once a week	6th	19
0313	57	Female	Other Asian	Intervention	Yes	2	Once a week	8th	48
0319	69	Female	White British	Intervention	Yes	3	Once a week	7th	84
0401	54	Male	White British	Control	Yes	7	More than once a week	6th	41
0403	70	Male	White other	Intervention	Yes	2	More than once a week	6th	48
0406	69	Female	White British	Control	Yes	1	More than once a week	3rd	48
0408	65	Male	White British	Intervention	Yes	1	More than once a week	6th	38
0410	74	Female	White British	Intervention	Yes	2	More than once a week	5th	60
0414	61	Female	White British	Control	Yes	2	Once a week	5th	77
0415	71	Female	White British	Intervention	Yes	2	More than once a week	6th	34
0416	57	Female	White British	Intervention	No	2	Once a week	5th	40

4.2.1 The SaltSwap intervention

Theme 1. The intervention and changes in knowledge and motivation

Participants commonly mentioned that the intervention had increased their awareness of the amount of salt in some products, particularly those they had not previously considered to be high in salt. Many also expressed surprise at the high salt content of products such as crisps, nuts, bread, and some ready meals, in the context of the daily recommended maximum. Participants also reported a general focus on salt, when selecting foods, that they had not had before.

> *"Although I must admit doing this it's heightened my awareness of salt in the diet…I was horrified at the levels of salt in crisps and things, so have gone for the no adding salt to that. Sauces, I've been surprised how much salt is in those." (ID0205, intervention)*

> *"I had never noticed [brandA] tomato sauce with low salt before. And that brought it home to me. So, it has made me look differently." (ID0415, intervention)*

> *"Fat, high calories. I am well educated in this but salt, for me it was completely new." (ID0215, intervention)*

Participants reported being aware of the impact of salt on blood pressure before the study, but some participants mentioned they were previously unaware of the value of reducing salt for controlling blood pressure. Some participants mentioned the recommended maximum salt intake per day, but it was not clear if this was something they knew before the intervention or new knowledge, and whether they understood this was a maximum limit rather than a recommended intake. Two participants reported being concerned about lowering their salt too much, and the impact on their health, perhaps indicating mixed messaging about salt intake recommendations.

> *"I've never had to look at it and now I look at it...think I'm allowed six grams today, that's what they recommend." (ID0415, intervention)*

"The thing that concerns me is like you get the... what is it? People suffer from goitre, so that's why I need to put in the salt with the… But you do need salt in your diet I understand." (ID0403, intervention)

A gap in knowledge seemed to be how to balance different nutrient recommendations. Several participants commented that they found it difficult to know how to make a 'healthy' choice if a product was lower in salt but higher in fat or sugar. Participants also reported some confusion around interpreting nutrition labels – see theme 7 'nutrition labelling' for more detail.

"So, a lot...of dairy things came up with high fat. Things like the cereals and things like that came up with the high sugars as alternatives. And I think that's been the hard thing is getting the balance; balance between the two." (ID0319, intervention)

Some participants perceived their salt intake to be low already, or not a significant factor in their blood pressure control, potentially reducing their motivation to make changes to their salt intake. Some participants mentioned that receiving feedback on their salt intake or blood pressure would motivate them to try to reduce their salt intake.

"But that's my feeling that I don't think we have a great salt intake. And OK, I have high blood pressure, but I think a lot of that was work-related." (ID0206, intervention)

"I guess I'd like to know where I am on the spectrum. So, as a result of the urine tests. Where do I sit…in terms of a male of my age? Because that may provide something...Motivation." (ID0309, intervention)

Several participants described how they would be more motivated to reduce their salt intake if they experienced ill-health or if they felt their salt intake was really damaging their health. One participant (ID0207) who had high blood pressure, in line with the study criteria, but was not diagnosed with hypertension, described how he would change his salt intake if it was damaging to his health.

"I suppose if I have a heart attack, I might finish up thinking differently about that, but at the minute." (ID0319, intervention)

"I'm not going to... unless I was like medically really unhealthy, and I don't think I am, that... and it was like damaging to my health then I would sort of say, 'OK fine, I'll grin and bear it,' and I'll do it." (ID0207, intervention)

Participants commented positively on the advice session delivered by HCPs, including key components of this such as identifying high-salt foods in their diet or setting goals. However, few participants mentioned their experiences creating an action plan to address their goal.

> *"That was quite helpful. I mean she put me on the tracker of identifying... I think there was a list in the booklet and it sort of says, 'Could you cut down salt in the bread and biscuits, the sauces, the pickles?' that type of thing. So, that was quite useful… I think because the first week we decided to look at sauces and stock cubes." (ID0205, intervention)*

> *"And we went through everything. We sort of set a goal, what to set and everything else, which is why I've changed bread." (ID0207, intervention)*

Theme 2. Using the SaltSwap app

I observed participants using the SaltSwap app in six shopping trips (of 11 trips observed), though all participants in the intervention group had used the app while shopping during the study and described this to me either during the shopping trip or interview. Of those who I did not observe using the app, three purchased only a small number of items for which they did not need to check the salt content or, had done so in a previous shopping trip or at home. One participant reported using the app initially and then swapping to using the nutrition labels instead. Participants engaged with the app in a positive way and were diligent in using it to look for suitable alternatives; spending a significant amount of time looking for lower-salt alternatives, using a mix of the app and product nutrition labels. Most participants had some success finding suitable lower-salt alternatives for products they would normally buy.

> *"I did it at home for [store] and found out there was an alternative for [brandA] pickles. With less salt. So, we got that this morning…I got some [brandB spreadable butter] last week... no, [brandC spreadable butter] because it was actually less salt." (ID0403, intervention)*

> *"Things such as the crackers, swapping them, corn crackers for lighter ones. That was a really interesting find." (ID0319, intervention)*

If the app did not identify suitable alternatives, participants often used labels to find a lower-salt product.

"But there was other products on the shelf, and I basically looked at them and I actually looked at the label….and I've found that these other products, not only were they slightly cheaper but they had less salt." (ID0207, intervention)

In some cases where no suitable alternative was available, this prompted participants to reduce how frequently they bought certain foods or avoid them altogether.

"I do like salted peanuts and I haven't been able to find anything that's low in salt. I did look it up on the app and it suggested that I went to almonds and things, but that's not the same as peanuts…. I probably would have bought them most weeks. Whereas now I think, 'No, it is a treat.'... I won't have those." (ID0205, intervention)

Participants mostly found the app acceptable and it helped focus their attention on the salt content of foods. I did not observe participants recording their purchased items in the app on completion of their shopping trip, the point where they would receive feedback on swaps made and goal achievement. Notably, none of the participants mentioned using this feedback screen which showed salt reduction achieved, or how this changed their shopping choices. Several participants mentioned the design or usability of the app, with a mix of positive and negative comments on ease of use. All participants observed using the app were able to do so without significant usability issues.

"In the main, it was easy to use." (ID0408, intervention)

"It was easy to scroll down. And it was nice to be able to see the bars before you opened it. So, we saw, you know, red, red, red, and green." (ID0319, intervention)

"if you're like me and, you know, your eyesight's not that brilliant, your fingers are... it's not easy." (ID0205, intervention)

Theme 3. App barriers

The most common issues experienced when using the SaltSwap app were products not being recognised by the app, suggested alternatives not being available in the store, or alternatives being perceived as unsuitable. One common reason for products being considered unsuitable was if the product had been misclassified in the database (e.g. glace cherries categorised with olives). However, participants also considered alternatives as unsuitable based on taste, or the

product utility, for example due to requirements of a recipe. One participant noted that they found the app offered too many alternatives and this made it unwieldy.

> *"the recipe I used crumbles feta cheese on the top. Now, a low salt alternative came out as a sort of cream feta. Which just landed up as a revolting looking mess" (ID0205, intervention)*

> *"But I actually got the [brandA] Thin and to be honest, I didn't like it very much. So, I wouldn't be having that again" (ID0218, intervention)*

> *"Yes, well I found the app quite difficult when I first tried to use it because there was such a variety of alternatives…I started to look at the contents rather than the app…and I was looking at the salt" (ID0403, intervention)*

Participants commented that some smaller stores, or those stocking primarily 'own-brand' products, had little variety on offer making it difficult to find alternatives. In some stores, alternative products were in a different part of the store and for some products, there were few low-salt options available. Some participants mentioned the increased time and effort required for shopping with the app.

> *"if you were... had to do this on every item on a busy day, your shop would be three times as long" (ID0206, intervention)*

> *"This is…tomato paste. See, I think being [store] they only do one." (ID0206, intervention)*

> *"Because if you eat a lot of ham, corned beef, those sort of things, then they are all in the red zone… Because if there was... you know if it had gone down to amber rather than red, one might have carried on." (ID0309, intervention)*

4.2.2 Salt consumption and purchase behaviours

Theme 4. Behavioural change

Participants in both the intervention and control groups described making changes to reduce their salt intake. These included swapping to lower-salt alternatives when shopping, looking at the salt content on nutrition labels, reducing purchasing frequency or portions of high-salt foods or avoiding them altogether, not adding salt to foods, using herbs and spices instead of

salt and not adding salt when cooking, and cooking home-made alternatives to store-bought foods.

> *"I wanted to buy some ham…And I looked at the salt content and put it back." (ID0406, control)*

> *"Because that's why I've started buying the fresh stock. And adding more of the fresh herbs. And spices and things." (IB0108, control)*

Examples of descriptions of these behaviours by intervention participants, and how these relate to the components of COM-B which were targeted in the SaltSwap intervention are shown in Table 5.5.

Theme 5. Barriers and facilitators to reducing salt intake

In addition to specific barriers related to the Saltswap intervention, participants in both groups raised similar barriers to choosing lower-salt foods, including the time required, the challenge of interpreting nutrition information, the lack of availability of lower-salt choices within some food groups and balancing salt reduction with other health influences.

> *"…say I've been over half an hour doing the thing. But if I was looking at everything, I'd be in here three/four hours" "But it is important but life's too busy; life's too quick, innit... for me." (ID0401 control)*

> *"Oh, that's not bad on salt either. But look, it's high on fat. So, with Slimming World you're not supposed to have more than I think three percent fat…" (ID0414, control)*

Other barriers raised by participants in both groups were price, taste, and cultural influences.

> *"Well, I think some of the ham has been more expensive. The bacon today was actually a cheaper one that has quite surprised me." (ID0410 intervention)*

> *"Because you know the Mediterranean diet? And it's feta cheese is part of our culture." (ID0215, control)*

One control participant believed that their blood pressure was high due to family history rather than diet therefore, changing their lifestyle was not important.

> *"So, I think within our family, you know when it's like family history rather than [healthy eating]." (ID0414, control)*

Table 5.5. Examples of participants' reported behaviour change and the related COM-B components (intervention participants).

Behaviours	Example quotes	COM-B component(s)
Swapping to a lower-salt product	*"Now we used to buy the deals here of different sorts of ham – but when I tried to do a salt swap on them it was quite difficult to find an alternative. So, what we do now is we buy sliced turkey" (ID0403, intervention)* *"I used to buy crisps without thinking about salt. And then I started the salt file, I just switched to these." (ID0313, intervention)* *"I used to buy a tomato sort of sauce. And in fact, because that was quite high in salt, I started using Passata little boxes. Because you get the sort of intense tomato flavour, but you don't get the salt." (ID0410, intervention)* *"Like I haven't been buying so much ham. I have bought chicken instead". (ID0415, intervention)*	Psychological capability -knowledge Reflective motivation Automatic motivation -disrupting habit Environmental opportunity – making it easy to identify lower-salt options
Avoiding high-salt foods	*"They were like a ripple type crisp, and I was surprised how much salt was in that. And in fact, I don't think I bought them in the end. Because I thought, 'Wow, I thought these were supposed to be, you know, healthy." (ID0206, intervention)* *"Anyway, I used to buy those particularly when it was the two for one type offers. Just stopped buying those completely, yeh" (ID0408, intervention)*	Psychological capability -knowledge Reflective motivation -intentions/persuasion Automatic motivation -disrupting habit
Changing cooking practices to reduce salt intake	*"And I've also... we've also this last week haven't cooked with salt either. Yeh, previously if we used in cooking potatoes; boiling potatoes up for mashed potatoes; always put a bit of salt in there. Even with your, you know, vegetables, put a bit of salt in there, but we haven't this time." (ID0207, intervention)* *"So, instead of using stock cubes. Which we know are high in salt, I tend to use Bouillon because I can use just a tiny bit of that. I will*	Psychological capability -knowledge, skills Automatic motivation -disrupting habit

	sometimes use that. Or what I do is I add that after I've taken my portion. And that, because it's not a stock cube has to be whatever, and what have you. With that I can stir that in…So, that works quite well." (ID0319, intervention)	
Swapping from a store-bought product to home-made, with no added salt.	*"after I'd seen those things and how high they were in salt, when I went and did my own, I didn't put any salt whatsoever in it at all, and I just used the Indian spices" (ID0218, intervention)*	Psychological capability -knowledge, skills Reflective motivation-persuasion
Reducing frequency of consumption or portion size.	*"I probably would have bought them most weeks. Whereas now I think, 'No, it is a treat.' And I would also not sit and eat the whole packet." 0205, intervention)*	Psychological capability -knowledge Reflective motivation -intentions

Many participants demonstrated a real willingness to try lower-salt options and to invest time and effort into identifying these. For some, emotion also played a role in their motivation or perceived capability to make changes to their diet, such as participant 0401, a father of five children who found it challenging to make healthy choices but felt guilty for buying unhealthy products for his children.

> *"…it is important but then everything has to sort of work together, but then it is important because if I get something and I think, 'Well, that's not really good for kids,' then I'm guilty." (ID0401, control)*

Making new habits and planning were described as ways to help with making lower-salt choices and having the time to look for lower-salt options enabled some participants to successfully do this.

> *"I think in the long term it will, you know, there will be a period of adjustment where you add that as another variable into the things you're thinking about. And once you've done that and have found a comfortable regime then it'll be OK." (ID0309, intervention)*

4.2.3 The wider environment

Theme 6. The store environment

Participants commented on the choice of products available, product promotions, marketing and store layout. There was a consensus that the store layout was influential in shaping their decisions and this influence was something to avoid.

> *"You know and say, 'Oh, yeah let's have one of those,' because it's right in your face at the checkout." (ID0403, intervention)*

> *"…just trying to ignore all the things that they're trying to throw at you and everything…" (ID0319, intervention)*

> *"…it's very important how the supermarkets are organised; they put some unhealthy things in front of you. But if you're not very disciplined you can follow the stream." (ID0215, control)*

Some participants expressed a concern that product marketing typically encourages unhealthy choices and how they try to avoid being influenced by this.

"It almost feels like a game trying to beat the manufacturers at their own game. Sort of like, OK, I'm not going to fall for that. But actually, we all do, don't we?" (ID0319, intervention)

Theme 7. Nutrition labelling

Use of nutrition labels to assess the salt content of foods was discussed in both the intervention materials and the general advice booklet received by control participants. All participants mentioned their use of nutrition labels, either unprompted during the think-aloud or during the interview (or both).

"I would say since I've started the salt study, I've looked at those labels more than in the past. In the past I used to only look at the sugar content." (ID0403, intervention)

Several participants specifically mentioned that they had previously used front-of-pack nutrition labels for sugar, or calories, but had not looked at the salt content and they only started to do so since beginning the SaltSwap trial. Participants also commented that the traffic light format labels were helpful, but raised limitations including the print being too small, some products not using the traffic light format, and difficulties interpreting the labels such as confusion over the percentage recommended intake (%RI). Two participants were observed using the %RI and confusing this percentage with the total maximum recommended salt intake of six grams.

"But then if we're only allowed 6% salt, it's saying that that's 4% of it. So, at the end, I don't know whether you can explain..." (ID0414, control)

"very confusing and complicated and very small." (ID0313, intervention)

One participant who shops for his family of seven reported finding the labels difficult to interpret and suggested a simpler format would be more helpful. Another participant mentioned that he just looks at the red and amber labels as a way of judging whether a product is unhealthy.

"I don't really know what that means. I think with that I'd be better off... Be better off if they just put on them good for you or bad for you." (ID0401, control)

Theme 8. Responsibility for dietary change

In the interviews, I asked participants about the extent of individual responsibility for making lower-salt purchases and how they perceive the role of retailers, manufacturers, and the government. A few participants believed it was primarily the responsibility of individuals to choose lower-salt products, but most considered that there was a split of responsibility between the individual and the food industry. Some participants felt very strongly about the role of manufacturers and retailers in helping people to make low-salt choices. Other participants highlighted the role of government, particularly in the regulation of industry.

> *"I don't think suppliers have taken salt seriously. I mean I don't think they're taking sugar terribly seriously, but they're certainly not taking, and they're not making it easy for people who want to cut down on the salt." (ID0309, intervention)*

> *"Yeah, that's what I think, it should be more pressure put on the manufacturers to do it for us." (ID0401, control)*

Among participants who commented that it was largely up to individual choice, there was also recognition that the food environment is influential and that some people would benefit from a more regulatory approach.

> *"I think you can go too far on the nanny state. I think you've got to try and allow people to think for themselves. I mean most people are pretty intelligent enough to know that if they're eating a jam doughnut it's going to be full of sugar…*

> *…there may be an element in society that maybe it would help to have this almost forced on them. Because perhaps their knowledge isn't so great. Maybe they just don't understand about…maybe have been brought up like that." (ID0108, control)*

Theme 9. Support

Participants generally believed there is a lack of support to make dietary changes to reduce their salt intake, with some having direct experience of trying to access support.

One participant recounted the limited nutritional support received previously, after suffering a heart attack.

> *"I think non-existent. Because even when we were doing phase three cardiac rehabilitation, we only had an hour and a half with a nutritionist. And that was it because she was never available again." (ID0408, intervention)*

In terms of availability, many participants felt there was not enough support available to help people reduce the salt in their diet. One participant noted that even if people are willing to go searching for it (e.g. online), there is an overwhelming amount of information and it is challenging to find accurate and valuable information. Some participants felt that their GP surgery would be a good place to provide support, and a couple of participants described experiences of dietician support for other conditions (e.g. diabetes) which they had found extremely helpful.

