An Investigation of Evaluation Approaches for Dietary Digital Interventions for Improving Children's Dietary Intake

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Contents

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List of Abbreviations

1MFU – 1-month Follow-up

3MFU – 3-month Follow-up

A&E – Accident and Emergency

ACER – Average Cost-Effectiveness Ratio

AUD – Australian Dollars

BCT – Behaviour Change Technique

BCTTv1 – Behaviour Change Technique Taxonomy version 1

BCW – Behaviour Change Wheel

BF – Body Fat

BMI – Body Mass Index

CAD – Canadian Dollars

CBA – Cost Benefit Analysis

CCA – Cost Consequence Analysis

CEA – Cost-effectiveness Analysis

CHU9D – Child Health Utility 9 Dimension

CI – Confidence Interval

CM – Colette Marr

COM-B – Capability, Opportunity, Motivation, Behaviour

CONSORT – Consolidated Standards of Reporting Trials

COVID-19 – Coronavirus

CRD – Centre for Reviews and Dissemination

CUA – Cost Utility Analysis

DALY – Disability Adjusted Life Year

DDI – Dietary Digital Intervention

DHI – Digital Health Intervention

DOCM – Design-Oriented Conceptual Model

DPT – Dual Process Theory

EMD – Emily Michalik-Denny

EPOCH – Evaluation of Interventions to Prevent Obesity in Early Childhood

EVPI – Expected Value of Perfect Information

F&V – Fruit and Vegetables

FOI – Freedom of Information

FOP – Front of Pack

GP – General Practitioner

HFSS – High Fat, Sugar, and Salt

HRQoL – Health-Related Quality of Life

HTA – Health Technology Assessment

HUI – Health Utility Index

ICER – Incremental Cost-Effectiveness Ratio

IDC – Intervention Delivery Costs

ITS – Interrupted Time Series

Kcal – Calories

MAR – Missing at Random

MARS – Mobile Applications Rating Scale

mHealth – Mobile Health

MI – Multiple Imputation

MM – Markov Model

MRC – Medical Research Council

NCMP – National Child Measurement Programme

NHS – National Health Service

NICE – National Institute for Health and Care Excellence

NMB – Net Monetary Benefit

PBC – Perceived Behavioural Control

PHE – Public Health England

PIS – Participant Information Sheet

POCM – Problem-Oriented Conceptual Model

PPI – Patient and Public Involvement

PSA – Probabilistic Sensitivity Analysis

PSSRU – Personal Social Services Research Unit

QALY – Quality Adjusted Life Year

QoL – Quality of Life

RCT – Randomised Controlled Trial

ROI – Return on Investment

SA – Sarah Abdi

SEAL – Secure Anonymised Information Linkage

SES – Socioeconomic Status

SM – Sundus Mahdi (the researcher)

SSB – Sugar Sweetened Beverages

WAItE – Weight-Specific Adolescent Instrument for Economic Evaluation

WC – Waist Circumference

WEIRD – White, Educated, Industrialised, Rich, Democratic

WGP – Weight Gain Prevented

WtHR – Waist to Height Ratio

WTP – Willingness to Pay

Y&H – Yorkshire and the Humber

Dissemination and Doctoral Development

Thesis-related dissemination

Publications

Mahdi, S., Buckland, N. J. and Chilcott, J. (2023) 'Economic and health impacts of the Change4Life Food Scanner app: Findings from a randomized pilot and feasibility study', *Frontiers in Nutrition, 10*, pp. 1125542. DOI: https://doi.org/10.3389/fnut.2023.1125542. *Reproduced in Chapter 7*.

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In preparation

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Mahdi, S., Marr, C., Buckland, N., & Chilcott, J. (2019) 'Methods for the economic evaluation of obesity prevention dietary policies and population level interventions in children: a systematic review and critical appraisal of the evidence', *UK Congress on Obesity*, Leeds, UK, September 2019. *Obesity Abstracts, **1**,* RFC1.3. DOI: https://doi.org/10.1530/obabs.01.RFC1.3.

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University of Sheffield (2022). Turning Ideas into Proposals.

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Abstract

To help promote healthier eating practises in children, Public Health England launched the Change4Life Food Scanner app, which provides nutritional feedback on barcode scanned products. The aim of this thesis was to develop a framework for evaluating dietary digital interventions (DDI) in improving 4-11 year old children's dietary intake.

A narrative review (Chapter 2) and content analysis of behaviour change techniques (BCTs) within the Food Scanner app (Chapter 3) were conducted to increase understanding of DDI mechanisms of behaviour change. A systematic review (Chapter 4), and stakeholder engagement (Chapter 5) explored the methodological approaches, and generated recommendations, to evaluating (cost) effectiveness of DDIs within a child population. Results informed aspects of a pilot randomised controlled trial (RCT), with feasibility and acceptability parameters, that evaluated the effectiveness (Chapter 6) and economic and health impacts (Chapter 7) of the app. Food diaries, questionnaires, healthcare resource use, and health-related quality of life measures were analysed in SPSS and STATA, whilst qualitative data was analysed thematically.

There was no preliminary evidence to suggest app (cost) effectiveness in improving diet. RCT methods were considered feasible, however improved alternatives are discussed. Four recommendations for the development and evaluation of DDIs emerged. Firstly, the effectiveness of DDIs is constrained by aspects of the current food system; DDIs should form part of broader interventions to achieve food system shifts. Secondly, in the light of difficulties in generating evidence of long-term intervention effects, economic modelling may be a solution to implementing empirical evaluations. Thirdly, the app can be improved through BCT and content development. Finally, app evolution and iterative evaluation processes should be embedded within evaluation frameworks to aid DDI developments.

Results can be used to aid DDI developments targeting child outcomes. Results can additionally support future evaluations of DDIs by demonstrating feasible approaches, alongside suggestions for improved methodologies.

1. Introduction and Rationale

1.1 Introduction

One in four children starting school are considered overweight or obese. By the time they reach year six, this figure rises to 4 in 10 (NHS Digital, 2022). Excess weight has been associated with level of deprivation in England; obesity prevalence more than doubles amongst children living in the most deprived areas, in comparison to children in the least deprived (NHS Digital, 2022). Poor diets and excess weight contribute to the prevalence and burden of obesity preventable diseases (Butland et al., 2007, World Health Organization, 2013, Public Health England, 2017a) and therefore negatively impact on the limited healthcare budget (Scarborough et al., 2011, Frontier Economics, 2022, Public Health England, 2017a). For this reason, it is imperative that greater focus is placed on weight gain prevention through the introduction of cost-effective interventions and policies that aim to improve population health.

Excess sugar consumption has been a key driver in the obesity epidemic. In 2015, Public Health England (PHE) reported that sugar intakes were above current recommendations, especially among school age children and disadvantaged groups (Tedstone et al., 2015); this continues to be demonstrated in more recent research (Henderson, 2022). Introducing policies that aim to reduce the consumption of sugar have been estimated to reduce Body Mass Index (BMI) and prevent the risk of excess-weight related health conditions over the life course, potentially saving the UK National Health Service (NHS) £500 million annually (Tedstone et al., 2015). Within this report, the term “sugar” will be used to imply added or free sugars. This includes honeys, syrups, and unsweetened fruit juices and excludes sugars naturally present in dairy-based milks (Swan et al., 2018).

1.2 Obesity prevention as a complex intervention

Obesity prevention is considered a complex intervention that takes place within a multifaceted changing system (Butland et al., 2007). When considering interventions, it is imperative to consider the context as a whole and the many contributing factors, individually and in interaction with one another, that may contribute to the obesity epidemic.

There has been a constant trend over time linking the increased availability of cheap energy dense foods with greater population intake (Cooksey-Stowers et al., 2017). Health promotion programmes, social marketing, education, and policy interventions have been suggested as potential methods to reverse environmental drivers of the obesogenic environment, if applied on a community level (Sanigorski et al., 2008). However, an intervention alone targeting a single behaviour may in itself not lead to a significant impact on obesity-related outcomes (Hawkes et al., 2015), even if it is successful in changing a particular observed behaviour within a given context. As the system is highly interconnected, interventions targeting one part of the system may trigger compensatory behaviours within another part of the system (Markey et al., 2016, Gressier et al., 2021). Changes need to be made across the system map simultaneously to see a significant shift in behaviour (Butland et al., 2007, Bagnall et al., 2019, Tedstone, 2015). A compensatory behaviour is when changes in one behaviour is replaced by another behaviour, contradictory or otherwise. Within the scope of this thesis, compensatory behaviours of interest are those pertaining to dietary intake. For instance, Capacci et al. (2018) investigated school-time snacking and sugar intake before and after the introduction of the French vending machine ban. The ban helped reduce sugar intake during school hours, however it did not affect total daily intake suggesting compensatory behaviours, or a replacement of energy intake from other sources. A multicomponent 12-month intervention delivered throughout 54 schools in the West Midlands also detected no significant changes in BMI z-scores (Adab et al., 2018). The authors acknowledged the need for wider environmental support in preventing obesity and that focusing on one aspect of the system is unlikely to generate change. When evaluating behaviours within complex settings, an awareness of a constantly changing and adapting system is necessary. Considering the status of the system at the time of implementing an intervention is necessary to inform interventions and evaluation approaches.

1.3 Current obesity prevention policies

The Government's childhood obesity plan for action report recommended a number of strategies to halve England's rate of childhood obesity by 2030 (HM Government., 2016, Department of Health and Social Care, 2018). Among these was a call for a soft drinks industry levy, imposing further restrictions on food and drink advertising and marketing to children, a call for clearer food labelling and improvements in methods to communicate relevant information to families, such as visual labelling through teaspoons of sugar. In addition, product reformulation policies have been set in motion, such as the sugar reduction programme, calling for 20% reductions in sugar content by 2020 (Tedstone et al., 2017). A progress report indicated that by year 3 of the programme (i.e. year 2019), retailers and manufacturers had only achieved a 3% reduction in total sugar per 100g in products (Coyle et al., 2020), whilst the final progress report continues to be withheld by government (Action on Sugar and WASSH, 2022). More positively, a 43.7% reduction in total sugar content per 100ml was achieved in beverages included in the soft drinks industry levy (Coyle et al., 2020). Similarly, due to the reported excess calorie consumption among children, 10% targets were implemented for calorie reduction by 2024, through product reformulation and portion size revisions (Pyne et al., 2020). The effectiveness of such reforms on dietary intake and the prevalence of overweight and obesity is unknown, especially considering the shortfall in reaching targets alongside lost leadership due to the closure of PHE (Action on Sugar and WASSH, 2022). In an analysis of government strategies and policies to tackle the obesity crisis ranging from 1992-2020, it was found that policies are not fully implemented nor adequately evaluated and mostly rely on individual agency as opposed to environmental reforms (Theis and White, 2021).

More recently, there has been a rise in the evaluation of complex interventions, including food policies in the UK. Lucas et al. (2017) reviewed the impact of school meal policies on children's diets. For example, the School Food Plan introduced in England in 2014 restricted the serving of fried foods, foods high in saturated fats and sugars, as well as Sugar Sweetened Beverages (SSBs). Their review highlighted the lack of monitoring and evaluation of school food policies and food-based guidelines, leading to a lack of evidence to support their implementation. Their review also highlighted the need to explore the long-term effects of healthy school meals on dietary outcomes. Transport for London implemented a ban on junk food advertising, which was found to have reduced purchases of high energy, sugar and fat products according to an interrupted time series (ITS) analysis (Yau et al., 2022a). Although the introduction of these policies brought about improvements in the overall diet quality, little is known about their effects on individual health outcomes. In the absence of long-term data, evaluations have estimated the cost-effectiveness of dietary policies. For example, sugar reformulations, based on 20% reduction targets, were estimated to reduce daily calorie consumption, reduce obesity prevalence, and decrease disease incidence through a modelling study (Amies-Cull et al., 2019). However, failure to achieve such targets led to lost benefits

(Amies-Cull et al., 2019). Although the evaluation of such complex interventions may be challenging, they are still being attempted using the best available evidence through a range of study designs and methodological approaches.

1.4 Nutritional labels

Front of pack (FOP) nutritional labelling is mandatory on most pre-packed foods in the UK (Department for Environment Food and Rural Affairs and Food Standards Agency, 2022). A vast amount of research has investigated the impact of FOP nutritional labels on consumer choices. In their systematic review, Crockett et al. (2018) found a significant reduction in calories (kcal) consumed when labelling was used on menus in restaurants; however, evidence from vending machines and grocery stores were of insufficient quality to reach any firm conclusions. On the other hand, other research has demonstrated that food labels may be more effective among those motivated to change their behaviour. When consumers were faced with a health goal, Machin et al. (2018) found that nutritional labels significantly improved healthy food choices, suggesting food labels may be effective if individuals are motivated to improve their diets.

In exploring the effectiveness of FOP labelling on parent food selection for their children, an RCT recruited parents of children aged 3-12 years and mailed out one of three hypothetical fast-food menus to them, which differed in their labelling technique (energy label, traffic light label, and no label conditions). Food labels reportedly helped inform food selection decisions in 19-22% of participants, despite results suggesting no significant impact made to total energy of intended purchases (Dodds et al., 2014). More recently, results from a hypothetical purchase task suggested parents were more likely to make healthier choices when calories, sodium and contextual information was presented alongside children's menus than a 'no nutrition information' control (Prowse et al., 2020). Food labelling has potential to shape parents' perceptions of what is healthful or not, which could guide their feeding decisions.

Supplementing nutritional labels with visual images of sugar quantity could help improve dietary choices. Despite being one of PHE's recommendations for action (HM Government., 2016), little research has investigated the use and impact of visual images. Mantzari et al. (2018) compared the impact of sugar images and warning labels on parental drink selection for their children. Participants were exposed to one of six warning images on SSBs (no image/image of health consequence of excess sugary consumption/image of sugar content in teaspoons) with or without additional calorie information. Results found that an image-based warning label reduced the selection of SSBs in comparison to other conditions. Although disease-based images (highlighting health consequences) were more effective than sugar content images, the sugar images were found to be more acceptable. It is likely that disease-based images triggered a negative emotional response from participants, unlike the sugar content image, which may have required participants to refer to their knowledge on the health consequences of excess sugar consumption. Public acceptability of new reforms is an important consideration when shaping policy, which places the sugar image condition in a favourable light. Adams et al. (2014) conducted a series of laboratory experiments to investigate the impact that images of sugar content have on consumer behaviour. It was hypothesised that if people were able to visualise the sugar content of SSBs more negative attitudes may develop and consequently reduce preference for consumption. Results found that without education, participants struggled to convert sugar grams into sugar cube quantity. In addition, when provided with visual images of sugar cubes, SSB attractiveness and consumption intentions were reduced. Similarly, participants were significantly more likely to select a sugar-free alternative when visual sugar content was displayed alongside SSBs. The experiments discussed above provide support that presenting visual images of sugar content on FOP labels could help consumers recognise the amount of sugar they will be consuming, and consequently see high-sugar drinks as less desirable. However, this may also rely on a certain level of knowledge on the health consequences of excess sugar to stimulate a negative response. Psychological theory helps further explain how visual images of sugar content may facilitate healthful consumer choices, as opposed to current labelling strategies, where sugar content is presented in grams.

1.5 Psychological theory

The Behaviour Change Wheel (BCW) (Michie et al., 2011) has been designed to help the development of effective behaviour change interventions. To achieve behaviour change, behavioural targets need to be specified: capability, motivation and opportunity. Capability describes both physical and psychological skills and abilities that allow engagement in the behaviour. Motivation involves brain processes which guide our decisions and behaviours, including those which occur automatically and those that require thought. Opportunity involves the external or environmental factors that make a behaviour possible, including both physical and social.

Using visual images of sugar content alongside current labelling strategies may provide a source of education, through increasing knowledge and understanding, thus increasing psychological capability and reflective motivation involving conscious brain processes to help make informed decisions. Visual images could also serve as a prompt or reminder to consider the sugar content within packaged food, therefore also increasing physical opportunity. Sugar images may additionally facilitate behaviour change through persuasion; the use of visual aids may stimulate action and increase both reflective (planning and evaluating) and automatic (acting out of desire or impulse) motivation. Increased salience of sugar content, using sugar images, may lead to a heightened disgust response, therefore reducing the desirability and automatic motivations around food and drink preferences (Lilo and West, 2022). It may also increase enablement through the provision of additional information, via visual aids, that are easy to interpret and facilitate comprehension, which could provide a means to increasing one's capability towards behaviour change.

Once behavioural targets have been established, suitable intervention functions consisting of behaviour change techniques (BCTs) can then be identified (education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling and enablement). Effective interventions are formed of intervention functions that help achieve behavioural targets. Characterising the active behaviour change components within interventions is supported by the use of the BCT Taxonomy version 1 (BCTTv1) which comprises of 93 BCTs (Michie et al., 2013). Depending on the choice of intervention functions, how an intervention is implemented can then be selected through a choice of policy categories (Michie et al., 2011).

Where the BCW describes a multicomponent framework for understanding behaviour, the Dual Process Theory (DPT) provides deeper insights into the role of decision-making processes (Marteau, 2017). The DPT describes human behaviour as either automatic, non-conscious and emotion-driven (system 1) or reflective, conscious and reason-driven (system 2). System 1 operates quicker than system 2, which allows one to free up cognitive capacity for other competing decisions or cognitively demanding tasks. Most behaviours are controlled by the automatic system, allowing quick decisions to be made and often times may be habitual requiring minimal effort or thought. In the case of FOP labels, many consumers lack the knowledge, time or motivation to make informed decisions about nutrition (Grunert et al., 2012), therefore requiring to rely on fast and prudent heuristics to satisfy their needs (system 1), rather than relying on reasoning (system 2). Considering the likelihood of consumers relying on automatic processes, the use of sugar images may help 1) simplify FOP labels so that they are less cognitively demanding to process (Becker et al., 2015), and 2) create new automatic associations between FOP labels, attitudes and behaviours (Hollands et al., 2011).

1.6 Cost-effectiveness evaluation

Given the scarcity in healthcare resources, it is critical to develop an understanding of the cost-effectiveness of policies and interventions, as such evidence is crucial for policy makers when making decisions on budget allocation. Health economic evaluation allows an intervention to be compared against competing alternatives, potentially including a 'do nothing' option. Comparisons are made in terms of both intervention costs and health benefits, and the way in which these are valued is dependent upon the decision-making perspective (see Appendix 1 for key concepts in health economics). Whether an intervention is deemed cost-effective, in relation to a comparator, depends on the cost effectiveness acceptability threshold. In the UK, an arbitrary threshold of £20-30k per Quality Adjusted Life Year (QALY) gained is utilised, and intends to represent society's willingness to pay (WTP) for additional health benefits (National Institute for Health and Care Excellence, 2013).

Many cost-effectiveness studies concerning sugar-reduction and food policies focus on hypothetical interventions or scenarios targeting adult outcomes, or recently acquired efficacy data, such as sugar taxation (Rogers et al., 2023, Pell et al., 2021), sugar reformulation scenarios (Amies-Cull et al., 2019), and high fat, sugar and salt (HFSS) advertisement bans (Mytton et al., 2020, Thomas et al., 2022a). Considering the drive towards and greater uptake of public health obesity prevention interventions within children, there is a fundamental need to evaluate their cost-effectiveness and long-term implications. However, what is considered as an "effective" intervention is dependent upon study aims. In some cases, such as policies, this may be changes in prevalence of overweight or obesity, whereas public health campaigns may work to merely create a shift in awareness, knowledge or attitudes towards a public health problem (Ghosh, 2016).

Applying consistent methodology when evaluating cost-effectiveness of studies can help facilitate comparability of results and enables ranking of different interventions and health care technologies (Haby et al., 2006). The Australian Assessing Cost-Effectiveness in Obesity studies are an example of this. An unhealthy food and beverage tax, reduction of advertising of junk foods and SSBs to children and FOP traffic light nutrition labelling were among the top cost-effective strategies out of 20 studies (Vos et al., 2010). However, the quality of the evidence for these interventions was deemed insufficient or not on the political agenda to warrant attention from a policy-maker perspective (Gortmaker et al., 2011). On the other hand, PRIMEtime predicts the occurrence of 19 non-communicable diseases based on changes in diet and obesity obtained from epidemiological data. The model was used to compare current obesity intervention policies, as standalone interventions or in conjunction with others, based on available efficacy data, whilst considering child outcomes (Cobiac et al., 2022). In addition, the Evaluation of Interventions to Prevent Obesity in Early Childhood (EPOCH) model considers an early childhood to late adolescence time horizon, allowing for the assessment of short-term cost-effectiveness of interventions (Hayes et al., 2019, Tran et al., 2022). Unlike long-term modelling, the EPOCH model assesses the costs and benefits specific to the earlier years of life. This may be complementary to models adopting a lifetime horizon, which provide estimates of costs and benefits of obesity prevention interventions accrued into adulthood. The centre of the model structure lies on an epidemiological model that predicts BMI trajectories; annual weight gain is predicted based on child age, sex, socioeconomic status (SES) and current weight status. A change in BMI is associated with changes in costs and effects (health related quality of life [HRQoL] outcomes) rather than simulating disease states, as these are more prevalent into adulthood (Schwander et al., 2016). There has been growing interest in economic modelling for the evaluation of long-term impacts of childhood obesity prevention and dietary interventions, as will be demonstrated within Chapter 4. Within these evaluations, there is complexity of assumptions made, as well as the uncertainty surrounding model structure and inputs, due to assumed causal pathways between outcome measures and long-term health benefits pertaining to costs (Lobstein et al., 2015). These complexities are discussed in further detail within Chapters 4, 5 and 7.

1.7 Change4life: a social marketing public health campaign

In 2009, PHE launched Change4Life, a social-marketing mass-media campaign aimed to prevent the rise in obesity (Mitchell et al., 2011). Change4Life comprises many components, including several smartphone apps that encourage healthier dietary behaviours. In 2016, a Sugar Smart app was released that aimed to nudge parents (i.e. influence their behaviours through small suggestions) to reduce their children's sugar intake (Public Health England, 2017b), resulting in over 3 million downloads (Public Health England, 2017c). In 2017, the Sugar Smart app was updated and rebranded as the Food Scanner app. Upon its initial release, the Sugar Smart app provided visual images of sugar cubes within products. Whereas, the Food Scanner app provides visual images of the amount of sugar, saturated fat and salt, alongside information on calories, as grams per pack, per portion and per 100g. Through the app, users can be signposted to the Change4Life website which consists of other key campaign messages, such as smart swaps (healthier alternative foods) and 100 calorie snacks ("100 kcal, two a day max"). Scanned products are saved within the app, allowing users to refer back to them without having to rescan products. This information is available when users are "offline" and may additionally result in a saturation in active barcode scanning over time. Further information on the Food Scanner app's content and features are outlined in Chapter 3.

Change4Life seeks to change behaviour by providing motivation and support to individuals, alert and inform the public of what they need to do to lead healthier lives and drive cultural acceptance of healthier behaviours. It aims to be highly accessible to those from disadvantaged backgrounds, through using accessible language and focuses on BCTs to generate positive behavioural outcomes (Metcalfe and Mitchell, 2014, Public Health England, 2017c). Through guidance from the Capability Opportunity Motivation-Behaviour (COM-B) model (Michie et al., 2011), Change4Life aims to provide necessary knowledge and skills (capability), change social norms and provide behavioural cues to action (opportunity), and increase motivation, whether through habitual processes, rational planning or goal setting (Public Health England, 2017c). To date, several studies have evaluated the effectiveness and public perceptions of Change4Life campaign messages. Through the use of digital platforms, public attitudes on the Sugar Smart app were investigated (Swift et al., 2018). The public generally viewed the app positively, where it was considered to provide knowledge and bring to light the truth regarding the sugar content of foods and beverages. A natural experiment was conducted investigating the impact the 6-week Sugar Smart campaign

(January 2016) had on children's sugar intake at baseline, during the campaign, and 1 month, 10 month and 12 months after the campaign (Bradley et al., 2020). Alongside dietary data collection, participants were interviewed to understand parental perceptions of the campaign alongside barriers to reducing child sugar consumption. Briefly, the campaign was found to have decreased participants' sugar intake at all time points except for the 12-month follow-up. The campaign additionally generated positive feedback from participants, whereby parents and children reported increased awareness that led to dietary changes and found the Sugar Smart app helpful in making purchasing decisions. In 2018, the Change4Life "100 cal snack" campaign was released, and was evaluated through an online survey which explored parental awareness, perceptions and understanding of the campaign, and whether children's eating behaviours had changed as a result of campaign messages (Day et al., 2022). The campaign lasted 2 months and encouraged parents to feed their children no more than 100 calorie snacks twice a day. The webpage provided access to healthy snack recipes and information on how to interpret the FOP traffic light labels. The Food Scanner app was also launched alongside this campaign. Results suggested that just over half of respondents were aware of the campaign, and those that were aware found it attention grabbing. Results additionally suggested improved reported attitudes around sugar consumption though did not lead to increased perceptions of campaign impact on dietary behaviours. In addition, most respondents were not aware of the Change4Life website, where additional resources and campaign messages could be accessed. The differences in results between these two evaluations of the Change4Life campaign could be the choice of participants. Bradley et al. (2020) recruited participants registered onto the Change4Life database, which suggests they have previous knowledge of, and are interested in, Change4Life campaign messages. Day et al. (2022) recruited parents from the general population, so may provide a less-biased viewpoint regarding perceptions and effectiveness of the campaign.

No published research has currently investigated the effectiveness and cost-effectiveness of the Food Scanner app as a standalone intervention, though research exists on other dimensions of the Change4Life campaign (Wrieden and Levy, 2016, Day et al., 2022, Lamport et al., 2021). As previously discussed, FOP labels and sugar images may have added benefits in guiding consumer decisions. Therefore, an evaluation of the Food Scanner app could help increase insight into the effectiveness of the use of such visual displays within an interactive government-funded mobile application in reducing child sugar and energy intake. It could also provide policy insight into the usefulness of presenting visual images of sugar alongside traffic light labels on packaged foods, to help make better-informed dietary decisions. An economic evaluation will help uncover whether a limited public health budget is being utilised in a cost-effective manner and whether app use impacts child HRQoL outcomes. To do this, the development of an explicit framework (i.e., methods and recommendations) for evaluating mobile interventions within the area of childhood nutrition and obesity prevention is required. This will consist of unpicking the decision problem, including identification of the complexities and difficulties of assessing clinical and economic effectiveness and designing a pilot and feasibility study to appropriately evaluate the app.