> *"And I think everybody feels hurried. No-one's prepared to sit down and talk in length about people's issues or about people's concerns" (ID0207, intervention)*

> *"I think from a point of view of the surgery, you can go in and they say, 'You've got high blood pressure, you'll have to take tablets for the rest of your life.' If they told you these are some suggestions to reduce your blood pressure, then I think that's a good place for it to come from." (ID0415, intervention)*

> *"When I became diabetic, for instance, they run courses…and the courses were absolutely fantastic. You know, and if you did something like that…to actually educate people." (ID0406, control)*

4.2.4 Influences

Theme 10. Health influence

Most people spontaneously mentioned the influence of health-related factors on their purchasing decisions during the shopping trip and subsequently in interviews. Despite being primed to think about salt via the study, their comments covered many facets of health, as depicted in the word cloud in Figure 5.3. One participant mentioned ten different aspects of health during the accompanied shop and interview. Participants

commented on health aspects of foods both in terms of *beneficial* properties of foods such as foods to improve sleep; and *negative* aspects related to foods, such as high sugar content, or use of chemicals.

> *"…it's the fish today, which I know has got omega oils and things in which is beneficial to health." (ID0218, intervention)*

> *"I have watercress very often. I think it's very good for blood pressure" (ID0313, intervention)*

> *"…especially for me as a diabetic, and I'm looking for low sugar, low fat if we can find it, but now low salt as well" (ID0410, intervention)*

Participants often phrased their behaviour as "trying" to eat healthily or reduce intake of salt or other nutrients, suggesting they perceived it as effortful. Several participants specifically mentioned the challenge of trying to identify healthy foods or mentioned products they considered unhealthy but were 'treats' they bought infrequently.

> *"…now we're trying to eat more healthily in terms of having been told that I've got high blood pressure…I think what this study is showing me, is that it's actually a lot harder than it seems." (ID0319, intervention)*

> *"But I find it hard in the food. I find it hard to buy healthy." (ID0401, control)*

Participants mentioned a variety of sources of information about what foods are healthy including the media, HCPs, organisations such as Slimming World and the British Heart Foundation, or word of mouth; demonstrating the breadth of sources and reliance on some sources which may not be evidence-based.

> *"you just hear in the media and everywhere that sugar's the killer…*
>
> *…Dr Wantage said for my potassium, chocolate is good." (ID0206, intervention)*

> *"we went on a cruise one year and it was saying that sweeteners can give you cancer and it's really bad for you, so it sort of put me off buying them." (ID0414, control)*

Figure 5.3. Word cloud showing the frequency different facets of health mentioned by participants.



Pre-existing health conditions such as high cholesterol or hypertension were also an important influence on participants' purchasing decisions, though this was also modified by the perceived benefit to be gained from changing their diet (see also theme 1 discussing motivation).

> *"When you get to my age, when you've got high cholesterol and you're on tablets for having had a stent. You tend to take slightly more care." (ID0309, intervention)*

> *"And I suppose now we're trying to eat more healthily in terms of having been told that I've got high blood pressure." (ID0319, intervention)*

Several participants reported difficulty weighing up different health concerns when making purchasing decisions.

"I think that's probably one of the hardest things with this, is actually working out the balance between things you're encouraged to have for other dietary reasons, for example, low saturated fats, high oily fish once a week etc, and then find it is not... it doesn't fit in with the low salt…that it's getting the balance." (ID0319, intervention)

"The really difficult thing is finding one, especially for me as a diabetic, and I'm looking for low sugar, low fat if we can find it, but now low salt as well. And that is tricky." (ID0410, intervention)

Theme 11. Price influence

Though price was mentioned frequently, participants largely talked about 'value' rather than absolute cost, seeking to get good value through special offers, or by comparing different products or pack sizes.

"Is that a special offer was it? Two for two pounds. Oh, you'll have to have the two then, don't you? Because I usually check what's on special here as well just in case there's anything quite nice" (ID0108, control)

Two participants specifically mentioned healthy foods being more expensive. One was a father with five children living at home who described the difficulty balancing health and price when shopping to a budget.

"I find it hard to buy healthy. One, for the money. It's just so dear though. So, because I love fish…I'll see what the shop comes to and if I've got a bit leftover I'll get myself a bit of fish. But it is dear, innit; fish is dear. And then you're fighting the price all the time…" (ID0401, control)

One participant specifically mentioned they would put price above health with certain products, despite later commenting that affordability was not an issue. Others were happier to spend a bit more if products were healthy and what they wanted.

"if I need bacon, I will go for whichever one's on offer. I'd base it on price rather than salt content…" (ID0416, intervention)

Theme 12. Family influence

A common thread was the strong influence of others in the household on purchasing decisions. This was for a variety of reasons including health concerns of household

members, taste preferences, or the complications of trying to cook for different people's routines.

> *"The main things that interest me is really what my husband is actually on at the time. If he's trying... trying to be good and he's trying to diet, then I tend to buy everything as I can – low fat, low sugar, and I buy for me as well because there's no point in buying two lots of food." (ID0108, control)*

One participant who lives in a three-generation household described how she cooks for the household and sometimes had to cook different foods for herself in order to reduce her salt intake. She also mentioned the importance of modelling to her grandson what she felt was a good approach to food choice and not wanting to be too focused on the nutritional content.

> *"…Trying to sort out who's eating what on what day. So, oh they had chicken in oyster sauce. I know that oyster sauce is really salty. I had cashew nuts…which aren't the salted version, and then with the stir fry, so there'd be one pan going with the stir fry and my cashew nuts in the other one going with their chicken and oyster sauce…*
>
> *…And you always, too, don't want to be influencing him in thinking that food is... I want to think of him as food is fun; food is fuel etc etc. Not wanting to be so self-conscious we're looking at labels" (ID0319, intervention)*

One participant who had diabetes and hypertension, and reported trying to lose weight, was influenced by her husband's preferences when shopping, even when she knew it would impact negatively on her own diet.

> *"He likes a packet of crisps, which is hard because then that's what makes me eat it." (ID0414, control)*

Theme 13. Aspects of self as an influence

I identified several factors in the data that could be summarised as 'aspects of self' such as identity, or role. Participants described characteristics about themselves and the impact of these on shaping their food choices. One participant described some foods as part of his culture and a Mediterranean diet, even though he knew they were high in salt.

"Because you know the Mediterranean diet? And feta cheese is part of our culture… But feta cheese gives a lot of salt." (ID0215, control)

Several participants described themselves as someone who 'makes things from scratch' rather than eating pre-prepared ready meals or convenience food, possibly highlighting a personal norm for buying raw ingredients to prepare meals.

"I mainly cook all the foods from scratch anyway... from scratch and basically, I don't buy convenience foods." (ID0207, intervention)

Comments from one participant with a role in public life highlighted how aspects of identity can influence the practicalities of shopping and the subsequent influence on purchasing decisions. He described how his choice not to have a car restricts him to using nearby small stores with less variety and fewer lower-salt options.

"As a deliberate philosophy, I don't have a car. I walk pretty well everywhere…But that imposes on your shopping habits. Because you can't go and do a big shop at the supermarket every Friday night….so you're dependent on what there is available." (ID0309, intervention)

Theme 14. Taste and preferences

Unsurprisingly, taste and general preferences played a part in product choice, even when participants were clear it was not the healthiest choice. Taste was mentioned far less frequently than other influences such as health, family or price, though it is possible it was an implicit influence on choice. At times, participants were willing to sacrifice taste over health concerns but in other cases taste or other preferences won.

"I've been buying the... is it low in salt or low in sugar baked beans, but I'm not a great lover of them." (ID0406, control)

"It's from cows grazed on the lush grass of Normandy's mineral-rich salt marshes, so it's probably quite salty. Never, ever checked it, but I love it; it's got so much flavour." (ID0108, control)

Theme 15. Habit and routine

Most participants referred to their routine and habitual purchases and the influence of this on how they shop. Some mentioned how habitual purchases makes their shopping quicker and easier.

> *"Habit is the obvious thing. Because it saves you having to think." (ID0309, intervention)*

> *"So, most of the shopping that I do is just done by memory almost. I'll come in the door and I'm a robot." (ID0401, control)*

However, in the context of this study, they were also willing to look for alternatives for routine purchases and some described how the intervention had disrupted their habitual purchases. Most participants were observed making some very rapid, habitual choices and other more considered choices, weighing up a number of the factors discussed in this theme.

> *"I'll say something to you is that I'm looking at different ways now of changing what we'd normally buy." (ID0207, intervention)*

5. Discussion

The main objectives of this study were to assess the impact of the SaltSwap intervention on shopping behaviours; understand peoples' experiences of trying to reduce salt intake particularly through purchasing lower-salt foods, and; explore the main influences on their food choices.

5.1 Summary of findings

5.1.1 The impact of SaltSwap

The intervention increased participants' knowledge of the major sources of salt, their awareness of the high salt content of some foods they routinely buy, and of the

availability of lower-salt options; all of which were aspects targeted by the intervention. It helped participants identify specific high-salt foods to swap and successfully encouraged them to set goals to make changes to their purchases. Participants invested time and effort to try and find lower-salt alternatives with the SaltSwap app, and even participants who I did not observe using the app often purchased lower-salt products previously identified with it. The intervention increased participants use of nutrient labels for salt, often in conjunction with the SaltSwap app, though some participants were unable to adequately interpret nutrition labels. It also increased participants' self-efficacy for choosing lower-salt foods, as evidenced by their description of making swaps or avoiding high-salt foods. The lack of action planning or use of the feedback on salt reduction function in the app was notable. The lack of comprehensive coverage of products within the app database and suggestions of unsuitable lower-salt alternatives (due to limitations within the app database) were the main barriers to successfully identifying lower-salt products and thus continued use of the app.

5.1.2 Experiences of trying to reduce salt intake

Participants in both the intervention and control groups changed their behaviour, for example: swapping to lower-salt foods, avoiding high-salt foods entirely, using nutritional labels, and changing their cooking practices to reduce their salt intake. Key barriers to reducing salt intake were the lack of availability of lower-salt options, the challenge of balancing salt reduction with other nutritional concerns, interpreting nutrition labels and lack of available support.

5.1.3 Influences on shopping

The SaltSwap intervention aimed to disrupt habitual shopping behaviour to enable a more reflective decision-making process and this seems to have been effective. Most

participants, across both groups, demonstrated a "systematic-processing" approach to shopping, vocalising the influence and consideration of a wide variety of factors on their shopping choices. Though habitual or routine purchases were a contributing factor in decision-making, a substantial proportion of purchases involved some degree of planning and consideration, weighing up factors such as health versus family requirements or price. Despite being primed with education to reduce salt intake, the salt content of foods was only one of many health-related considerations shaping participants' shopping choices. A broad range of influencing factors may need to be addressed to change individual purchasing behaviours to encourage lower-salt intake. Intervention content is not delivered into a vacuum but into a decision-making context that is already complex, with many factors vying for priority in the systematic-processing approach to purchasing decisions.

5.2 Contribution to the literature

This study provided a detailed qualitative evaluation of a behaviourally informed salt reduction intervention, exploring the mechanisms of impact of the intervention and how the included BCTs were enacted, providing valuable insights into the potential for this multi-component intervention to reduce salt intake. The results identified important areas for improvement of the SaltSwap intervention, not raised through the quantitative analysis such as insight into participants' motivation to reduce salt intake and barriers to purchasing lower-salt foods.

Other qualitative studies investigating salt reduction behaviour have reported that individuals with hypertension are willing and motivated to reduce their salt intake (218,301). Here, I found participants were not always motivated by having high blood

pressure alone, possibly indicating an underestimation of the health risks of high blood pressure, particularly in those with raised blood pressure but not currently diagnosed or treated for hypertension. This inertia to reduce their salt intake to improve their blood pressure could also be explained by possible discounting of future health risk from existing high blood pressure, i.e. displaying the 'time preference' phenomenon whereby people place less value on benefits achieved at some point in the future, rather than immediate gratification (302). Alternatively, participants were simply unconvinced of the personal benefit of reducing salt for reducing their own blood pressure. A similar phenomenon was identified in a qualitative study exploring people's views on self-management of blood pressure. The authors identified that even in patients who knew the CVD risks associated with high blood pressure, most considered that they were not personally at risk, generally, because their blood pressure was treated (although not necessarily controlled to target) or because they experienced no symptoms (303).

Key barriers to making healthy choices when shopping were consistent with previous studies, including the difficulty balancing the needs of others in their household, and the time and effort required when shopping (304,305). Additional barriers included the lack of availability of lower-salt alternatives in some stores, the lack of support available to reduce salt intake and the challenge of balancing different nutritional requirements. Other authors have pointed out that taking a single nutrient approach to dietary advice can ignore the effects of nutrient interactions and synergies (306,307) or substitution effects whereby reducing one 'bad' nutrient can lead to increases in another with the total effect being dependent on the replacement nutrient (308,309). However, in specific diseases, where the contribution a nutrient has a predominant aetiological effect, such as salt in hypertension, this single-nutrient approach may be justified. In my research, the challenge of a single-nutrient approach was largely that of applying it in real-life where

people purchase foods, not nutrients. Of note, both in the online supermarket study (Chapter 2) and a previous salt reduction supermarket study, analysis of purchasing data showed no material increase in other nutrients (e.g. sugar or fat) indicating that overall, most lower-salt foods tend not to be substantially higher in other 'bad' nutrients (103,140).

This study uniquely explored influences on supermarket purchasing decisions and salt reduction behaviours among individuals who had received advice to reduce their salt intake. It confirmed findings from other research in a general population, not already primed with salt-reduction (or other nutrition) advice, that food shopping choices are not purely habitual but are strongly influenced by systematic decision-making (310). Being 'health conscious' or concerned about health have been highlighted as key drivers of purchasing decisions, in other literature (201,278–280), and this was borne out here. However, despite participants being primed to consider the effect of salt on their health, this was only one of many health-related considerations for most participants and not always the primary health-related driver of shopping choices.

In the literature on food purchasing behaviour change, price has been highlighted as a prime lever to encourage behaviour change. Interventions employing price discounts for 'healthy' foods (e.g. fruit and vegetables) or price increases (e.g. taxes) for 'unhealthy' items (e.g. those high in sugar, salt, or saturated fat), are among the most effective at influencing purchasing decisions (3,311–313). Several qualitative studies investigating influences on food purchasing have found that price was a major factor in shopping choices, though two of these were specifically in low-income parents (198,289,290). Absolute price was less often mentioned in my study; participants generally referred to

value and few participants mentioned the total cost of their shopping in terms of a set budget, possibly reflecting the socio-demographic characteristics of the sample.

A Danish study investigating determinants of food purchasing decisions showed that strong personal norms around salt reduction increased shoppers' willingness to purchase lower-salt foods. They found that participants were more willing to purchase lower-salt options for foods classed as 'utilitarian' (i.e. functional, practical) as opposed to those considered 'hedonic' (i.e. enjoyable) (201). Consistent with this, several participants indicated personal norms around salt reduction (e.g. identifying as someone who cooks from scratch and eats few processed foods) and their willingness to purchase lower-salt foods was reflected in their shopping behaviour. However, willingness to purchase lower-salt options or avoid high-salt foods extended to hedonic foods (e.g. cheese, nuts) possibly in direct response to the salt reduction advice provided.

In this study, most participants were observed (or described) using nutrition labels, for salt content and other nutrient information. This is the opposite of what was found in two previous think-aloud studies; one where no participants spontaneously used nutrition labels (280) and another among low-income families which reported low use of labels (290). The difference may be due to differences in characteristics of the study sample, or potentially due to the fact participants in this study had been primed to consider the salt content of foods and the blood pressure risk from a high-salt diet. The latter hypothesis is supported by a study of nutrition label use in Australia, which found that people who were aware of the risk of increased blood pressure associated with high salt intake, were more likely to report reading the salt content of nutrition labels, than people who were not aware of this risk (101). The difficulties reported here in interpreting nutrition labels and the challenge of deciding if something is 'healthy' or

not based on the label information, aligns with other research on nutrition labelling (314) and is the rationale behind implementation of warning labels in some countries to clearly highlight products with high content of energy or nutrients of concern (315).

5.3 Strengths

The qualitative methods chosen were well-suited to the research aims, generating valuable detail on how the intervention worked and its potential for changing salt purchasing and intake behaviour, highlighting key areas for intervention improvement. The study sample included grocery shoppers across a wide age range (for a hypertension population) and a reasonable representation of men (39%), considering data reports that men are less likely to have responsibility for household grocery shopping (316). Though the sample size of 18 was small, the focus of the research was narrow. Moreover, in the last few accompanied shops and interviews, no new data arose and all research objectives were addressed by the data collected from this sample, suggesting a larger sample would not have substantially altered the interpretation of the data.

The use of interviews to collect qualitative data invites the possibility of recall bias. A strength of this study is the combination of interviews with the think-aloud method, whereby behaviours are directly observed and can substantiate or refute recollections of behaviour, described in the interviews. Data quality and validity were key considerations throughout the collection, coding and analysis of data and my rigorous approach to quality and validity was a strength of this study. I considered how my personal characteristics as the interviewer might impact on the quality and nature of the participant responses (284,299). I was also conscious of the transparency of my views

on the importance of salt reduction, and the impact this may have on participants' behaviour and responses (317). During interviews, I was mindful of this and made efforts to use language that was neither approving nor disapproving of participants' responses. I also attempted to mitigate against social desirability bias, by clearly setting out, at the beginning of the accompanied shopping trip, that participants were to shop as they normally would. Additionally, I reiterated that positive and negative comments were welcome and no responses were considered right or wrong.

Furthermore, I was cognisant of the potential that I could unconsciously steer the interview to generate data to support the SaltSwap intervention. To avoid this, I used a well-scripted topic guide with example questions, to ensure a broad range of topics were covered consistently across interviews. My existing relationship with participants through previous contact in the study developed a rapport with participants which encouraged an open and honest dialogue. They typically appeared to be at ease during the think-aloud shopping trip, displaying natural, unforced shopping behaviours. My approach to data analysis was also rigorous, with detailed descriptions of codes, iterative development of coding framework and a second round of coding to ensure consistency of application of codes.

5.4 Limitations

This study was open to several biases which may have impacted the validity or generalisability of these results. The study sample was selected from within a feasibility trial sample which had limited ethnic, geographic and socioeconomic diversity, as I discussed in Chapter 4, limiting the available pool of potential participants. Participants volunteered to be included in this study, indicating some interest in healthy eating and

changing their diet to help control their blood pressure, potentially introducing bias due to a more 'health-conscious' study population. Evidence suggests that 'health-conscious' shoppers are more likely to use nutrition labels (100,104,310) and this may be a marker of a more systematic- rather than heuristic-processing approach to food purchasing; more open to engagement with the intervention. In addition, other characteristics of the participants not captured here may be important determinants of their purchasing decisions or salt reduction behaviours, e.g. health literacy, and may not be reflective of the general population.

Most participants reported that they did not change their shopping habits and behaviours due to being observed, however, their unconscious behaviours may have been influenced, e.g. social desirability bias influencing their effort to seek out lower-salt options or to describe the behaviours encouraged in the study. I was aware of this and tried to avoid reinforcing these behaviours during the observation and interview.

5.5 Next steps

The results of this study identified some limitations in the SaltSwap intervention that could be addressed before a future large-scale trial assessing its effect on blood pressure is carried out. The intervention increased some participants' motivation to change their salt intake by making them aware of the importance of salt intake in blood pressure control, but some participants did not believe that their salt intake was high, or that their elevated blood pressure was the result of high salt intake, and therefore expressed little motivation to change. Providing feedback on their actual salt intake may enhance participants' intrinsic motivation to reduce it. However, where this might enhance motivation in those with a genuinely high salt intake it may counterproductively reduce

motivation for individuals with a result near or below the recommended salt intake. The intervention messages may need to be tailored to reflect the benefit of lower-salt intake in people with hypertension to mitigate against any negative impact on motivation in those with borderline high intake.

A further improvement in the intervention would be to enhance implementation of action planning. Results of this study, together with data from the intervention fidelity assessment in Chapter 4, indicated that action planning was not comprehensively delivered by HCPs and participants did not fully engage with it. Action planning is considered a critical part of the self-regulation process, of moving from intention to behaviour change (208,209). It is possible that the training provided to HCPs was insufficient to equip them with the confidence to deliver action planning, or that the resources provided were insufficient to guide participants through this process. Improving the action planning component of the intervention would be feasible but may require additional HCP training to increase confidence in delivering this and potentially increase the duration of the intervention advice session. An alternative explanation is that the feedback participants received on their goal achievement was not sufficient to reinforce continued action planning or adjustment of action plans over the intervention period. Feedback allows monitoring of progress towards a goal, known to positively influence goal achievement (318) and has been shown to be an important self-regulatory BCT for dietary interventions (225). The tailored feedback on salt reduction achieved through swaps would likely be improved with corresponding improvements to the product database, as this will allow better recognition of products, and recording of swaps in the app.

Participants in this study found it challenging to incorporate salt-reduction advice with other nutritional advice or health concerns. Presenting advice about salt reduction in a broader nutritional context could be added to the HCP session while highlighting that lower-salt alternatives are not typically higher in sugar or fat. Minor changes could be made to the information resources without substantially impacting the time required for training or the intervention duration.

5.6 Conclusions

The SaltSwap intervention was designed using the BCW to target specific aspects of capability, opportunity and motivation in order to change purchasing behaviour. The results of this study indicate that some important aspects have been adequately addressed, e.g. knowledge about the sources of dietary salt and habit disruption, but other aspects such as reflective motivation and environmental opportunity (i.e. suggestions of suitable swaps) could be improved. Despite this, participants used the SaltSwap app and information from the intervention session to make significant changes to their salt purchasing behaviour, the intended result of the intervention. Shoppers who have been advised to reduce their salt intake need to invest time and effort to identify lower-salt alternatives for their regular purchases, and although participants reported some success with this, availability of lower-salt options was a clear challenge. Changes to the shopping environment to address this, could support the success of the SaltSwap intervention.

Chapter 6. Discussion

In my introductory chapter, I highlighted that despite strong evidence for the benefit of limiting salt intake in reducing blood pressure, the evidence for effective, individual-level, interventions to reduce salt intake, which could be delivered by generalist practitioners, is sparse. Furthermore, the evidence indicates that changing food purchasing behaviour using 'swaps' is a promising strategy, and particularly relevant in a context where most of the salt people consume is from processed and packaged foods. National guidance recommends that advice to limit salt intake is provided as a key component of the management of hypertension (109). In the UK, the prevention and management of hypertension is largely delivered in primary care - management of hypertension accounts for 12% of all primary care visits - offering an opportunity to deliver interventions to those with or at risk of hypertension (109).

The objective of this research was to develop a dietary intervention suitable for delivery in a primary care setting, to help people reduce their salt intake in order to better manage their blood pressure. The specific aims were to:

- examine the effect of offering lower-salt alternatives in a supermarket shopping environment;
- to use these findings, along with a detailed behavioural analysis, to develop an intervention suitable for delivery in primary care to help individuals with hypertension reduce their salt intake;
- to evaluate this intervention;
- to explore people's experiences of trying to reduce their salt intake following dietary advice to do so, to inform future intervention development.

The main findings of the primary research contributing to this thesis are presented here.

1. Summary of main findings

1.1 The impact and acceptability of offering lower-salt swaps

In an experimental online supermarket study (Chapter 2), I demonstrated that offering lower-salt alternatives to people with high blood pressure when they shopped online, significantly reduced the salt content of the total basket of purchased foods and was considered acceptable by participants. Offering shoppers alternative products with substantial reductions in salt, including 'out-of-category' items, resulted in greater reductions in the salt content of their total shopping than offering alternatives which were generally closer in character to the original but with only a little less salt; without impacting swap acceptance. Importantly, offering swaps reduced the salt content of participants shopping baskets with no significant increases in sugar, saturated fat, energy content, or cost. The online supermarket platform was a useful tool to test my intervention theory ahead of real-world application in the SaltSwap app. The acceptability of 'out-of-category' swaps demonstrated in this study, directly informed the way alternatives were offered in the SaltSwap app I later developed (Chapter 3) and tested (Chapters 4 and 5).

Prior research on the use and acceptance of healthier swaps has highlighted the need to better understand what drives swap acceptance (162,164). In this research, I found that shoppers who had previously been advised to reduce their salt intake and those who considered health important when making food choices accepted more swaps and achieved a greater reduction in salt content. This suggested that arming individuals with advice and encouraging them to prioritise health when shopping could be a plausible mechanism to increase swap acceptance and enhance the effect of swap-based interventions to reduce salt. From this, I reasoned that

contact with HCPs in the primary care setting presents an opportunity to boost the salience of general population advice to reduce salt and to create the necessary motivation to do so.

Although some online supermarket shopping sites do offer shoppers swaps to lower-calorie products (180), to my knowledge, none of the major UK online grocery shopping retailers offer lower-salt alternatives. This study adds to the evidence already synthesised in a review of supermarket interventions which identified swaps as a beneficial strategy (3); and demonstrates the potential value of offering salt reduction swaps in commercial online grocery shopping sites.

1.2 Development of an intervention to reduce salt intake

From my review of the literature, I surmised that a brief intervention delivered in primary care which focused on choosing lower-salt products when grocery shopping could support salt reduction in people with hypertension. I used the BCW framework to complete a structured behavioural analysis of the core influences on this behaviour (Chapter 3), also drawing on the findings from the online supermarket study which identified factors associated with increased swap acceptance (Chapter 2). The detailed behavioural analysis helped me to determine the key intervention objectives as increasing knowledge around salt intake and health, intrinsic motivation to change, self-efficacy to reduce their salt intake, and the opportunity to do so, using proven BCTs. The intervention also incorporated goal setting, action planning and feedback, to enhance self-regulation in order to facilitate reduction in salt intake. Though the intervention focused on reducing the purchase of high-salt foods, it also encompassed other salt reduction behaviours such as reducing salt added in cooking or when eating out. Specification of intervention content as BCTs allowed me to identify a plausible

causal pathway for the intervention, facilitating assessment of the hypothesised mechanisms of impact as well as the primary endpoints, as part of the intervention evaluation.

The increasing ownership and use of mobile phones (245,319) and use of health-related apps (136,320) indicated that inclusion of an app could be a feasible and acceptable way to help people reduce their salt intake. Delivering aspects of the intervention via an app enabled point-of-choice support to identify lower-salt options and feedback on purchases; elements not easily implemented through face-to-face advice alone. Moreover, mobile apps have the benefit of being to hand most of the time and can deliver support where and when it is needed (321). Meanwhile, the in-person tailored advice from a HCP delivered aspects of the intervention such as verbal persuasion and problem-solving which are less suited to remote delivery.

1.3 The feasibility of the SaltSwap intervention and trial design

In line with the Medical Research Council framework on evaluating complex interventions (186), I next conducted a feasibility trial (Chapter 4) to test whether the intervention was robust and to evaluate the procedures which would be used in a future trial to test intervention effectiveness. I showed that the SaltSwap intervention was feasible to deliver in primary care with a high degree of fidelity, by non-specialist practice nurses or healthcare assistants, and that these HCPs found it acceptable and within their skillset to deliver. The SaltSwap intervention was considered helpful and acceptable by participants and enabled users to identify lower-salt alternatives when shopping. Participants found the SaltSwap app acceptable and indicated they would be interested in using it if it was made available. Barriers to using the app were largely focussed on limitations of the app database, rather than

functionality or ease of use, indicating it is an appropriate tool for this hypertension population, typically older adults.

The trial outcome measurements were sufficiently robust to allow evaluation of the intermediary and clinical outcomes targeted by the intervention in a future large-scale trial. However, I noted that improvements to the SaltSwap app database would be required for more accurate assessment of the salt content of purchased foods. Compliance with baseline data collection and participant attendance at the six-week follow-up were high. The recruitment rate was low compared to some other dietary trials but with a large eligible population, this should not present a problem for future recruitment. However, measures may be required to ensure the representativeness of the sample population, or to better identify participants who may be most likely to benefit from this approach to target the intervention accordingly.

As a feasibility study, this trial was not designed to provide evidence of effectiveness but the direction of effect is towards a reduction in both salt intake and blood pressure. Previous individual-level interventions for reducing salt intake that have been shown to be effective tend to be intensive, existing of multiple sessions and delivered by specialist behaviour change staff or nutritionists (30,110). In general, the literature highlights a lack of effective interventions suitable for delivery in primary care settings, where the management and prevention of hypertension typically occurs (127). This research demonstrates that the SaltSwap intervention has the potential to fill this gap, being both feasible to deliver and with potential to change behaviour. Reductions in salt purchased, salt intake and blood pressure in the control group, though not significant, suggest that consideration needs to be given to the nature of the comparator in any future trial.

1.4 Impact of SaltSwap on antecedents of behaviour change

My findings on intervention participants' experiences of the SaltSwap intervention, through the think-aloud shopping study and participant interviews (Chapter 5) supported the acceptability of the intervention, with most participants reporting they found the HCP advice session helpful and reporting (or being observed) using the app. In addition, I found that the SaltSwap intervention successfully targeted key antecedents of behaviour change identified through the behavioural analysis and specified in the logic model as proposed mechanisms of action of this intervention in reducing salt intake (Chapter 3). These were: increasing participants' knowledge of the major sources of salt; increasing awareness of the high salt content of some foods they routinely buy and of lower-salt options; increasing their self-efficacy, intention and motivation to reduce their salt intake; identification of specific foods which contribute substantially to their salt intake; increasing use of product nutrition information; and setting goals to reduce their purchase of high-salt foods. Although SaltSwap increased some participants' motivation to change their salt intake by making them aware of the importance of salt intake in blood pressure control, the qualitative study results indicated that increasing knowledge and awareness of the general benefits of salt reduction does not necessarily lead to a change in beliefs about the benefit to the individual personally, and may be insufficient to motivate people to reduce their salt intake. The results suggested that reflective motivation could be increased with direct feedback on participants' personal salt intake. Furthermore, observations and interviews identified that participants rarely used the feedback and self-monitoring aspects of the intervention to record and review salt reduction achieved through swaps they had made, key components of the self-regulation process discussed in Chapter 3. In part, this was related to technical issues with the app which limited participants' ability to record swaps made but may also indicate a broader lack of engagement with the self-regulation cycle.

1.5 General experiences of trying to reduce salt intake following dietary advice

In the qualitative think-aloud study in Chapter 5, I investigated the effects of advice to reduce salt intake, either via the SaltSwap intervention or generic printed information received by the control group, on participants' shopping behaviours and salt intake. Both forms of advice encouraged people to swap to lower-salt foods (or avoid high-salt foods entirely), use nutrition labels more frequently to identify lower-salt options, and reduce their use of salt in cooking. In contrast to previous studies, which have found minimal use of nutrition labels (280,290), my observations in this research were that most people used nutrition labels. One of these previous studies observed no spontaneous use of nutrition labels among a small sample of people who all reported positive attitudes towards healthy eating and a moderate to high degree of high nutritional knowledge, typically characteristics that would be associated with the use of labels (280). The quantitative results from Chapter 4 show that only half of participants in my study reported use of nutrition labels for salt at baseline, but most (72%) used labels for sugar, fat or calories indicating a reasonably nutritionally aware or 'health-conscious' group. However, the intervention and control groups both increased their use of nutrition labels for salt over the course of the study suggesting that dietary advice can encourage engagement with nutrition labelling, among those motivated to make dietary changes. This study also highlighted two key challenges in encouraging people to reduce their salt intake, not previously raised in the literature: availability of lower-salt options (especially in smaller stores), and the difficulty balancing salt reduction with other nutritional concerns.

In Chapter 5, I identified important influences on people's shopping behaviour following advice to reduce salt intake including health, price, family, aspects of self, preferences and

habit, or routine. This is consistent with previous research which has highlighted the multi-factorial nature of influences on shopping decisions (310). Other studies investigating the key influences on food shopping have described 'health' (201,278–280), as an important factor in peoples' decision-making, however, there is little evidence on *how* this affects shopping behaviour or the multi-faceted nature of 'health'. Despite receiving advice focussed solely on salt reduction, most participants in my study considered an array of health-related factors when making food purchasing decisions. The "systematic-processing" approach to decision-making shown here, involving consideration of multiple factors, underscores the need to ensure dietary advice is appropriately prioritised in the crowded decision-making context of grocery shopping.

2. Overall strengths and limitations

2.1 Strengths

A strength of my DPhil research was the thorough, rigorous and evidence-based intervention development approach, using the BCW framework. Use of the BCW facilitated identification of the key aspects which could influence the purchase of high-salt foods and helped focus my literature search to the most pertinent questions. It also ensured a strong theoretical rationale for the intervention, highlighted in the literature as a fundamental basis for behavioural change interventions (229,322). The evidence of the impact of theory on the *effectiveness* of interventions is inconsistent (206), however, this may be driven more by the choice of appropriate theory, implementation of theory, the lack of transparent reporting of theoretical constructs or simply the implicit rather than explicit use of theory (130,187). The transparent use of appropriate theory to inform intervention design has additional important benefits. It facilitates accumulation of evidence to support or oppose theoretical constructs and can help

to explain why interventions are effective or not, leading to refinement of the intervention or application to other contexts (322).

Use of the BCW in my research led to the development of a detailed logic model, explicitly setting out the hypothesised mechanisms of behaviour change, allowing assessment and understanding of the impact of the intervention. The logic model helped me to link the target behaviour, it's determinants and the theoretical components of the intervention. The evaluation approach for the SaltSwap intervention followed best practice guidelines for evaluating behaviour change interventions, employing comprehensive quantitative and qualitative measures (186,323). The mixed-methods approach I used was invaluable. The qualitative data added a richness to the trial evaluation, enabling me to thoroughly understand the impact of the intervention, and the barriers experienced by individuals trying to reduce their salt intake, which would not have been transparent from quantitative data alone. The quantitative research presented in Chapter 2 and 4 used RCT designs, a robust design to investigate intervention effects while controlling for confounding.

As I noted in the introductory chapter, there is little evidence for the effect of interventions to change individuals' food purchasing behaviour to reduce salt intake. Across the three studies in this thesis I have consistently shown that offering lower-salt alternatives to high-salt foods is feasible to deliver and acceptable to shoppers and that in an online or physical supermarket setting, individuals were successfully encouraged to swap to lower-salt alternatives.

A valuable by-product of the development of the SaltSwap intervention was the development of purchase-scanning functionality within the app. This allowed study participants to easily record their supermarket purchases, providing an efficient, accurate record of the nutrient

content of purchased foods without the time-intensive process of matching receipts to products and nutrient information. Though the database used here had significant limitations, future development of this app can include a more comprehensive and easily updated product database, which would allow more thorough capture of nutrient data. Gaining access to retailer data to assess dietary behaviour change interventions is challenging, and with many consumers dividing their household grocery purchases across several retailers, a tool that allows researchers to assess the impact of an intervention on purchasing behaviour, independent of retailers, is potentially highly valuable. This research demonstrated the potential for such purchase scanning tools and participants' willingness to use them.

2.2 Limitations

Across all studies included in my thesis, sampling bias will undoubtedly have influenced the generalisability of the results. Due to the high degree of engagement required from participants, it is likely that participants had different attitudes towards salt reduction and healthy eating than those less willing to engage in such research. Generalisability is a particular limitation of the feasibility trial and the think-aloud study, as discussed previously in Chapter 4. Further, the sample in these studies had a remarkably low baseline salt intake, not representative of the general population and potentially correlated with higher levels of health literacy and healthy eating behaviours, though these were not measured. This 'healthy volunteer bias' is likely to have affected not just the secondary outcomes (change in salt intake and salt purchased), but also dampened the ability of the intervention to demonstrate impact on antecedents of behaviour change such as knowledge and motivation. This is challenging to overcome with an intervention which requires significant engagement and personal agency and has implications for generalisability.

A particularly important source of bias in the qualitative aspects of this thesis relates to my role as the intervention developer, and the sole qualitative interviewer and data analyst. I was cognisant that my closeness to the intervention may have biased my data collection and interpretation of the data to show the intervention more favourably. The risk of this type of confirmation bias is higher when using subjective outcomes as I have here. Although I had excellent guidance from my supervisors and other experienced qualitative researchers ultimately, I was responsible for conducting and guiding the interviews and the interpretation was my own. Furthermore, my own preconceptions and assumptions were likely to colour not only my analysis of the qualitative data but also to influence the researcher-participant interaction and how participants responded in interviews. I attempted to distract participants from viewing me as a researcher and to position myself as supermarket shopper also, by engaging with them in small talk pertaining to general shopping experiences, while being conscious not to reinforce my views about dietary salt. As described in Chapter 5 (section 5.3), I took steps to mitigate researcher biases by using a well-scripted interview guide and instructions for participants but my influence as both intervention developer and primary qualitative researcher will no doubt have coloured the findings to a degree, as will have my transparent views on the subject matter.

Despite a comprehensive evaluation of the SaltSwap intervention in this thesis, the lack of a quantitative outcome of app usability is a limitation. Although the qualitative assessment was valuable and provided a richness of data not available in quantitative metrics, it is timely and costly so not a suitable approach for repeat assessment; this is particularly relevant for re-evaluation of usability following improvements to the app. A quantitative instrument such as the Systems Usability Scale (324) would be an appropriate tool to compare usability against an improved version or within different population groups.