1.8 Aims and objectives

This PhD aims to investigate suitable evaluation approaches for dietary digital interventions (DDI) in improving 4-11 year old children's dietary intake and preventing childhood obesity, with a particular focus on the Change4Life Food Scanner app (version 1.6). To achieve this, Chapters 2 and 3 will focus on developing an understanding of the literature around mobile dietary apps, their mechanisms of behaviour change and processes by which the Food Scanner app functions aim to reduce children's sugar and overall energy intake. Chapters 4 and 5 will then explore the methodological approaches to evaluating app-based interventions within a child population. Finally, Chapters 6 and 7 will implement an evaluation of the Change4Life Food Scanner app (version 1.6) based on learning from previous chapters (see Figure 1 for an overview of proposed methods). The feasibility study aims to inform the process of evaluating the effectiveness and cost-effectiveness of the Food Scanner app amongst the general population. Such an evaluation could help advise whether public funds are better invested in more effective strategies to combat the obesity crisis. Finally, Chapter 8 will integrate findings from Chapters 2-7 where findings of proceeding chapters will strengthen and expand on conclusions of preceding chapters. The objectives of this PhD thesis are as follows:

1. Provide an overview of the current literature within dietary digital interventions, their components and effectiveness outcomes (Chapter 2).
2. Map out the behaviour change techniques in two versions of the Change4Life Food Scanner app (Chapter 3).

3. Conduct a systematic review and critical appraisal of the evidence relating to the methods for the economic evaluation of obesity prevention dietary interventions in children (Chapter 4).
4. Develop a problem-oriented conceptual model, through stakeholder engagement, bringing together the logical pathway by which the Food Scanner app operates to prevent obesity and future disease incidence (Chapter 5).
5. Assess the feasibility and acceptability of a randomised controlled trial (RCT) in evaluating the Change4Life Food Scanner app for reducing children's sugar and energy intake (Chapter 6).
6. Assess the feasibility of evaluating the economic and health impacts of the Change4Life Food Scanner app (Chapter 7).
7. Integrate the outcomes of this thesis considering implications and future directions (Chapter 8).

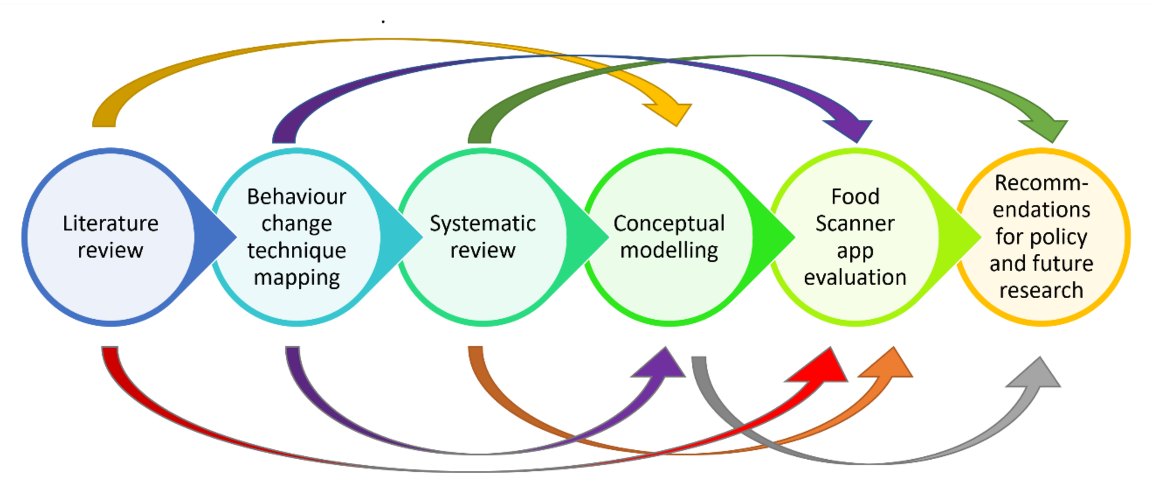


Figure 1. Integration of PhD objectives.

The outcomes of this thesis are expected to generate several recommendations. Recommendations will be app-specific and concern the development and improvement of the design and delivery of the Food Scanner app, alongside dietary apps more generally. These will be informed by outputs relating to Chapters 3, 5 and 6. Recommendations will also relate to effectiveness and cost-effectiveness evaluation approaches concerning dietary apps, including design, methodology and assumptions (Chapter 5, 6, and 7). In addition, outputs of this thesis are expected to generate recommendations for the economic evaluation of dietary interventions more generally (Chapter 4). Outputs of this thesis are additionally expected to generate preliminary findings relating to the Food Scanner app's effectiveness and cost-effectiveness. Such outputs could contribute to discussions surrounding cost-effective food policies, revisions of budget allocations and be impactful in driving public health nutrition and food policies (see Figure 2).

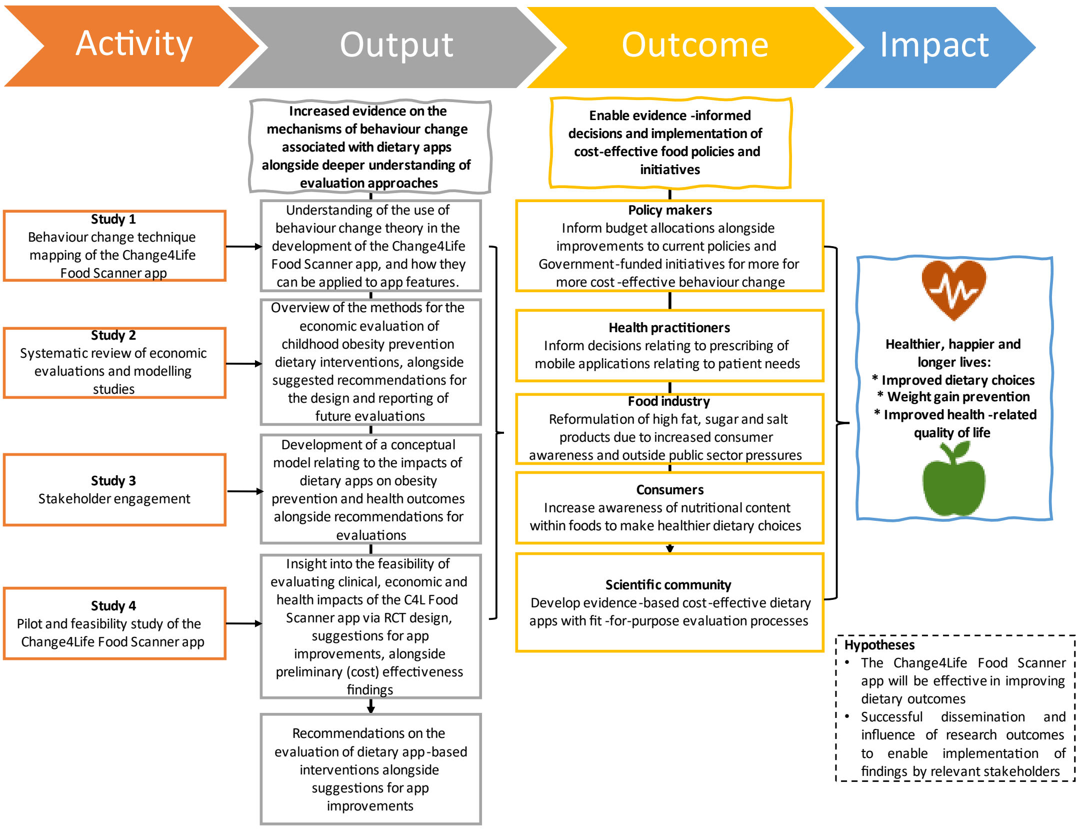


Figure 2. PhD activities and related impacts

2. A Narrative Review of Dietary Digital Interventions

The introductory chapter outlined the complexities of the food system and the need for more rigorous approaches to evaluating policies and strategies implemented by the UK Government. The Food Scanner app, released as part of the flagship Change4Life mass-media campaign, was highlighted as a potential intervention for improving children's dietary behaviours. Despite the Food Scanner app's nation-wide availability and popularity, this version of the app has not been evaluated, though the precursor Sugar Smart app, as part of the wider Change4Life campaign, has been (Bradley et al., 2020). The current chapter aims to widen our understanding of dietary mobile health (mHealth) interventions and their mechanisms of behaviour change. MHealth interventions are an aspect of dietary digital interventions, and digital health interventions (DHI) more generally. Where mHealth interventions refer to the specific form of digital technology (i.e. mobile applications), DHIs are broader and consist of all digital technologies (e.g. computer, mobile, wearable sensors) that aim to lead to changes in knowledge or behaviour (Murray et al., 2016). This chapter will explore, via a narrative review, the factors relating to app engagement including app-related factors and psychological precursors, the current evidence relating to the effectiveness of dietary mHealth interventions.

2.1 Introduction

Smartphone use has grown in popularity over the years. A mobile consumer survey in the UK suggested that 87% of respondents owned or had access to a smartphone (Lee, 2019). A unique feature of smart technology is the access to mobile applications ("apps"). Mobile apps are self-contained programmes that can be downloaded and accessed easily, making them a useful tool to deliver and administer behavioural interventions that can reach large populations (Middelweerd et al., 2014).

Obesity prevention apps have potential above other methods of dietary intervention delivery. Unlike face-to-face interventions, which are time consuming, expensive and difficult to scale up, mHealth interventions can be delivered anywhere at any time, placing less burden on both the individuals delivering and receiving the intervention. MHealth interventions can be tailored to different groups of people and not all assume a ‘one size fits all’ approach. They are easily acquirable, and many are free to download, therefore increasing their attractiveness to the user. Despite these advantages, and the growing popularity of mHealth interventions, the majority are not evidence based (Schoffman et al., 2013). More recently, theory-based strategies, such as the use of appropriate BCTs, are guiding app content and development decisions amongst researchers, which may potentially enhance the effectiveness of dietary apps (Michie et al., 2013, Dennison et al., 2013). The aim of this chapter is to conduct a narrative review of the literature in relation to dietary mHealth interventions. This chapter is not intended to be comprehensive or systematic, as is this case in Chapter 4, but rather demonstrate the areas of research and corresponding findings around mHealth dietary interventions. This will provide a background and context for proceeding chapters.

2.2 Methods

The search strategy was conducted on PubMed and was ongoing throughout 2018-2023. The literature was searched using a combination of broad terms: (1) “diet”, “nutrition”, “food” or “nutrition label”, (2) “mobile app”, “mobile intervention”, “smartphone app”, “mHealth”, or “app engagement” (3) “child”, and (4) “economic evaluation”, “evaluation” or “effectiveness”. Upon identifying relevant studies, related content was additionally reviewed on journal websites, in addition to references. Weekly emails relating to newly published research sent via journal mailing lists were also reviewed for relevant literature. Journals included Public Health Nutrition, Obesity, British Journal of Nutrition, and BMC Public Health.

As this was not a systematic review, but rather an overview of the current literature relating to dietary mobile interventions, there was no formal inclusion criteria. Though generally studies were reviewed if they related to factors impacting app engagement, conducted an evaluation of dietary apps especially those comprising of nutritional labelling content and barcode scanning features, and reviewed the use of BCTs within apps. Studies that discussed the methodological challenges of evaluating DHIs were also reviewed, though discussed in further detail within Chapter 5.

2.3 Results and Discussion

2.3.1 Factors impacting app engagement

Emerging research on the use of apps to improve diet and physical activity has investigated design, user uptake and effectiveness. A descriptive comparative analysis was undertaken to examine whether mobile apps support healthier food purchasing behaviour (Flaherty et al., 2018). Many apps lacked user customisation, nutritional content and the use of BCTs to support healthy food purchasing behaviours. Similarly, Schoeppe et al. (2017) reviewed BCT content within commercially available apps aiming to improve diets of children and adolescents. On average, there were 6 BCTs per app, whereby instructions on how to perform a health behaviour, general encouragement, contingent rewards and feedback on performance were the most frequently adopted BCTs. These studies suggest that improvements of app features and content, alongside a primary focus on behavioural outcomes, may potentially impact on user engagement and app effectiveness positively. There was no explicit description of BCTs, or the design process, relating to the Food Scanner app outlined within publicly available PHE materials. Therefore, to evaluate the effectiveness of the Food Scanner app, BCT mapping was undertaken to provide a context of how the app aims to improve food choices and dietary behaviours (see Chapter 3). This will help form a comparison between the app of interest and existing app-based dietary interventions.

App features and app acceptability may impact on user uptake and future engagement. A cross-sectional study explored user perspectives on dietary apps in Europe (Vasiloglou et al., 2021). Most participants reported ease of use, free to download, and automatic calorie estimation as important indicators for app use. On the other hand, barriers to using a dietary app included the omission of major foods, incorrect calorie and nutrient estimation, unconvincing portion size estimates and non-personalisation. The majority of the sample preferred the use of metrics (e.g. grams), as opposed to the use of common household measures (e.g. cups and spoons) to measure portion sizes. More recently, participants completed a discrete choice experiment where they had to choose between two choice sets with their preferred features at a given price and payment plan (Sadrmousavigargari et al., 2022). Results indicated that participants were willing to pay for customised information, and information that aids healthier food choices (e.g. salt and fat alerts). Participants also preferred receiving information on individual objects, rather than a group (i.e.

basket) at any one time, and preferred monthly rather than yearly payments. Unlike survey-based approaches, this study presents a novel approach to investigating the importance of app features in the context of monetary value, which can complement existing research especially when working with limited budgets to create valuable and effective mobile applications.

Barriers and facilitators of app use were further investigated within a systematic review (König et al., 2021). With a focus on the individual, themes included: goal setting and goal striving, motivation, routine and lack of awareness or knowledge. With a focus on the app, themes included: app features, usability, trustworthiness, technical issues and financial costs. Participants favoured the inclusion of comprehensive food databases for self-monitoring purposes, access to nutrition knowledge through feedback, and availability of rewards through gamification features. Similar outcomes were identified within another systematic review of health apps more generally (Szinay et al., 2020). Outcomes of these reviews could help support and provide recommendations to stakeholders in the development of smartphone apps to boost uptake and engagement (Szinay et al., 2020, König et al., 2021, Vasiloglou et al., 2021).

2.3.2 Effectiveness of dietary apps

Researchers have taken an interest in exploring the sociodemographic characteristics of health app users. Due to their wide-scale reach, there is an assumption that mobile apps have the potential to promote behaviour change among hard-to-reach groups, ethnic minorities and those of lower SES. However, issues relating to costs of smartphones and mobile data demands may create barriers to bridging the health inequalities gap and create a digital divide (Bommakanti et al., 2020). In fact, research has suggested that health app users are more likely to consist of younger population groups, higher education and have greater e-health literacy (Bol et al., 2018, Carroll et al., 2017). Given this information, it is clear an inspection of sociodemographics alongside health literacy are important factors to consider within evaluations as has been the case within Chapter 6.

Psychological predictors of behaviour change are often associated with mHealth intervention effects. Carroll et al. (2017) assessed the psychological predictors of health app use, as well as behaviour change. Findings from a U.S cross-sectional survey indicated that individuals who had downloaded health apps were more likely to hold positive diet and physical activity intentions and engage in behaviour change. This provides insights into existing motivations to adopt healthier behaviours amongst app users and will therefore be considered within the feasibility study (Chapter 6). Similarly, a cross-sectional survey investigated the mechanisms by which dietary apps lead to behaviour change amongst adults living in the United States (West et al., 2017). Participants reported that the use of dietary apps increased their motivation, improved their self-efficacy and confidence to eat a healthy diet. Over half of participants also reported that dietary apps led to positive behavioural changes and increased the consumption of healthy foods. These studies suggest that health apps may facilitate healthful behaviours in those that are motivated to change. However, the above findings are constrained by cross-sectional study designs that have relied on participant self-reported perceptions on how effective dietary apps have been in modifying their behaviour, as opposed to actual data on behaviour change.

Experimental designs can provide insight into the causal relationships between interventions and behaviour and can complement cross-sectional outcomes. Nollen et al. (2014) conducted a pilot RCT to investigate the impact of a 12-week app-based intervention targeting fruit and vegetable (F&V) intake, SSB consumption and screen time amongst ethnic minority girls. Using a 24-hour dietary recall, it was found that participants who had greater app engagement had greater reductions in SSB consumption in comparison to those less engaged, highlighting the need to maintain long-term app interest for continuing behaviour change. Similarly, secondary data analysis of pre and post evaluation data examining adolescent engagement styles with a lifestyle behaviour app (Aim2Be) was conducted (Lin and Mâsse, 2021). The app included a dietary component, boasted gamification features and BCTs. Participants were required to engage with the app for 4.5 months and completed measures at baseline and 4.5 months. Mediators of behaviour change were investigated which included health knowledge, self-efficacy, and autonomous motivation. Results suggested that those most engaged with all app features had a significant increase in F&V consumption alongside improvements in nutrition health knowledge, intrinsic motivation in healthy eating and self-efficacy in healthy eating in comparison to teens who did not use most app features.

Few trials have investigated the effectiveness of dietary apps in improving child outcomes through parental intervention. The MINISTOP RCT was evaluated to prevent childhood obesity in 4.5 year olds. Parents were encouraged to log their child's food intake via the app where they could receive feedback, information, advice, and strategies on how to improve dietary behaviours. After six month, there was a significant decrease in SSB consumption though no significant reductions in body fat amongst children in the intervention arm in comparison to the control arm (Nyström et al., 2017). Significant findings were not sustained at 12-month follow-up (Delisle Nyström et al., 2018). More recently, a standalone dietary app targeting 3-6 year olds aimed to improve the nutritional content of lunchboxes. Parents received push notifications addressing barriers to packing healthy lunchboxes alongside access to resources with suggestions for healthy food swaps. No significant reductions in energy from discretionary foods were reported (Pearson et al., 2022) which may have been due to poor app engagement. On the other hand, Vazquez-Paz and colleagues piloted an app which consisted of an education component (food benefits and preparation methods); a behavioural monitoring component (food diaries); a behavioural adjustment component (personalised daily and weekly goals); and a child-focused rewards component. Reductions in the consumption of ultra-processed foods were reported, alongside significant increases in F&V consumption over the one-month trial period, and increases in parents' knowledge of nutrition guidance (Vázquez-Paz et al., 2022). Across studies, app engagement decreased with time. Authors flagged that further exploration is needed on how mobile apps can maintain their effects over longer periods alongside improved implementation strategies.

Systematic reviews can help synthesise the diversity of research outcomes in relation to the effectiveness of dietary apps. Schoeppe et al. (2016) conducted a systematic review to investigate the efficacy of dietary apps in children and adults. Review findings suggested that the majority of studies adopted RCT designs, had short follow-up periods (1 month – 9 months), small sample sizes and targeted adult populations. Only half of identified studies showed significant health improvements. Greater app usage was also associated with greater improvements in healthy eating. Studies explored within the review demonstrate that evaluations of DDIs are still in their infancy and need scaling up to produce more reliable and generalisable outcomes.

A limited number of reviews have assessed the effectiveness of mobile apps used by parents to prevent childhood obesity. Findings suggested that obesity prevention apps targeting parents showed small or no effectiveness in anthropometric outcomes (Bonvicini et al., 2022, Yau et al., 2022b) nor were they effective in improving F&V intake (Zarnowiecki et al., 2020). On the other hand, multicomponent interventions that included a mobile app component were more effective than standalone mobile app interventions in improving dietary behaviours, whilst gamification was a key feature of effective interventions (Yau et al., 2022b, Antoun et al., 2022). Despite the lack of available evidence to suggest significant improvements in dietary outcomes, mobile apps were considered essential given they can reach families (Bonvicini et al., 2022).

2.3.3 Nutrition labelling apps

Nutritional labelling has been found to aid consumers make healthier choices (Croker et al., 2020), whereby their effectiveness can depend on the format and visual display presented (Cecchini and Warin, 2016). Nutritional labels have the power to highlight excessive levels of saturated fat, sugar and salt, leading to industry-level product reformulations (Shangguan et al., 2019, Michail, 2017). The provision of such information through a smartphone app overcomes issues relating to voluntary uptake of a uniform FOP labelling system by the food industry and can provide rich and engaging information to the consumer.

A number of dietary apps have been designed to aid consumers make well informed food choices through the provision of nutritional information, similar to those found on the front of packed goods (Neal et al., 2017, Dunford et al., 2014, Eyles et al., 2017). The Starlight RCT allowed consumers to scan barcodes of packaged foods, which returned nutritional information in either one of three formats: traffic light label, healthy star rating label or a nutrition information panel (control). The authors investigated the effects of these different labels on consumer self-reported food choice over a four-week intervention period (Ni Mhurchu et al., 2017). The intervention did not significantly improve healthy food choices, indicated by a nutrient profile score. However, participants who were assigned to the healthy star or traffic light label conditions were significantly more likely to find the labels useful and easy to understand and had improved nutritional knowledge compared to controls. Further analysis of the Starlight study found that label viewing decreased as the intervention period progressed (Ni Mhurchu et al., 2018). Shoppers were also least likely to check nutritional labels for confectionery, and more likely to view nutritional labels for cereals, snack foods and bakery products. In addition, products scanned and later purchased were healthier than those scanned and not purchased, indicating that label viewing in general, using a mobile app, may encourage healthier food purchases.

Further investigation of different nutrition labelling formats has been explored through mobile apps. The FoodFlip© app presents FOP nutritional information through different interpretative nutrition rating systems (Ahmed et al., 2020). Canadian adults were randomised to receive nutritional information in one of four formats and were asked to scan 20 products from a given list that varied in healthfulness. Traffic light labels and 'high in' warnings were rated significantly higher, than a healthy star and a nutrition facts table, in their ability to compare product healthfulness. The FoodFlip© app was rated positively, whereby the majority of respondents liked the barcode scanner function, felt that the product search feature and the app was easy to use, and that the app provided them with information that they can use and understand (Ahmed et al., 2020). Although this study generated positive outcomes in relation to the FoodFlip© app, whether the app would be effective in improving dietary choices in a real-world setting was not explored and cannot be assumed based on controlled experimental findings. More recently, Mauch et al. (2021) conducted a feasibility study with a mixed-methods design to investigate user perspectives on commercially available dietary apps targeting families. Outcomes of their research was intended to help inform future app developments and improvements. Participants completed baseline and follow-up surveys, alongside semi-structured interviews. Surveys included a validated Short Food Survey as a measure of dietary intake, alongside psychological predictors based on the COM-B model. Self-reported app engagement was additionally reported weekly, including frequency and duration. A subsample also completed a 4-week app-testing period. Participants reported that a barcode scanner app was helpful for selecting foods, however there was a lack of need for such support. Despite this, the barcode scanner app was used more frequently than other apps, such as meal planners and recipe apps. Hedonic values, purpose and app look and feel were the main factors influencing app use or take up, as well as barriers relating to time, habits and routines.

The studies outlined within this section have highlighted preferences of traffic light labels above other nutritional labelling formats alongside the use of barcode scanner features. These findings present positive indicators in relation to the Change4Life Food Scanner app, which boasts both features. The studies discussed above have also emphasised key domains that can support the investigation of user acceptability of the Food Scanner app, including nutrition knowledge, use of FOP nutrition labels, app likeability and usefulness, alongside barriers to app engagement. Such dimensions have been considered within the pilot and feasibility study (Chapter 6).

2.3.4 Change4Life

In their marketing strategy, PHE emphasised the importance attached to using digital technologies for health promotion (Metcalfe and Mitchell, 2014). The Sugar Smart campaign, which comprised of a dietary app, was considered a success, where three in 10 mothers reported decreasing the amount of sugar they fed their child. For mothers that had used the associated app, eight in 10 mothers reported reductions in child sugar consumption (Public Health England, 2017c). These results indicate a positive additive effect of using a digital component within interventions to strengthen the effects of behaviour change. Although the Food Scanner app (previously known as the Sugar Smart app) lies within a larger multicomponent intervention, the Change4Life campaign, it also constitutes as a standalone intervention (see Chapters 1 and 3 for more information on the components of the Food Scanner app).

2.3.5 Limitations of current studies

Self-reported data has been a popular choice of data collection in relation to dietary interventions outlined above due to the availability of validated, low-cost tools, making them a convenient and time-efficient choice (Wark et al., 2018). For this reason, it will be adopted as the main data collection method within the feasibility study outlined in Chapters 6 and 7. However, it is important to note that perceived reductions in dietary intake (Eliason et al., 2020, Tompkins et al., 2015, Adamo and Brett, 2014), alongside measurements of dietary intake via self-reports (Ravelli and Schoeller, 2020), can lead to inaccuracies in data collected, and results should therefore be interpreted with caution.

RCTs have often been the chosen study design to measure intervention effects. Although RCTs are considered the gold standard, their suitability for evaluating DHIs, which are considered complex interventions, have been questioned (Michie et al., 2017, Skivington et al., 2021). In most cases, the dietary apps discussed within this chapter have been designed and developed by research teams who have autonomy over app content, features and app updates. In such cases, RCT designs may be suitable for the evaluation of the "final version" of the app (McNamee et al., 2016). Otherwise, regular app updates and the complexity of app features, content and BCTs may require careful consideration of appropriate study designs and study methods. For this purpose, stakeholder engagement was carried out (Chapter 5) to guide evaluation decisions.

2.4 Conclusions

Findings from this brief narrative review has made some indication that nutritional labelling through a mobile app may improve food choices in an adult population (Ni Mhurchu et al., 2018, Ahmed et al., 2020). An evaluation of the Food Scanner app will further investigate whether the provision of sugar content information in the form of visual sugar cubes leads to reductions in reported child sugar consumption (Chapter 6). Issues identified within this chapter, including the use of BCTs within interventions and the impacts of demographics, psychological predictors, and app engagement on behaviour change will be considered within proceeding chapters. Evaluation considerations such as sample sizes and follow-up periods will additionally be discussed. These chapters will develop a problem-oriented conceptual model (Chapter 5) and an evaluation of the Food Scanner app (Chapters 3, 6 and 7), respectively. Proceeding chapters will also continue with and further develop the issues raised, the literature highlighted and discussions outlined within this current chapter. Literature from this current chapter will also help inform the study methods and measures adopted within the pilot and feasibility study (Chapter 6).

3. An Assessment of Behaviour Change Techniques in Two Versions of a Dietary Mobile Application: The Change4Life Food Scanner

Having developed an understanding of the factors that may facilitate or impede dietary app engagement, alongside an overview of the current literature that has investigated the effectiveness of dietary app-based interventions (Chapter 2), deeper insight into the processes by which the Food Scanner app aims to change behaviour is necessary. BCTs are the active ingredients present within an intervention and through these components, whether acting in isolation or in interaction with one another, can intervention outcomes and health benefits be predicted. The findings of Chapter 3 will contribute to the development of a conceptual model (Chapter 5) and will facilitate the evaluation of the Food Scanner app (Chapter 6). This study has been published within a peer-reviewed journal (Mahdi, S., Michalik-Denny, E. K. and Buckland, N. J. (2022) 'An Assessment of Behavior Change Techniques in Two Versions of a Dietary Mobile Application: The Change4Life Food Scanner', *Frontiers in Public Health, 10*, pp. 803152. DOI: https://doi.org/10.3389/fpubh.2022.803152). This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY) and the copyright therefore belongs to the authors. It has been reproduced, with the permission of all co-authors, for the purposes of this thesis.

3.1 Introduction

Children's diets are heavily dictated by their parents. Interventions that target families' nutritional choices may play a key role in preventing and tackling childhood obesity, and reducing the burden of preventable diseases (Butland et al., 2007).

Smartphone use is popular and provides access to downloadable applications ('apps'). Smartphone applications are self-contained programs that can be accessed easily and are far-reaching, making them potentially a cost-effective and useful method of delivery for behavioural interventions (Middelweerd et al., 2014). As such, there has been a rise in the development and feasibility testing of app-based interventions targeting childhood obesity prevention through parental behaviour change. However, given this area of research is still growing, data on app-effectiveness is limited (Meinert et al., 2020, Rossi et al., 2020, Henriksson et al., 2020), and the majority of app-based interventions are not evidence based (Schoffman et al., 2013). Research suggests that interventions with a theoretical basis are more effective in targeting determinants of behaviour change (Michie et al., 2013) and the National Institute for Health and Care Excellence (NICE) guidance advises that behaviour change interventions ought to include BCTs which have been found to be effective in changing behaviour (National Institute for Health and Care Excellence, 2014). The Medical Research Council (MRC) guidance on evaluating complex interventions also stresses the importance of underlying theory and has placed programme theory as a core element of evaluations (Skivington et al., 2021). Programme theory explains how an intervention is anticipated to result in desired effects. This includes an outline of the key components of an intervention (Chapter 3), how components interact, mechanisms of behaviour change (Chapter 3) and contextual factors that may impact on mechanisms of behaviour change (Chapters 5 and 6) (Skivington et al., 2021). MRC guidance additionally postulates that policies or interventions developed by others must still be theorised before evaluations are undertaken.

A systematic review, investigating the quality of dietary apps targeting children, found that app quality ratings correlated with the presence of BCTs and app features (Schoeppe et al., 2017). In another review of eleven mobile apps designed to support healthier food purchasing behaviour, 1-14 BCTs were identified per app (Flaherty et al., 2018). All apps had elements of 'goal setting (outcome)' and 'self-monitoring of outcomes of behaviour'. Yet, some of the most frequently used BCTs are not the most effective (Brannon and Cushing, 2015), and there is limited evidence to support BCT content in apps targeting families. More recently, interventions targeting parents for childhood weight management have considered the BCW in their design to determine the inclusion of evidence based BCTs (Michie et al., 2011). However, the number of available studies that have included BCT mapping of family-based DDIs are limited (Sutherland et al., 2021) and data on intervention effectiveness is yet to be published (Curtis et al., 2015). In many cases transparency around the use of BCTs goes unreported. Recent NICE guidance has recommended research be conducted to evaluate the specific components and characteristics of DHIs, and to what extent they are individually effective at changing behaviour (National Institute for Health and Care Excellence, 2020). Therefore, to know which BCTs are most effective within dietary apps, these apps need to be evaluated in terms of efficacy and BCT content (Murray et al., 2016).

The Change4Life Food Scanner app was developed by PHE as part of a wider public health campaign to promote healthy lifestyle choices (Public Health England, 2017c). The app targets 5-11 year old children and their parents and has over 500,000 installs on Google Play (Google Play, 2022). The app aims to encourage parents to improve their children's dietary intake by promoting healthier food choices. Users can scan the barcode of packaged products and receive feedback about the nutritional content of the item (e.g., through traffic light nutritional labels or sugar cubes, salt sachets or fat slabs to describe quantity). Understanding the BCTs used in the Change4Life Food Scanner app is important to allow for the comparison of BCTs used within various dietary apps. This is essential to allow complex interventions that adopt BCTs to be adequately evaluated (see Chapters 5 and 6) and could later help inform the development of effective mHealth interventions (see Chapters 6 and 8).

Although research currently exists on the range of BCTs currently adopted in dietary mHealth interventions, the majority of these are not focused on child outcomes (Schoeppe et al., 2017) and are reviews of the BCTs incorporated in a range of dietary apps available on the app market (Flaherty et al., 2018, Direito et al., 2014, Villinger et al., 2019). It is unclear which BCTs are related to which apps, and whether these apps have been developed by reliable sources. Additionally, one of the difficulties analysing app-based interventions is that they are frequently updated, including both content and design features (this is further discussed within Chapter 8). The Food Scanner app underwent a major update in June 2020 after this research had commenced. Changes to the BCTs used during the lifecycle of app-based interventions could lead to complications in the evaluation process and are therefore important to assess. Publicly available materials concerning the Food Scanner app do not give any description of BCTs formally described in the development and design process. Therefore, the aim of this research was to map out the BCT content of two versions of the Food Scanner app to understand the intervention's intended mechanism of behaviour change. Additionally, this research aimed to compare the BCT content of the previous and new version of the app.

3.2 Methods

3.2.1 Study design

A descriptive comparative analysis of the use of BCTs in the outdated (v1.6; March 2016) and updated (v2.0; June 2020) version of the Food Scanner app was undertaken in August 2020. BCTs used for continued app use (app engagement) and encouraging healthy dietary choices were the outcomes of interest. Dietary choices included reference to any food groups and/or macronutrients.

3.2.2 Coder training

Two coders undertook an online training program affiliated with the BCTTv1 which consisted of six training sessions and two assessments (required pass rate competency ≥60%) (Wood et al., 2015). The BCTTv1 is a nomenclature of 93 BCTs clustered into sixteen domains, designed to aid researchers and experts in reporting intervention content (Michie et al., 2013).

3.2.3 BCT mapping

Both coders independently used the updated version of the app until they had accessed all features and were no longer able to generate new outputs from the app ("data saturation") (McHugh et al., 2018). The coders then independently mapped the BCT content of the app using the BCTTv1. Mapping involved recording "evidence" of each BCT as it occurred. Results were compared between both coders in a discrepancy discussion and a consensus was reached. Within the discrepancy discussion, coders voiced uncertainty about the presence of a few BCTs, whereby the evidence was insufficient to formally code the presence of a BCT (i.e. where the presence of a potential BCT did not fully match the description provided in the BCTTv1). In such cases, the term 'near-misses' was applied. Identifying 'near-misses' could help to identify areas of the app which could be modified to strengthen the effect of the intervention by fully delivering the near-missed BCTs. In addition to mapping out BCTs from the app directly, the coders researched both versions of the app online to gain a deeper understanding of the apps' intended purposes and features. This included reviewing the app descriptions provided on Google Play and the Apple app store, as well as reviewing any app demonstrations on YouTube. This was undertaken as a validity check to ensure that no app features had been overlooked during app use and testing. In cases where an app feature discussed online was not identified despite extensive app use, the underlying BCT was mapped as a ‘near-miss’.

The first coder (SM) mapped the outdated version by directly using the app. The second coder (EMD) used secondary evidence that was available online, as at the time of mapping the outdated version was no longer available. The secondary evidence for the outdated version was verified by the first coder given their previous exposure and use of the outdated version of the app. This included app descriptions, video tutorials, screenshots of features, and evidence descriptions provided by the first coder (first coder’s BCT findings removed). Both coders mapped the updated version by using the app. Inter-rater reliability was assessed using Kappa. Each coder indicated whether each of the 93 BCTs in the taxonomy were present in the outdated and updated versions of the app. This data was entered into SPSS Statistics (version 25) and a Kappa score was calculated for each version of the app. For the outdated version, the Kappa score was 0.94 and for the updated version was 0.89. Both of these Kappa scores are indicative of very good agreement (Altman, 1990). As part of the mapping exercise, coders documented BCT presence, the features of the app where BCTs were present, the frequency of each BCT presence, and the average occurrence of each BCT. A Pearson Chi-Square test of independence was also undertaken to compare BCT presence between app versions.

3.3 Results

3.3.1 Outdated version (v1.6)

Eight out of ninety-three BCTs (8.6%) were identified including ‘goal setting behaviour’, ‘feedback on behaviour’, ‘social support (unspecified)’, ‘instruction on how to perform the behaviour’, ‘salience of consequences’, ‘prompts/cues’, ‘behaviour substitution’ and ‘credible source’. These BCTs belong to eight of sixteen domains (50%) including ‘goals and planning’, ‘feedback and monitoring’, ‘social support’, ‘shaping knowledge’, ‘natural consequences’, ‘associations’, ‘repetition and substitution’ and ‘comparison of outcomes’. On average, each

BCT appeared in 2.5 different features of the app. The most frequent BCT was ‘feedback on behaviour’ which involves monitoring behaviour and providing informative or evaluative feedback on the performance of the targeted behaviour. Feedback occurred through the use of traffic light labels, the visual depiction of sugar/fat/salt content, calorie information, traffic lights and written feedback on scans. The second most frequently occurring BCT was ‘social support (unspecified)’ which was delivered through signposting to further information and through the provision of encouragement in response to scanning items that were considered to be a healthy choice (see Appendix 2 for the mapping results and all available evidence of where BCTs were present).

3.3.2 Updated version (v2.0)

Eleven of ninety three BCTs (11.8%) were identified including ‘goal setting behaviour’, ‘feedback on behaviour’, ‘social support (unspecified)’, ‘instruction on how to perform the behaviour’, ‘salience of consequences’, ‘information about social and environmental consequences’, ‘information about emotional consequences’, ‘prompts/cues’, ‘credible source’, ‘social reward’ and ‘social incentive’. These BCTs belong to eight of sixteen domains (50%) including ‘goals and planning’, ‘feedback and monitoring’, ‘social support’, ‘shaping knowledge’, ‘natural consequences’, ‘associations’, ‘comparison of outcomes’ and ‘reward and threat’. On average, each BCT appeared in 2.7 different features of the app. The most frequently occurring BCT was ‘feedback on behaviour’ which had several modes of delivery including ‘low badges’, ‘woah badges’ and a virtual reality feedback feature. The second most frequent BCT was ‘instruction on how to perform behaviour’ which was present in the instructional section of the app.

3.3.3 Comparison of outdated and updated versions

Figure 3 displays the commonalities and differences between the two versions of the app. The updated version had a significantly greater BCT presence than the outdated version of the app [X^2 (1, N = 93) = 48.06, p < .001]. The updated version included three more BCTs than the outdated version and had a higher mean occurrence of each BCT (see Table 1). Although each version comprised of BCTs from eight of the BCTTv1 taxonomy domains, the outdated version included a BCT from ‘repetition and substitution’ while the updated version included BCTs from ‘reward and threat’. The outdated version of the app incorporated the BCT ‘behavioural substitution’, however there was no evidence of this BCT in the updated version. Furthermore, the updated version was found to include the BCTs ‘information about social and environmental consequences’, ‘information about emotional consequences’, ‘social reward’ and ‘social incentive’ which were not present in the outdated version of the app. There was a comparatively higher emphasis on the domain of ‘natural consequences’ in the updated version while the outdated version focused more on ‘social support’. While the BCT ‘salience of consequences’ was delivered in both versions of the app by the visual depiction of salt, fat and sugar content in the form of salt sachets, fat lumps and sugar cubes, the updated version also incorporated a virtual reality and animation element. This provided the user with a 3D image imposed onto the camera view of their device, bringing to life the nutritional content.

Across both versions, most of the BCTs coded were designed to instigate both app engagement (through scanning barcodes) and healthier dietary choices, with the exception of ‘instruction on how to perform behaviour’ which targeted app engagement only, and ‘prompts/cues’ which targeted dietary choices only.

3.3.4 Near-misses

For the outdated version, coders rated ‘information about social and environmental consequences’ as a near-miss. This related to phrases such as “Woohoo! This choice makes a great start to the day.” Although the language used indicates approval, it was not clear that such a phrase was related to approval of the target behaviour, a pre-requisite for coding this BCT.

For the updated version, ‘social reward’ was coded as a near-miss and referred to the ‘Good Choice’ badge feature of the app. The presence of a ‘Good Choice’ badge was described on the Food Scanner app store and online. However, it was coded as a near miss because the badge was not displayed while using the app (despite extensive app use).

Across both app versions, ‘behavioural practice’ was considered a near-miss. ’Behavioural practice’ referred to a feature where users are prompted to scan barcodes of packaged products. However, it was not clear that the feature explicitly prompted practice in a context where the performance is necessary.

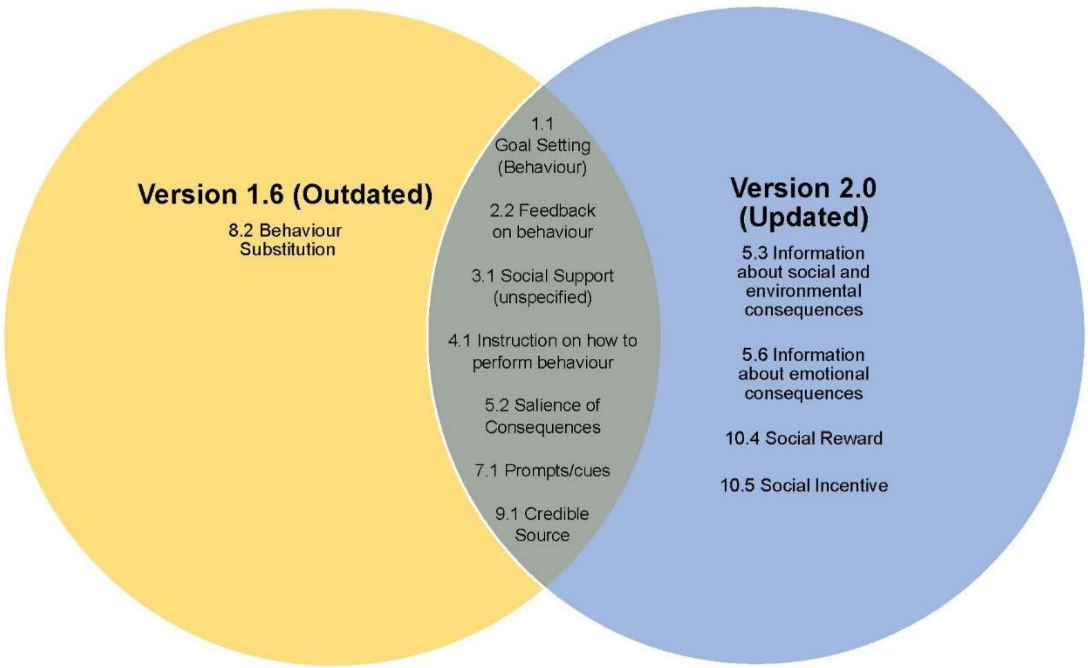


Figure 3. Venn diagram displaying the BCT commonalities and differences between the outdated and updated versions of the Change4Life Food Scanner App

Table 1. A comparison of Behaviour Change Techniques in the Outdated (v1.6) and Updated (v2.0) versions of the Food Scanner app

	Version of Change4Life Food Scanner App			
	Outdated Version (v1.6)		Updated Version (v2.0)	
Code, BCT Label and Domain	**BCT Present**	**No. of Occurrences of BCT**	**BCT Present**	**No. of Occurrences of BCT**
1.1 Goal Setting Behaviour *Goals and Planning*	✓	2	✓	1
2.2 Feedback of Behaviour *Feedback and Monitoring*	✓	7	✓	7
3.1 Social Support (Unspecified) *Social Support*	✓	3	✓	1
4.1 Instruction on how to perform the behaviour * *Shaping Knowledge*	✓	2	✓	5
5.2 Salience of Consequences *Natural Consequences*	✓	1	✓	2
5.3 Information about social and environmental consequences *Natural Consequences*	X	0	✓	2
5.6 Information about emotional consequences *Natural Consequences*	X	0	✓	2
7.1 Prompts/cues[†] *Associations*	✓	2	✓	3
8.2 Behaviour Substitution *Repetition and Substitution*	✓	2	X	0

9.1 Credible Source	✓	1	✓	1
Comparison of Outcomes				
10.4 Social Reward	X	0	✓	2
Reward and Threat				
10.5 Social Incentive	X	0	✓	1
Reward and Threat				
Total Number of BCTs present	8	--	11	--
Mean occurrence of each BCT	--	2.5	--	2.7

NB. BCTs have been coded for both app engagement and improved dietary choices.
* BCT targeted app engagement only
† BCT targeted dietary choices only
✓ BCT present
X BCT absent

3.4 Discussion

Both versions of the Change4Life Food Scanner app used a small proportion of the total number of BCTs within the BCTTv1. The outdated version used 8.6% and the updated version used 11.8%. Across both app versions, the BCTs ‘goal setting (behaviour)’, ‘feedback on behaviour’, ‘social support (unspecified)’, ‘instruction on how to perform behaviour’, ‘salience of consequences’, ‘prompts/cues’, ‘credible source’, ‘behavioural substitution’, ‘information about social and environmental consequences’, ‘information about emotional consequences’, ‘social reward’ and ‘social incentive’ were found to be present. The updated version of the app was comparatively more BCT intensive in terms of content and occurrence and had a higher focus on the domain ‘natural consequences’, adopting three BCTs from this domain, whereby the outdated version only encompassed one BCT from this domain.

The BCT content of the Food Scanner app aligns with similar research that has investigated BCT presence in dietary interventions and includes effective BCTs. BCTs from the domains ‘goals and planning', 'feedback and monitoring', 'shaping knowledge' and 'social support' have been found to be common components of dietary interventions (Schoeppe et al., 2017, Flaherty et al., 2018, Villinger et al., 2019, Antezana et al., 2020). These BCTs (with the exception of 'shaping knowledge') have been outlined within NICE guidance as effective strategies for changing behaviour (National Institute for Health and Care Excellence, 2014). Of the BCTs used in the Food Scanner app, 6/8 (75%) BCTs in the outdated version and 8/11 (73%) BCTs in the updated version have been found to have an effectiveness ratio of 50% or greater in similar interventions (Ashton et al., 2020, Ashton et al., 2019, Martin et al., 2013). Other BCTs were included that have also been used in previous research but have limited evidence for their effectiveness ('social incentive' [updated app version], 'instruction on how to perform behaviour' and 'credible source' [both versions]) (Ashton et al., 2020).

Although, the updated version of the Food Scanner app includes more BCTs than the outdated version, the outdated version had a greater percentage of BCTs that have been found to be effective (Ashton et al., 2020, Ashton et al., 2019, Martin et al., 2013). The outdated version of the app included the BCT 'behavioural substitution', however, this BCT was removed in the updated version. Evidence suggests that 'behavioural substitution' has a high effectiveness ratio in dietary interventions (Ashton et al., 2019), suggesting that the app update removed a potentially effective BCT. There are however other indicators of intervention effectiveness. For instance, the updated version had a greater number of BCT occurrences in comparison to the outdated version. A previous study found a positive correlation between BCT frequency and intervention effectiveness indicating that the update could improve the efficacy of the Food Scanner app (Direito et al., 2014). These findings contrast with a systematic review which found no association between the number of BCTs and intervention effectiveness (Villinger et al., 2019). Given the contradictory evidence, further research is needed to investigate the association between BCT prevalence and intervention effectiveness.

The Food Scanner app, particularly the updated version, has a strong focus on 'natural consequences' and 'feedback', delivering BCTs from these domains in several ways. BCTs 'salience of consequences' and 'feedback on behaviour' have been found to have effectiveness ratios of 83% and 52%, respectively (Ashton et al., 2020, Ashton et al., 2019, Martin et al., 2013). Evidence suggests interventions that have a narrow BCT focus (contain several BCTs from the same domain) tend to be more effective, further indicating that the updated version of app possesses a feature of an effective intervention (Villinger et al., 2019, Samdal et al., 2017, Webb et al., 2010). While both versions deliver the BCT ‘salience of consequences’ through the visual depiction of nutritional content in the form of salt sachets, fat slabs and sugar cubes, the updated version incorporates a 3D and animation element to the delivery. This emphasises the consequences of consuming nutrient poor food in an innovative way making the mechanism of delivery of this BCT more prominent in the updated version. Additionally, while the updated version of the app incorporates ‘information about social and environmental consequences’, this BCT has been found to have a non-effective ratio of 100% in interventions tackling childhood obesity. This indicates that the app contains at least one BCT that may be ineffective in this setting (Martin et al., 2013). However, evidence suggests that inclusion of some ineffective BCTs does not have a detrimental impact on an intervention’s overall effectiveness (Villinger et al., 2019). Given that ‘information about social and environmental consequences’ has not previously been found to be an effective BCT, providing information about the health consequences instead may be an alternative solution. ‘Information about health consequences’ has been found to be an effective BCT in improving diets of children through parental behaviour change (Sutherland et al., 2021) and young adults with a 100% effectiveness ratio, and is one that is recommended for use in interventions with the same setting as the Food Scanner app (Ashton et al., 2019, Martin et al., 2013).

The coders noted incidences of near-misses. This included ‘information about social and environmental consequences’ (outdated version). Although this BCT has previously been found to have a 100% non-effectiveness ratio (Martin et al., 2013), its use has been advised through the use of the BCW within similar interventions (Curtis et al., 2015). Although ‘social reward’ was mapped within the updated version of the app, its presence could have been amplified thus potentially strengthening the impact of this BCT, given it has previously been reported to have a 57% effectiveness ratio (Ashton et al., 2020). ‘Behavioural practice’ was considered a near-miss in both versions of the app. Adjustment of the feature to prompt barcode scanning to explicitly prompt the practice of choosing healthier alternatives, could potentially improve the app’s effectiveness, given that this has been found to have a 100% effectiveness ratio in similar settings (Martin et al., 2013). Its inclusion within similar interventions has also been advised (Curtis et al., 2015, Wehling et al., 2020). Strengthening the content of the Food Scanner app could help increase BCT presence, and potential app effectiveness. Additional suggestions for app improvements are discussed in Chapters 6 and 8.

The effectiveness of BCTs adopted within interventions may depend upon the recipient. Therefore, caution should be taken when comparing results to previous studies. Although the Food Scanner app has been designed to improve dietary outcomes of primary school-aged children, the intervention will most likely be received by the parent. The healthiness of the home environment and decisions over what to feed their child will depend upon changes in parental behaviour. The app could also be seen as a "shared" intervention, whereby the parent engages the child and decisions are made collectively. Therefore, the use of BCTs within existing studies may not be fully applicable to the Food Scanner app. More recently, mHealth interventions targeting parents have used the BCW Framework to guide the inclusion of BCTs. The SWAP IT trial, which was found to be effective in reducing energy content of packed lunchboxes, integrated six BCTs, including 'provision of information about health consequences', 'action planning', 'demonstration of behaviour', 'adding objects to the environment', 'prompts and cues', and 'instruction on how to perform the behaviour' (Sutherland et al., 2019a, Sutherland et al., 2021). Of these, only 'prompts and cues', and 'instruction on how to perform the behaviour' were identified within both versions of the Food Scanner app. Similarly, the Health Heroes app, which aimed to manage healthy portion sizes and a balanced diet in children, was also developed through the guidance of the BCW (Curtis et al., 2015). Twenty-one BCTs were identified, of which six are present within the Food Scanner app. These included 'instruction on how to perform the behaviour', 'feedback on behaviour', 'goal setting', 'prompts/cues', 'information about social and environmental consequences' (updated version only), and 'social support (unspecified)'. Results relating to preliminary effects of the Change4Life Food Scanner app in improving dietary choices are outlined in Chapter 6, followed by a discussion of the use of effective BCTs within interventions (Chapters 6 and 8).

Existing research has identified several effective BCTs in interventions of childhood obesity prevention that have not been implemented within the Food Scanner app. Guidance has recently been published on the use of suitable BCTs for interventions which support families with primary school-aged children on a 'healthy weight journey' (Wehling et al., 2020). Seven of seventeen (41%) of the recommended BCTs were incorporated in the Food Scanner app including ‘goal setting (behaviour)’, ‘feedback on behaviour’, ‘social support (unspecified)’, ‘instruction on how to perform behaviour’, ‘social reward’, ‘prompts/cues’ and ‘behavioural substitution’ (dropped in the updated version). Other suitable BCTs that were recommended but were not present within the Food Scanner app included ‘problem solving’, ‘action planning’, ‘self-monitoring of behaviour’, ‘demonstration of behaviour’, ‘behavioural practice/rehearsal’, ‘graded tasks’, ‘restructuring the physical environment’, ‘behavioural contract’, ‘information about health consequences’ and ‘framing/reframing’. Further consideration of the inclusion of these BCTs may strengthen the app’s effectiveness in improving dietary choices. However, little is currently known whether the inclusion of an exhaustive number of BCTs have positive or adverse impacts on behaviour change given that this will increase app complexity. This may interfere with users’ experience of, and engagement with the app (Davis and Ellis, 2019).