I identified some specific limitations of the intervention development approach, related more to my experience in these methods than the methods themselves. Firstly, using the co-design approach I would ideally have recruited a larger and more demographically varied co-design panel to provide a wider perspective on the intervention design. In part, this was limited by my lack of experience in recruiting and engaging a co-design panel. A key skill in co-design is to ensure deep engagement of the co-design members leading to "co-interpretation of the research" (325) and I feel that with more experience I could have better facilitated this level of engagement. In applying this co-design method in future, I would draw more on expertise of those with greater experience in these methods.

Although the BCW is a comprehensive framework and allows researchers with specialist domain expertise to develop behaviour change interventions with an appropriate theoretical basis, input from a specialist in behaviour change may have strengthened the intervention, and perhaps highlighted some of the intervention limitations earlier. Despite undertaking intensive training in the BCW approach, there were times through the intervention development process where, as a non-specialist in behavioural theory, I was cognisant of my lack of knowledge and expertise in the field of psychology and the potential impact of this on the intervention development. For example, I was able to determine through the COM-B analysis, that increased reflective and automatic motivation were required, however, I lacked the specialist knowledge of how best to address this in the intervention. Finally, the lack of accurate data on purchased salt content could potentially have been mitigated by more detailed piloting of the intervention as part of the development process, though it is a delicate balance to get the optimal degree of piloting for a feasibility study.

3. The wider context for individual salt reduction strategies

In the introductory chapter, I reviewed the wider literature on salt reduction strategies. There is clear evidence that population-level interventions are effective for reducing average salt intake, while individual-level interventions seemed only to be effective if they involved multiple sessions or intensive behavioural support and were delivered by specialist staff. In most studies, benefits were greater for people with hypertension. Work undertaken as part of my thesis has contributed important new evidence on how an individual-level intervention might feasibly be delivered in primary care by generalist practitioners with enhanced support from a behaviourally informed app. Given the potential for delivery at scale and increased intervention reach, it is pertinent to consider the roles of brief interventions and mobile health apps in the delivery of behaviour change interventions, and the complementary roles of population- and individual-level interventions and how these can be combined in public health strategies.

3.1 Brief interventions for lifestyle modification

NICE guidance for the management of hypertension advocates that "lifestyle advice" is offered to people with suspected or diagnosed hypertension, including advice to maintain a low-salt diet, exercise regularly, reduce alcohol consumption, eat a healthy diet and for smokers to stop smoking (109). For several of these lifestyle risk factors such as smoking, prevention of alcohol misuse and obesity, there is clear guidance on recommended interventions and evidence for the effectiveness of brief interventions for behaviour change (326–328). This is not the case for salt reduction, though it is noteworthy that absence of evidence does not equate to evidence of absence (of effect).

The role of brief interventions (BI) in healthcare, is to deliver significant and sustainable impact with the minimum input and contact required (329). Brief interventions can offer several benefits over more intensive, multi-session interventions including lower costs, reduced participant burden, potential to be delivered by non-specialist staff, and increased reach due to the small number of interactions (329). The latter is particularly pertinent with a highly prevalent condition such as hypertension, which affects nearly 12 million adults in the UK (330).

Brief nutrition interventions show potential effectiveness for dietary behaviour change. One systematic review of RCTs of BI delivered in a range of settings (e.g. university, workplaces, primary care) and for a variety of dietary behaviours but mainly including fruit and/or vegetable consumption or fat intake, found that over half of all studies showed a beneficial effect (331). Over half of interventions (59%) were delivered through printed materials (without in-person advice). This review found that studies providing tailored education in addition to more instructional intervention components, such as feedback, or the use of action planning were more effective for achieving the desired behavioural change. This aligns with other research which highlighted the effectiveness of tailored education interventions for dietary behaviour change (131).

Brief interventions have been successfully developed for other dietary behaviours. One pilot RCT study which evaluated an intervention consisting of educational materials and an interactive patient website for reducing cholesterol, delivered in primary care by non-specialist staff (332) showed significant reductions in LDL and total cholesterol after three and six-months. There are also examples of successful BIs for weight loss. The provision of a leaflet on ‘Ten Top Tips’ for weight loss, based on habit-formation theory and delivered

through primary care, resulted in greater weight loss in the short-term (0.87 kg, 95% CI -1.47 to -0.27), compared to 'usual care' which varied from 'lifestyle advice + monitoring' to referral to commercial weight management (333). In another example, a BI based on self-regulation theory, involving tips for weight management, self-regulatory approaches and pictorial information on the physical activity equivalent of the calorie content of foods, successfully prevented weight gain over the Christmas holidays, compared to a generic advice leaflet (334). In a further weight-loss trial, researchers evaluated a BI delivered in primary care, consisting of referral to an intensive, behavioural, weight loss programme with physician follow-up. This trial showed a significantly greater weight-loss at 12-months in the referral group (-2.43 kg) than with physician advice to lose weight (-1.04 kg) (335). The philosophy behind this intervention, to provide 'momentary motivation' via a HCP contact to engage in more intensive support, is similar to that employed in the SaltSwap intervention; where the 'intensive support' is provided by an app, delivering in-the-moment nutritional support on an ongoing basis.

Together these examples demonstrate the effectiveness of BI for dietary behaviour change, where appropriate theoretical approaches have been employed, delivering BCTs which have been shown to be effective for dietary change and providing adequate training and resources to HCP to deliver these interventions (e.g. accessible training, intervention checklists and educational materials). They also underscore the value of effective BI which can be delivered in primary care, with potential to reach many people at low-cost. A lack of support for individuals to reduce their salt intake was highlighted by participants in the think-aloud study in Chapter 5 yet the evidence pointing towards the effectiveness of robustly developed BIs, indicate there is clearly a role for these in dietary salt reduction. In the SaltSwap intervention, I applied a theoretically informed approach to the intervention development and included

BCTs proven to be most effective for dietary behaviour change. The training and associated resources delivered to HCPs proved to be sufficient for HCPs to feel confident delivering the intervention and resulted in high fidelity of delivery. Furthermore, the initial evaluation of SaltSwap presented in this thesis, indicates that it offers potential as a BI for salt reduction. The evidence shows that salt reduction leads to greater reductions in blood pressure in those with higher baseline blood pressure and those with existing hypertension (36), presenting a target population who could stand to gain particular benefit from an individual-level brief intervention which can enhance the impact of population-level efforts.

3.2 Mobile apps for health behaviour change

Nowadays, apps are frequently used to influence a range of behaviours from increasing physical activity, supporting smoking cessation, reducing alcohol consumption, and encouraging healthier diets (191,244,336–338). However, there is still a lot we do not know about their use or effectiveness. Despite the abundance of behaviour change apps, evaluation of the efficacy of these is still the exception, not the rule (339). Furthermore, popularity does not necessarily equate to efficacy. For example, an RCT of the effects of one highly popular diet tracking app, showed minimal weight loss with the app and no benefit over usual care (340).

Two recent reviews of apps for changing health behaviours, covering a wide arrange of behaviours, found a benefit of health apps on health-related behaviour change in three-quarters of all studies (341,342). Two pertinent issues were raised through these reviews. Firstly, for apps to be effective they require users to engage with them. One survey of use of health apps among adults over 60-years identified key barriers to use as data privacy, lack of trust and fear of mis-diagnosis (137). Delivery of an app through a trusted HCP (such as in

SaltSwap) could potentially overcome barriers of this nature. Other authors have identified the need to achieve 'effective engagement' which may not be sustained use but 'sufficient use to achieve intended outcomes' (229,343). My research identified that users engage with the SaltSwap app, at least in the short term. The intention of the intervention is to help users identify high-salt foods they buy regularly and find lower-salt alternatives to these. As such, long-term sustained engagement is not required if these lower-salt alternatives can become habitual purchases.

The second issue raised in these reviews is the need for mobile health apps to incorporate appropriate BCTs, ideally those with some evidence for effectiveness. Most health behaviour change requires a degree of self-regulation and, therefore, it is unsurprising that effective apps tend to include self-regulatory BCTs. In a review of apps specifically for diet and physical activity behaviour change, around half of apps for diet and two-thirds of apps for physical activity showed significant improvement in health outcomes (150). The authors concluded that effective interventions tended to be multi-component and include goal-setting, self-monitoring and feedback, important components of self-regulation. These self-regulatory BCTs have consistently been reported as the most effective interventions in diet and PA interventions, not specifically mobile app-based (206,225). As I noted in Chapter 3, using both an app and in-person mode of delivery in the SaltSwap intervention facilitated inclusion of a wider range of BCTs than just one component alone. My research showed that the SaltSwap intervention led to effective engagement with the app component and provided some evidence that the chosen BCTs were successfully delivered. It also highlighted areas for improvement to enhance the delivery of BCTs involved in the self-regulation process such as feedback and action planning.

One review of behaviour change apps for physical activity, diet, alcohol and mental health found only 25% on average had evidence of benefits. However, among apps to improve healthy foods choices, six out of eight (75%) studies reported positive outcomes (344). This raises the question of whether apps may be better suited to support dietary behaviour change than other lifestyle interventions. However, given the small numbers, this could be due to other intervention factors such as the choice of appropriate BCTs and this was not investigated in the review.

A critical point in the consideration of health behaviour change apps, in addition to their comparative effect over more traditional face-to-face interventions, is their unique reach, which is often not considered in efficacy trials (342). Even a small beneficial effect on salt intake could be valuable if the intervention can be delivered to a large proportion of the population, contributing to the achievement of national salt reduction goals.

3.3 Population versus individual interventions

The UK has been a forerunner in implementing population-level salt reduction strategies (345,346). However, despite considerable success with this approach in the past, the average salt intake in the UK is still 40% higher than recommended, with 70% of adults consuming above the recommended level (53). The most recent national data show no significant reduction in salt intake since 2009, and average intake was slightly higher in 2019, at 8.4 g/day (53) compared to 8.0 g/day in the previous survey in 2014 (249), suggesting additional actions are required to make further progress. The research in this thesis highlighted two areas where individual-level interventions could enhance the impact of population-level approaches: reformulation and nutrition labelling.

Firstly, reformulation to reduce the salt content of foods has been a key component of the UK's population salt reduction strategy and has resulted in significant reductions in the mean salt content of many food categories which contribute substantially to salt intake (e.g. cereals, breads, snack foods). One study reported a 7% reduction in crude sodium content of UK foods over a five-year period of voluntary reformulation (85). However, the most recent assessment of the UK voluntary salt reduction targets found that only half of the targets for average salt content (g/100g) were met in some food categories (88). One result of the voluntary approach is that some manufacturers have made ambitious progress while others have lagged behind, leading to a wide variation in salt content across some food categories (88); for example, a 70% difference in salt content across different breads (87). With such a variation in salt content across foods, the full benefit of the reformulation strategy can only be achieved when individuals are motivated and enabled to choose available lower-salt options, reinforcing the need for individual-level interventions that can support people to do this. In turn, this consumer demand is likely to feedback into competitive pressure on businesses to reduce salt content.

Secondly, lack of use or engagement with nutrition labels is one proposed reason for the lack of benefit demonstrated in labelling studies (100). Reviews on the effect of nutritional labelling consistently conclude that a positive attitude towards a healthy diet is an important predictor of label use (100,104,347). The results of the feasibility trial and the think-aloud study demonstrated an increased use of nutrition labels for salt content over the course of the study, suggesting that priming individuals with advice to reduce salt intake can increase engagement with nutrition labelling. These results indicate that there is a role for individual-level interventions to increase engagement with nutrition labelling, thereby enhancing the potential benefits of this population-level intervention.

This synergistic nature of individual and population interventions works in both directions. Population-level interventions can help to create an environment conducive to individual-level advice. Providing advice, knowledge and motivation will not be enough on its own to reduce salt intake when most of the salt consumed is already in the food chain. Among the barriers to reducing their salt intake reported in the think-aloud shopping study in this thesis two pertinent issues were raised: first, the availability of lower-salt options and second, that retailers do not make it easy for individuals to choose lower-salt or healthier products. For people to habitually change to lower-salt options, these need to be readily available, acceptable and identifiable without undue effort, underscoring the important role of reformulation and nutrition labelling. In addition, evidence suggests that instore interventions which manipulate promotion, placement and availability are effective for promoting healthier purchases (3,156,157). Participants in the think-aloud study in Chapter 5 felt that the store environment was not favourable to making lower-salt choices, indicating that retailers are not going far enough to implement structural or environmental interventions of this kind to encourage healthy choices.

4. Implications for research

Through my review of the literature and the research conducted as part of my thesis, I identified several important areas for future research. Firstly, the results of this research indicate the SaltSwap intervention is feasible and a future large-scale RCT is warranted to assess the effect on blood pressure. However, in Chapters 4 and 5 I identified several improvements to both the HCP advice and SaltSwap app components of the intervention which should first be addressed to enhance the intervention. Specifically, these included strengthening the reflective motivation and action planning aspects of the HCP advice

session, and improvements to the database of foods and nutrients which underpins the SaltSwap app, to provide more comprehensive, and up-to-date, coverage of supermarket products. The amendments are reflected in a revised logic model, highlighting additional elements required in the intervention to drive the required behaviour change (Figure 6.1)

Following improvements to the SaltSwap app, an RCT to assess the effect of the app alone on the salt content of purchased foods over the short term (four to eight weeks), with a large enough sample size to detect significant changes in purchase outcomes, is indicated. As a stand-alone app intervention, with outcomes measured remotely through the app, it would be possible to have a no-intervention comparator to more clearly test effectiveness of the app; though, in the absence of the HCP advice session, I would anticipate the beneficial effect to be smaller. Although the salt content of purchased foods is only an interim outcome in achieving the primary endpoints of reduced salt intake and blood pressure, the substantial costs and time involved in collecting biomarker and clinical outcomes would be avoided while testing the ability of the app to change purchasing behaviour and collect more robust data on purchase outcomes. This could be an interim step ahead of a large-scale RCT to assess the effect of the SaltSwap intervention on blood pressure, employing a similar trial design as used here but recruiting a more representative sample, perhaps by identifying potential participants during routine screening. A future effectiveness trial should implement the procedural improvements outlined in Chapter 4 and include short-term outcomes to assess the effect of the intervention and longer-term outcomes to assess sustained behaviour change.

Additionally, the role of the wider environment in shoppers' purchasing decisions was highlighted here and is well documented in the literature discussed in Chapter 1. Attempts to change the purchasing behaviours of individuals are likely to be more successful together

with complementary changes to the wider shopping environment. Future research should investigate how structural changes within stores, and availability and promotion of lower-salt products, can be implemented in such a way to be acceptable to manufacturers and retailers as well as supporting healthful decision-making to reduce individuals' salt intake. This may involve understanding any barriers which prevent manufacturers and retailers in implementing changes and understanding the effect these structural interventions have on the purchase of lower-salt foods.

5. Implications for practice

This research identifies several implications for practice. The online supermarket study in Chapter 2 highlighted the potential benefit of offering lower-salt swaps to consumers shopping for groceries. This approach could be implemented in commercial online supermarkets, alongside further detailed evaluation to determine the most appropriate parameters to enhance swap acceptance, to optimise salt reduction, and provide an indication of the effect size and hence potential benefit in a real-world environment. However, I was unable to find a retail partner willing to test this as part of my DPhil research, indicating there may be a lack of appetite among retailers to transparently evaluate this approach.

Secondly, the trend towards a reduction in salt intake and systolic blood pressure in the SaltSwap feasibility trial control group indicates that generic advice targeted to those with high blood pressure may provide some value as a stand-alone intervention. Almost two-thirds of participants found this advice helpful. Furthermore, the advice component of the SaltSwap intervention was highly acceptable to both HCPs and participants, and fidelity of delivery was high with minimal training. Although this research provides no evidence of effectiveness, HCPs already delivering health promotion for patients with hypertension could

easily incorporate generic advice to reduce salt intake as part of routine practice, if appropriate training and patient resources were available. This may be particularly applicable in more motivated patients, such as those willing to engage in other blood pressure self-management strategies. I was unable to identify any comprehensive training resources to enable and encourage practice nurses or healthcare assistants to deliver brief dietary advice for salt reduction. However, the potential value of this has been recognised at a national level and plans are underway to develop the SaltSwap HCP training materials into a general training resource for HCPs nationwide.

Finally, mobile apps provide a low-cost, scalable approach to delivering dietary advice to individuals. Even if, as a stand-alone intervention, the effect on clinical outcomes is small, an intervention highlighting the variation in salt content, promoting lower-salt alternatives, and enhancing intrinsic motivation could influence public attitudes towards the importance of salt reduction and increase demand for availability and promotion of lower-salt products. Another potential spill-over effect of greater individual engagement is to increase public support for more regulatory population approaches to salt-reduction. Research on other health behaviours has postulated that increasing public awareness of harm from a behaviour (e.g. smoking) and perceived benefit of reducing this behaviour, could increase public support for government intervention to address it (348,349). Making the SaltSwap app widely available to the general population may go some way to building this momentum. A similar approach has been taken with sugar reduction in the UK. Public Health England launched the Sugar Smart app in 2016, which provides information about the sugar content of foods and lower sugar options, as part of the Change4Life sugar reduction programme. The programme aimed to increase awareness of the sugar content of foods, generate engagement with families on sugar reduction and build support for ‘upstream’ sugar reduction policies (350,351). No specific

evaluation of the Sugar Smart app has been published but one study evaluated the effect of the overall Sugar Smart programme showed a significant reduction in total dietary sugar intake (g/day) in 5-11-year olds, during and after the campaign, assessed using a 24-hour dietary recall survey (352).