One method to deliver ‘feedback on behaviour’ in the updated version of Food Scanner app was to include ‘woah badges’ when high fat/sugar/salt items were scanned. Such feedback messages may produce defensive responses (Kessels et al., 2010) and deter users from engaging with the app. In other work, parents rated a disease-based image as the least acceptable option to promote selection of healthy beverages for their children, possibly due to triggering a negative emotional response (Mantzari et al., 2018). Similarly, a meta-analysis showed that threat-inducing messages are less effective in achieving behaviour change in comparison to other methods (Earl and Albarracín, 2007). Language tone and content used in food purchasing apps can also impact user engagement. Personalised messages have been found to enhance user experience and message salience (Flaherty et al., 2019). Furthermore, the integration of notifications and reminders were also helpful to prompt goal priorities. When carrying out app updates, it is therefore important to consider the delivery of BCTs in an engaging format. This will encourage users to engage with the app for the minimum time necessary to gain sufficient exposure to BCTs that could lead to potential behaviour change (Michie et al., 2017). Barriers and facilitators to app engagement are further discussed in Chapters 5, 6 and 8.

This research contributes to the growing body of literature concerning the use of effective BCTs in dietary app-based interventions for primary school-aged children and offers a unique insight into how BCT content evolves with app updates and maintenance. However, there are some limitations. Firstly, there was minimal information available concerning the design and content development of the app. For example, it was unclear whether the app was designed according to behaviour change theory. This information would have enabled the coders to verify the presence of BCTs and flag any shortcomings in BCT delivery. Secondly, only the BCT content of accessible features of the app could be mapped; there may have been more BCTs present but the features in which they were delivered were not accessed. This happened on at least one occasion; despite the use of the Food Scanner, and purposely scanning healthy products, the 'Good Choice badge' feature could not be accessed. Thirdly, coding the outdated version of the app was not fully independent. The second coder used secondary online research due to a major app update leading to the unavailability of v1.6. Despite this, there was a high inter-rater reliability between coders when mapping the outdated version of the app. Fourthly, there is no standardised guidance on identification of near misses. The current study used general guidance from the online training, however it is possible that other near misses were present but overlooked. Given that the identification of near misses could improve future revisions of intervention content, a standardised process for their identification ought to be developed or potentially incorporated within existing BCT coding frameworks. This will highlight missed opportunities of BCT inclusion which may strengthen app development and app effectiveness. Finally, no formal comparison of BCTs was made between differences in dietary choices during the mapping process. More extensive evaluation of the BCT content could compare the use of BCTs between food groups. However, a comprehensive table of BCTs alongside direct examples from the app has been provided within Appendix 2 where it is apparent which food group has been targeted within BCT use.

To advance the evidence-base around the use of effective BCTs, an evaluation of the app is necessary to verify the results of this current research. A pilot and feasibility trial will be undertaken within Chapters 6 and 7 to investigate whether the app is effective in reducing children's sugar consumption over a 3-month period (Mahdi et al., 2019, Mahdi et al., 2023). There is also evidence to suggest that multicomponent interventions, whereby the use of a health app is part of a more complex intervention, are more effective than standalone app interventions (Schoeppe et al., 2016). Although there is benefit in evaluating the components of complex interventions separately, future research needs to evaluate the Food Scanner within the broader context of the Change4Life campaign, given that the two are intertwined and the app signposts users to further information on the Change4Life webpages. Recent findings have suggested the effectiveness of a Sugar Smart app (an older version of the Food Scanner app), in reducing sugar consumption when evaluated as part of the multicomponent national Change4Life Sugar Smart campaign. However, findings were not maintained at 12 months follow up (Bradley et al., 2020). The BCTs used in the Sugar Smart app are unknown. However, the app was designed to specifically concentrate on sugars only, rather than macronutrients in the diet, and app features were more simplified than v1.6, the app version under investigation throughout this thesis (Bradley et al., 2020). Given that the use of BCTs and design features of the Food Scanner app are currently more advanced, users may have a more favourable experience with the app now than before. In addition, although the current study investigated the presence of BCTs, important consideration is needed regarding intervention fidelity. Intervention fidelity explores the extent to which an intervention is being delivered, received and enacted in the way it was designed to (Borrelli, 2011). Although all app-based interventions will be delivered similarly, the exposure to BCT content and design features is highly dependent upon users' engagement with the app (Yardley et al., 2016, Perski et al., 2017), and consequently app success in changing behaviour. As such, all BCTs identified within the Food Scanner may not be received by the user. Incorporating measures of intervention fidelity is an integral part of intervention evaluation and ought to be incorporated in future trials of digital interventions. Currently this is a gap within the mHealth literature and has been an underexplored area of research. Suggestions for enhanced measures of app engagement and content exposure are explored within Chapter 8.

In conclusion, the current research showed the Change4Life Food Scanner app contains several BCTs that have been found to be effective in dietary interventions. The app does not include many BCTs that have previously been found to be effective within family-based interventions promoting a healthy weight. Recommendations to improve the content of the Change4Life Food Scanner app include strengthening the delivery of features, including more potentially effective and recommended BCTs which are from the same or similar domain and ensuring major app updates do not remove potentially effective BCTs. Chapters 4-5 will explore how the Food Scanner app can be evaluated in light of this information, whilst Chapters 6-7 will explore the feasibility and acceptability of evaluating the Change4Life Food Scanner app, which will further our understanding of the use of appropriate BCTs to engage families.

4. Methods for the Economic Evaluation of Obesity Prevention Dietary Interventions in Children: A Systematic Review and Critical Appraisal of the Evidence

The previous chapters have set out a foundation of knowledge relating to dietary mobile applications, including design features and BCTs. To design a plausible evaluation framework within the scope of this thesis, a systematic review and critical appraisal was conducted to explore the methods for the economic evaluation of obesity prevention dietary interventions in children. This systematic review will help provide insights into evaluation approaches of dietary mobile interventions alongside guidance on how such methods can be adopted when evaluating the Change4Life Food Scanner app. This systematic review has been published within a peer-reviewed journal (Mahdi, S., Marr, C., Buckland, N. J. and Chilcott, J. (2022) 'Methods for the economic evaluation of obesity prevention dietary interventions in children: A systematic review and critical appraisal of the evidence', *Obesity Reviews, 23*(9), pp. e13457. DOI: https://doi.org/10.1111/obr.13457). This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY) and the copyright therefore belongs to the authors. It has been reproduced, with the permission of all co-authors, for the purposes of this thesis.

4.1 Introduction

In 2016, the World Health Organisation estimated that over 18% of 5-19 year olds were affected with overweight or obesity (World Health Organization, 2021). The main cause of overweight and obesity is an imbalance between energy consumption and energy expenditure. Diets high in saturated fat and sugar lead to excess energy consumption and contribute to the prevalence and burden of obesity related diseases, including type 2 diabetes mellitus, cardiovascular disease and cancers (Butland et al., 2007, World Health Organization, 2013, Bray, 2004). Interventions that aim to improve population diet are therefore a priority for policy makers, and evidence on the economics of such interventions is becoming internationally recognised as being crucial to support effective public health policy making (National Institute for Health and Care Excellence, 2015, Institute for Clinical Economic Review, 2020, Rabarison et al., 2015, Canadian Agency for Drugs Technologies in Health (CADTH), 2017).

Health economic evaluations assess additional costs and benefits of an intervention against a comparator (e.g. usual practice). How this is conducted is dependent upon several factors, including the type of economic evaluation approach and whether a healthcare or societal perspective is adopted. Economic evaluations can be conducted alongside clinical trials, where costs and benefits are derived from trial data. Alternatively, clinical effectiveness data can be input into an economic model to derive long-term cost and benefit outcomes. Where the former provides a cost-effectiveness estimate using actual trial data, the latter provides long-term projections of healthcare and societal resource use, costs and associated benefits. There are four main types of economic evaluation: (i) cost-minimisation analysis: when different treatment options have equivalent outcomes, therefore the cheapest option is used, (ii) cost-effectiveness analysis (CEA): a comparison of additional costs by additional benefits (natural units); (iii) cost-utility analysis (CUA): a comparison of additional costs by additional health-related utilities (e.g. quality-adjusted life years, disability adjusted life years and health years gained); and (iv) cost-benefit analysis (CBA): health and/or non-health benefits are valued in monetary terms (distinctly different to a return on investment [ROI] which accounts for financial benefits only) (Drummond et al., 2015).

Six systematic reviews have been identified concerning the economics of childhood obesity prevention (Erdol, 2014, McKinnon et al., 2016, Doring et al., 2016, Oosterhoff et al., 2018, Korber, 2015, Zanganeh et al., 2019). Most recently, Zanganeh et al. (2019) conducted a quality appraisal of the literature and reviewed the methods adopted within economic evaluations of nutrition and physical activity-based interventions. However, this study was primarily descriptive in nature and did not provide a critical analysis of the methods, including strengths and limitations, adopted within studies. Oosterhoff et al. (2018) also examined key aspects in the design of economic evaluations on school-based interventions and highlighted key issues and recommendations for future economic evaluations. However, such reviews have either: lacked a comprehensive search strategy, potentially compromising the inclusion of key texts (Erdol, 2014, McKinnon et al., 2016, Oosterhoff et al., 2018); focused on a narrow population group or intervention setting (Doring et al., 2016, Oosterhoff et al., 2018); or focused solely on physical activity interventions (Korber, 2015).

There is a lack of recent consensus on the scope and content of model based economic evaluations for childhood obesity prevention dietary interventions (Lenoir-Wijnkoop et al., 2011), leading to variations in assumptions adopted and disparities in final cost-effectiveness outcomes. This systematic review conducts a comprehensive search and assessment of the literature to develop an understanding of the design of economic evaluations and models, their structure, and methods. The aim of this review is to describe current approaches to the economic evaluation of childhood obesity prevention interventions and make recommendations to assist in the design of such an evaluation in relation to the Food Scanner app (see Chapter 7).

4.2 Methods

4.2.1 Search strategy and selection criteria

The systematic review was registered on PROSPERO [CRD42018115790]. It was initially conducted between November 2018 to January 2019 and later updated to December 2021. Bibliographic databases included Medline/PubMed, PsycInfo, Embase, Cochrane Library, Web of Science, SCOPUS, Centre for Reviews and Dissemination (CRD [DARE, NHS EED and HTA]), EconLit and the Cost Effectiveness Analysis (CEA) Registry. Databases were systematically searched using piloted free text and MeSH terms (Appendix 3) (Centre for Reviews and Dissemination, 2008). In addition, the grey literature was searched using broad terms: ‘economic evaluation’, ‘child’ and ‘obesity’ and/or ‘diet’. This included Google, Google Scholar, Grey Literature Report in Public Health and OpenGrey.eu. For Google-based searches, the first 20 pages of results were examined. Citations of included studies were also searched. Due to the high agreeability rate between the two reviewers in the first set of screening, and resource constraints, only one reviewer screened studies and extracted data from the updated search strategy, unless stated otherwise. Findings from the initial and updated search strategy have been pooled and reported in accordance with PRISMA guidelines (Liberati et al., 2009).

4.2.1.1 Inclusion criteria

Criteria for eligible studies included interventions targeting diet and nutrition, either solely or as part of a multicomponent intervention, and with a focus on obesity prevention. Economic studies included economic evaluations alongside trials, or model-based studies of a single intervention only. The economic analysis of a single intervention, rather than pooled effectiveness data of multiple interventions, was selected due to the high level of heterogeneity found within the design and content of dietary interventions (Wolfenden et al., 2014, Brown et al., 2019a). This also enables an investigation of approaches adopted when single clinical studies are evaluated, allowing easier replication for those taking on a similar approach. No restrictions were placed on the design of the intervention under investigation nor the type of comparator under investigation. The review was restricted to English-language papers on studies conducted in high-income countries targeting 2-18 year olds. This starting age was chosen as children's diets and nutritional needs are comparatively different to subsequent years (NHSUK, 2019, U.S. Department of Agriculture and U.S. Department of Health and Human Services, 2020). No restrictions were placed on clinical or economic study outcomes, which included both direct or proxy measures of obesity prevention. No restrictions were placed on the setting in which interventions were based.

4.2.1.2 Exclusion criteria

Studies published before the year 2000 were excluded, to ensure the inclusion of up-to-date practices, and for pragmatic purposes, given available resources. Modelling studies of hypothetical policies were excluded as they rely on data from multiple intervention studies rather than the evaluation of a single intervention. This review focused on obesity prevention; therefore, weight loss and obesity treatment studies were excluded. Studies targeting niche population and patient groups were also excluded. Finally, studies that measured obesity-related health conditions with no reference to obesity-prevention or dietary improvements within their aims were excluded.

4.2.2 Data extraction and quality appraisal

Two data extractions tables were developed, piloted and refined. Two reviewers (SM and CM) independently extracted data and compared for completeness and accuracy. Any conflicts were discussed until agreement was met.

The Cochrane Public Health Group data extraction and assessment template form (Cochrane Public Health, 2011) and the Consolidated Standards of Reporting Trials (CONSORT) 2010 checklist (Schulz et al., 2010) informed the data extraction table of effectiveness studies. Extracted data included study design, intervention description (settings, comparator, strategy and duration), population, sample size, participant characteristics, attrition rates, missing data management, outcome measures and results. For extraction of economic evaluation data the Consolidated Health Economic Evaluation Reporting Standards checklist was adopted (Husereau et al., 2013). This included study design, economic outcomes, perspective, time horizon, discount rate, resources and costs, evaluation/modelling methods, databases utilised, methods for dealing with uncertainty and cost-effectiveness outcomes.

Following guidance provided by the CRD the BMJ 35-item checklist was used to assess the quality of economic evaluations (Drummond and Jefferson, 1996). Items designed for the critical appraisal of decision-analytic models developed for health technology assessment (HTA) were embedded to cover issues relating to modelling studies (Philips et al., 2004). These included structural assumptions, model type, time horizon, health states and cycle length. Two items from the Paediatric Quality Appraisal Questionnaire were also embedded in order to capture insights into methods for capturing parent and child impacts, including productivity and school absence (Ungar and Santos, 2003). One reviewer assessed the quality of all studies (SM) and a second reviewer (CM) independently validated 20%.

4.2.3 Data synthesis

A narrative synthesis of the methods used by the economic evaluations was conducted. Characteristics of effectiveness and cost-effectiveness studies were summarised and details concerning economic evaluation and modelling study methods were identified, compared and set within the context of the broader methods literature. Descriptions of cost-effectiveness studies, together with reported sensitivity analyses, were used to make recommendations concerning the scope and content of economic evaluations, models and key parameters. Research findings are presented based on a classification of key methodological challenges adapted from Weatherly et al. (2009). Within their paper several reviews exploring the economics of various public health interventions were investigated in which key methodological challenges were commonly identified across studies: attribution of effects; measuring and valuing outcomes; intersectoral costs and consequences; and equity considerations.

4.3 Results

4.3.1 Literature search: identification of economic analyses

In the search conducted between December 2018-January 2019, 13,706 studies were initially identified and 3931 duplicates were removed. One reviewer (SM) screened 9775 titles and excluded 7520 studies that were not related to the main inclusion criteria relating to obesity prevention (phase 1 screening). Two reviewers (SM and CM) independently screened 2255 titles and abstracts (phase 2 screening). There was 71% agreeability between reviewers and after discussions a final number of 45 studies were included for full text screening (phase 3 screening). Seventeen studies were independently included and 22 excluded, whilst the remaining six studies were discussed between reviewers leading to a further two inclusions. One additional paper was identified via the reference list of included studies and included in the review (Mernagh et al., 2010). In total, 20 papers comprising of 19 separate studies, with one study split across two papers (Haby et al., 2006, Carter et al., 2009), were included in the systematic review.

In the updated search strategy conducted up to December 2021, 5563 studies were initially identified, and 1336 duplicates were removed. One reviewer (SM) screened 4227 titles and excluded 3145 studies that were not related to the main inclusion criteria relating to obesity prevention (phase 1 screening), followed by the screening of 1082 titles and abstracts (phase 2 screening). A final number of 27 studies were included for full text screening (phase 3 screening) whereby a second reviewer (CM) screened 30% of full-texts. There was 100% agreeability between the two reviewers leading to the inclusion of 7 additional studies and the exclusion of 20. No additional papers were identified from references or the grey literature.

In total, 27 papers comprising of 26 separate studies were included within this systematic review, and 46 papers were excluded overall after full-text screening. Main reasons for exclusion included: not an economic analysis (14/46), not based on a single effectiveness study, such as a hypothetical policy (13/46), not meeting criteria for population characteristics, such as age (8/46) and not an obesity prevention nutrition-based intervention (7/46). Four additional studies were excluded due to there being no intervention comparator, the study was not in the English language, the authors had no access to the paper and study data was previously reported and had been included in the initial search strategy. Figure 4 shows the pooled study selection process.

Quality appraisal outcomes are presented in Appendix 4 and Appendix 5. There was 81% concordance in the scoring of studies between the two reviewers. None of the studies fulfilled all the quality criteria and only 19/35 items from the BMJ checklist were fulfilled by at least 80% of studies.

4.3.2 Study characteristics

4.3.2.1 Characteristics of intervention programmes

With the exception of two studies, all were school-based interventions (Haby et al., 2006, Reeves et al., 2021). Four studies self-identified as school and community-based interventions (McAuley et al., 2010, Moodie et al., 2013, Brown et al., 2007, Brown et al., 2021), one targeted day care services (Reeves et al., 2021) and one was a youth-camp based intervention (Haby et al., 2006). Eight economic studies were solely based on diet and nutrition interventions (An et al., 2018, Haby et al., 2006, Te Velde et al., 2011, Mernagh et al., 2010, Brown et al., 2021, Reeves et al., 2021, Reilly et al., 2018, Kenney et al., 2019), and 15 were nutrition and physical activity based (Adab et al., 2018, Beets et al., 2018, Brown et al., 2007, Conesa et al., 2018, Ekwaru et al., 2017, Graziose et al., 2017, Haby et al., 2006, Ladapo et al., 2016, McAuley et al., 2010, Mernagh et al., 2010, Rush et al., 2014, Wang et al., 2008, Coffield et al., 2019, Oosterhoff et al., 2020, Vieira and Carvalho, 2019).

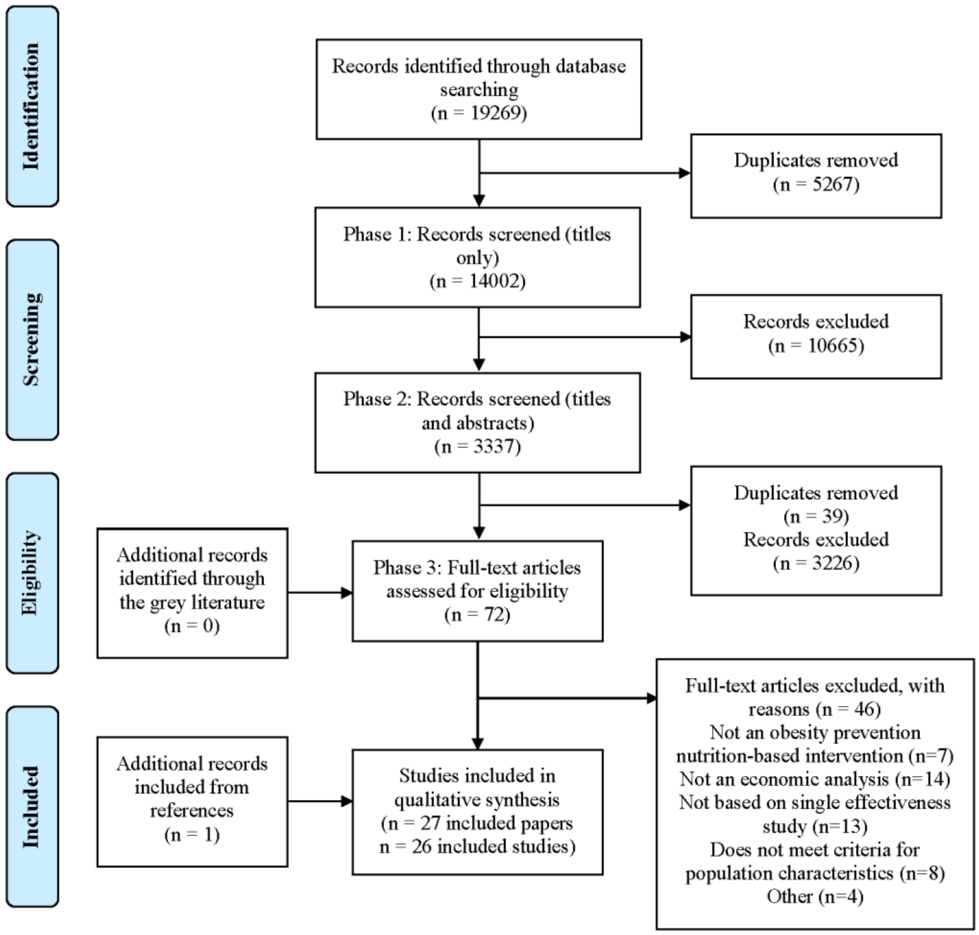


Figure 4. PRISMA flowchart of the study selection process

The majority of interventions were compared to a usual practice or 'do nothing' scenario (Adab et al., 2018, An et al., 2018, Brown et al., 2007, Conesa et al., 2018, Ekwaru et al., 2017, Graziose et al., 2017, Haby et al., 2006, Kesztyus et al., 2013, Rush et al., 2014, Wang et al., 2008, Wang et al., 2003, Wyatt et al., 2018, Mernagh et al., 2010, Coffield et al., 2019, Kenney et al., 2019, Reeves et al., 2021, Vieira and Carvalho, 2019, Moodie et al., 2013). One intervention was compared to a control condition where the control school was given money to purchase school equipment (McAuley et al., 2010), and four interventions were compared to usual practice with delayed intervention exposure (e.g. waiting list) (Kesztyüs et al., 2017, Ladapo et al., 2016, Brown et al., 2021, Beets et al., 2018). One study comprised of three intervention arms (Reilly et al., 2018), and another comprised of two (Oosterhoff et al., 2020). Intervention arms were compared between each other alongside a usual-practice comparator, whereas one study compared outcomes between two interventions with no control comparator (Te Velde et al., 2011). Further intervention characteristics are described in Appendix 6.

4.3.2.2 Economic evaluation approach

Table 2 summarises methods and results of economic analyses. Twelve studies conducted an economic evaluation alongside a clinical trial, of which one conducted a cost-utility analysis (Adab et al., 2018), eight conducted a CEA (Beets et al., 2018, Conesa et al., 2018, Kesztyüs et al., 2017, Kesztyus et al., 2013, Ladapo et al., 2016, Wang et al., 2008, Brown et al., 2021, Reilly et al., 2018) and one conducted both (McAuley et al., 2010). One study conducted a cost-consequence analysis (CCA) (Vieira and Carvalho, 2019) and one conducted both a CEA and CCA (Reeves et al., 2021). Fourteen studies modelled long-term health and cost outcomes, of which eight applied cost-utility methods (Ekwaru et al., 2017, Graziose et al., 2017, Rush et al., 2014, Wyatt et al., 2018, Mernagh et al., 2010, Haby et al., 2006, Moodie et al., 2013, Oosterhoff et al., 2020), one conducted a CBA (An et al., 2018), and three conducted both (Brown et al., 2007, Te Velde et al., 2011, Wang et al., 2003). One paper conducted a CEA (Kenney et al., 2019) and one paper conducted a ROI analysis (Coffield et al., 2019). Eight papers adopted Markov decision analytic models (An et al., 2018, Ekwaru et al., 2017, Wyatt et al., 2018, Mernagh et al., 2010, Haby et al., 2006, Moodie et al., 2013, Kenney et al., 2019, Oosterhoff et al., 2020), two reported the use of decision trees (Wang et al., 2003, Wyatt et al., 2018) and the remainder did not refer to the modelling method adopted (Brown et al., 2007, Te Velde et al., 2011, Rush et al., 2014, Graziose et al., 2017, Coffield et al., 2019).

4.3.2.3 Study perspectives and intervention costs

Study perspective refers to the scope of the criteria that the decision maker uses in coming to a decision or defining policy. In a health economic analysis, it therefore includes both health outcomes and costs in relation to the sector under investigation (e.g. NHS, public sector, or societal). All but one study stated the perspective of the economic analysis (Beets et al., 2018). Fourteen studies claimed a societal perspective (An et al., 2018, Brown et al., 2007, Graziose et al., 2017, Haby et al., 2006, Kesztyüs et al., 2017, Kesztyus et al., 2013, McAuley et al., 2010, Te Velde et al., 2011, Wang et al., 2008, Wang et al., 2003, Vieira and Carvalho, 2019, Coffield et al., 2019, Kenney et al., 2019, Moodie et al., 2013), four studies were reported from a healthcare perspective (Rush et al., 2014, Wyatt et al., 2018, Mernagh et al., 2010, Reilly et al., 2018), and three studies conducted both (Te Velde et al., 2011, Oosterhoff et al., 2020, Reeves et al., 2021). Three studies also reported from an institutional/school system perspective (Conesa et al., 2018, Ekwaru et al., 2017, Ladapo et al., 2016) and one from a public sector perspective (Adab et al., 2018).

This section will describe how intervention costs were collected and what they consisted of. Discussion of non-intervention costs are discussed further below. Nineteen studies reported an estimate of staff salaries to implement the intervention, training delivery or training receipt (Graziose et al., 2017, Kesztyus et al., 2013, Wang et al., 2008, Vieira and Carvalho, 2019, Brown et al., 2021, Coffield et al., 2019, Reeves et al., 2021, Conesa et al., 2018, Ekwaru et al., 2017, Ladapo et al., 2016, Wyatt et al., 2018, Oosterhoff et al., 2020, Reilly et al., 2018, Kesztyüs et al., 2017, Wang et al., 2003, Kenney et al., 2019, Te Velde et al., 2011, Brown et al., 2007, Beets et al., 2018). Nineteen studies included costs of intervention material and material maintenance (where applicable) (Wang et al., 2008, Adab et al., 2018, Mernagh et al., 2010, An et al., 2018, Kesztyüs et al., 2017, Kesztyus et al., 2013, Wang et al., 2003, Brown et al., 2021, Coffield et al., 2019, Kenney et al., 2019, Vieira and Carvalho, 2019, Reeves et al., 2021, Te Velde et al., 2011, Wyatt et al., 2018, Oosterhoff et al., 2020, Reilly et al., 2018, Conesa et al., 2018, Ladapo et al., 2016, Brown et al., 2007). Examples include, water dispensers, books, handouts, sports equipment, food provision, and promotional costs. Ten studies reported additional costs, such as transport, overnight accommodation and utilities (Kesztyus et al., 2013, McAuley et al., 2010, Wang et al., 2008, Wang et al., 2003, Kenney et al., 2019, Vieira and Carvalho, 2019, Oosterhoff et al., 2020, Reilly et al., 2018, Ekwaru et al., 2017, Beets et al., 2018). Two studies reported intervention comparator costs, taking the form of usual school activity costs (Wang et al., 2008, Reeves et al., 2021). Intervention development costs were usually excluded, as this was considered a sunk cost. Five studies excluded school staff costs as the intervention was either embedded within the curriculum or did not increase staff workload

(Carter et al., 2009, Kesztyus et al., 2013, McAuley et al., 2010, Wang et al., 2003, Wyatt et al., 2018). One study reported the exclusion of unrelated health care costs due to additional years of life (Carter et al., 2009), and out of pocket expenses by individuals due to the intervention (Mernagh et al., 2010).