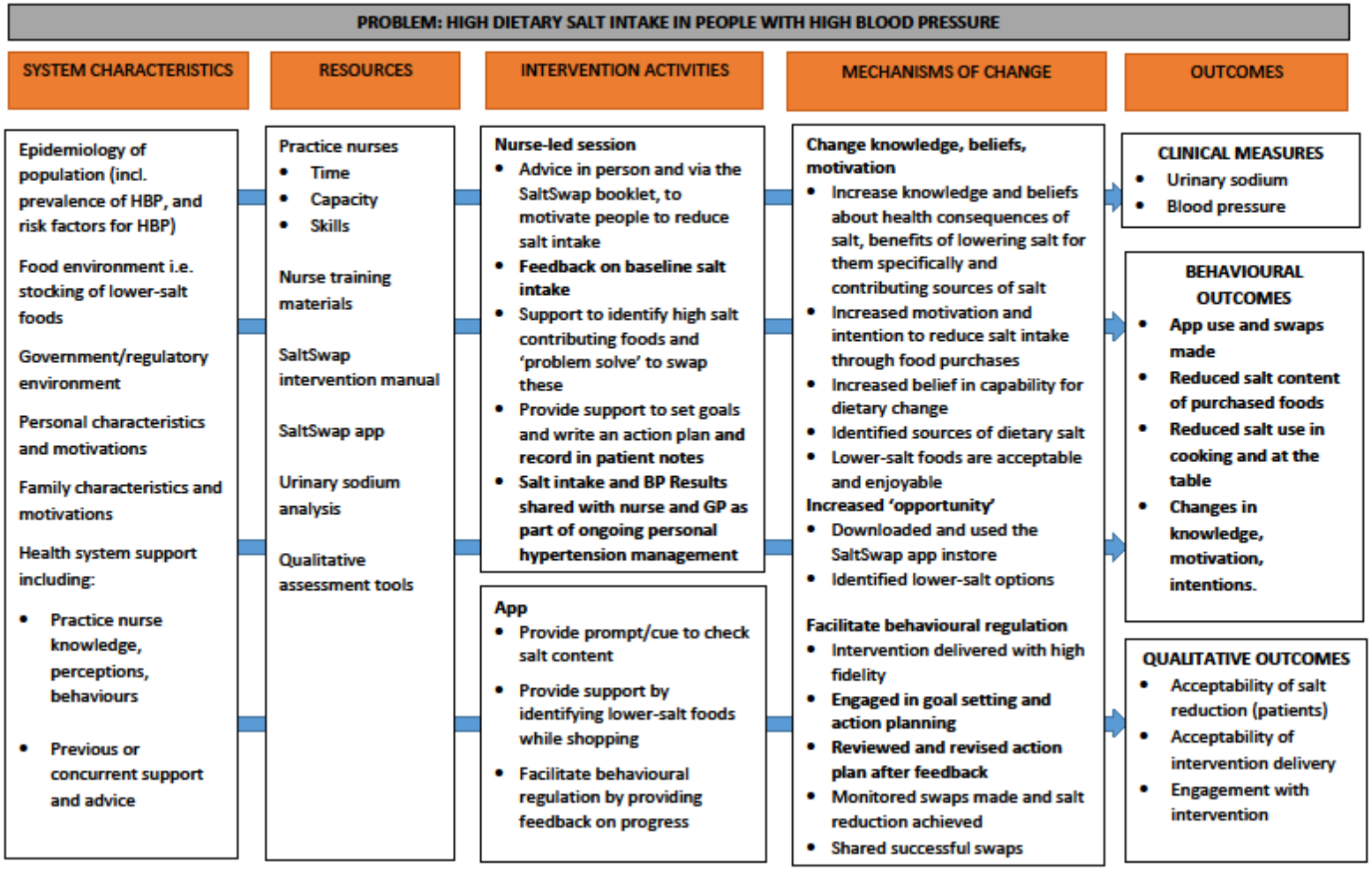
6. Implications for policy

If a future trial shows the SaltSwap intervention is successful, clinical guidelines to encourage reduction of salt intake could extend to signposting to effective strategies. Effective individual-level interventions will likely be necessary to drive reductions in salt intake and blood pressure among people with hypertension. Nevertheless, this research highlights that the environmental context influences the potential success of individual-level salt reduction interventions. Synergistic population-level strategies such as reformulation and regulatory approaches to provide availability of lower-salt alternatives and make it easy for people to eat a low-salt, nutritionally balanced diet are also important and could enhance individual-level interventions.

7. Conclusions

The research presented here provides evidence for the acceptability, feasibility, and impact on antecedents of behaviour change, of an intervention to reduce salt intake in individuals with high blood pressure, which could be delivered in routine primary care. If proven effective for reducing salt intake and blood pressure, this brief intervention could provide a cost-effective and scalable solution to address one of the key lifestyle risk factors for CVD.

Figure 6.1. Revised logic model.



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Appendix 1. Search strategies

Cochrane Library search 20 Jan 2020
(salt OR sodium):ti AND ("hypertension"):ti,ab,kw OR ("blood pressure"):ti,ab,kw AND (diet):ti,ab,kw Limited to Cochrane reviews. Search results 62
Excluded further studies in pregnancy, Chronic Kidney disease, diabetic kidney disease, diabetes, weight-loss studies, other dietary factors (e.g. saturated fatty acids or fruit and vegetable consumption).
10 results remaining

Medline OVID search 20 Jan 2020	
Search database: **Medline (Ovid MEDLINE® Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE®) 1946 to present**	
1	salt.ab,ti.
2	sodium.ab,ti.
3	"hypertens*".ab,ti.
4	1 or 2
5	blood pressure.ab,ti.
6	3 or 5
7	4 and 6
8	limit 7 to "systematic review"
9	"diet*".ab,ti.
10	intake.ab,ti.
11	9 or 10
12	8 and 11
	From results, excluded those dealing with chronic kidney disease alone, diabetes, pregnancy or in children or not in English. Results=49 reviews.

Appendix 2. Published peer-reviewed article

Payne Riches, S. et al. (2019) 'Optimising swaps to reduce the salt content of food purchases in a virtual online supermarket: A randomised controlled trial.', Appetite. Elsevier, 133, pp. 378–386. doi: 10.1016/j.appet.2018.11.028. https://pubmed.ncbi.nlm.nih.gov/30502442/

All co-authors have given permission to include material from this published paper in my thesis.

Appendix 3 CONSORT 2010 checklist for RCT reporting: OLS study

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title, page 39
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	NA
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	39
	2b	Specific objectives or hypotheses	42
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	42
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	43
	4b	Settings and locations where the data were collected	44
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	47
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	49
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	50
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	44
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	44

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	44
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	44
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	44
	11b	If relevant, description of the similarity of interventions	47
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	50-51
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	50-51
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	52,54
	13b	For each group, losses and exclusions after randomisation, together with reasons	52,54
Recruitment	14a	Dates defining the periods of recruitment and follow-up	43
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2.1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 2.2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 2.2,2.3, 2.4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	53, 58, 59
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA

Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	65-67
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	66-67
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	67-69
Other information			
Registration	23	Registration number and name of trial registry	43
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	*v*

Appendix 4. OLS product categorisation

Appendix Table 1. Example OLS product groups and categories.

Group	Category
Bread	Brown Bread
	Dietary Bread
	Half and Half Bread
	Seeded Bread
	White Bread
	Fresh Granary & Malted Bread
	Fresh Organic Bakery
	Fresh Speciality Bread
	Fresh White Bread
Cereals	Better for You Cereals
	Children's
	Crunchy Cereals
	Hot Cereals
	Traditional Cereals
Cheese	Counter – Cheese
	Cheddar Cheese
	Cheese Sliced & Grated
	Continental Cheese
	Flavoured Cheese
	Healthy Eating Cheese
	Organic Cheese & Dairy
	Regional Cheese

Appendix 5. OLS participant post-task participant survey

Demographic characteristics

1. Gender (M/F)

2. Age
- 18-24
- 25-34
- 35-44
- 45-54
- 55-64
- 65 or older

3. Weight and height (in units chosen by participant).

4. Household income (total household income before tax)

- Below £15, 500
- Between £15, 600 and £25,000
- Between £26,000 and £35,000
- Between £36,000 and £50,000
- £51,000 or above

5. Socio-economic status (highest educational level) - “What is the highest education qualification you have achieved?” (categories based on UK census categories)

- None
- Up to 4 GCSE's (Including 1-4 O Levels/CSE/GCSEs (any grades), Foundation Diploma, NVQ level 1, Foundation GNVQ or equivalents)
- 5 or more GCSE's or 1 A-level (Including 5+ GCSEs (Grades A*-C),1 A Level/ 2-3 AS Levels, NVQ level 2, Intermediate GNVQ, City and Guilds Craft, BTEC First/General Diploma, RSA Diploma, Apprenticeship or equivalents)
- 2 or more A-levels (Including 2+ A Levels, 4+ AS Levels, NVQ Level 3, Advanced GNVQ, City and Guilds Advanced Craft, ONC, OND, BTEC National, RSA Advanced Diploma or equivalents)
- Bachelor's degree (Including BA, BSc, NVQ Level 4-5, HNC, HND, RSA Higher Diploma, BTEC Higher level or equivalents)
- Post-Graduate degree or qualification (Including Higher Degrees e.g. MA, PhD, PGCE, Professional qualifications e.g. teaching, nursing, accountancy or equivalents)

6. Online shopping experience

How often, on average over the past year, have you shopped online for food or groceries to be delivered to you (e.g. Tesco.com, Ocado.com, mysupermarket.co.uk)?

- Never or not in the last year

- 1-3 times in the last year
- 4-11 times in the last year
- 1-3 per month
- Once per week or more often.

7. How often, on average over the past year, have you shopped online for any non-food items to be delivered to you (e.g. books, clothes, and electronics)?

- Never or not in the last year
- 1-3 times in the last year
- 4-11 times in the last year
- 1-3 per month
- Once per week or more often.

Health related questions

8. Have you (or a household member) ever been diagnosed with high blood pressure?

- Participant: Yes/No/Not sure
- Household member Yes/No/Don't know

9. Have you (or a household member) ever been advised by your doctor or health professional to cut down your salt intake?

- Participant: Yes/No/Not sure
- Household member Yes/No/Don't know

10. Have you (or a household member) previously tried to cut down your salt intake?

- Participant: Yes/No/Not sure
- Household member Yes/No/Don't know

11. The online supermarket you have just used may have offered you alternative lower salt foods to some of the foods you originally chose. Were you offered any swaps in this shopping task today?

- Yes/No

12. This is something I would like to have when I do my usual shopping.

- Strongly agree
- Somewhat agree
- Indifferent
- Somewhat disagree
- Strongly disagree

13. When making a choice of foods or drinks to buy, what are the top three things that affect your decision?

- Price
- Appearance
- Taste (preferences - yours or your families' likes and dislikes)
- Habits
- Healthiness
- Convenience (to prepare or to consume)
- Special offers
- Organic
- Special diet e.g. gluten free, nut free (yours or your families')
- Other (e.g. animal welfare, locally produced, packaging)

14. How often do you look at the nutrition labels for the following, when grocery shopping (or other occasions when buying packaged food or drinks)?

- Salt: Always/Often/Sometimes/Rarely/Never
- Sugar: Always/Often/Sometimes/Rarely/Never
- Fat: Always/Often/Sometimes/Rarely/Never
- Calories: Always/Often/Sometimes/Rarely/Never

15. Is there anything else you would like to tell us about your experience with this shopping task today?

[FREE TEXT ANSWER]

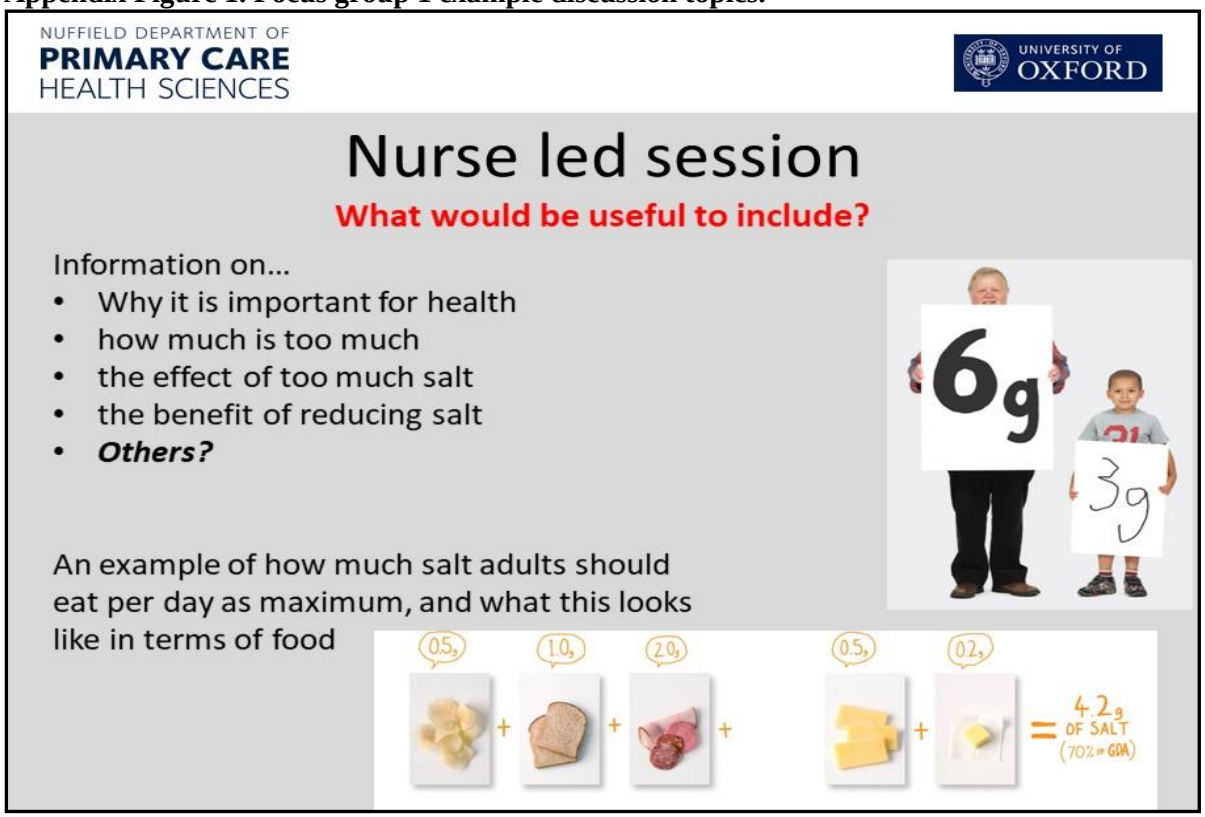
Appendix 6. OLS excluded participants' characteristics

Appendix Table 2. Key baseline characteristics of participants who were excluded (non-adherence) compared to those who were included (with chi-squared *p*-vlaue for difference).

Characteristics	Excluded	Included	Total N (%)	*p* -value
Total	193	947		
Age				*p*<0.001
18-24	8 (4)	5 (1)	13 (1)	
25-34	21 (11)	28 (3)	49 (4)	
35-44	48 (25)	51 (5)	99 (9)	
45-54	19 (10)	161 (17)	180 (16)	
55-64	30 (16)	319 (34)	349 (31)	
65 or older	67 (35)	383 (40)	450 (39)	
Sex (n,%)				*p*=0.008
Male	132 (68)	550 (58)	682 (60)	
Female	61 (32)	397 (42)	458 (40)	
Household income (total before tax)				*p*=0.001
Below £15, 500	23 (12)	172 (18)	195 (17)	
Between £15, 600 -25,000	31 (16)	224 (24)	255 (22)	
Between £26,000 - 35,000	53 (27)	200 (21)	253 (22)	
Between £36,000 - 50,000	35 (18)	187 (20)	222 (19)	
£51,000 or above	51 (26)	164 (17)	215 (19)	
Highest educational level				*p*=0.322
None	17 (9)	59 (6)	76 (7)	
Up to 4 GCSE's	27 (14)	149 (16)	176 (15)	
5 or more GCSE's or 1 A-level	30 (16)	132 (14)	162 (14)	
2 or more A-levels	28 (15)	189 (20)	217 (19)	
Bachelor's degree	55 (29)	273 (29)	328 (29)	
Post-Graduate degree or qualification	36 (19)	145 (15)	181 (16)	
Participant has a household member who has been diagnosed with high blood pressure	68 (40)	254 (31)	322 (32)	*p*=0.035
Participant has ever been advised by their doctor or health professional to cut down their salt intake	113 (59)	385 (41)		*p*<0.001
Participant ever tried to cut down their salt intake	144 (75)	649 (69)		*p*=0.005

Appendix 7. Co-design focus group resources

Appendix Figure 1. Focus group 1 example discussion topics.



1. Group discussion questions
    a. Do you think there are specific foods you should avoid if you want to lower your salt intake?
    b. Do you think you could identify low salt or high-salt products?
    c. Have you tried to reduce your salt intake before and how did it go? What were the barriers? What would help?
    d. Why do you/don't you buy low salt products?
    e. How do you feel about purchasing lower salt foods and fewer high-salt foods?

Appendix 8. SaltSwap intervention booklet

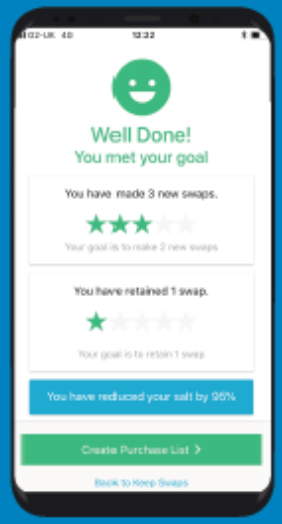
In addition to this booklet, participants were provided a link to the SaltSwap app video tutorial, see supplementary materials.



SaltSwap



SALT SWAP CAN SHOW YOU LOWER SALT ALTERNATIVES FOR MANY EVERYDAY PRODUCTS



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How Does Eating Salt Affect My Health?

Eating too much salt can raise your blood pressure.

How Does Eating Salt Affect My Health?

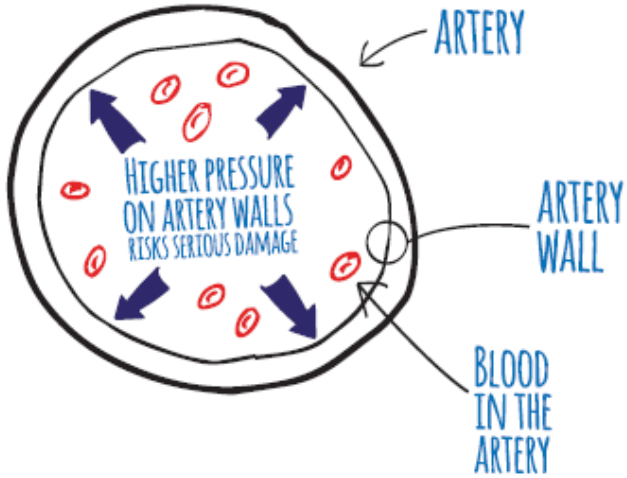
How does this affect my health?

High blood pressure puts added force against the walls of your arteries (the blood vessels that carry blood away from your heart).

Over time this extra pressure can damage the arteries, which makes them more likely to become narrowed and hardened by fatty deposits.

When this happens to your coronary arteries (the arteries that supply your heart muscle with oxygen-rich blood) this is coronary heart disease, which can lead to angina and heart attack.

When this happens in the brain, this can lead to stroke or more subtle long-term damage that can lead to dementia.



How does salt raise my blood pressure?

Salt is sodium chloride. Eating too much salt increases the amount of sodium in your blood stream.

This reduces the ability of your kidneys to function properly and leads to extra fluid in your blood vessels.