4.3.2.4 Time horizon and Discount rates

Discounting of costs and benefits is not required in the case where intervention effects last one year or less, as was the case in eight studies (Brown et al., 2021, Reeves et al., 2021, Reilly et al., 2018, Vieira and Carvalho, 2019, Kesztyüs et al., 2017, Kesztyus et al., 2013, Wang et al., 2008, Ladapo et al., 2016). However, two studies lasting two years or over were not discounted (Conesa et al., 2018, Beets et al., 2018). Ten studies indicated a discount rate of 3% (An et al., 2018, Brown et al., 2007, Ekwaru et al., 2017, Graziose et al., 2017, Haby et al., 2006, Te Velde et al., 2011, Wang et al., 2003, Coffield et al., 2019, Kenney et al., 2019, Moodie et al., 2013), four studies indicated a discount rate of 3.5% (Adab et al., 2018, Mernagh et al., 2010, Rush et al., 2014, Wyatt et al., 2018) and one study utilised a discount rate of 5% per annum (McAuley et al., 2010). One study applied a 4% discount rate for costs and a 1.5% discount rate for benefits, per annum (Oosterhoff et al., 2020). Though typically discount rates are selected based on country-specific recommendations, seven studies did not justify their discounting choices (Adab et al., 2018, Brown et al., 2007, Ekwaru et al., 2017, McAuley et al., 2010, Wang et al., 2003, Mernagh et al., 2010, Kenney et al., 2019).

4.3.2.5 Sensitivity analyses

All but three studies provided details of a sensitivity analysis (Beets et al., 2018, Brown et al., 2021, Vieira and Carvalho, 2019). Probabilistic sensitivity analysis (PSA) was most often conducted within studies and seeks to explore the impact of parametric uncertainty in the model (An et al., 2018, Brown et al., 2007, Carter et al., 2009, Haby et al., 2006, Ekwaru et al., 2017, Graziose et al., 2017, Te Velde et al., 2011, Wang et al., 2003, Kenney et al., 2019, Oosterhoff et al., 2020). Though the use of PSA allows description of the parametric uncertainty within economic outcomes, other methods investigate uncertainty of assumptions within the analysis through the variation of one (one-way sensitivity analysis) (Wang et al., 2003, Te Velde et al., 2011, Mernagh et al., 2010, Rush et al., 2014, Haby et al., 2006, Adab et al., 2018, An et al., 2018, Conesa et al., 2018, Graziose et al., 2017, Kesztyüs et al., 2017, Kesztyus et al., 2013, Ladapo et al., 2016, McAuley et al., 2010, Wang et al., 2008, Wyatt et al., 2018, Moodie et al., 2013, Reeves et al., 2021, Reilly et al., 2018, Coffield et al., 2019, Oosterhoff et al., 2020) or multiple parameters (two-way or multi-way sensitivity analysis) at a time (Haby et al., 2006, Graziose et al., 2017, Wang et al., 2003, Ekwaru et al., 2017, Coffield et al., 2019). Further details of modelling methods are outlined in Appendix 7 and the parameters commonly investigated within sensitivity analysis are outlined in Appendix 8.

4.3.3 Key findings and methodological challenges

Key findings have been categorised into four domains adapted from Weatherly et al. (2009): modelling long-term impact of interventions; measuring and valuing health outcomes; cost inclusions; and equity considerations. A critical appraisal of the methods undertaken within cost-effectiveness studies and key considerations for future economic evaluations of childhood obesity prevention strategies is provided in Table 3. The results are presented as a narrative synthesis and critical appraisal of the methods identified in the economic evaluations.

Table 2. Characteristics of economic evaluations

Author (year), country	Study design; outcomes	Perspective; time horizon; discounting	WTP threshold; Key results (base case)
Economic evaluations alongside trials			
Adab et al. (2018), UK	CUA; QALYs saved; cases of obesity prevented	Public sector; 18months; 3.5%/annum	£20-30,000 WTP; £46,083/QALY
Beets et al. (2018), USA	CEA; changes in no. of days F&V, water, deserts and SSBs served	Perspective not declared; 2 years; none declared	No WTP; Cost/child/week for one day improvement of F&V = \$0.16; SSB = \$0.18; Water = \$0.28; Dessert improvement = \$0.25
Brown et al. (2021), Australia	CEA; intervention cost and ICER per decrease in total and discretionary energy (kJ) packed inside the school lunchbox	Societal; 10 weeks; none	40 AUD WTP = 99% likely cost-effective; 0.54 AUD per reduction in total lunchbox energy, 0.24 AUD per reduction in kJ from discretionary foods.
Conesa et al. (2018), Spain	CEA; cost/no. of obesity cases avoided, decrease in obesity prevalence, BMI unit decrease, BMI z-score decrease	Institutional; 28 months; none declared	€5/child for 2% reduction in obesity prevalence WTP; €2.4/child/year to reduce the obesity prevalence in boys by 2%
Kesztyus et al. (2013), Germany	CEA; change in WC and WtHR	Societal; 1 year; none	€35 WTP; €11.11/1 cm of WC; €18.55 /unit of WtHR

Author (year), country	Study design; outcomes	Perspective; time horizon; discounting	WTP threshold; Key results (base case)
Kesztyüs et al. (2017), Germany	CEA; cases of obesity averted	Societal; 1 year; none	€123/year parental WTP; Costs/case of incidental abdominal obesity averted varied between €1515 - €1993 depending on the size of the observed population, €25.04/child /year
Ladapo et al. (2016), USA	CEA; F&V servings, free/reduced price lunches, full price lunches, all lunches served, snacks served	School; 5 weeks; none	$50,000 WTP; $1.20/additional fruit served during meals, 8.43/additional full priced lunch, $2.11/additional free/reduced-price lunch, $1.69/reduction in snacks sold
McAuley et al. (2010), New Zealand	CEA and CUA; kg of WGP; HRQoL using the HUI (parental proxy)	Societal; 2 years; 5%/annum	No WTP; no sig diff in HUI scores so did not continue with cost-utility analysis; $1708/kg of WGP in 7 y/o children; $664/kg of WGP in 13 y/o children
Reeves et al. (2021), Australia	CEA, CCA; service implementation of dietary guidelines	Health sector and modified societal perspective; 1 year; none	No WTP; CEA: intervention dominated, Intervention costs= 4634 AUD, control costs= 7640 AUD, ACER= -2897 AUD.
Reilly et al. (2018), Australia	CEA; compliance of healthy canteen policy	Health service delivery; 12 months; none	No WTP; Incremental cost per point increase in proportion of schools reporting adherence: High intensity vs usual: $2982, Medium intensity vs usual: $2627, Low intensity vs usual: $4730. No statistical difference in

Author (year), country	Study design; outcomes	Perspective; time horizon; discounting	WTP threshold; Key results (base case)
			effectiveness between high and medium intensity.
Vieira and Carvalho (2019), Portugal	CCA; comparison of costs and benefits (medical costs averted)	Societal; academic year; none	No WTP; total costs = €7915.53, €36.14/child, €18.18/child (scale-up), cost of treating obesity = €3849.15/adult with obesity
Wang et al. (2008), USA	CEA; cost/% BF reduction	Societal; 1 year; none	No WTP; $317/0.76% reduction in %BF/student
Modelling studies			
An et al. (2018), USA	CBA, MM; cases of childhood overweight prevented, net benefits	Societal; lifetime; 3%/annum	No WTP; $14.5 saved/dollar spent, $174 net benefit/student
Brown et al. (2007), USA	CUA, net monetary benefit; child and projected adult obesity cases averted	Societal; 64 years; 3%/annum	$30,000 WTP; $900/QALY saved, $68,125 base case net-benefit
Coffield et al. (2019), USA	ROI; comparison of costs accrued over 2 year intervention and costs averted 10 years post intervention	Modified societal; 10 years; 3%/annum	No WTP; intervention cost= $384,717, healthcare spending and productivity losses averted = $581,837, ROI = $1.51/$1 invested.

Author (year), country	Study design; outcomes	Perspective; time horizon; discounting	WTP threshold; Key results (base case)
Ekwaru et al. (2017), Canada	CUA, MM; person years of excess body weight, obesity, and chronic disease and QALYs based on 43 health states	School system; 80 years (males), 84 years (female); 3%/annum (costs discounted for 10 years and health outcomes up to 84 years)	\$50,000 WTP; \$33,421/QALY gained
Graziose et al. (2017), USA	CUA, decision analytic model; reduction in adult obesity, associated medical costs averted and QALYs saved	Societal; 10-40 years; 3%/annum	\$50,000 WTP; \$275/QALY
Haby et al. (2006) - benefits Carter et al. (2009) – costs, Australia	CUA, MM; total age-specific BMI units (kg/m2); DALYs saved; net cost/DALY saved	Societal; lifetime (100 years); 3%/annum	\$50,000 WTP; cost/DALY saved/child: \$21,100 (Tamir et al); \$5912.50 (Manios et al.); \$2800 (James et al.); \$38.57 (Gorn et al.)
Mernagh et al. (2010), New Zealand	CUA, MM; cost/QALY	Healthcare; lifetime (100 years); 3.5%/annum	\$50,000 WTP; \$205,101.45/QALY (APPLE); \$168,391.38/QALY (BAEW); \$134,252.49/QALY (SNPI)
Kenney et al. (2019), USA	CEA, MM; cost/case of obesity prevented	Modified societal; 10 years; 3%/annum	No WTP; \$6542 (95% UI: \$1741-\$11,918)/case prevented, \$0.31(95% UI:

Author (year), country	Study design; outcomes	Perspective; time horizon; discounting	WTP threshold; Key results (base case)
			$0.15-$0.55) healthcare cost saving/dollar invested
Moodie et al. (2013), Australia	CUA, MM; change in BMI and DALYs averted over the lifetime of the cohort	Societal; lifetime (100 years); 3%/annum	$50,000 WTP; $29,798/DALY saved (intervention population); $20,227/DALY saved (modelling to national level)
Oosterhoff et al. (2020), Netherlands	CUA, MM; cost/QALY	Healthcare and societal; lifetime (100 years); 4%/annum (costs), 1.5%/annum (benefits)	€20,000 WTP; €253.18 healthcare perspective intervention cost/child, €260,152 societal perspective intervention cost, ICER=€19,734
Rush et al. (2014), New Zealand	CUA; BMI and QALYs based on health state preference-based utilities	Healthcare; lifetime (2-100 years); 3.5%/annum	$50,000 WTP; Project Energize vs. 2006 younger children ICER: $30,438; Project Energize vs. 2004 older children ICER: $24,690
Te Velde et al. (2011), Netherlands	CUA; DALYs averted/100,000 children, NMB	Healthcare and societal; lifetime; 3%/annum	€19,600/DALY WTP; €5728/DALY averted (prochildren vs no intervention); €10,674/DALY averted (school guiten vs no intervention)

Author (year), country	Study design; outcomes	Perspective; time horizon; discounting	WTP threshold; Key results (base case)
Wang et al. (2003), USA	CUA, CBA; cases of adulthood overweight prevented and QALY saved	Societal; 25 years (40-65 years); 3%/annum	$30,000 WTP; $4305/QALY saved
Wyatt et al. (2018), UK	CUA, MM; QALY, life year gained, weight-related event avoided	NHS and Social Care; 30 years (33-62); 3.5%/annum	£20-30,000 WTP; Dominated

Abbreviations: ACER, average cost-effectiveness ratio; AUD, Australian dollars; BF, body fat; BMI, Body Mass Index; CAD, Canadian dollars; CBA, cost benefit analysis; CCA, cost-consequence analysis; CEA, cost-effectiveness analysis; CI, confidence interval; CUA, cost utility analysis; DALY, disability adjusted life year; F&V, Fruit and vegetables; HRQoL, health related quality of life; HUI, health utility index; IDC, intervention delivery costs; ICER, incremental cost-effectiveness ratio; MM, Markov Model; NMB, net monetary benefit; QALY, quality adjusted life year; ROI, return on investment; SSB, sugar sweetened beverage; WC, waist circumference; WGP, weight gain prevented; WtHR, waist to height ratio; WTP, willingness to pay; y/o, year old.

4.3.3.1 Modelling long-term impact of interventions

Several challenges in modelling the long-term impact of interventions were identified. These include the omission of childhood benefits, such as child health gains, when adopting lifetime horizons; the approaches used to project long-term outcomes from childhood to adulthood; and assumptions concerning the maintenance of intervention effects over time. Each of these main issues will now be discussed.

Methodological guidance commonly requires a lifetime horizon in economic analysis. This is particularly relevant in economic evaluations of obesity prevention studies, as many of the benefits of obesity prevention interventions will occur in adulthood. Nevertheless eight studies, all of which conducted economic evaluations alongside trials, based their time horizons on trial duration, which ranged from 5 weeks (Ladapo et al., 2016) to 28 months (Conesa et al., 2018). Whereas, modelling studies included cost and benefits over a lifetime (Mernagh et al., 2010, Rush et al., 2014, Haby et al., 2006, Moodie et al., 2013, Oosterhoff et al., 2020, Te Velde et al., 2011, An et al., 2018), or truncated analyses at 84 (Ekwaru et al., 2017), 65 (Brown et al., 2007, Wang et al., 2003, Wyatt et al., 2018), or 40 years (Graziose et al., 2017). Where truncated lifetime approaches were adopted, authors justified this based on a paucity of long-term outcomes data. Two studies modelled costs and benefits over a 10-year time horizon, as this was most relevant for policy makers and due to the long-term uncertainty regarding intervention effects (Kenney et al., 2019, Coffield et al., 2019). One study modelled intervention costs and benefits to cover both the childhood (up to 20 years old) and adulthood years (Oosterhoff et al., 2020). However, in most instances health outcomes and associated costs were only modelled throughout adulthood. In doing so, childhood economic benefits of interventions were often overlooked. Emerging research suggests that obesity impacts directly upon child health through early changes in metabolic risk factors (Huang et al., 2011, Hao et al., 2018) and negatively impacts on healthcare resources early on in life (Kuhle et al., 2011). Failing to include childhood health outcomes risks underestimating the economic benefits of early intervention and increases levels of uncertainty when longer time horizons are considered. Moreover, some decision makers are interested in early outcomes in their own right (Hayes et al., 2019). One solution is to present economic outcomes over a selected range of time horizons up to death, allowing the impact on uncertainty to be explicitly communicated (Hayes et al., 2019, Brown et al., 2019b). For example, results can be presented for 1, 5, 10, 20 and 50 years (Frew, 2016). This will enable the case of investment to be presented and will demonstrate how interventions can positively impact short-term outcomes and avert health complications that may not present until adulthood.

Studies utilised different approaches to modelling long-term outcomes from childhood-based effectiveness data. Most commonly, literature was used to obtain childhood to adulthood BMI trajectories (An et al., 2018, Graziose et al., 2017, Wyatt et al., 2018). In two cases, adult obesity impacts were based directly on rates of child overweight averted in two stages, firstly at 21-29 years, then again at 40 years. This was due to a lack of single progression estimates in published data arising within relatively early studies (Brown et al., 2007, Wang et al., 2003). Such methods did not account for within-group differences (e.g. sex) that may result in variability in intervention effects (unlike regression models) (Ekwaru et al., 2017). Alternatively, future weight was categorised based on population survey data in annual (Rush et al., 2014, Mernagh et al., 2010) or five year increments (Haby et al., 2006, Moodie et al., 2013). When this method was used, the impact of the intervention on mean BMI was subtracted from each simulated individual in the population cohort. This approach often assumed a constant relationship between BMI and age; in addition, subtracting the average decline in BMI across all individuals does not capture the variability of intervention effects across the varying characteristics in the intervention arm (e.g., whether weight gain prevention interventions result in greater BMI reductions amongst individuals with overweight/obesity as opposed to healthy-weight individuals). Another approach utilised a childhood BMI trajectory to estimate the effect of the intervention on child weight status up to 20 years of age, before entering an adulthood chronic disease model (Oosterhoff et al., 2020). In doing so, this method, accommodates assumptions surrounding the immediate and short-term effects of the intervention. The final approach used regression methods to estimate intervention impact on energy consumption and child weight given age, sex and height (Haby et al., 2006). This method controls for subgroup differences in weight status transition probabilities and therefore may result in improved model predictions. Studies that adopted a 10-year time horizon, either used an annual depreciation rate over 10 years (Coffield et al., 2019) or shifted children's individual growth trajectories, after exposure to the intervention to estimate future weight status (Kenney et al., 2019). Growth trajectory estimates considered demographic characteristics, growth, health behaviours and obesity risk (Kenney et al., 2019). In all cases, when deriving parameter estimates, it is imperative that new models adopt the latest epidemiological data to accurately reflect the rising trends in overweight/obesity, and associated costs.

Maintenance of intervention effects was assumed within all base-case analyses except one (Coffield et al., 2019). This is problematic because weight regain after weight loss is a well-documented problem, meaning that economic outcomes may be overestimated (Kraschnewski et al., 2010). One study used an annual depreciation rate of 2.62%, acknowledging the likelihood that intervention effects are not maintained in the long-term, which reflects clinical findings (Coffield et al., 2019). The depreciation rate was based on previous research that calculated the percentage of weight regain after weight loss over a 10-year follow-up period (Thomas et al., 2014). Since data on the maintenance of intervention effects within obesity prevention is currently lacking for children, adult-based estimates were adopted. To account for intervention effects degrading over time, another study used data on F&V consumption from adolescence to young adulthood to justify a 30% lifetime extrapolation of intervention effects within sensitivity analysis (Te Velde et al., 2011). Other studies examined the impact of declines in intervention effectiveness through sensitivity or scenario analysis (Mernagh et al., 2010, Kesztyus et al., 2013, Kesztyüs et al., 2017, Rush et al., 2014, Te Velde et al., 2011, Graziose et al., 2017, Ekwaru et al., 2017, Oosterhoff et al., 2020), allowing the assessment of parameter and structural uncertainty within the economic evaluations. These analyses led to substantial differences in cost-effectiveness outcomes in comparison to base-case scenarios. However, such assumptions were seldomly supported by evidence from longitudinal studies, with approximately half of studies justifying their choice of variables within sensitivity analysis (Adab et al., 2018, Haby et al., 2006, Carter et al., 2009, Kesztyus et al., 2013, Kesztyüs et al., 2017, McAuley et al., 2010, Moodie et al., 2013, Rush et al., 2014, Wang et al., 2008, Wang et al., 2003, Wyatt et al., 2018, Oosterhoff et al., 2020, Coffield et al., 2019, Kenney et al., 2019, Reeves et al., 2021, Reilly et al., 2018). Previous work has also demonstrated how incorporating an intervention decay rate can substantially affect the cost-effectiveness of an obesity intervention (Brown et al., 2019b), suggesting the importance of factoring in changes to intervention effectiveness over time.

Table 3. Critical appraisal of methods undertaken within cost-effectiveness studies

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
Modelling long-term impact of interventions		
Inclusion of childhood benefits	**(-)** Most modelling studies modelled outcomes in the adulthood years. Although children and/or adolescents were targeted within effectiveness studies, the shorter-term benefits of interventions on child health were not modelled. Inclusion of the shorter-term benefits may provide useful insights into the immediate benefits, if any, that interventions may have (Oosterhoff et al., 2020). ‡ §	• The short-term health and benefit gains from interventions in the childhood and adolescent years should be assessed potentially through modelling. Modelling the short-term outcomes could demonstrate immediate benefits. Such findings may be beneficial to decision makers who will not only see the benefits in the long term but also in the foreseeable future, within their funding cycles. §
Two-step projections	**(+)** Two-step probability estimates allow the use of multiple datasets to estimate child to adulthood BMI trajectories. This enables long-term modelling of outcomes in the absence of longitudinal data (Brown et al., 2007, Wang et al., 2003, Oosterhoff et al., 2020). Variations of this approach included the transformation of BMI population survey data to approximate future BMI values,	• As childhood obesity is linked to long term health disbenefits, all modelling studies should aim to carry out long-term projections of intervention outcomes. In cases where this may not be possible, shorter-term surrogate markers may be used where

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	in addition to the use of multiple cross-sectional studies of BMI in children and adults to inform multiple linear regressions based on age effects (Haby et al., 2006, Rush et al., 2014, Mernagh et al., 2010, Moodie et al., 2013). Alternatively, childhood BMI trajectories were used to estimate child weight status up to early adulthood before entering adulthood model (Oosterhoff et al., 2020). * † § **(+)** Growth trajectories factored covariates such as demographic characteristics and health behaviours, when used to predict future weight status.(Kenney et al., 2019, Oosterhoff et al., 2020) § **(-)** Within studies, the two-step approach generally assumed a constant relationship between BMI and age and did not account for individual differences. *§ **(-)** There is a danger of using available parameters that are outdated and not reflective of increased obesity rates in the last 20 years (Baker, 2019). †	they have well-established links to long-term outcomes. • New data should be incorporated within existing models in cases where evaluations are based on existing model structures. Epidemiological data will need to be constantly updated to provide more accurate estimates that are relevant to the trends faced in present societies. §
Multiple logistic regression models for weight status transition probabilities	**(+)** Inclusion of covariates when obtaining weight status transition probabilities (including age, sex and current weight status) allows for the consideration of expected	• Weight status transition probabilities should consider the differences in weight status transitions by subgroups.

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	variability between population subgroups which increases the reliability of predictions (Ekwaru et al., 2017). * §	
Adulthood obesity predictions based on childhood intervention outcomes	**(+)** In cases where there was a lack of evidence to support lifetime projections up to the elderly years, assumptions included maintenance of BMI projections from adulthood, whilst keeping all other environmental factors held constant (Mernagh et al., 2010, Rush et al., 2014). Transparency of assumptions adopted are important for purposes of replication and future improvements to model development. † **(+)** Sensitivity analysis was used to explore intervention effect decay (Rush et al., 2014, Te Velde et al., 2011, Mernagh et al., 2010, Graziose et al., 2017, Kesztyüs et al., 2017, Kesztyus et al., 2013, Ekwaru et al., 2017, Oosterhoff et al., 2020, Kenney et al., 2019, Coffield et al., 2019). This provides valuable insights into the tipping point by which interventions are no longer cost-effective. † § However, arbitrary percentages were used due to lack of data (Ekwaru et al., 2017, Mernagh et al., 2010, Moodie et al., 2013).	• Sensitivity analysis can provide insights into the level of maintenance that will need to be achieved for an intervention to be cost-effective. Whether this is achievable will need to be assessed (Moodie et al., 2013). • Weight regain after weight-loss is a prominent obstacle within obesity prevention trials. The possibility of weight regain and diminishing intervention effects needs to be incorporated within models and adjusted within scenario analysis for a fuller examination of cost-effectiveness outcomes. §

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	(+) Where dietary intake was the primary intervention outcome, evidence on the monitoring of fruit and vegetable intake was taken into consideration to form the basis of maintenance of intervention effects, and was varied within sensitivity analysis (Te Velde et al., 2011). * § **(+)** An annual depreciation rate was considered within base case analysis to acknowledge the likelihood that intervention effects diminish with time (Coffield et al., 2019). § **(-)** Maintenance of intervention effects was usually not considered within base-case scenarios of models, despite availability of evidence suggesting intervention effects reversing in the long-term (Brown et al., 2019b). There was no evidence from included studies, nor data collected from interventions to evaluate the extent to which weight changes persisted from childhood over time, or whether there were cases of overweight relapse (Wang et al., 2003, Brown et al., 2007, Graziose et al., 2017). † §	
Measuring and valuing health outcomes		
Potential Impact Fractions	**(+)** BMI was treated as a continuous rather than a categorical variable when considering expected disease due	• The use of BMI as a continuous outcome measure is more accurate

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	to changes in exposure to the risk factor by BMI unit (Haby et al., 2006, Moodie et al., 2013, Te Velde et al., 2011). This is a more accurate reflection of the association between BMI and diseases in comparison to methods that have used weight status to determine disease presence (Brown et al., 2007, Graziose et al., 2017, Wang et al., 2003, Ekwaru et al., 2017, Mernagh et al., 2010, Wyatt et al., 2018), such as is the case with transition probabilities for remaining healthy, developing a weight-related condition or death. * § **(+)** Stability was assumed of all incidence and mortality rates from causes other than the diseases included in models (Te Velde et al., 2011). Although this may not be representative of best current evidence, this ensures that costs and benefits are specifically evaluated for obesity-related disease states.*	than the use of categorical weight status to accurately reflect the associations between weight and disease. §
Relative risks of disease incidence and mortality conditional on BMI	**(+)** Due to low incidence rate data, it was assumed that BMI did not lead to many illness cases before the age of 20 years. Inclusion of illness from age 20 years is considered an improvement in comparison to studies that have	• All incidence rate data relating to obesity-related disease should be included within models. The presence of metabolic risk factors, indicative of early-disease onset, could still lead to

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	investigated disease incidence during older adult years (Mernagh et al., 2010, Rush et al., 2014). * **(-)** General population incidence rates obtained from a country not related to the study population, was frequently used with no justification (Mernagh et al., 2010, Rush et al., 2014). †	increased healthcare resource use and costs. For example, prescription drugs for cholesterol is indicative of an unhealthy diet, despite the absence of overweight or obesity (le Roux et al., 2020, Kit et al., 2012). § • Should obesity-related parameter estimates be unavailable from the country of intervention under evaluation, the use of another country's data may be a suitable alternative. Suitability can be determined by factors such as similar lifestyle, diet, obesity prevalence and population characteristics.
QALYs attributed to obesity related diseases	**(+)** Disutility was not applied to BMI categories in order to avoid potential of double-counting in cases where someone also had an obesity-related disease (Mernagh et al., 2010, Rush et al., 2014, Te Velde et al., 2011). However, the absence of disutility risks underestimating the direct impact	• Models should incorporate an element of disease severity due to changes in exposure to the risk factor (disease) by BMI unit. This could be embedded within Potential Impact

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	of overweight or obesity on health-related quality of life, in the absence of disease (De Beer et al., 2007). * **(-)** Obesity-related disease states were not included in cases where evidence suggests low incidence rates by weight status, thus risking the exclusion of cases of illness within evaluations. *§ **(-)** Models did not consider different stages of disease severity, but rather the presence or absence of a chronic illness. QALYs attributed to diseases represented the average quality of life (QoL) over the duration of the illness (Mernagh et al., 2010, Rush et al., 2014). It is expected that greater disease severity would be associated with greater BMI (Zabarsky et al., 2018, Andreyeva et al., 2004) and lower HRQoL (Jia and Lubetkin, 2005, Williams et al., 2005). ‡ §	Fractions and taken further to attribute appropriate QALYs by disease severity. § • Given the substantial health benefits and cost-savings associated with the avoidance of at least one health state, the inclusion of disease states with low incidence rates ought to be incorporated within models. §
Disutility for excess weight or chronic disease	**(+)** Highest disutility value was applied in cases where someone had obesity as well as a chronic illness to avoid risk of double-counting (Ekwaru et al., 2017). This considers both the impacts of HRQoL of obesity and chronic disease. *§	• Where factors may be highly correlated (e.g. obesity and disease states), care should be taken when attributing utilities to weight status in case of double-counting benefits (or lack thereof). Methods such as

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	(-) Adult based utility decrements had been applied to younger age groups (Ekwaru et al., 2017). HRQoL is typically more impaired within the older than younger years (Zabelina et al., 2009). Though the consideration of obesity-related health impacts within the younger years is a progressive step within models, the use of adult-based data may overestimate the benefits of this. †	applying the highest disutility value between weight status and disease state may be an optimal approach to adopt. • Careful consideration needs to be taken when choosing the most appropriate utility values from the literature, including: the population describing the health state (e.g. age, sex), elicitation technique used to derive utility value, sample size and country (Wyatt et al., 2018).
Costs and benefits by weight status	**(-)** Cost and benefit outcomes were based on long-term weight status categories (healthy/overweight/obese) (Brown et al., 2007, Graziose et al., 2017, Wang et al., 2003). This assumes that overweight/obesity will impact all individuals equally when outcomes vary by sociodemographics (Scharoun-Lee et al., 2009, O'Dea, 2008, Wang and Beydoun, 2007, Coffield et al., 2019, Kenney et al., 2019, Vieira and Carvalho, 2019). *§	• Models should consider covariates within utility and cost estimates. Where there is a lack of existing data, future research should consider the impact of weight status on utility outcomes by sociodemographic classifications.