This increases the pressure on the walls of your blood vessels – the arteries – leading to high blood pressure.

MYTHBUSTER

"But my blood pressures under control!"

Your blood pressure might not be high enough to need treatment or your doctor might say they are happy with it now you are on treatment, but reducing your blood pressure can still help you.

"How much benefit can I get from reducing my salt intake?"

Reducing your salt intake by 3g a day can reduce your blood pressure by between 5 and 7 points[1], this could help you avoid needing to take medication. 3g could be just one serving of bacon.

We know that lowering your blood pressure by even 5 points will reduce the risk of heart attacks by 9% and stroke by 14%[2].

1. Law, MR, Frost, CD, Wald, NJ. By how much does dietary salt reduction lower blood pressure? Analysis of observational data among populations. *BMJ* 1991; 302: 811–815.
2. Ettehad, Dena et al. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. *The Lancet* 2016; 387:(10022): 957 - 967

EAT LESS THAN 6g PER DAY

How much?

The recommended maximum amount of salt for adults is 6g per day (or 3 g for children) – that's about one level teaspoon.

This is referred to as the guideline daily amount or GDA.



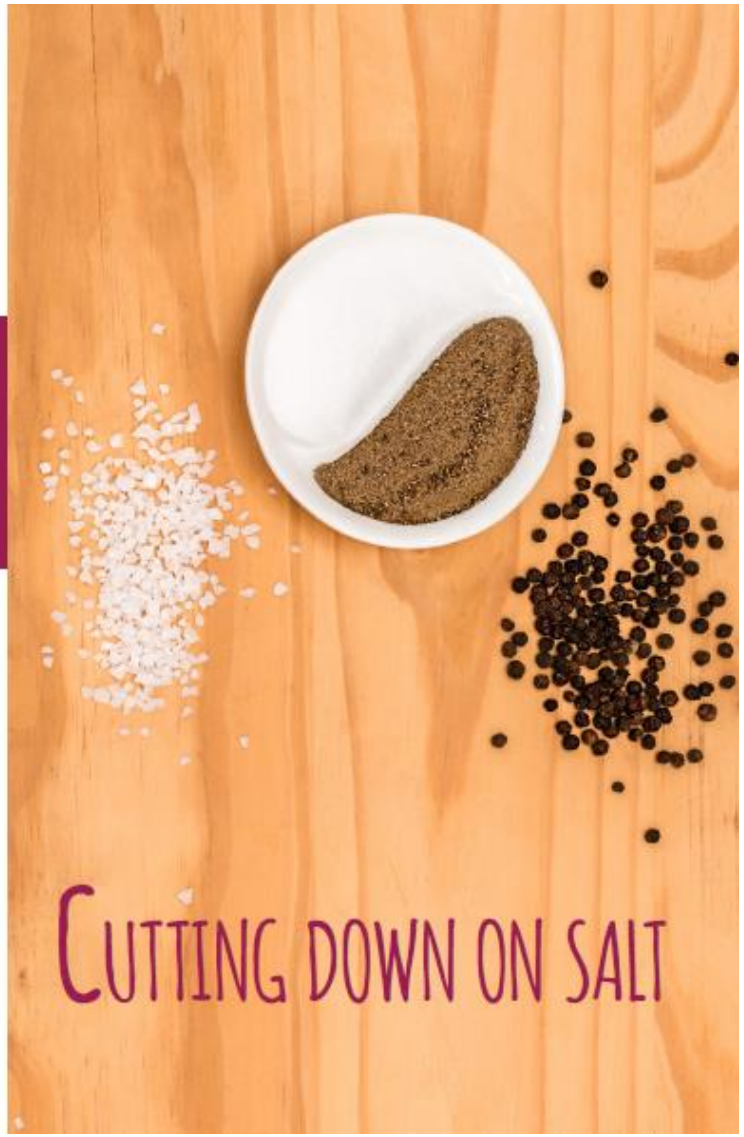
= 6g of salt

On average, adults in the UK consume ***8g*** of salt each day.

It's not just the salt that you add to your meal or the salt you add during cooking that is included. The salt which is already 'hidden' within many everyday foods also counts towards this limit.

A standard sandwich lunch could contain as much as ***70%*** of your maximum daily amount.





Cutting down on salt

To really cut down on salt, you need to become aware of the salt that is already in the everyday foods you buy, and choose lower-salt options.

Use the Salt Swap App, or nutrition labels on packaging to help you do this.

Some foods are almost always high in salt because of the way they are made such as processed meat and cheese, where salt acts as a preservative.

Other foods, such as bread and breakfast cereals, can contribute a lot of salt to our diet too. But that's not because these foods are always high in salt – it's because we eat a lot of them.



These show whether the food is low (green), medium (yellow) or high (red) in salt.

The app shows you lower salt options, and how much you could reduce your salt intake by swapping!

Common high salt foods

The following foods are often high in salt. To cut down on salt, try to eat them less often, have smaller amounts or swap to a lower salt variety!

- bread and bread products such as crumpets, bagels and ciabatta
- sandwiches
- breakfast cereals
- pasta sauces
- ready meals, pizzas and soups
- processed meats such as sausages, bacon, ham, burger patties or salami
- smoked meat and fish
- cheese
- prawns
- crisps and salted or dry-roasted nuts
- anchovies, olives and pickles
- tomato ketchup, mayonnaise, soy sauce and other table sauces
- stock cubes or gravy granules

Fact

Around 75% of the salt we eat is already in everyday foods such as bread, breakfast cereal and ready meals[1].

There is often a lot of variation in salt across different types and brands of everyday foods, so there are often options to swap to lower salt varieties without giving up the foods you like.

1. NHS Choices website (www.nhs.uk/Livewell/Goodfood/Pages/salt.aspx)

Activities

Activities

Activities: summary of key points

Summary of key points:

- Too much salt can cause high blood pressure, leading to heart disease and stroke.
- Lowering your salt intake could lower your blood pressure enough to avoid taking medication.
  (A reduction of just 3g salt per day can reduce blood pressure 5-7 points and reduce your risk of heart attack by 9% and stroke by 14%.)
- Most of the salt we eat comes from the everyday foods we buy.
- Making some simple swaps to lower salt foods can reduce your salt intake.
- The amount of salt often varies across different types or brands of everyday foods, so you can often swap to lower salt varieties without giving up the foods you like.
- Some swaps will reduce salt more than others but even small reductions help if it is a product you eat regularly.

Examples of lower salt swaps

BREAD

Instead of:
Tesco Finest Super Seeded Bread

1g per 100g
(0.88g per 2 slices, e.g a sandwich)

32%
or 0.28g less salt per serving

Swap to:
Tesco Wholemeal Farmhouse Loaf



0.8g per 100g
(0.6g per 2 slices)

Or even better...
Swap to one large wholemeal pitta bread with only 0.4g salt per pitta bread, almost half a gram less salt for your sandwich!



Bacon

Instead of:
Cooperative Irresistible range Dry cured smoke back bacon 6 slices



3.05g salt per 77g serving (2 rashers)

34%

or 1.04g less salt per serving

Swap to:
Cooperative Irresistible range Wiltshire cured smoke back bacon 6 slices



2.01g salt per 77g serving (2 rashers)

Or even better...
Swap to turkey bacon, such as Mattesson's Smoked Turkey Rashers at 1.65g salt per 75g serving



Ham

Instead of:
Waitrose British Finely Sliced Wiltshire Smoked Ham



0.76g per 33g serving

32%

or 0.24g less salt per serving

Swap to:
Ocado British Honey Roast Sandwich Ham



0.52g per 33g serving

Or even better...
Waitrose Roast Beef Topside at only 0.3g per 33g serving – 60% less salt!



BEANS

Instead of:
Heinz baked beanz



1.2g salt per half can

25%

or 0.3g less salt per serving

Swap to:
Heinz 'no added sugar' baked beanz



0.9g salt per half can

Examples of lower salt swaps

Activities: Set a goal and assess yourself

Activity One

The following foods contribute the most to adults' daily salt intake:

Bread
Bakery goods (e.g. biscuits, cake, pasteries etc)
Bacon
Ham
Other processed meats (e.g. sausage, salami etc)
Savoury snacks (e.g. crisps or salted nuts)
Soups
Ready meals
Pizza
Cereals
Butter and margerine
Table and cooking sauces (e.g. ketchup or soy sauce)
Pasta sauces and pesto's
Stock cubes or gravy granules

- Discuss which of these foods you or your household frequently buy?
- Identify any that you might be able to swap for lower salt brands or varieties?
- Discuss any problems or barriers you think you might have in making these changes and how to overcome them?

Activity Two: Set a goal!

How many swaps do you want to make, over all?

_____ SWAPS.

Activity Three: Self-assess yourself

How confident are you that you will make this change? (circle one)

1 2 3 4 5

(Not at all confident) (Very confident)

What would make you feel more confident that you can do this?

Activity Four: Make an action plan

Use the next page to make your first action plan.

Action plans help you to specify more precisely what you are going to do, how and when.

Thinking through and writing down an action plan to reach your goal makes it more likely you will do it!

Activity Four (cont): My salt swap action plan

	Number of Swaps	Items to swap	When? How?*
Example	2	Bacon Cereal	In my regular weekly supermarket shop I will scan my usual products and find a lower salt alternative
Week 1			
Week 2			
Week 3			
Week 4			
Week 5			

*i.e. in weekly shopping? In the store?

Downloading the Salt Swap app

The Salt Swap app is free of charge.

You will need an internet connection (3G, 4G or Wi-Fi) to download the app.

Download on the App Store

For iPhone visit the App Store and search for 'Salt Swap'

GET IT ON Google Play

For Android-based phones (e.g. Samsung) visit Google Play and search for 'Salt Swap'.

Once you have downloaded and opened the app you will be asked to accept the Terms of Use.

Once you have clicked the Accept button the app is ready to use.

If there are other members of your household who own a smartphone and shop for household food and drink you may also direct them to the app store they can also download and use the app (using the activation code).

If you have any problems please contact the Salt Swap study principle investigator, Sarah Payne Riches:

Telephone: (01865) 617195

email: saltswap@phc.ox.ac.uk

Tips to cut down on salt

At the dinner table

- Banish the salt shaker from your table.
- Taste your food before you season it. If it needs that little something extra, try adding pepper or fresh herbs instead.
- Switch salty snacks for fruit and vegetables – fresh, dried, tinned in natural juices all count.

When shopping

- The amount of salt varies between brands and varieties of the same product so compare nutrition labels on food packaging when buying everyday items. Look for foods with a green colour coding for salt.
- Try to eat red (high-salt) foods only occasionally, or in small amounts. Aim to eat mainly foods that are green (low) or amber (medium).
- You can really cut your salt intake by choosing the pizza, ketchup or breakfast cereal that's lower in salt. Try choosing one or two foods a week to check and swap when you're food shopping.

The Salt Swap app can help you find lower salt alternatives

- Watch out for the salt content in ready-made pasta sauces. Tomato-based sauces are often lower in salt than cheesy sauces or those containing olives, bacon or ham.
- For healthier snacks, choose fruit or vegetables such as carrot or celery sticks, or a pot of yogurt. If you are going to have crisps or crackers, check the label and choose the ones lower in salt. Choose unsalted nuts rather than salted or dry roasted varieties.

Tips for eating out

If you're eating in a restaurant or cafe, or ordering a takeaway, you can still eat less salt by making smart choices of lower-salt foods.

- **Pizza:** *choose vegetable or chicken toppings instead of pepperoni, bacon or extra cheese.*
- **Pasta dishes:** *choose one with a tomato sauce with vegetables or chicken, rather than bacon, cheese or sausage.*
- **Burgers:** *avoid toppings that can be high in salt, such as bacon, cheese and barbecue sauce, and opt for salad instead.*
- **Chinese or Indian meal:** *go for plain rice. It's lower in salt than pilau or egg fried rice.*
- **Sandwiches:** *instead of ham or cheddar cheese, go for fillings such as chicken, egg, mozzarella, or vegetables like avocado or roasted peppers. And try having salad and reduced-fat mayonnaise instead of pickle or mustard, which are usually higher in salt.*
- **Breakfast:** *instead of a full English breakfast, go for a poached egg on toast with mushrooms and grilled tomatoes. If you do have meat, have either bacon or a sausage, but not both.*
- **Salad:** *ask for dressings or sauces on the side, so you only have as much as you need. Some dressings and sauces can be high in salt and fat.*

Cooking with less salt

Many people add salt to food when they're cooking. But there are lots of ways to add flavour to your cooking without using any salt.

Check out these salt alternatives:

- *Use black pepper as seasoning instead of salt. Try it on pasta, scrambled egg, pizza, fish and soup.*
- *Add fresh herbs and spices to pasta dishes, vegetables and meat. This works really well even with foods such as potatoes, pasta, rice and couscous. Try garlic, ginger, chilli and lime in stir fries.*
- *Look for reduced-salt stocks – or even make your own stock and gravy*
- *Try baking or roasting vegetables such as red peppers, tomatoes, courgettes, fennel, parsnips and squash to bring out their flavour.*
- *Make sauces using ripe tomatoes and garlic.*
- *Go easy on soy sauce, mustard, pickles, mayonnaise and other table sauces, as these can all be high in salt.*
- *Citrus fruits such as lemons and limes can add a zesty kick to fish, chicken and pork. Use them as a marinade with olive oil and garlic or simply squeeze the juices over your meal.*
- *Don't throw away your salt-free vegetable cooking liquid. Use it for gravies, soups, stews and sauces, instead of salty stock cubes.*

Other sources of information or support:

NHS Choices:
www.nhs.uk/Livewell/Goodfood/Pages/salt.aspx

British Heart Foundation:
www.bhf.org.uk/heart-health/preventing-heart-disease/healthy-eating/salt

Blood Pressure UK
www.bloodpressureuk.org/microsites/salt/Home

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The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, the Department of Health and Social Care or the University of Oxford.

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

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Version 2.0 [19 June 2018]

Appendix 9. App market review

Aim

The aim of this review was to identify any existing apps which provide nutritional information on food or drink products (specifically salt content), identify lower-salt alternatives, and provide feedback on salt reduction achieved through swapping to lower-salt products.

Methods

I searched the two main app platforms, Google Play for Android and the App Store for iPhone using the following search terms: Food swap; Food switch; Nutrient swap; Nutrient switch; Food alternative*; Nutrient alternative*; Salt swap; Salt switch; Sugar swap; Sugar switch; Diet swap; Food label. I reviewed the top 100 results from each of these search terms to identify if they had the following key features:

1) Provides nutrient information for the selected food or drinks product;

2) Identifies a healthier alternative with respect to any nutrient or food property.

The search was initially conducted on the 5th June 2017 for Google Play Store and 6th June 2017 for Apple iTunes. I excluded games and puzzles, recipe-based apps; those which only provide nutrition information and tracking but no alternatives; and apps which did not list a specific swap for the initial product but just provided generalised healthy eating advice. I used both the app description and the app images to identify if the app met both feature criteria. If the app appeared to have or alluded to meet these criteria it was included, and I subsequently looked at the app website and/or downloaded it to my iPhone to test the functionality further. I included apps from within and outside the UK, but I used search terms in English and only included apps with a description in English.

The criteria which Google Play and the Apple Store use to prioritise apps and order the search results is propriety and not transparent. Conducting the same search repeatedly on the same day resulted in a slightly different subset of apps displayed in the top 100. Though I only formally conducted this systematic search once, subsequent informal searches did not reveal any additional apps.

Apps which included the two key features were downloaded and tested against a wider set of suitability criteria, specifically:

1. Database coverage of UK supermarket foods
2. The appropriateness of swaps offered (for reducing salt consumption)
3. Availability for both iPhone and Android phones
4. Ability of the app to collect data on grocery items purchased.
5. Feedback functionality or other behaviour change functionality such as social support/social networks, goal setting etc.
6. Whether a network connection is required in store (many UK supermarkets have no Wi-Fi or mobile data coverage)

Results

I found 12 apps that met or appeared to meet the key-features criteria, from their descriptions. Only four of these met these criteria and were assessed further for suitability: Foodswitch UK; Edo; ipiit; and CodeCheck (Appendix Table 3). Only two apps contained a suitable selection of UK products, Foodswitch UK (353) and Edo (148) and were available for both Apple and Android phones. Foodswitch UK offers swaps on a comparatively transparent basis of traffic light scores for each nutrient whereas Edo uses a proprietary score, the ‘Edo score’ so it is not clear how suitable the swaps are on a per nutrient basis. Both apps also offer an ability to ‘share’ with social media. Edo has some additional features under the Premium section such as allowing customisation of your preferred filters, but no other

specific, identifiable behaviour change functionality. Neither app could collect data on purchased products to enable the analysis of nutrient content of purchased products.

Conclusion

No current app offered functionality for goal setting or feedback or allowed collection of data on total food purchases and the nutrient content of these which are needed to deliver the intervention. A new bespoke app was required.

Appendix Table 3. App market review results.