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
Consideration of wider intervention effects	**(-)** Utilities were only captured for direct intervention effects (or for the outcome of interest) and indirect positive effects of the intervention were not considered or measured, potentially leading to an underestimation of cost-effectiveness. ‡ § **(-)** Few economic evaluations alongside trials considered child HRQoL using preference-based outcome measures (McAuley et al., 2010, Adab et al., 2018). There is mixed evidence to suggest that such measures are sensitive enough to detect differences by weight status. *§	• Consider evaluating other benefits not directly attributable to the intervention, as not doing so may underestimate the wider intervention benefit. This may not be solely health behaviours, but also individual psychological impacts that may lead to other health benefits as well as cross-sectoral benefits. § • Within the economic evaluation of trials, improved assessment tools need to be designed to detect changes in HRQoL amongst healthy children taking part in a weight gain prevention intervention to protect themselves from future disease. §
Choice of outcomes	**(-)** There was variability in the choice of outcome measures within clinical trials, including objective measures such as BMI (An et al., 2018, Brown et al., 2007, Ekwaru et al., 2017, Mernagh et al., 2010, Rush et al., 2014, Moodie et al., 2013, Vieira and Carvalho, 2019, Coffield et al., 2019,	• In the face of high uncertainty within modelling outcomes, more reliable and objective methods should be adopted to measure dietary or energy intake, for example, doubly labelled

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	Oosterhoff et al., 2020, Kenney et al., 2019), and subjective measures of dietary intake (Haby et al., 2006, Te Velde et al., 2011, Brown et al., 2021). Given short-term follow up of interventions, it is unlikely that any significant changes in BMI or cases of overweight/obesity avoided would have been detected to allow meaningful modelling of long-term intervention impacts. * **(-)** Although there is value in using BMI when assessing health risks of overweight and obesity, this is not the most reliable measure as it does not differentiate between excess fat, muscle and body mass (Bhurosy and Jeewon, 2013).	water, or the use of adjustment equations for self-reported data. • Where there is a lack of data or evidence from RCTs to support long-term projections of intervention effects, alternative data sources ought to be considered. Amongst other considerations include non-experimental data, prospective studies and the application of econometric methodology (Weatherly et al., 2009). • Alternative outcome measures may be better predictors of disease, other than BMI, including waist circumference, or potentially objective dietary intake (Candari et al., 2017).
Cost inclusions		
Costs attributed gradually	**(+)** Converting costs into rates allows gradual costs of obesity to be considered. Given that not everyone will live the same number of years, individuals will incur different	• Conversion of costs into rates may prevent overestimation of obesity-related costs. The inclusion of

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	amounts of obesity-related costs (Carter et al., 2009, Moodie et al., 2013). This compares to the use of a block cost estimate for the presence or absence of obesity or related diseases (Brown et al., 2007, An et al., 2018, Te Velde et al., 2011, Graziose et al., 2017, Rush et al., 2014, Wyatt et al., 2018, Wang et al., 2003). The use of rates could help ensure that obesity-related costs are not overestimated. [* §]	covariates, such as age, within equations may further improve estimation of rates though this could introduce further complexity into evaluations.
Costs attributed for overweight and obesity related health states	**(-)** Not all costs related to all obesity associated health states were included, e.g., medical care costs associated with obesity during adolescence and young adulthood. Exclusion of healthcare costs could lead to an underestimation of cost-effectiveness outcomes. [† §] **(-)** Costs were calculated by weight status/BMI category as opposed to BMI unit, which may overlook cost inclusions (Mernagh et al., 2010, Brown et al., 2007, An et al., 2018, Te Velde et al., 2011, Graziose et al., 2017, Rush et al., 2014, Wyatt et al., 2018, Wang et al., 2003). [*] **(-)** Models do not consider the potential changes in healthcare costs at different ages and assume one cost for overweight or obesity. Use of healthcare resources may	• Economic analyses ought to expand their inclusion of healthcare costs given the growing evidence of the costs associated with obesity within the childhood years. For example, increased use of GP services and outpatient visits (Breitfelder et al., 2011). These are often overlooked within cost-effectiveness analyses when considering cost inclusions as cost-estimates are limited to adulthood healthcare resource use.

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	differ with age, due to greater likelihood of comorbidities, differences in treatment options and plans (Kim and Basu, 2016). *	• Consideration of BMI as a continuous variable within evaluations may lead to more accurate estimations of medical and pharmacy costs, expanding to younger age groups (Østbye et al., 2014).
Wider cost inclusions	**(+)** Those with obesity may die earlier than healthy weight individuals. The consideration of life expectancy when calculating labour productivity cost estimates could help prevent overestimations of cost-effectiveness outcomes (Brown et al., 2007, Wang et al., 2003). In addition, given that weight gain prevention interventions have wider policy implications, they are likely to hold cross-sectoral costs and consequences. * **(-)** Obesity prevention may result in longer years lived, leading to non-obesity related healthcare costs which was considered by only one study (Oosterhoff et al., 2020). § **(-)** Opportunity costs of lost time for parents and informal caregivers were rarely considered. Childhood obesity prevention interventions typically involve time commitments from guardians. Cost-savings from	• Societal or public-sector perspectives may be more appropriate than a healthcare perspective for obesity prevention interventions, given that public health interventions could lead to numerous cross-sectoral costs and benefits. Studies taking a societal perspective ought to have broader inclusion of costs relating to societal impacts, including costs of improved diet, parent/caregiver opportunity cost of lost time, work/school absenteeism due to weight-related sick days for both adult and child. §

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	opportunity costs of lost time can also be accrued from the prevention of cases of overweight or obesity (e.g. less visits to the GP with the child). *§ **(-)** Although some studies had involved parents throughout the roll out of interventions (Adab et al., 2018, Ekwaru et al., 2017, Haby et al., 2006, Carter et al., 2009, Kesztyüs et al., 2017, Kesztyus et al., 2013, Foster et al., 2008, Te Velde et al., 2011), there was rarely consideration of intervention effects on parents or other family members within models (Coffield et al., 2019), potentially leading to an underestimation of the total benefits and cost-savings of interventions on population health. *§ **(-)** Studies had not included differential diet costs. Doing so would suggest whether interventions have a negative financial impact on individuals, e.g., whether there are financial implications to changes in diets. §	• Spill over effects ought to be included within obesity prevention studies, should evidence suggest that interventions have had a positive effect on other family members. §
Equity considerations		
Equity considerations	**(+)** Various subgroup characteristics were explored within economic evaluations, usually conducted through analysis by subgroup and further explored within sensitivity analysis (Mernagh et al., 2010, Haby et al., 2006, Carter et	• Equity ought to be explored within economic evaluations, given the strong link between obesity and SES (Baker, 2019, Hales et al., 2017,

Methods	Strengths (+) and Limitations (-)	Considerations for future evaluations
	al., 2009, Moodie et al., 2013, Brown et al., 2007, An et al., 2018, Te Velde et al., 2011, Graziose et al., 2017, Rush et al., 2014, Oosterhoff et al., 2020); 95% confidence intervals were used to guide sensitivity analyses in cases where there was a lack of data sources to guide variations in model parameters (Wang et al., 2003). * † §	Ogden et al., 2018). However, studies may not be sufficiently powered to detect meaningful differences between subgroups. Alternative methods such as the use of weights ought to be considered, although these are more computationally complex to administer. §

NB. All recommendations presented are subject to data availability.
Abbreviations: BMI, body mass index; HRQoL, health related quality of life; QALY, quality adjusted life year; RCT, randomised controlled trial.
* Based on evaluation decision.
† Could be improved through further data collection.
‡ Limitations of cost-effectiveness studies more generally.
§ Discussed within the body of the text.

4.3.3.2 Measuring and valuing health outcomes

A number of methodological issues associated with measuring and valuing health outcomes were also identified. These related to the methods for associating weight status to disease incidence and mortality, methods for linking disease severity to health utility, the scope of obesity related diseases considered, the wider non-weight related potential health impacts and the use of current utility instruments.

Inclusion of disease states within models was done through various means, including incorporating Potential Impact Fractions, which calculate the proportion change in expected disease or death by change in BMI (Haby et al., 2006, Moodie et al., 2013, Te Velde et al., 2011). The use of a continuous risk factor (e.g. BMI) allows greater precision than a categorical classification of weight status (e.g. healthy weight/overweight/obese) when predicting disease incidence and mortality rates (Zabarsky et al., 2018, Andreyeva et al., 2004, Nyberg et al., 2018). The use of categorical classifications carries an assumption that all individuals within a classification have the same disease incidence when there is great variability in BMI within each classification. Other studies applied transition probabilities for remaining healthy, developing a weight-related condition or death in progressive time intervals (Ekwaru et al., 2017, Mernagh et al., 2010, Wyatt et al., 2018, Oosterhoff et al., 2020). Although disease states can provide a deeper perspective into the long-term implications of obesity risks through the incorporation of related costs and consequences, models did not consider how different stages of disease severity could impact upon health utility outcomes. One study considered the impact of increased life years, due to obesity prevention, on age-related chronic disease (Oosterhoff et al., 2020). On the other hand, economic evaluations alongside clinical trials used a variety of clinical outcomes to measure health benefits. This included anthropometric outcomes (Wang et al., 2008, Kesztyus et al., 2013, McAuley et al., 2010, Vieira and Carvalho, 2019), servings of food (Ladapo et al., 2016, Beets et al., 2018, Reeves et al., 2021), energy content of packed lunches (Brown et al., 2021), obesity prevalence (Conesa et al., 2018, Kesztyüs et al., 2017), and compliance of a healthy canteen policy (Reilly et al., 2018, Reeves et al., 2021). Differences in outcomes, without the use of a generic outcome measure such as a QALY, increases the difficulty in understanding the significance of the outcome beyond the scope of the immediate study. It also increases difficulty in comparing the cost-effectiveness of different trialled interventions, particularly if there are no standard threshold values associated with these outcomes, as is the case with QALYs.

Similarly, when valuing disease states, potential differences in utility by disease severity have not been factored. Some studies used estimates of QALYs attributed to obesity-related diseases (Rush et al., 2014, Wyatt et al., 2018, Mernagh et al., 2010). Others used QALY measurements associated with obesity in general (Brown et al., 2007, Graziose et al., 2017, Wang et al., 2003), and one study assigned decrements in health utilities for every year lived with excess weight, obesity or chronic disease within the model. To avoid double counting, the highest disutility value was applied in cases where someone had both obesity and a chronic illness (Ekwaru et al., 2017). Future studies ought to consider the inter-connected relationship between obesity, disease and disease severity, whereby time spent with higher BMI classifications are associated with greater health complications, lower HRQoL and greater healthcare costs (Østbye et al., 2014, Søltoft et al., 2009). Moreover, there was a common assumption that perfect health was associated with healthy weight status in all studies. This may be an overestimate as evidence suggests that health complications occur as a result of unhealthy diets, regardless of weight status (Phillips et al., 2019, Ezzati and Riboli, 2013, Brennan et al., 2010, Cuenca-García et al., 2014).

The number of obesity-related chronic disease states used within models also varied from four (Wyatt et al., 2018) to fourteen (Mernagh et al., 2010, Rush et al., 2014), and commonly included diabetes, cancers, stroke, hypertension and heart disease. Although disease states were omitted from models (Wang et al., 2003, Brown et al., 2007, Wyatt et al., 2018), potentially due to lack of available data or low incidence rates by weight status, this could exclude relatively rare conditions with a significant economic burden. More simplified models have based cost and benefit outcomes directly on long-term weight status, whereby cost of illness is associated with overweight/obesity status (Wang et al., 2003, Brown et al., 2007, Graziose et al., 2017, Coffield et al., 2019, Kenney et al., 2019, Vieira and Carvalho, 2019). This assumes that overweight/obesity will impact health states of individuals equally, yet costs may vary by age, sex, SES and ethnicity (Scharoun-Lee et al., 2009, O'Dea, 2008, Wang and Beydoun, 2007, An, 2015, Finkelstein et al., 2008).

No study considered the wider non-weight related potential health gains from improvements in nutrition (Penney and Kirk, 2015). This could underestimate the potential impact of interventions in cases where recipients make behavioural changes that have no impact on weight outcomes (Lobstein et al., 2015).

Two economic evaluations alongside clinical trials used utility instruments; the Health Utility Index (McAuley et al., 2010) and the Child Health Utility 9 Dimension (CHU9D) measure (Adab et al., 2018) to capture the impacts of obesity prevention interventions. Given children are unlikely to face detrimental health conditions to the same extent as adults, neither intervention led to significant changes in QALY outcomes. Indeed, two previous studies in children have found no statistically significant association between HRQoL and weight status (Eminson et al., 2018, Tan et al., 2018). Though more recently, a meta-analysis of international studies found small but significantly lower utility values among 6-15 year olds with overweight or obesity in comparison to those of healthy weight. This may flag potential differences in the sensitivity of different utility-based measures among different paediatric populations (Brown et al., 2018). Improved assessment tools may need to be designed to detect changes in HRQoL in weight gain prevention trials among disease-free children.

4.3.3.3 Cost inclusions

Limitations involving the inclusion of costs were identified across studies. These comprised of the methods by which costs were included within models, the exclusion of healthcare costs associated with overweight and obesity related health states, and the exclusion of wider costs and potential cost-savings.

The costs included in an economic evaluation can have a marked impact on the results. Most models opting for healthcare and societal perspectives incorporated costs associated with either obesity in general or obesity-related disease (An et al., 2018, Brown et al., 2007, Wang et al., 2003, Graziose et al., 2017, Rush et al., 2014, Te Velde et al., 2011, Wyatt et al., 2018, Oosterhoff et al., 2020, Coffield et al., 2019, Kenney et al., 2019). Mernagh et al. (2010) considered health care and medical costs associated with both healthy weight and weight-related diseases, whereas others quantified the number of lost sick days for individuals with and without obesity (Brown et al., 2007, Wang et al., 2003). These methods apply a block total cost for the disease state which may lead to an overestimation of healthcare resources, since age of death is not considered and could have implications on reduced healthcare use. In the case of Coffield et al. (2019), healthcare costs were included if significant associations were found within regressions between healthcare costs and BMI changes. On the other hand two studies considered gradual healthcare resource use over the lifetime (Carter et al., 2009, Moodie et al., 2013). Carter et al. (2009) and Moodie et al. (2013) converted obesity-related disease costs for each sex and 5-year age group into rates for the Australian population. All disease-specific rates for each sex and age group were summed to give a total obesity-related disease cost rate. Total cost rates were incorporated into lifetables at each one-year age group via extrapolation methods. More recently published studies within this review considered medical care costs for both children and adults (Coffield et al., 2019, Oosterhoff et al., 2020, Kenney et al., 2019), taking into consideration GP and specialist visits as well as a comparison of medical costs between those with healthy weight and overweight/obesity (Oosterhoff et al., 2020). Exclusion of such costs could risk inaccurate calculations of cost-effectiveness outcomes. In addition, only one study incorporated both obesity-related chronic disease cost and disease costs associated with longer years lived (independent of weight) (Oosterhoff et al., 2020).

Other costs were also not considered by most models, which may have been due to the study perspective undertaken. Only three studies, all of which undertook a societal perspective, incorporated productivity costs by quantifying the number of lost sick days for individuals with and without obesity (Brown et al., 2007, Wang et al., 2003, Oosterhoff et al., 2020). In addition, 65% of studies did not discuss the relevance of productivity changes to the study question (Adab et al., 2018, An et al., 2018, Brown et al., 2007, Ekwaru et al., 2017, Graziose et al., 2017, Kesztyüs et al., 2017, McAuley et al., 2010, Mernagh et al., 2010, Moodie et al., 2013, Te Velde et al., 2011, Wang et al., 2008, Wyatt et al., 2018). Considering the impact of obesity on productivity (Goettler et al., 2017), omitting these costs may lead to a large underestimation of the economic value. Moreover, preventing cases of childhood overweight/obesity may lead to a reduction in supervised healthcare visits, and consequently reduction in opportunity costs of lost time. However, only four studies (one public sector and 3 societal perspectives), considered opportunity costs of lost time for parents and informal caregivers (Adab et al., 2018, Moodie et al., 2013, Carter et al., 2009, Oosterhoff et al., 2020), whilst others considered such inclusions within sensitivity analysis (Wang et al., 2003, Adab et al., 2018), and one study opting for a societal perspective considered school absences (Oosterhoff et al., 2020) which also holds repercussions to parent/carer workplace productivity costs through increased absenteeism. As such, societal perspectives may be better suited than healthcare perspectives, due to cross-sector cost implications.

The family unit plays an integral component within childhood obesity-prevention studies. Childhood obesity prevention interventions are likely to impact the whole household, and not just the recipient child, especially as changes in diet will likely be the result of food purchasing behaviours. This is particularly the case when interventions are not restricted to changes within the school environment, but also involve parents in their administration (Adab et al., 2018, Ekwaru et al., 2017, Carter et al., 2009, Haby et al., 2006, Kesztyüs et al., 2017, Kesztyus et al., 2013, Mernagh et al., 2010, Te Velde et al., 2011, Oosterhoff et al., 2020, Coffield et al., 2019, Brown et al., 2021). As such, childhood obesity prevention trials may lead to spill-over effects onto other family members (Zanganeh et al., 2021), accruing greater intervention benefits and cost-savings from disease prevention (Coffield et al., 2019). Changes to dietary behaviours can also hold financial repercussions to the household, given that healthier substitutions are more costly than unhealthy, energy-dense foods (Rao et al., 2013, Cade et al., 1999, Jetter and Cassady, 2006). However, these were rarely considered within studies.

4.3.3.4 Equity considerations

The consideration of equity is a key component for economic models of particular relevance for public health interventions (Frew and Breheny, 2019). Health inequalities describe differences in health status between population subgroups associated with economic or social conditions (Braveman and Gruskin, 2003). Childhood obesity is a worldwide concern that impacts those within disadvantaged groups disproportionately (Hales et al., 2017, Ogden et al., 2018, Baker, 2019). However, less than half of included papers considered equity within their evaluations. Four studies compared outcomes by gender (An et al., 2018, Haby et al., 2006, Carter et al., 2009, Te Velde et al., 2011, Moodie et al., 2013), four studies considered cost-effectiveness outcomes by ethnicity (Brown et al., 2007, Graziose et al., 2017, Mernagh et al., 2010, Rush et al., 2014), and three considered SES (Mernagh et al., 2010, Rush et al., 2014, Oosterhoff et al., 2020), of which two identified differences in incremental cost effectiveness ratios between SES groups (Rush et al., 2014, Oosterhoff et al., 2020). An intervention that is rejected for scale up as it is not cost-effective in a general population, may be cost-effective in a socioeconomically or other disadvantaged group. In such instances, an opportunity to reduce health disparities is missed. Likewise, morbidity and mortality rates may differ by subgroup, potentially leading to inaccurate cost-effectiveness estimations when parameters are derived from the general population.

4.4 Discussion

This systematic review has assessed the different methods undertaken by studies investigating the cost-effectiveness of dietary obesity prevention interventions in children and adolescents. It extends previous research by providing a critical synthesis of the strengths and limitations of assumptions adopted within evaluations and provides recommendations for the economic evaluation conducted in Chapter 7. Despite the heterogeneity in evaluation approaches, including methods by which adult obesity was predicted from child intervention outcomes, and the choice and methods by which obesity-related health states, health benefits and related costs were explored, there were key similarities across evaluations. It was generally assumed that intervention effects were maintained, and that the only benefit from interventions was related to obesity prevention. In addition, potential confounding factors were constant from childhood to adulthood and subgroups were rarely included within transition probability calculations, utility estimates and costs. Key considerations for future evaluations are outlined below.

When modelling the long-term impact of interventions, assuming that intervention effects are maintained from childhood through to adulthood carries a danger of over-estimating cost-effectiveness outcomes. Children and adolescents are amenable to changes from the point at which trial data is collected at childhood until adulthood, as will be reflected within the conceptual model developed within Chapter 5. Therefore long-term predictions of outcomes may be questionable, especially when intervention effects are known to diminish with time (Jeffery and French, 1999), and health outcomes relating to the prevention of obesity-related chronic illness are more likely to present with older age as opposed to childhood. A common approach used within modelling studies was to project adult BMI from child outcomes and then calculate the long-term costs and benefits based on adult parameters. Using sensitivity analysis, the long-term impact of intervention effectiveness can be varied, though when done, these assumptions are seldomly supported by evidence from longitudinal studies. Recently, Oosterhoff et al. (2020) elicited expert opinions on the likely trends in intervention effect maintenance during and after intervention exposure, which were used to model possible BMI trajectories for primary school aged children and adolescents separately. The most popular opinion elicited by experts suggested effect maintenance during intervention exposure, followed by a decay of the relative effects. Results suggested considerable differences between reference intervention effects and expert elicited scenarios. Brown et al. (2019b) investigated the impact of effect decay on cost-effectiveness of obesity prevention interventions in the early years. Results suggested no health care cost savings if intervention effects decayed to zero after 10 years post-intervention, in comparison to the substantial cost-savings should intervention effects be maintained into adulthood. This raises a need for longer follow-up periods within obesity-prevention trials to track the maintenance of intervention effects and establish the factors relating to their success or failure over time (Scaglioni et al., 2008, Lazzeretti et al., 2015). Such data could reduce the uncertainty in modelling the long-term impact of interventions in childhood. Currently, very few studies exist that provide a relative estimate of intervention effect maintenance, though these estimates are within adult populations (Thomas et al., 2014). There is also a need to incorporate weight management modules within new or existing cohort or prospective studies, to track the maintenance of intervention effects. The concept of tracking outcomes is discussed further within Chapter 8. Whilst such research may be costly and time-consuming, it would allow us to better understand the implications of much short-term intervention research. In developing and validating models of long-term effects, researchers should explore other reliable sources of data, including commercial providers or existing registries (The National Weight Control Registry, 2020).

In the obesogenic environment, unhealthy diets are more prevalent due to the availability, affordability and accessibility of calorie-rich foods (Caspi et al., 2012, Cummins and Macintyre, 2002). Changes need to be made across systems in order to see a significant shift in behaviour to reduce obesity prevalence (Butland et al., 2007). Obesity prevention interventions need to be ongoing and sustainable, spanning throughout the life course, tailored to each stage of life where transitions and settings could impact on one's behaviour and lifestyle. Whole-systems approaches may be a potential avenue for exploration, where modifications are made to whole communities (Coffield et al., 2019, Allender et al., 2016). Though this will incur additional substantial costs, the availability of such interventions will ensure that individuals will have constant exposure to obesity prevention strategies, increasing likelihood of long-term behaviour change. However, adopting a life course approach may pose challenges for economic evaluation, as has previously been reported (Sweeney et al., 2018). For instance, given the number of players involved in implementing a whole of system intervention, spanning across numerous sectors and implemented by both formal (e.g. school) and informal (e.g. parents) parties, tracking of cost inclusion estimates and intervention maintenance costs will be difficult and timely. Until long-term data is available, there may be uncertainty regarding suitable follow-up periods for intervention effect size estimates, alongside a suitable comparator. Data collection requirements may be burdensome for community members, and need to be feasible (Gubbels et al., 2015). There is also a likelihood that intervention benefits will extend beyond child and adolescent recipients (Frew, 2016), and may lead to non-weight related health outcomes. The exposure to multiple behaviour change strategies may interact with one another leading to expected or unexpected consequences, which may be difficult to predict and account for (Shiell et al., 2008). As such, the development of system dynamic models that capture the internal structure of the obesity system may have the potential to predict outcomes that may arise from system shifts (Sweeney et al., 2018). Whole-system approaches are a recurring topic throughout this thesis in relation to understanding the mechanisms and effectiveness of the Change4Life Food Scanner app.

Review findings have also highlighted the potential underestimation of cost-effectiveness outcomes due to the neglect of wider intervention benefits and health outcomes. Engagement in healthier lifestyles may have an impact on child wellbeing (Biddle and Asare, 2011, Wille et al., 2008), which is seldom investigated within economic evaluations in children, despite its perceived importance when making decisions on public health investments (Frew and Breheny, 2019). In addition, preference-based measures may not be sensitive enough to detect changes in HRQoL amongst children (Brazier and Deverill, 1999). This will be considered within Chapter 7. New and emerging research is only just starting to investigate child-based factors that could be incorporated into models. Age- and sex-specific utility values have recently been estimated from the CHU9D measure within an Australian population of 10-17 year olds. Findings suggested differences in utility values between boys and girls, with significant associations between utilities and BMI z-scores with age (Killedar et al., 2020). These findings highlight the importance of factoring in age and sex covariates when modelling long-term costs and benefits within childhood obesity prevention models. The usability of preference-based weight-specific instruments for economic evaluations, such as the Weight-specific Adolescent Instrument for Economic evaluation (WAItE), have also been investigated. Outcomes have suggested a high correlation between the WAItE, existing generic preference-based HRQoL measures, and weight-specific measures. The WAItE also has an ability to differentiate between weight status and an ability to pick up meaningful changes in HRQoL (Oluboyede and Robinson, 2019). As such, weight-specific measures may be better suited for identifying differences in HRQoL in younger populations (Pakpour et al., 2019). However, difficulty persists in assessing HRQoL in healthy individuals who are taking part in weight-gain prevention interventions to protect long-term health. This flags the need to develop better measurement tools designed to detect changes in healthy populations (Lenoir-Wijnkoop et al., 2011). Difficulty linking health gains to health utilities within children also calls to question the suitability of cost-utility analysis. Alternative methods such as cost-benefit analysis, where monetary valuations of intervention benefits could be derived via WTP methods (Perkins et al., 2015), may have some value. For example, Webb et al. (2020) investigated commissioners' WTP for community programmes targeting childhood obesity prevention. Results suggested that a one portion increase of F&V consumption per child was highly valued alongside high programme completion rates. On the other hand, WTP methods may not be ideal when used to value obesity prevention interventions among parents (Drouin et al., 2019). Given varying levels of deprivation among the public, parents may not be able to afford, and therefore not willing, to pay out of pocket for interventions (Kesztyüs et al., 2014).

When considering cost inclusions, various international recommendations suggest the use of a healthcare perspective within base-case evaluations of HTAs (National Institute for Health and Care Excellence, 2013, ISPOR, 2020b, ISPOR, 2020a). However, rarely do obesity prevention dietary interventions fit within the scope of a healthcare perspective, given they have wider policy implications and cross-sectoral consequences (Weatherly et al., 2009). These include school attendance and performance, employment, and productivity, or financial repercussions to individuals due to higher costs of maintaining healthier lifestyles (Lenoir-Wijnkoop et al., 2011). These factors are further explored within the evaluation in Chapter 7. Most studies did not factor child-related productivity costs and their implications, nor healthcare related costs within the childhood years, which may have been due to the lack of data available at the time of evaluation. Recent research investigated the impact of overweight and obesity on school absenteeism in an Australian population of 6-13 year olds to calculate the indirect repercussions to caregiver lost productivity. Results found that children with obesity missed on average one extra day of school annually in comparison to those without overweight or obesity. This amounted to $338 in indirect carer productivity losses per child (Carrello et al., 2021). There has also been an increase in studies investigating childhood obesity related healthcare costs, with findings suggesting substantial medical costs as early as the first 5 years of life (Hayes et al., 2016), and greater utilisation of general practitioner (GP) and specialist weight services (Black et al., 2018, Oosterhoff et al., 2020, Finkelstein et al., 2008). Due to this, child healthcare resource use was embedded within the evaluation in Chapter 7. Although the inclusion of such costs can be a laborious task, economic evaluations ought to consider cross-sectoral costs or discuss potential intervention impacts across sectors. Resource pathways and associated costs were further explored within stakeholder engagement in Chapter 5.

Decision makers have expressed that economic evidence should consider minimising inequality alongside maximising efficiency (Frew and Breheny, 2019), and called for a formal weighting of outcomes by population subgroups. This recommendation has implications for appropriate modelling methods that can capture heterogeneity of effects, for instance patient level population models and alternative methods of analysis including perhaps separate cost-effectiveness analyses by subgroup. This also has implications for both primary research, for example increased sample sizes to detect subgroup effects, and secondary modelling that would require subgroup specific parameter inputs (Lal et al., 2018).

4.4.1 Comparison with previous literature

This paper provides an updated review of the literature. In 2019, Zanganeh et al. (2019) published a comprehensive systematic review exploring the methods, study quality and results of economic evaluations for childhood and adolescent obesity interventions. Similarly, Oosterhoff et al. (2018) explored the design, issues and potential solutions to economic evaluations of school-based lifestyle interventions in 4-12 year olds. However, both search strategies were conducted up to early 2017. Fourteen of the included studies within this current paper were published between 2017-2021, demonstrating how this area of research is expanding rapidly and the need to regularly update systematic reviews within this domain.

Previous research has acknowledged the shortcomings in methodological recommendations concerning economic evaluations. Frew (2016) discusses how current recommendations for economic evaluations are not suited to the evaluation of childhood obesity prevention and outlines key obstacles. These included issues with the conduct of cost utility evaluations, the use of QALYs for measuring intervention benefits, current issues with cost analyses of interventions and long-term healthcare savings, and the unsuitability of healthcare perspectives. More recently, Fattore et al. (2021) provided recommendations on the type of economic evaluation framework that is most appropriate to conduct concerning nutrition-based interventions, given intervention design and purpose. They also adopted the use of the Weatherly framework to outline the main challenges in the economic evaluation of nutrition interventions and provided useful recommendations that complement those presented in this paper. For example, when measuring and valuing outcomes, nutrition interventions may generate value far greater than health outcomes and QALYs alone, including mental and social outcomes. In addition, studies do not consider the potential loss of utility during the intervention period where behaviour change is in progress, or the psychological impact changing one's diet may have on an individual. Despite its strengths, Fattore et al. (2021) is not a systematic review of the literature, does not discuss the impact of nutrition interventions on children and adolescents, nor does it focus on obesity prevention. As such, this current systematic review has complemented previous research by not only providing an overview of the characteristics of current economic evaluations, but also delving into a discussion of the evaluation and modelling techniques and assumptions undertaken within this specific area. This has resulted in a comprehensive critical appraisal of the methods and the provision of useful recommendations for the economic evaluation of the Change4Life Food Scanner app (Chapter 7), and future economic evaluations of childhood obesity prevention interventions.

4.4.2 Limitations and recommendations for future research

An early decision was made to exclude studies modelling hypothetical scenarios and those assessing the impact of multiple effectiveness studies. Inclusion of hypothetical studies could have diversified the nature and methods of studies under review. However, closely examining methods by which economic evaluations and modelling studies are conducted within implemented single clinical studies was deemed more suitable for the purposes of this thesis, to generate guidance on the evaluation of the Change4Life Food Scanner app. Similarly, given the growing popularity of childhood obesity prevention interventions within infancy (Doring et al., 2016, Tan et al., 2020), the exclusion of studies targeting children two years old and younger may have led to shortfalls in our understanding of the economics of obesity within the early years and over the life course. In addition, due to a lack of capacity, authors of included studies were not contacted for any unpublished work, which could have minimised publication bias. Most nutrition-based interventions within this review incorporated a physical activity component. Given that physical activity-based search terms were not included in the search strategy, as the focus of this review was on nutrition economics, studies whereby diet was a secondary rather than primary focus may have not been identified. Finally, although I adopted recommendations for reporting of systematic reviews by the CRD, the data extraction process was time consuming and resulted in the extraction of more data than was reported. Future systematic reviews may consider the recommendations put forth by Jacobsen and colleagues, whom investigated the key challenges of conducting systematic reviews of economic evaluations, to help focus the reporting of review findings (Jacobsen et al., 2020). In addition, there has since been published guidance on critical appraisal of systematic reviews of economic evaluations, that has implications for their undertaking and reporting, that could have impacted on the methods of my work (Mandrik et al., 2021).

Based on the current findings, there are several recommendations for future economic evaluations of childhood obesity prevention interventions. Firstly, interventions ought to consider the possibility of weight regain and diminishing intervention effects within future projections. Where available data is scarce or where there is uncertainty around long-term intervention effects, comprehensive sensitivity and scenario analysis should be conducted. Secondly, few studies had considered collection of child preference-based measures, despite the existence of validated measures. A greater focus on the development of outcomes measures sensitive to changes in HRQoL and wellbeing in healthy children ought to be developed for use within public health prevention interventions, given such interventions focus on promoting healthier lifestyles as opposed to weight loss. Thirdly, very few studies had considered parental or caregiver opportunity costs; non-obesity related health benefits, including cross-sectoral costs and consequences should be incorporated. Finally, combating health inequalities is core to public health interventions. It is imperative for studies to explore differences in cost-effectiveness by subgroups should data permit this.

4.4.3 Conclusions

This systematic review provides an overview of economic evaluations of childhood obesity-prevention dietary interventions. It has extended previous research by providing a deeper understanding of model structures, and the possible assumptions that can be embedded within analyses. In doing so, several key methodological challenges were identified within four organisational themes: (1) modelling long-term impact of interventions; (2) measuring and valuing health outcomes; (3) cost inclusions; and (4) equity considerations. Considerations for future evaluations have been outlined and discussed. The findings of this review have also highlighted the lack of research that has investigated the cost-effectiveness of dietary mobile apps targeting child outcomes. Although findings have been useful to inform economic evaluations and modelling studies generally within obesity prevention, little is known whether evaluations of digital interventions should adopt similar methodological approaches, and where the differences may be. These gaps in knowledge will be used to inform the aims and objectives of Chapter 5 relating to stakeholder engagement, to help inform evaluation decisions. The findings from this systematic review will also be used to advise methodological decisions and aid the choice of assumptions made within Chapter 7, whereby the economic and health impacts of the Change4Life Food Scanner app will be investigated. The outcomes of the systematic review could also help inform future developments of this thesis, such as the production of a design-oriented and mathematical model to conduct a formal assessment of the long-term effects of the Food Scanner app, or any similar dietary mobile intervention, which will be discussed in further detail within Chapters 7 and 8.

5. Stakeholder Engagement for the Conceptual Modelling of a Dietary Digital Intervention

The systematic review presented in Chapter 4 found little research on the health economics of DDIs. This brings to focus the gap within the literature exploring the conceptualisation of dietary apps alongside suitable steps for their evaluation, which is particularly important given their complexity. The objectives of this chapter are to, 1) introduce the concept of conceptual modelling; 2) design a draft conceptual model of the decision problem based on available literature and learnings from previous chapters; and 3) conduct stakeholder engagement for the conceptual modelling of a dietary digital intervention.

5.1 Introduction

5.1.1 App development and evaluation

Developing and evaluating digital health interventions is a challenge. Given the scarcity in healthcare resources, it is critical to develop an understanding of the cost-effectiveness of interventions, as such evidence is crucial for policy makers when making decisions on budget allocation. Considering the drive towards and greater uptake of public health obesity prevention interventions within children, as well as the increase in popularity of app-based dietary interventions (Villinger et al., 2019), there is a fundamental need to evaluate their cost-effectiveness and long-term implications. A systematic review (Chapter 4) was conducted to explore the methods and approaches utilised to conduct economic evaluations and long-term modelling of costs and health benefits of obesity prevention dietary interventions in children. However, this review did not identify any studies of DDIs in children.

DDIs are complex interventions in a complex setting. They can either be implemented in isolation, or as part of a multicomponent intervention. For example, although the Change4Life Food Scanner app can be received in isolation, given it is publicly available on the app market, it was originally released as part of a wider public health campaign as a tool to support the broader health messages within the campaign. Complex interventions consist of several interacting components. Their design and characteristics may have repercussions for evaluation approaches that challenge the RCT paradigm, which are based on linear logic models (Ariss and Nasr, 2022). To address this, guidance on evaluating complex interventions have identified the need for and use of logic models as a basis for specifying the relationship between the intervention, evaluation, generalisability of the evaluation, and addressing generalisability of evidence in evaluation designs (Skivington et al., 2021). Part of this process includes the development of a conceptual model, which helps relate to the economic aspects of evaluations.

An international workshop of experts within the field have recognised and provided recommendations to the challenges faced when developing and evaluating DHIs (Michie et al., 2017, Murray et al., 2016). Amongst topics discussed were intervention development, promoting user engagement, and evaluating the effectiveness and cost-effectiveness of such interventions (Michie et al., 2017). Key challenges have been reported; within the topic of pace and efficiency include the rapid speed of technological development in comparison to intervention evaluations and reporting of outcomes (Murray et al., 2016). Within user engagement are issues pertaining to the insufficiency of engagement with DHIs to lead to behaviour change. In addition, there is a lack of clarity as to what constitutes as sufficient engagement that will yield the desired outcome (Michie et al., 2017). Depending on the digital intervention in question, some may require ongoing engagement to maximise outcomes, whilst others may require one period of in-depth engagement to acquire new knowledge, skills or habits (Yardley et al., 2016). To overcome this, it was suggested that combinations of both objective and subjective measures ought to be collected regarding users' app usage as well as experiences of using the app. For these purposes, such factors were taken into consideration when designing the Food Scanner app evaluation (Chapter 6).

Issues surrounding the evaluation of effectiveness and cost-effectiveness include difficulties classifying comparator or control conditions within interventions (Murray et al., 2016), and difficulties controlling confounding variables within the environment, especially due to the availability of other digital interventions (Murray et al., 2016, Michie et al., 2017). It was recommended that digital app evaluations need to be designed in such a way that generalisability beyond the testing conditions is possible. This has been considered within the app evaluation in Chapters 6 and 7. As for conducting economic evaluations, the importance of identifying all relevant costs at every stage of app development, as well as future costs such as maintenance and software updates, need to be considered alongside the lifespan of the intervention. Costs surrounding the promotion of the health app is also vital, as cost-effectiveness may be dependent upon mass uptake whilst human input may also be required to encourage user engagement (McNamee et al., 2016). App uptake, reach and retention are therefore crucial considerations when projecting potential benefits, for those directly engaged with the app and for those within wider social networks, otherwise the benefits of the app may be underestimated in comparison to cost estimates (Michie et al., 2017). Efforts to collect data on costs associated with the development and maintenance of the Change4Life Food Scanner app are discussed in Chapter 7. Lastly, before conducting economic evaluations, it is also worth considering the study design that ought to be implemented. RCTs are deemed the “gold standard”, and it is within their nature to investigate the impact of a constant independent variable on behaviour change (McNamee et al., 2016). However, many digital interventions are not constant, whereby they are gradually evolving and developing. For this reason, RCTs may not be an appropriate method to evaluate DDIs; if the DDI is not closely monitored the validity of intervention outcomes may come under scrutiny. For such purposes the researcher (SM) registered to become a beta tester for the Food Scanner app; beta-testing allows monitoring of app developments by seeing any new updates before the public. In addition, to investigate the appropriateness of RCT designs, a feasibility trial was conducted to evaluate the app (Chapter 6). It has also been advised that in cases where an RCT is conducted to evaluate a DHI, separate data collection methods ought to be established as opposed to collecting outcome data from the app itself. This is so the intervention is not confounded by the measurement method (Murray et al., 2016). Other recommendations included the use of intermediate measures, or surrogate outcomes, when measuring the benefits of an app (McNamee et al., 2016). This may be useful when the expected benefits of an intervention are only likely to be detected in the long-term, as is usually the case with HRQoL and wellbeing outcomes used for economic evaluations.

The ways in which models are produced can highly affect final cost-effectiveness results. Therefore, to evaluate the Change4Life Food Scanner app, an understanding of the decision problem needs to be formed alongside the development of a conceptual model. These are key activities that are undertaken by modellers when developing economic models (see Figure 5) (Chilcott et al., 2010).

5.1.2 Introduction to conceptual models

Before designing and implementing mathematical models it is necessary to gain deeper understanding of the decision problem by providing an abstract representation of complex phenomena in an expressible format. Conceptual modelling for health economics has been defined into two categories: problem-oriented and design-oriented, which work together to inform the relevant characteristics of the final economic model (see Figure 6) (Tappenden, 2012, Tappenden, 2014, Lacy et al., 2001). These are different to programme theories and logic models. Programme theories explain how and why a programme (or intervention) is expected to work, whilst logic models are a graphical representation of programme theory that map out the links between intervention components and expected outcomes (Maden et al., 2017).

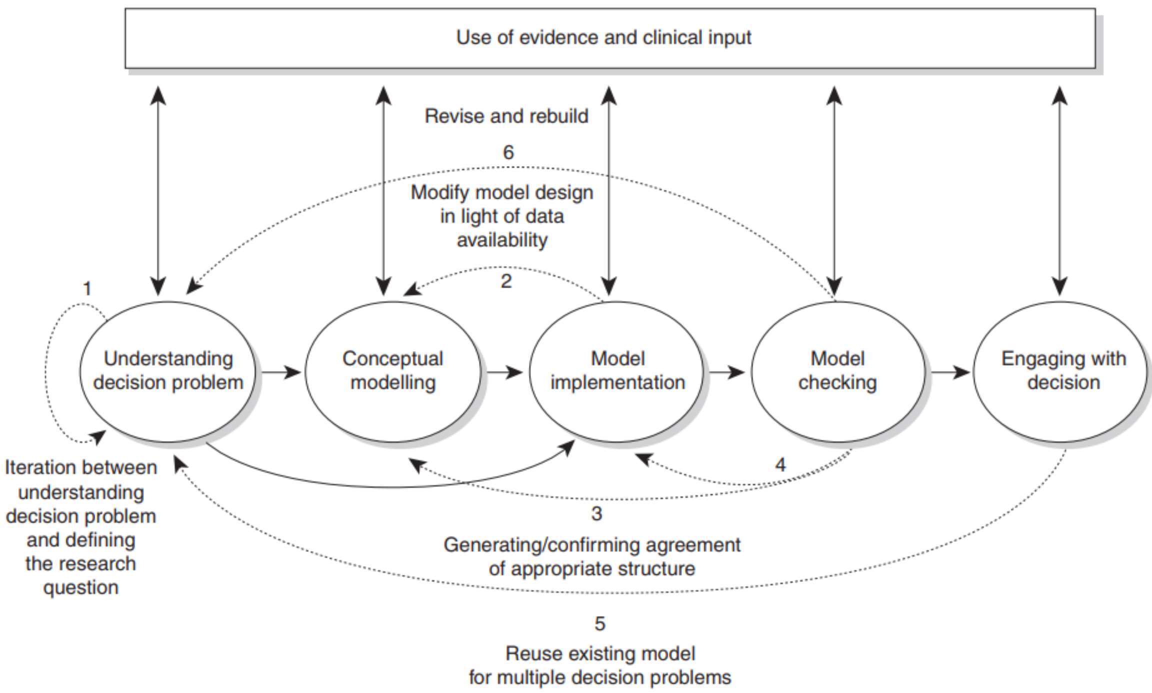


Figure 5. Stylised model development process. Reproduced from Chilcott et al. (2010).

5.1.2.1 Problem-Oriented Conceptual Model (POCM)

To address the design of an economic model, an explicit understanding of the decision problem needs to be developed. This includes constraints and causal influences that may impact on the outcomes of interest. The role of POCMs is to act as boundary objects to facilitate meaningful conversation between stakeholders and analyst on how the model will capture intervention impacts, on both health benefits and cost outcomes. The POCM should also reflect the current knowledge of the health condition (obesity) and system in which it exists and can be prevented. POCM's do not concern themselves with modelling methodology and they are primarily used to describe the extent of the decision problem. They provide a broad and general perspective of the decision problem in comparison to logic models. Two types of POCMs have been identified: disease process models and service pathway models. Disease process models are concerned with relevant disease events, and their impact on outcomes, whilst service pathway models focus on health care interventions and treatments received, and related cost and resource impacts. Both models are required when designing a POCM for the Food Scanner app although this will be framed around the process in which the Food Scanner app (the "treatment") leads to behaviour change, and what this means for obesity and related-disease prevention.

5.1.2.2 Design-Oriented Conceptual Model (DOCM)

DOCM is concerned with designing the economic model structure, based on the POCM structure. However, within this process many assumptions and simplifications are necessary in taking one from the complexity of a decision problem to the simplicity of a mathematical model. In designing the model, this will provide further clarifications regarding the model evidence requirements and parameter inputs prior to model implementation. This may also lead to comparisons between competing model designs along with their justifications. Led by the POCM, which asks "what is relevant?", DOCMs additionally ask, "what is feasible?", which is constrained by available evidence and model development resources (Tappenden, 2014).

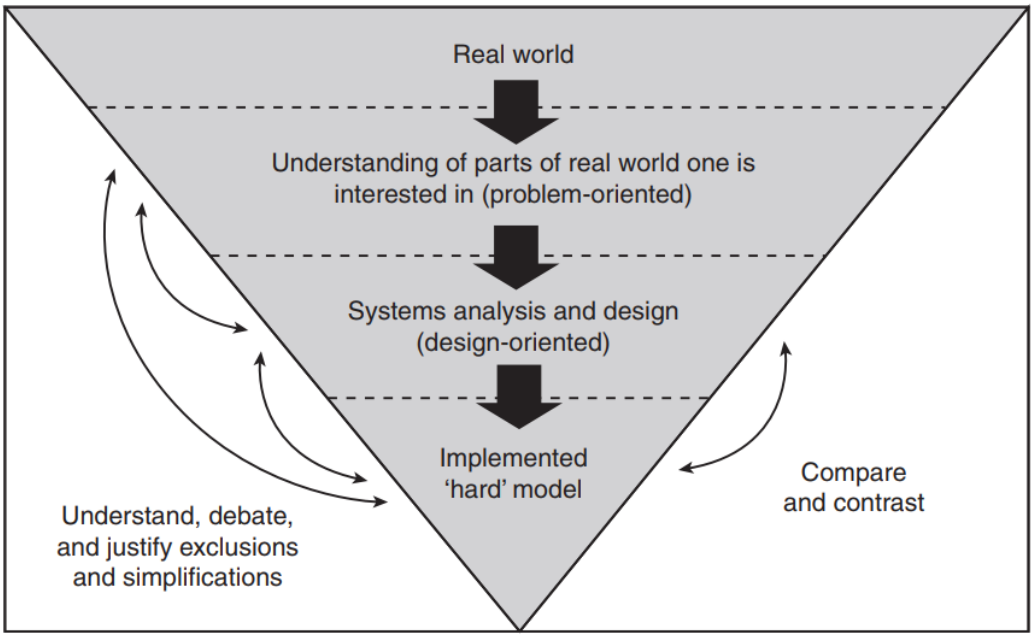


Figure 6. Hierarchy of conceptual models. Reproduced from Tappenden et al. (2014).

5.1.3 Introduction to stakeholder engagement

Stakeholder engagement in health research is the inclusion of relevant players that are either interested in, affected by, or affect health policies and related health outcomes. Stakeholder engagement is fundamental when designing interventions and evaluations (Martin et al., 2020), to help inform methodological approaches, content and scope (Gibbs et al., 2023, Gillespie et al., 2021). This is particularly the case when developing economic evaluations to ensure that outcomes are relevant to policy makers and can be used to inform budget allocations (Husereau et al., 2022). How stakeholders can be identified and included within discussions surrounding the development of economic models has been outlined within Squires et al. (2016). Squires et al. (2016) have also put forth key principles of good practice when developing a conceptual model. This includes opting for a systems approach to modelling; developing an understanding of the decision problem that could help justify the model structure; stakeholder input throughout the model development process; and identifying the key impacts of public health interventions. Although stakeholder workshops have previously been conducted to address key issues in the economic evaluation of DHIs (Michie et al., 2017), and have provided recommendations for practice (Murray et al., 2016, Yardley et al., 2016, Hekler et al., 2016, Michie et al., 2017), they have not been within the scope of dietary apps and paediatric populations. In fact, Murray et al. (2016) outlined areas to explore in future methodological research. These included the identification of appropriate short-term proxy outcomes, improving methods for early pilot work alongside a discussion of whether additional investment in further research is needed. Other suggestions for future research included improved understanding of how to improve the internal validity of RCTs of DHIs (e.g. recruitment/retention), and improved methods for addressing missing data. Enabling comparison between studies was also raised, including the identification of contextual factors, specification of target populations, specification of the DHIs (e.g. active components), and specifications of appropriate comparators (or control condition, in the case of experimental research). These recommendations for future research were considered within the methods of the current chapter and informed the methods of following chapters (Chapters 6 and 7).

5.1.4 Aims

Although digital technologies have been rising in popularity over the last decade, especially the use of mobile applications in more recent years, there is still little research to support the understanding of how such technologies should be evaluated from an effectiveness and cost-effectiveness perspective. Current guidance has been centred around the use of digital interventions in general, and not specific to mobile applications. In addition, given the rise in obesity worldwide (Chapter 1), there has been an increase in the development of obesity-prevention, diet-based mobile applications. To my knowledge, no study has investigated the methods by which dietary app-based interventions should be evaluated. As such, stakeholder engagement was deemed imperative for the conceptualisation of the decision problem and to seek guidance on methods and approaches to undertake within the economic evaluation of dietary apps in general. The stakeholder event aims to:

1) discuss factors that need to be assessed within dietary digital interventions.
2) explore current perspectives of the causal pathway by which a dietary app may lead to obesity prevention and improved health and wellbeing outcomes within a complex system.
3) discuss potential issues and recommendations for evaluating the effectiveness and cost-effectiveness of dietary apps.