	Apps and App Store Description	Shortlist requirements		Additional suitability requirements					
		Nutrient info	Healthier alternatives	UK Foods	Appropriate swaps	Android and iPhone	Data collection	Behaviour change functions	Accessible without network/wifi
Apps reviewed for suitability									
	**Foodswitch UK** Scan barcodes of packaged foods with your camera and see what's in the food you're eating. See similar foods that are healthier based on established nutrition criteria. Share your healthier food choices with your friends via Facebook, Twitter or email.	✓	✓	✓	✓	✓	x	x	✓
	**Edo** Edo helps you to understand what's on food labels so you can know exactly what's inside your food and choose consciously. You have just to scan the barcode printed on each food product and Edo will show you how healthy it is for you with a 0-10 rating. Besides, Edo also indicate: if it's Gluten Free; if it's Lactose Free; healthier alternatives for you	✓	✓	✓	x	✓	x	x	x
	**Ipiit Foodscan** ipiit food scanner helps you check products for food allergy triggers, specific ingredients and nutrition facts when grocery shopping. Create personalized preferences like Gluten (Celiac), Lactose, Milk, non-GMO, MSG, Wheat, Corn Syrup (HFCS), Eggs and many more.	✓	✓	x	Not tested	Not tested	Not tested	Not tested	Not tested

	Scan barcodes in a grocery store or at home and ipiit will help you decide whether the product fits your diet. Scan barcodes of US food products while grocery shopping or at home, and get all the relevant information (allergy triggers, nutrition facts, ingredients) Find better alternative products that fit your profile								
	**CodeCheck labels** Simply scan the barcode on foods or cosmetics and find out in seconds whether your granola is gluten free, if your yogurt is lactose free or if there are toxins in your shower gel. To see at a glance how recommendable a product is in relation to health and ecology, CodeCheck uses a simple rating circle: the greener the circle, the less cause for concern you have with the product. Red, on the other hand, indicates the presence of critical ingredients. Better alternatives: Is there palm oil in your pizza or toxins in your shampoo? We will show you! And with each scan of the barcode, we will also automatically suggest healthy, or toxin-free cosmetics	✓	✓	x	x	✓	x	Not tested	x
Shortlisted only apps – not meeting shortlist requirements and not reviewed further for suitability									
	**Food Maestro** Quickly check food labels for ingredient and nutritional facts. Our barcode scanner will automatically analyse a food label against each profile you have set-up so you can find food products suitable for all members of your family. Use as a food allergy app, or to scan search for products as a diet planner, or simply to make healthy food choices based on nutritional facts. The food app enables you to discover products available in supermarkets that you never realised were suitable - it's easy to do a food search or use the product barcode scanner to discover new foods	✓	X						

	**Be Food Smart** The Be Food Smart app is here to help you and your family make healthier food and drink choices. It's time to get scanning! Just find a food or drink barcode to quickly see what's inside. You might be surprised by what you find! You'll also find loads of simple hints and tips to help you make healthier choices, plus food detective activities for the kids and fun mini-mission ideas for the whole family	✓	X						
	**Sugar Smart (PHE)** The Sugar Smart app is designed to show quickly and easily how much total sugar is in the things you're buying, eating and drinking, to help you spot it more easily so you can make healthier choices and cut your sugar intake	✓	X						
	**Bad Better Best** BBB provides you with the best food alternatives to your fit in with your current diet, based on proven nutritional research. BBB gives you realistic food and beverage alternatives to thousands of junk foods and foods you thought were healthy that actually make you fat, tired and depressed; and Healthier, more nutritious food options that deliver on taste like your favourite guilty pleasures.	X	x						
	**InR Food** InRFood analyses food nutrition from the ground up, tracks the ingredients that you consume with your meals, customizes nutritional concerns specifically for you and also helps you discover better healthier alternatives.	✓	X						
	**Smart Restart (Change4Life)** Change4Life's Smart Restart app helps you introduce a healthy change and stick with it for six weeks - with support, encouragement and good ideas to keep you on track. Beat the treats – swap some of your kids' treats for heathier alternative.	x	X						

	**Crave Swap** CraveSwap helps you make better food choices. Pick a food that you are craving and CraveSwap will suggest a healthy alternative to your craving based on a nutrient you could be craving	Not clear	Not clear						
	**NutriTool** Has a smart search which allows users to easily identify healthy alternatives. Just enter a food (or through barcode scanner) and it will show healthier alternatives.	Not clear	Not clear						

Appendix 10. SaltSwap app database

Appendix Table 4. Example product groups and categories in the SaltSwap app

Group	Categories
Cheese	Blue cheese
	Cheddar cheese
	Cheese sliced and grated
	Cheese variety packs
	Continental cheese
	Feta, haloumi and goat's cheese
	other cheese
	Processed cheese
	Soft cheese
	Soy and lactose free cheeses
	Territorial Cheese
Sliced & continental meats	Cabanossi and twiggy sticks
	Chorizo
	Hotdogs/frankfurters
	Pancetta and prosciutto
	Polish salami
	Salami
	Sliced beef
	Sliced chicken
	Sliced ham
	Sliced luncheon meat
	Sliced meat variety packs
	Sliced pork
	Sliced turkey

Appendix Table 5. Example of the salt content variety between and within product categories.

Group	Category	Number of products	Products with salt content ≤0.1 g/100g	Products with salt content ≥1 g/100g
Breakfast cereal	Hot cereal (e.g. oats, porridge)	534	319 (60%)	7 (1%)
	Ready-to-eat cereal (e.g. cornflakes)	994	102 (10%)	158 (16%)
	Muesli and granola	602	415 (69%)	7 (1%)
	Variety packs	2	-	-

Appendix 11. Feasibility trial protocol publication

Payne Riches S, Piernas C, Aveyard P, Sheppard JP, Rayner M, Jebb SA. The Salt Swap intervention to reduce salt intake in people with high blood pressure: protocol for a feasibility randomised controlled trial. Trials. 2019 Oct 11;20(1):584.

https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3691-y

All co-authors have given permission to include material from this published paper in my thesis.

Appendix 12. Feasibility trial CONSORT 2010 checklist for reporting feasibility and pilot studies

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	108
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	NA
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	108-109
	2b	Specific objectives or research questions for pilot trial	110
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	110
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	111
	4b	Settings and locations where the data were collected	115-116
	4c	How participants were identified and consented	111, 113
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	114,115
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	116-122 Outcomes and measures
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA

	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	116-117
Sample size	7a	Rationale for numbers in the pilot trial	123
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	113
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	113
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	113
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	113
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	113
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	123-124
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	126, 128
	13b	For each group, losses and exclusions after randomisation, together with reasons	126, 128
Recruitment	14a	Dates defining the periods of recruitment and follow-up	126
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	129-130

Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Tables 4.3, 4.5
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Tables 4.3, 4.5
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	137-143
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	144
	19a	If relevant, other important unintended consequences	Table 4.5
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	146-151
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	147-149
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	154-156
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	154-156
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	110
Protocol	24	Where the pilot trial protocol can be accessed, if available	110
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	*v*
	26	Ethical approval or approval by research review committee, confirmed with reference number	126

Appendix 13. Baseline visit participant questionnaire

Staff initials: ☐☐☐

Date: ☐☐☐☐☐☐☐☐(ddmmyyyy) Study ID No.

1. SOCIODEMOGRAPHIC INFORMATION

1.A. HIGHEST EDUCATIONAL LEVEL- "What is the highest educational qualification you have achieved?" (categories based on UK census)

☐ None

☐ Up to 4 GCSE's (Including 1-4 O Levels/CSE/GCSEs (any grades), Foundation Diploma, NVQ level 1, Foundation GNVQ or equivalents)

☐ 5 or more GCSE's or 1 A-level (Including 5+ GCSEs (Grades A*-C),1 A Level/ 2-3 AS Levels, NVQ level 2, Intermediate GNVQ, City and Guilds Craft, BTEC First/General Diploma, RSA Diploma, Apprenticeship or equivalents)

☐ 2 or more A-levels (Including 2+ A Levels, 4+ AS Levels, NVQ Level 3, Advanced GNVQ, City and Guilds Advanced Craft, ONC, OND, BTEC National, RSA Advanced Diploma or equivalents)

☐ Bachelor's degree (Including BA, BSc, NVQ Level 4-5, HNC, HND, RSA Higher Diploma, BTEC Higher level or equivalents)

☐ Post-Graduate degree or qualification (Including Higher Degrees e.g. MA, PhD, PGCE, Professional qualifications e.g. teaching, nursing, accountancy or equivalents)

1.B. ETHNICITY

White	White British ☐	White Irish ☐	White Other ☐	
Mixed race	White & Black Caribbean ☐	White & Black African ☐	White & Asian ☐	Other mixed background ☐
Asian or Asian British	Indian ☐	Bangladeshi ☐	Pakistani ☐	Other Asian background ☐
Black or Black British	Caribbean ☐	African ☐	Black Other ☐	
Chinese or other ethnicity	Chinese ☐	Other ☐ (please specify)		

2. SMOKING HABITS

Do you smoke (cigarettes, cigars, tobacco)?

Current smoker ☐ Ex-smoker ☐ Never ☐

3. SALT AND HEALTH KNOWLEDGE

1) Do you think the amount of salt you eat affects your blood pressure?

☐ Yes
☐ No
☐ Don't know

4. GROCERY SHOPPING BEHAVIOUR

How often do you do grocery shopping (spending £25 or more) for yourself or your household?

☐ More than once a week
☐ Once a week
☐ Once a fortnight
☐ Once a month
☐ Less than once a month

How many people, including yourself, are there in your household who you regularly shop for? (not counting infants under 1 year old)

☐ 1 i.e. just yourself
☐ 2
☐ 3
☐ 4
☐ 5 or more

What type of supermarket or shop do you regularly shop at? (please tick all that apply)

☐ Supermarkets
☐ Online supermarket(s)
☐ Corner shop or convenience store
☐ Greengrocers/Fruit and vegetable shop
☐ Butchers or meat market
☐ Other fresh food markets (farmer's market, farm shop, fish market or fish monger, delicatessen, bakery)

When making a choice of foods or drinks to buy, what are the top three things that affect your decision?

☐ Price
☐ Appearance
☐ Taste (preferences - yours or your families' likes and dislikes)
☐ Habits
☐ Health
☐ Convenience (to prepare or to consume)
☐ Special offers
☐ Organic
☐ Special diet e.g. gluten free, nut free (yours or your families')
☐ Other (e.g. animal welfare, locally produced, packaging)

How often do you look at the nutrition labels for the following, when grocery shopping (or other occasions when buying packaged food or drinks)?"

☐ Salt: Always/Often/Sometimes/Rarely/Never
☐ Sugar: Always/Often/Sometimes/Rarely/Never
☐ Fat: Always/Often/Sometimes/Rarely/Never
☐ Calories: Always/Often/Sometimes/Rarely/Never

5. EATING OUT

In the last 7 days, on how many days out of that seven did you eat BREAKFAST out (e.g. takeaway or at a café)?

☐ 0
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ Don't know;
☐ Never eat breakfast

In the last 7 days, on how many days out of that seven did you eat LUNCH out (e.g. takeaway or at a café or restaurant)?

☐ 0
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ Don't know;
☐ Never eat lunch

In the last 7 days, on how many days out of that seven did you eat your MAIN EVENING MEAL out (e.g. takeaway or at a café or restaurant)?

☐ 0
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ Don’t know;
☐ Never eat a main evening meal

Study ID No. ☐☐☐☐☐

Staff signature:_____ Date: _____ (ddmmyyyy)

Appendix 14. Shopscanner app

A restricted version of the SaltSwap app was used by all participants in the baseline period and by control participants in the intervention period. This version, called Shopscanner, was used purely to record shopping purchases. Users could scan product barcodes to record products in the app 'purchase list' or if the product did not have a barcode, they could manually enter the product name, pack size and quantity. This app did not show nutrient information about products nor did it recommend swaps to any alternative products. Participants were provided a leaflet with instructions on how to download this version of the app from the App Store or Google play. Participants registered to use this app (and subsequently SaltSwap) with their email address and a self-selected username and password.

NUFFIELD DEPARTMENT OF
PRIMARY CARE
HEALTH SCIENCES

Chief Investigator: Sarah Payne Riches (Doctoral student)
Telephone number: 01865 617195
Email: saltswap@phc.ox.ac.uk

Downloading the ShopScanner App

The ShopScanner app is free of charge. You will need an internet connection (3G, 4G or Wi-Fi) to download the app. Go to the App Store for iPhone (or Google Play for Android phones e.g. Samsung, Nokia, Huawei)

Go to the search box and type in **Shop Scanner**. The app should look like this:

ShopScanner

You will be taken to a screen to download the app. Once you have downloaded and opened the app you will be shown some brief instructions for the app.

Using the App

You will need to register an account in the App, using your email and a chosen password.

Please use the same email that you used when you signed up to the study.

If you have any problems please contact the Salt Swap study principle investigator, Sarah Payne Riches, telephone: 01865 617195 or email: saltswap@phc.ox.ac.uk

To use the ShopScanner app you will need to register using your email, a chosen username and password.

Scan the barcode of each product you buy using your phone camera.



Simply click on 'Scan' and hold the phone with the camera facing toward the product barcode and your camera will automatically recognise and scan the barcode. You may need to allow the camera to focus on the barcode for a few seconds.

After each item, click, 'Scan' to scan the next item.
Scan all items you purchase in your shopping trip. If they don't have a product barcode, or the app doesn't recognise the barcode, you can enter item manually by clicking the 'Enter Manually' button.
When you have scanned or entered all products click 'Finish Purchase List' and that is all there is to it.



SHOPSCANNER APP INSTRUCTIONS Version 2.0 18 Sep 2018

DRAFT

Appendix 15. Saltswap trial follow-up questionnaire

Staff initials: ☐☐☐

Date: ☐☐☐☐☐☐☐☐(ddmmyyyy) Study ID No.

1. DIET AND HEALTH

1) Prior to this study have YOU ever been advised by your doctor or health professional to cut down your salt intake?
   - ☐ Yes
   - ☐ No

   Prior to this study has any OTHER HOUSEHOLD MEMBER (not yourself) ever been advised by their doctor or health professional to cut down their salt intake?
   - ☐ Yes
   - ☐ No

1) Have YOU previously tried to cut down your salt intake?
   - ☐ Yes
   - ☐ No

   Has any OTHER HOUSEHOLD MEMBER (excluding yourself) previously tried to cut down their salt intake?
   - ☐ Yes
   - ☐ No

2) Do you think the amount of salt you eat affects your blood pressure?
   - ☐ Yes
   - ☐ No
   - ☐ Don’t know

3) Has being involved in this study made you think more about the salt you eat?

   Strongly agree
   Somewhat agree
   Indifferent
   Somewhat disagree
   Strongly disagree

4) Would you say that being involved in this study has improved your knowledge about dietary salt? (E.g. the recommended daily amount of salt you should eat, foods which are high in salt, the relationship between salt and blood pressure?
   Strongly agree
   Somewhat agree
   Indifferent
   Somewhat disagree
   Strongly disagree

5) Over the course of this study have you made any of the following changes: (please tick all that apply)

a. Reduced the amount of salt you use in cooking (for example by adding less salt or changing to a different recipe)
b. Reduced the amount of salt you add to your food at the table
c. Swapped some higher salt products for lower salt ones when shopping
d. Eaten less of some high salt foods (by either eating particular foods less frequently or eating smaller amounts of them)?

1) Since being involved in this study, how often do you look at the nutrition labels for the following, when grocery shopping (or other occasions when buying packaged food or drinks)?
   a. Salt: Always/Often/Sometimes/Rarely/Never
   b. Sugar: Always/Often/Sometimes/Rarely/Never
   c. Fat: Always/Often/Sometimes/Rarely/Never
   d. Calories: Always/Often/Sometimes/Rarely/Never

2) During the study, did you use any other forms of support to help you reduce the amount of salt you eat? (E.g. Apps, tools, advice, contact with health professionals)

☐ Yes
☐ No

6a) If yes, what forms of support did you use?

[FREE TEXT]

3) What else do you think you would find useful in helping you to reduce the amount of salt you eat?

[FREE TEXT]

Study ID No. ☐☐☐☐☐

Intervention-specific questions (Advice and app group)

1) On a scale of 1-5, how helpful was the advice session led by your health care provider to reduce the amount of salt you eat?

Very unhelpful 1 2 3 4 5 Very helpful

2) Thinking about the advice you received from your health care provider, which aspects of that did you find:

Helpful (tick all that apply):

a. Motivated me to try to reduce my salt intake
b. Motivated me to shop for products with lower salt
c. Helped me to understand more about the importance of salt for my blood pressure
d. Helped me identify specific actions I could take to reduce my salt intake
e. Other: please explain

_____

Unhelpful: (tick all that apply)

f. I didn't understand the content of the session
g. The session was too short and basic
h. It was too general to motivate me to change my diet
i. I didn't think it was relevant to me
j. Other: please explain

_____

3) On a scale of 1-5, how helpful was the Salt Swap app in helping you choose lower salt foods?

Very unhelpful 1 2 3 4 5 Very helpful

4) How often did you use the Salt Swap app to help you buy foods with lower salt content in your shopping trips?

a. Always
b. Most of the time
c. Occasionally
d. Never

5) Would you be interested in using a free app like the Salt Swap app if it was publicly available in future?

Yes
No
Don't know

6) Please include any other comments you may have with regards to this study:

_____
_____
_____
_____

Intervention-specific questions (BHF booklet)

1) On a scale of 1-5, how helpful was the British Heart Foundation booklet to reduce the amount of salt you eat?

Very unhelpful	1	2	3	4	5	Very helpful

2) Please include any other comments you may have with regards to this study:

_____
_____
_____
_____

Staff signature:_____ Date: _____ (ddmmyyyy)

Appendix 16. 24-hour urine sample instructions

Oxford University Hospitals NHS
NHS Foundation Trust

Department of Clinical Biochemistry

Patient Instruction Sheet for 24 hour Urine Collection

THIS TEST REQUIRES YOU TO COLLECT ALL URINE PASSED OVER A 24 HOUR PERIOD

You have been given a bottle(s) in which to collect the urine. This bottle may contain liquid when given to you. Please do not remove this liquid, as it is used to preserve the urine. **Please take note of all warning notices on the bottle, as the liquid can be harmful.**

COLLECTION PROCEDURE

1. After waking on the morning you are due to start the collection, pass the first urine into the toilet. Write this date and time on the collection bottle.
2. Collect all urine passed over the next 24 hours into the bottle(s). This includes the first urine passed the following morning. The end time should be the same time of day as when you started.
   Write this date and time on the collection bottle.
3. If you have needed to use more than one bottle to collect your 24-hour sample, please write on the bottles that there is more than one. A good way to do this is to write '1 of 2' on the first bottle and '2 of 2' on the second.
4. The collection is now complete.

Please ensure that all of the bottles are clearly labelled with the following information:

- Your first name and surname/ family name
- Your date of birth
- Your NHS or hospital number (if you were given a request card, this should be written on it)
- The date and time you started collecting the sample (when you passed the first urine into the toilet)
- The date and time you finished collecting the sample
- The name, and the ward or surgery of the doctor who asked for the collection

N.B. Incomplete information on the bottle may delay your sample being processed by the laboratory.

To help us process your sample as quickly as possible:

If, for any reason, you do not manage to collect all urine passed in the bottle(s), please write this on the bottle(s) so that we know that the collection is not complete.

If a request card was given to you with the bottle, please attach it to the bottle using sticky tape.

If you do not have a request card and know the name of the test you are collecting the urine for, please write this on the bottle(s). There may be a label with your name and a barcode already on the bottle – if there is, you will not need a separate request card.

If you have been asked to do 24-hour collections for several different tests, you may have been given different types of bottle. You will need to do a separate 24-hour collection for each type of bottle. Please do not mix different bottle types during the course of a collection. If you have any questions about the collection or the test, please contact the surgery / ward that requested it.

BIO-JCH-LI-PI24HrUrPlain - Patient Instruction Sheet for Plain 24 hour Urine Collection

(From SOP BIO-JH-LP-AcidB Preparation of 24 Hour Urine Bottles version 1.5)

Appendix 17. Think-aloud instructions

These instructions were compiled with input from colleagues with experience of think-aloud studies, Kerstin Frie and Gill Cowburn.

Think aloud instructions

November 2018

The aim of this observed shopping trip is for me to understand the way you usually shop and also how the information you have received in the study has influenced your shopping habits. I'd like you to just do your shopping in the usual way and talk to me as you do it, about what you are thinking and what you are doing. We can have a practise first in a moment.

This type of accompanied shopping trip is called a 'think-aloud study'. Try to speak freely, without filtering your thoughts. You can say as much or as little as you like. If you are quiet for a period I might prompt you to tell me what you are thinking.

The first thing to make clear is that this is not a test! There is no right and wrong! Also please don't worry about hurting my feelings if you are critical – we are here to understand the need for improvements so I want your honest response.

If you have any questions as we go along feel free to ask them. I may not be able to answer right away since I am interested in how you do without someone standing next to them to help them, but if you still have questions when we are done I will try to answer them then.

You may have noticed the audio recorder – with your permission I will record what you say as we go. This will only be used for the purposes of the study and will be anonymised and stored using only your study ID not your name. It means I don't have to take so many notes.

First let's practice. We are going to start with [item of clothing, fruit and veg etc – something unrelated to salt].....

Appendix 18. Interview topic guide for qualitative study

GUIDE FOR 'THINK-ALOUD' STUDY POST-SHOPPING INTERVIEW

Participants in the Think aloud study will carry out their usual shopping while 'thinking-aloud' as they do it and will be observed by the researcher.

After the shopping trip, the researcher will conduct a semi-structured interview with participants in order to gather more in-depth information about the task(s) observed in the think-aloud session and better understand how the intervention of control advice have influenced the shoppers' behaviour.

Topic areas for the interview (intervention group)

1. The participants shopping habits in general and what influences their shopping choices
2. Using the app when shopping (i.e. the process)
3. Likes and dislikes about the app (content, functionality, general mode of delivery)
4. How the app changed their purchases (or not)
5. What they thought about the session with the practice nurse?
6. How the session delivered by the practice nurse (advice, activities and leaflet) influenced their salt purchasing and consumption behaviour
7. Perceptions about their ability to change their behaviour around salt intake.
8. What is the impact on their ability and/or sense of empowerment to change their wider dietary behaviour?
9. How do they feel about the effort required to eat healthily – has this made it seem easier or harder work?

10. How has being in the study influenced the amount of salt they eat in other ways?
11. How do they feel about the general shopping environment, how it affects their shopping choices and who is responsible for the healthiness of foods available?
12. How as the intervention influenced their beliefs about individual level versus population level intervention?

Example questions

1. Tell me about your shopping habits generally?
    - What sorts of things mainly influence what you buy or don't buy?
    - How important is health for you when you are shopping? (both regarding salt and other factors)
    - How would you describe your typical shopping basket?

2. How did you find that shopping trip?
    - Was it fairly typical?
    - In what ways do you think having someone observe you and doing the think-aloud changed the way you shopped?

3. Tell me about your experiences using the app as part of your shopping?
    Probes:
    - In what ways did you find it helpful/unhelpful
    - Were there things you found difficult about using the app?
    - How did shopping with the app differ from your usual shopping?
    - Tell me about some of the swaps you considered with the app?
    - If the swaps offered weren't what you wanted, what sorts of things would you want offered as swaps? Similar things or new ideas you might not have considered?

4. You recently had a session with a nurse as part of this study, can you tell me a little about that?
    Probes:
    - How do think the session with the nurse affected your shopping habits– today and recently in general?
    - How has it affected your eating habits, regarding salt and more generally? In what ways? If not, can you tell me why not?
    - How useful (or not useful) did you feel the session was overall? Can you tell me which parts in particular made you feel this way?

5. How do you feel about trying to eat less salt?
   Probes:

   - What do you find easy or difficult?
   - What about how it affects your shopping?
   - How do you think that focusing more on salt has changed your eating habits more generally? E.g. if it affects whether you eat more or less healthily?

6. How do you feel about the general shopping environment for example how it affects your shopping choices?

7. How do you feel about the availability of healthier foods e.g. those with lower salt?
   Probes:

   - What about the range of salt content in everyday packaged foods?
   - What about the labelling of foods with high or low salt?
   - What about the price of foods that are lower in salt - did you notice any difference?
   - Some people think it is just up to shoppers to make healthy choices if they want to. What do you think about that?
   - What do you think about the role of stores like [retailers] in helping you to reduce the amount of salt you eat?

8. What about the level of support for people to eat less salt or just more healthily overall?

Topic areas for the interview (control group)

1. The participants shopping habits in general and what influences their shopping choices
2. What they thought about the information in the leaflet?
3. How the BHF leaflet influenced their salt purchasing and consumption behaviour
4. Perceptions about their ability to change their behaviour around salt intake.
5. What is the impact on their ability and/or sense of empowerment to change their wider dietary behaviour?

6. How do they feel about the effort required to eat healthily – has this made it seem easier or harder work?
7. How has being in the study influenced the amount of salt they eat in other ways?
8. How do they feel about the general shopping environment, how it affects their shopping choices and who is responsible for the healthiness of foods available?
9. How as the intervention influenced their beliefs about individual level versus population level intervention?

Example questions

1. Tell me about your shopping habits generally?

- What sorts of things mainly influence what you buy or don't buy?
- How important is health for you when you are shopping? (both regarding salt and other factors)
- How would you describe your typical shopping basket?

2. How did you find that shopping trip?

- Was it fairly typical?
- In what ways do you think having someone observe you and doing the think-aloud changed the way you shopped?

3. You recently received a leaflet with tips on eating less salt. Can you tell me a little bit about this?

– In what ways did you find it helpful/unhelpful
– How do think it has affected your shopping habits – today and recently in general?
– How has it affected your eating habits, regarding salt and more generally? In what ways? If not, can you tell me why not?
– How useful do you think it is getting information in a leaflet about salt reduction to read at home?

4. How do you feel about trying to eat less salt?

- What do you find easy or difficult?
- What about how it affects your shopping?

- How do you think that focusing more on salt has changed your eating habits more generally? E.g. if it affects whether you eat more or less healthily?

5. How do you feel about the general shopping environment for example how it affects your shopping choices?

6. How do you feel about the availability of healthier foods e.g. those with lower salt?

– What about the range of salt content in everyday packaged foods?
– What about the labelling of foods with high or low salt?
– What about the price of foods that are lower in salt - did you notice any difference?
– Some people think it is just up to shoppers to make healthy choices if they want to. What do you think about that?
– What do you think about the role of stores like [retailers] in helping you to reduce the amount of salt you eat?

7. What about the level of support for people to eat less salt or just more healthily overall?

Appendix 19. Final coding framework for qualitative data.

Appendix Table 6. Themes, codes and code description for final coding framework for qualitative study.

Themes	Code name	Code description
Theme 1. Intervention & changes in knowledge & motivation	Knowledge and beliefs	Describing their knowledge & beliefs, current, previous or new knowledge from the study
	HCP advice session	Descriptions or comments on their experience of the HCP advice component of the intervention. Frequently dual-coded with knowledge and beliefs or behavioural regulation.
	Motivation and willingness to change	Including what motivates them to reduce salt intake and factors or beliefs that negatively impact their motivation and willingness
	Emotions	Described emotions when talking about shopping or dietary change. Emotion as a key influencer of motivation
	Feedback & behavioural regulation	The role of feedback and experiences/comments about behavioural regulation techniques such as action planning, self-monitoring and goal setting.
Theme 2. Using the App	Using the app	General comments and observations about the SaltSwap app, use and usability.
Theme 3 App barriers	App barriers	Barriers to using the Saltswap app or issues experienced when using it
Theme 4. Behavioural Change	Behaviour and behaviour change	Examples or discussion of changing their shopping or diet behaviour to reduce salt intake
	Justification	How they justify buying foods and how they judge foods or label them as naughty or treats. May include how they judge others' choices?
	Control leaflet	Comments about the general advice leaflet received as the control condition
Theme 5. Barriers and facilitators to salt reduction	Barriers & facilitators	Barriers to eating a lower-salt diet and choosing low salt foods
	Skills	Skills for shopping for, or cooking low-salt food

	Shopping traits	Including planning, use of a list, meal planning and how these factors influence or might influence, their decisions. This also includes store types frequented and the impact of this on shopping decisions
Theme 6. Store environment	The wider environment	Including how this supports and provides opportunities for dietary change (or not)
	Environmental opportunity	How the environment shapes opportunities for healthy choices
Theme 7. Nutrition labelling	Nutrition labelling	Description of use of labelling or barriers to use. Includes their experiences of labelling and their beliefs about and understanding of labelling as well as their knowledge about labelling and use of it.
Theme 8. Responsibility	Responsibility	Comments about personal, retailer or government responsibility for making healthy choices and encouraging/supporting purchase of lower-salt food.
Theme 9. Support	Support	Comments about the availability and quality of support from healthcare providers or others to help reduce salt intake
Theme 10- 15 Influences on food purchasing choices.	Health influence	Describing how health influences their shopping and diet
	Price influence	How price, and special offers influence shopping choices
	Family influence	Describing influence of family on shopping or diet in general
	Habit & routine as an influence	Describing habitual or routine purchase and consumption behaviour
	Aspects of self as an influence	Including aspects such as identity and role, skills, childhood experiences of diet and salt.
	- Childhood experiences	How their childhood experiences influenced what they eat, buy and how they cook
	- Identity	How they identify themselves with regard to health and diet, impact of culture
	- Living with high blood pressure	How living with high blood pressure influences their choices?
	- Role	Their role in the household and how this influences their choices
	Taste and preferences	How taste and their or their family's preferences influence their shopping choices
	Other influences	'Other influences' including quality, brand, organic, date, freshness, location or provenance and influence of this on choices. quality, pack size, convenience.
Not included in thematic analysis	*Effect of observer*	*Descriptions of whether the observation of their shopping trip altered their behaviour*

Appendix 20. Thematic analysis framework: themes and examples

Appendix Table 7. Categories, themes and subthemes (codes) used in the data analysis and interpretation

Categories & themes	Description	Examples
The intervention		
Theme 1. The intervention overall & impact on knowledge, motivation, intentions	Describing their knowledge, current, previous of new knowledge from the study and their motivation to change their salt intake (intervention participants only). Descriptions or comments on their experience of the HCP advice component of the intervention. Factors that motivate people to reduce salt intake or beliefs that negatively impact their motivation and willingness to change, and how they justify their choices. It includes emotions described when talking about shopping or diet, as emotion is a key influencer of motivation. This also includes the role of feedback and experiences/comments about behavioural regulation techniques such as action planning, self-monitoring and goal setting.	*"I have been quite surprised on how high in salt breads are. That's been a bit of an eye opener." (ID0205, Intervention)* *"Well I hadn't realised that there were crisps that were lower in salt…But I've been really shocked at how much salt some food has in...and I mean the [store] ready meals." (ID0410, Intervention)* *"since been into this programme, has it made me look at different things in a different way, in a different manner? Yes, I suppose it has…I have decided now, like I said, is that to look at the way we do things – don't put salt in my cooking now" (ID0206, Intervention)* *"And strangely enough, you do get used to it. It's like not having sugar in your tea. Yes, I suppose it's a bit bad in some ways, but if it hasn't affected the flavour and what I can actually do with something, then it's absolutely fine." (ID0205, Intervention)* *"Yes, yeh, I think I could continue. What I want to do though is wait and find out what the blood pressure is... and I would be interested to see if it remains the same or whether it has changed....And if the... see the results of the urine test at the end of the study to see if the salt*

	.	*content has decreased there…it would be interesting because it does confirm that you've done the job well." (ID0403, Intervention)* *"Well, I mean that was quite interesting because she was talking about targeting specific things each week. "And she said, 'Well, if you kind of concentrate on a couple of things, and then you get into the pattern of doing those and knowing what to look for, then the following week you move on to something different.' And I think that was quite sensible advice really" (ID0410, Intervention)*
Theme 2. Using the SaltSwap app	General comments and observations about the SaltSwap app.	*"I think my last shop, some of the sort of snacky crisp type things. They were like a ripple type crisp, and I was surprised how much salt was in that. And in fact, I don't think I bought them in the end. Because I thought, 'Wow, I thought these were supposed to be, you know, healthy.'" (ID0206 Intervention)* *"because I have found that the bacon, the app was good for finding low salt bacon" (ID0410, Intervention* *"I think it's a gadget which I'm comfortable using that's made me more conscious of looking at the salt levels where normally, I would look at sugar levels more than salt" (ID0206, Intervention)*
Theme 3. App barriers	Barriers to using the Saltswap app or issues experienced when using it including functionality and usability.	*"where it gives you as an indication to use a different brand or a different make or a different product slightly, it's... the product's not been available in the store." (ID0206, Intervention)*

		"I think the worst thing is the difficulty of trying to manage a mobile phone in one hand, your shopping list in another, pushing a trolley and negotiating round people. And then once you've got... it's using the app – the most frustrating thing is if it doesn't come up, the barcode, isn't recognised." (ID0205, Intervention) *"I found was just requiring too much time and too much effort, where you come shopping and you don't expect to be using your brain to analyse everything." (ID0415, Intervention)* *"I think it's too stressful to hang around too long and look at things too much. So, therefore I think you lose patience a little bit and sort of think, 'Oh, blow this.'" (ID0205 Intervention)*
Salt consumption and purchase behaviours		
Theme 4. Behavioural change	Examples or discussion of changing their shopping or diet behaviour, including both intervention and control group participants.	*"I am definitely looking more at the labels than I used to. Occasionally, I would glance through it, but I have to admit very rarely do I look at the salt. But now I am." (ID0108, Control)* *"It's making me definitely take something that's got less salt, whereas I might not definitely take something with less fat. It just makes you... I can't remember what it is was I looked at now, but something had forty nine percent of your daily intake of salt. No way." (ID0415, Intervention)*
Theme 5. Barriers & facilitators	Barriers to eating less salt or more healthily in general.	*"Yoghurts – I usually try and go for low sugar or fat free or both. I have found though that when I've been finding*

		lower salt ones the levels of fat and sugar have been higher." (ID0205, Intervention) *"This is what I find quite difficult when some measurements are given in hundred grams and some are... So, but I mean to stand there and do all that I'd need a calculator as well to work out, you know" (ID0205, Intervention)* *"So, I think it is about how much time, making it easy and... but yeh, no, I think for us it's not been a big deal changing; it's just been interesting." "So, I would rather do something beforehand, make my choices beforehand and then go in with my revised list" (ID0416, Intervention)* *"the problem was with the salt swap that the ones with less salt were not as tasty as those with more salt" (ID0403, intervention, age 70, male)*
The wider environment		
Theme 6. The store environment	How the grocery store environment shapes opportunities for healthy choices. Including comments on how the wider environment supports dietary change for salt reduction (or not)	***"****And somebody that's got a low income couldn't go miles, to different places to pick up something that would be lower salt" (ID0218, Intervention)*
Theme 7. Nutrition labelling	Description of use of nutrition labelling or barriers to use. Includes their experiences of labelling and their beliefs about and understanding of labelling as well as their knowledge about labelling and use of it.	*"I've been trying to use what they call the traffic light system. But it's all right if it's just... but because you get the different signs for different things, then you've got to look and think, 'Oh right, that's... that is high in salt,' then for argument's sake, 'That's high in...' and then you're trying to weigh it all up and when I'm doing that*

		amount of shopping, after about picking three things up you've had enough of it" (ID0401, Control)
Theme 8. Responsibility	Comments about personal, retailer or government responsibility for people making healthy choices.	*"Well, retailers are out to make money which is obviously their game and that's fine. But if it has been clinically proven that something is bad for you then perhaps I think the government should step in and say, you know, 'We need a limit on this.'" (ID0205, Intervention)* *"let's stop being manipulated by these big supermarkets that basically encourage you to buy cheap or buy what you don't really want because there's a special offer on. So, basically it's encouraging people to not eat healthy." (ID0207, Intervention)* *"I think…for people to lower their salt content, it has to come from the government; it has to be through the manufacturers. To actually make a big difference…yeh. So, I think that would be the biggest benefit " (ID0218, Intervention)* *"there's going to be a certain percentage of them who would be led by advertising and won't be proactive about a healthy diet. And so, I think there has to be legislation and the supermarkets to be responsible." (ID0403, Intervention)*
Theme 9. Support	Comments about the availability and quality of support from healthcare providers or others to help people make healthy choices with their diet.	*"There is no special place you can go to. You either read about it or you perhaps ask to be referred to a dietician of some kind."(ID0108, Control)*

		"No, I don't think, no. Not enough support, yeh." (ID0313, Intervention)
Influences		
Theme 10. Health	Describing how health influences their food shopping decisions, salt intake	*"I try and buy bread that is either wholemeal or half and half. Health, that's more health I would think. Crisps and things, nuts, I like those sorts of things but am conscious that I shouldn't be having them." (ID0206, Intervention)* *"I think that's probably one of the hardest things with this, is actually working out the balance between things you're encouraged to have for other dietary reasons, for example, low saturated fats, high oily fish once a week etc," (ID0319, Intervention)*
Theme 11. Price	How price, and special offers influence shopping choices and salt intake	*"I would probably use cod fillets because it's cheaper to be honest." (ID020,5 Intervention)*
Theme 12. Family	Describing influence of family on shopping choices and salt intake	***"****Right, I'm buying Active. One of these. They're saying there's quite a lot of salt in those. My wife prefers them because of the active element" (ID0206, Intervention)*
Theme 13. Aspects of self	Aspects of self[2] includes identity, role, and childhood experiences which impact their diet and shopping decisions.	*"That's basically how being a half Italian is that's basically how we were sort of like brought up. And we were sort of like brought up... lived on... live on olive oil.*

[2] *The concept of 'self' is described in the psychological literature as "the individual's belief about himself or herself, including the person's attributes and who and what the self is" (354). This may include personality traits, and social roles as well as physical descriptions.

		I cook with olive oil. I don't cook... we don't really cook with oil. I'd never use fat." (ID0207, Intervention) *"I was brought up post-war baby and it was very frugal, I still eat, I think, to my mind, quite healthily…" (ID0108, Control)*
Theme 14. Taste and preferences	How taste and preferences influence their shopping choices	*"So, and I've always bought the low salt version - Kallo. Yeh, because I like... I prefer the taste of those." (ID0416, Intervention)*
Theme 15. Habit & routine	Describing habitual or routine behaviour	*So, this is set of things which we're buying every week (ID0215, Intervention)*

Appendix 21. Hierarchy chart

Appendix Figure 2. Chart showing the frequency of transcript excerpts under each category and theme.