5.2 Methods

5.2.1 Development of a draft conceptual model

A draft problem-oriented conceptual model was developed to explore the mechanisms by which the Food Scanner app reduces sugar intake and prevents obesity in 4-11 year old children. In this process, existing evidence and considerations from available ecological and conceptual models were considered (see Figure 7). The role of the model was 1) to facilitate the discussion and allow assumptions and beliefs to be made explicit, 2) record a description of the system that all stakeholders can recognise whilst exploring potentially conflicting perspectives and 3) provide a basis for making explicit judgements about simplifications and assumptions necessary in moving towards the design of a mathematical model. A description of the draft conceptual model, alongside supporting literature, is discussed within Appendix 9.

5.2.2 Stakeholder engagement

5.2.2.1 Recruitment

Stakeholder engagement was carried out to inform the conceptual model of the Food Scanner app evaluation. This involved an interactive half-day workshop at the University of Sheffield, and interviews for those unable to attend (one in-person interview with two stakeholders simultaneously, at their place of employment, lasting 90 minutes and a single online video call lasting 60 minutes) between November 2019-January 2020. Participants were identified through relevant publications, existing networks and targeted decision makers working within policy. All contact details were obtained from public sources and invitations were sent through email. Additional participants had directly contacted the researcher through recommendations from contacted invitees. Examples of people and organisations contacted included local authorities (Derbyshire and Nottingham), NHS Digital, Public Health England, academics and researchers, charities, GPs, and the Healthy Weight Networking Group. Attempts were made to recruit a range of expertise within the fields of childhood obesity, health economics and digital interventions. Ethical approval was obtained by the University of Sheffield Research Ethics Committee (030786) in October 2019.

5.2.2.2 Stakeholder engagement session

In organising the stakeholder engagement workshop, recommendations from online resources and the literature were sought (Rhizome, no date, Pavelin et al., 2014), alongside conversations with colleagues on their experiences of conducting successful workshops. The outcomes of these resources helped generate an agenda alongside engaging activities for the session. They also helped ensure appropriate time-management and preparation of materials required for the session to run smoothly (Rhizome, no date). Materials included an encrypted Dictaphone (to record the session), easel, flipchart paper, marker pens, dot stickers and post-it notes.

Stakeholders were provided with a draft version of a conceptual model, developed prior to any stakeholder engagement (see Figure 7), alongside a discussion document outlining key objectives of the session, and a summary of key texts. At the beginning of the workshop/interview, all participants provided informed consent, agreed to the recording of the session, and briefly introduced themselves and their area of expertise/research interests. The session was facilitated by the researcher and was supported by another doctoral student (SB), who took on transcribing responsibilities, within the School of Health and Related Research, University of Sheffield. The session included a structured interview guide that was shared with participants in the form of a presentation and included several activities to stimulate discussions. The presentation consisted of a brief background to childhood obesity, an overview of the researcher's PhD aims on evaluating DDIs and a description of the Change4Life Food Scanner app. Each of the five objectives were then presented alongside some contextual slides and key questions to facilitate discussions, which were informed by Squires et al. (2016), Murray et al. (2016) and the NICE evidence standards framework for digital health technologies (National Institute for Health and Care Excellence, 2019):

Objective 1: The role of apps within interventions.
This objective consisted of two sections. The first section included an opening discussion on dietary apps as complex interventions, where participants were asked the following questions:

1. How may dietary apps be employed?
2. Should they form part of a multicomponent public health preventive intervention, or could they act independently in their own right?
3. Are all dietary apps considered interventions, and in what circumstances would they not be?

4. What are the different methods of recruitment or app dissemination that may impact on the level of user engagement?

Objective 2: Describe the pathways by which dietary apps may impact on dietary intake and childhood obesity prevention.

The second section aimed to describe the pathways by which dietary apps may impact on dietary intake and obesity prevention. This included a presentation of a draft conceptual model that outlined an overview of the process by which a DDI leads to behaviour change, short-term and long-term outcomes relating to dietary intake and obesity prevention (see Figure 7). Workshop attendees were then divided into two groups (Group A and Group B) and provided with an A1 print out of the draft conceptual model along with marker pens and asked to make amendments to the conceptual model where they saw fit. Where an interview took place instead, participants were asked to discuss their thoughts directly with the interviewer. To guide group discussions, the following key questions were presented as prompts:

1. What are the factors to consider and outcomes to measure within evaluations of dietary digital (app-based) interventions?
2. What are the positive and negative consequences of such factors?
3. Through what mechanisms may different dietary apps work to prevent childhood obesity?
4. What would happen in the absence of such dietary app-based interventions?
5. What are the short-term and long-term impacts of dietary app-based interventions?

Upon completion of discussions, workshop attendees reported back to the whole group and shared amendments were made to the conceptual model. The conceptual model was later updated to reflect the stakeholders' feedback and circulated to stakeholders at a later date to confirm views were accurately captured.

Objective 3: What are the priority outcomes?

Workshop attendees were asked to brainstorm together the short-term and long-term outcomes that we would want to capture from a dietary app. This was jotted onto flipchart paper. Upon doing so, participants were asked what they felt were the key priority outcomes from this brainstorm, given aspects of feasibility and time constraints when conducting complex research. They were provided with a red, orange and green sticker and asked to indicate their top 3 priority outcomes, respectively. A group discussion then followed to discuss discrepancies in choices. Those taking part in interviews did not have this interactive element and were merely asked to voice priority outcomes from their perspective.

Objective 4: Resource use and costs

Participants were introduced to the nature of economic evaluations, resource use and associated costs. In groups (Group A and Group B), workshop participants were asked to refer back to the conceptual model and to draw out a mind map of the resources used and associated costs of the Change4Life Food Scanner app. They were asked to think about this from an intervention, user, healthcare and societal perspective. Participants were then asked to feedback to the whole group. Those taking part in interviews were asked to verbalise to the interviewer the resources and costs of using a dietary app, rather than generating a brainstormed output.

Objective 5: Simplifying the conceptual model

Economic modelling was introduced to participants as a way of evaluating intervention cost-effectiveness. It was explained that the complex causal pathway (conceptual model) would need to be simplified and this could be done through determining the model boundary by considering what factors are more relevant for inclusion; and what is realistic to measure given time and resource constraints. Examples of DOCMs were provided to demonstrate the simplification of economic models. Post-it notes were provided to participants, and they were asked to note essential and preferable factors that could be captured within an economic model. Post-its were stuck onto a flipchart and a group discussion took place enquiring about people's choices. Interview participants were asked to openly discuss their thoughts on the essential and preferable factors.

5.2.2.3 Qualitative analysis

All audio recordings were transcribed. Data was analysed qualitatively using thematic analysis methods. Thematic analysis provides the researcher with the main themes, or patterns, emerging from responses, organised hierarchically. Utilising a grounded theory approach, themes were derived based on findings emerging from participant responses, rather than categorising responses into pre-defined themes informed by the literature (Braun and Clarke, 2006).

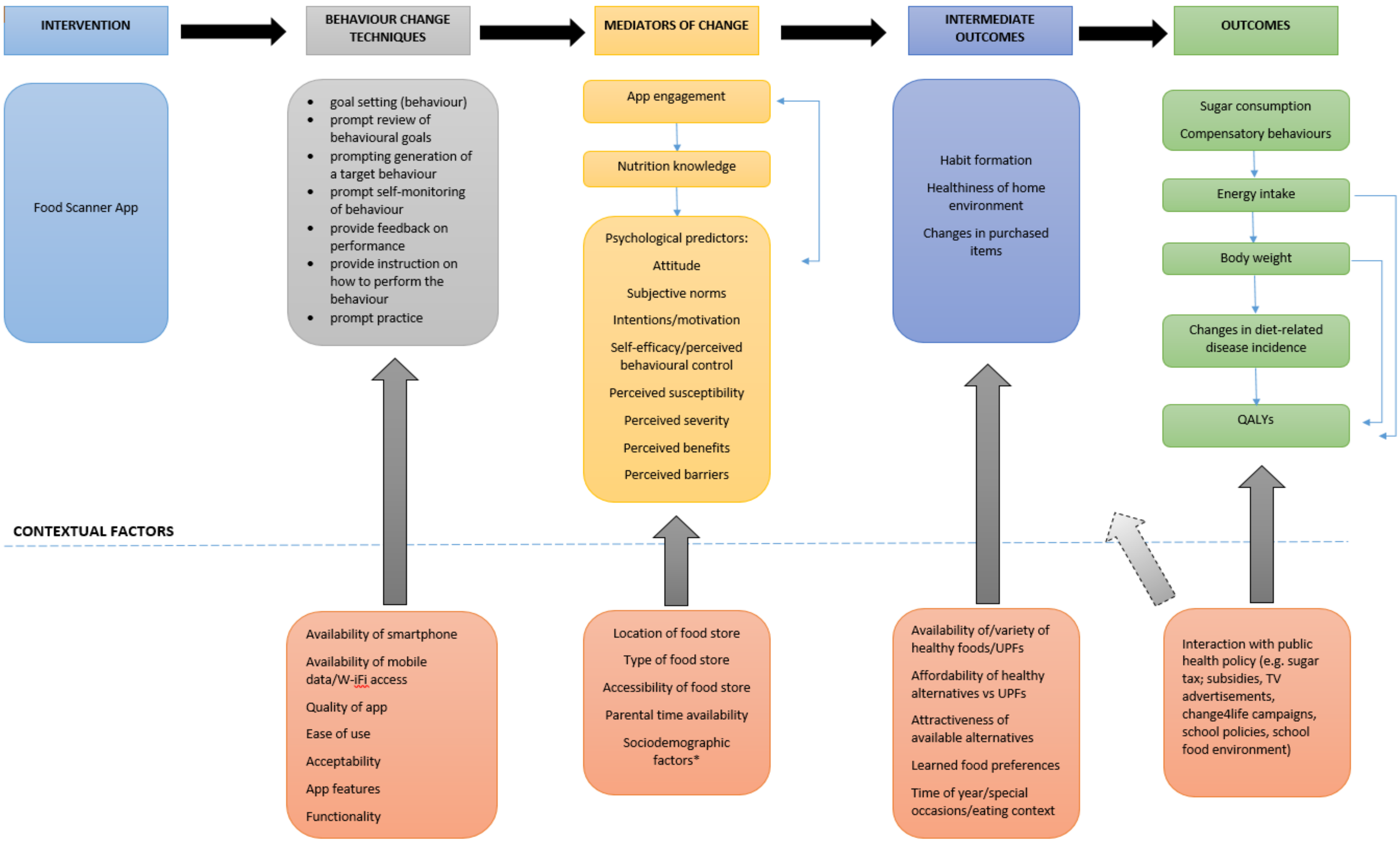


Figure 7. Prior problem-oriented conceptual model of the Food Scanner app.

The researcher (SM) independently coded all transcripts using NVivo software, thus creating a codebook in the process. A second coder (SA) was asked to independently code 10% of all transcripts, which resulted in a 70% agreement score. The agreement score was calculated by calculating the sum of all agreements and dividing by the total number of coding decisions. A discrepancy discussion took place where coding decisions were compared. Any disagreements were discussed until consensus was reached. One of the main differences in coding practice between the two coders was down to precision; SM generally had broader codes, whereas SA had more specific codes (e.g. 'evaluation considerations' [SM] vs. 'clarifying short/long term time frames' [SA]). Other differences in coding practices related to the comprehensiveness of codes generated by SA (e.g. 'use of healthcare resources as a potential short/long term outcome'), whilst SM would use numerous topic-based codes (e.g. 'long term outcomes', 'app within complex system', 'wider app benefits', 'healthcare resource use'). SM revised the coding strategy by breaking down broad codes into more specific, information rich codes. Upon revising the codes allocated to the transcripts, SM independently grouped codes into themes. Codes and themes were then revised and refined to ensure that they addressed the five core aims and objectives of the stakeholder engagement.

5.3 Results

5.3.1 Sample characteristics

Stakeholder engagement consisted of one group workshop (n=9), one 2-to-1 interview (n=2) and one single interview (n=1), generating a total sample of 12 participants. The total sample consisted of 9 academics, 2 Government workers and 1 non-profit. The sample consisted of 6 (50%) participants with an expertise in digital interventions, 5 (42%) had a background in health economics, and 9 (75%) had an interest within obesity (see Table 4).

Table 4. Characteristics of study participants (n=12)

Characteristic	N (%)
Research field	
Digital interventions	6 (50)
Health economics	5 (42)
Public health nutrition and obesity	1 (8)
Sector	

Academic	9 (75)
Government	2 (17)
Non-profit	1 (8)
Other background	
Child health	1 (8)
Diabetes	2 (17)
General Practitioner	1 (8)
Public health nutrition and obesity	6 (50)
Tobacco and Alcohol	2 (17)

5.3.2 Revised conceptual model

Stakeholders identified the pathways by which the Change4Life Food Scanner app may impact on dietary intake and childhood obesity prevention (see Figure 8). The model is split into two sections; the upper section describes the pathways to behavioural outcomes leading from app uptake, whilst the lower section describes contextual factors that may facilitate, or hinder behaviour change success. The model begins with the provision of the Food Scanner app (v1.6), which comprises of eight BCTs through which behaviour is shaped (updated BCTs were informed by findings from Chapter 3). Alongside BCTs are app design features that are important to maintaining user engagement. A cycle loop above 'intervention content' considers likely changes to BCTs and app content with app updates and development. Through using the app, users' nutrition knowledge and psychological predictors of behaviour change may improve, leading to a general increase in awareness of healthy diets. These are considered proximal outcomes.

Although intermediate outcomes are changes in behaviour, they often precede the main desired effects. Within the model, changes in purchased items, habit formation, and healthiness of home environment are predicted to lead to parental outcomes, child mediators of change and environmental outcomes. Environmental outcomes are a result of the food system responding to consumer demands and changes in behaviour. Parental and child outcomes describe how changes in sugar intake lead to changes in dietary and energy intake, which may have an impact on body weight. These are considered medium-term outcomes, whilst environmental outcomes are considered distal.

Increases in child BMI percentiles and increases in adult body weight may lead to changes in metabolic trajectories in the lead up to disease, and changes in weight and diet-related disease incidence. In the long-term this is predicted to lead to increased use of healthcare resources, increased sick days off school or work, and a negative impact on physical and mental HRQoL and wellbeing, as has been suggested within the systematic review in Chapter 4 (Mahdi et al., 2022a). Stakeholders posited that childhood outcomes will continue into adolescence and will get worse into adulthood, which has been verified within the literature (Simmonds et al., 2016). These are considered distal outcomes.

Ideally, the Food Scanner app will lead to improvements in knowledge and awareness of nutrition in the short-term. This will lead to a decrease in sugar consumption and thus a reduction in total energy intake in the short to medium-term. This will then lead to a reduction in BMI in the medium-term, which will be protective of ill-health in the long-term. Alternatively, poor diets could directly lead to changes in metabolic trajectories in the lead up to disease, irrespective of BMI. Contextual factors consider other aspects within the system that may facilitate or hinder behaviour change. App engagement may interact with contextual factors and/or other policies within the system which may have additional positive impacts on behavioural outcomes.

5.3.3 Outcomes arising from thematic analysis

Codes, themes, and supporting quotes for each of the five objectives are reported fully in Appendix 10. The main findings of each objective, by theme, are reported below, alongside supporting statements in italics (*P* indicates participant number; *I* indicates interviewer). Results presented below are directly from the stakeholder engagement sessions.

5.3.3.1 Objective 1: The role of apps within interventions

Four themes emerged when discussing the role of apps within interventions: 1) understanding what is meant by digital app-based interventions; 2) reflections concerning the Food Scanner app; 3) dietary apps within a wider context; and 4) app reaching the public.

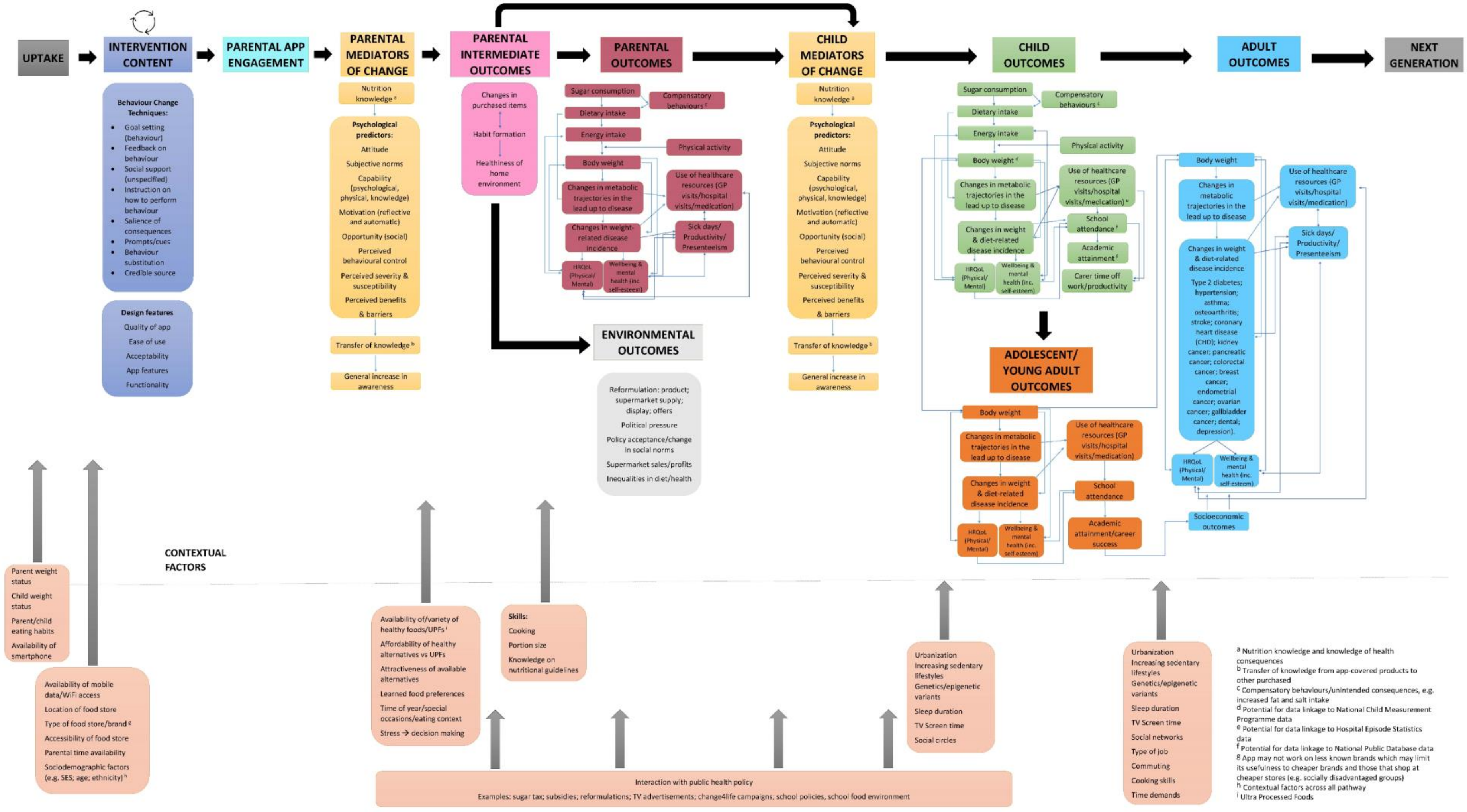


Figure 8. Revised problem-oriented conceptual model of the Food Scanner app

Discussions covered aspects of whether dietary apps should be considered as part of complex interventions or whether they could act as interventions within their own right; under what conditions would an app not be classified as an intervention; and the various methods of recruitment or app dissemination that may impact on the level of user engagement.

5.3.3.1.1 Theme 1: Understanding what is meant by digital app-based interventions

To gain an understanding of whether dietary apps should be considered as interventions, stakeholders covered a number of topics within discussions. It was agreed that digital interventions would use digital technology (e.g. computer-based, tablet, smart-phone) to intervene on health outcomes. Digital public health interventions could be deemed as simple or complex depending on the number of components that they comprise, the level of interactivity with the user, and with the aim of changing somebody's behaviour. Complexity was also viewed as an app's ability to change the environment of people who are not using the app. To change behaviour, evidence based BCTs ought to be incorporated within digital interventions. A dietary app aimed at the parent can have a behaviour change effect on the child, in such circumstances these interventions should be classified as targeting the parent rather than the child, which is often the case with the Food Scanner app:

P1: "So I suppose, well, coming from a behavioural science perspective [mhm] which I think is quite important to note cos there are obviously lots of different stakeholders in this area, I think I would probably define it as, I mean, it could be a simple intervention rather than complex and I would think of it in terms of the, kind of, different components to it, so for example a simple tracker that doesn't really have that many other features could probably be debateable whether that's a complex intervention or not, erm, but I think also, important to note that it could be, um, delivered across. So, the core programme needs to be, erm, kind of, informed by people science erm but then could be delivered across lots of different platforms that uses computer technologies so could be an app, website, wearable."

Another participant said:

P11: "It's an intervention for the parents [yeah] to then change the behaviour [yeah] of the children but like completely [yeah] as you say, with that causal pathway, like that's the next step [yeah] but the, the app is an intervention for the parents [yes] not an intervention for the children [yeah]."

5.3.3.1.2 Theme 2: Reflections around the Food Scanner app

The Change4Life Food Scanner app was seen to be designed for information provision purposes, whereby an emphasis is placed on how information is communicated to users, with the purpose of easing information processing around nutritional content of packaged products to help consumers make healthier food choices. However, in doing so the timeframe in which the app is required to be used was seen as unclear, and whether its purpose is to teach new knowledge over the short-term, or whether it should be used continuously to aid shopping choices. The focus of the app on packaged products was seen as a shortcoming, as this excludes its potential effectiveness within the out of home sector, especially when this is common amongst households, and within cooked meals generally. Its usefulness in providing nutritional information that could help consumers in their purchasing decisions is inhibited when consumers may lack the knowledge on how to prepare or cook meals. Therefore, the app was seen as mostly useful for snacks. A number of suggestions were put forward that could help improve the app and its potential effectiveness by expanding its functionality. These included suggestions for healthier swaps within the same price range, a food diary feature where users could track what they have eaten and receive feedback (e.g. feedback that you have overconsumed on a particular macronutrient, feedback on predicted weight gain given food intake data, or feedback on the health consequences of consuming a particular product):

P8: "I suppose if people are realising their snacks high sugar and then their thinking about well actually what about my meals. But then, that doesn't, the app doesn't support you through something like need some help with cooking skills or something [?? 2:13:33]. But like you said if there's no way to point you to then it's limiting that potential benefit."

5.3.3.1.3 Theme 3: Dietary apps within a wider context

Dietary apps may be formed of BCTs (app content) as well as delivery features. The way in which a BCT is delivered within an app may have an impact on outcomes as opposed to the mere presence of a BCT. Stakeholders flagged the need to understand how different components of an intervention may influence behaviour. In the case where an app forms part of a larger complex intervention, it was advised that the app ought to be evaluated both separately and as part of the wider intervention in which it comprises, to understand the additive effectiveness that the app may contribute. It was suggested that investigating a wider campaign on its own may pose difficulties in attributing which component of the campaign was driving changes in outcomes of interest. Despite the Food Scanner app being informative in helping people make healthier choices, participants flagged several barriers that may prevent users from achieving this. Given that we live in complex environments, if the unhealthier options available in supermarkets are cheaper than healthier options this may act as a barrier to behaviour change, especially if users have insufficient funds to make healthier swaps. Although the app was perceived to be useful as an independent intervention, stakeholders highlighted the importance that it's used alongside other supporting environmental changes:

P2: "So I think, you know, if you think of the Change4Life as 1 enormous intervention, you need to look at the effectiveness of each of the individual components, whether that's the broad mass media campaign about Change4Life or like, as a whole, the Change4Life app for physical activity, the Change4Life app for dietary assessment. So I think its, there's no one way to do it, it's not like do all of it or just do this [yep], I think you sort of need to do both [mm]."

5.3.3.1.4 Theme 4: App reaching the public

Two stakeholders discussed the difficulty in raising awareness of credible apps. They outlined the potential impact that commercial influences and credible sources have over the level of attention or uptake an app receives on the app market, regardless of whether an app is effective or evidence based. Therefore, it was argued that there is a need to shift the public's awareness to where they can find high quality apps, with an emphasis placed on promotional campaigns and the role of healthcare professionals to start utilising and promoting credible portals to their patients, such as the NHS apps library, and the apps within them:

P1: "I think there's scepticism towards apps and also that people don't really know which ones to recommend, so if there were some, sort of, forms of trusted app portals that they could also go to, then I think sort of, [yeah] there could be more promotion happening from trusted healthcare professionals [mhm] as well."

5.3.3.2 Objective 2: The pathways by which dietary apps impact on dietary intake and childhood obesity prevention

Eight themes emerged when discussing the role of apps within interventions: 1) behaviour change techniques; 2) factors impacting app uptake; 3) factors impacting app effectiveness/usefulness; 4) health outcomes; 5) direct impact of app on psychological and behavioural factors; 6) impacts of app on the whole family; 7) wider/indirect app benefits; and 8) contextual factors impacting app effectiveness.

5.3.3.2.1 Theme 1: Behaviour Change Techniques

Depending on how and which BCTs are used could determine whether someone is required to use the app continuously (such as is the case with monitoring behaviours), or only use it over a short period to bring about changes in behaviour. Other stakeholders flagged the need to know whether discontinued app use was in fact due to behaviour change:

P3: "The story you need to build up is, they're gonna start using the app and then to varying degrees they'll stop using the app. So, you'll have that sort of like time over the use, but then you want to be able to say if they've stopped are they still, have the behaviour still changed or does stopping indicate that they have started buying chocolate? And so it, to move on to the childhood outcomes adolescent you need confidence in that it actually changed a habit, it actually maintained a change."

This could be investigated through exploring the association between food purchased/consumed and continued/discontinued app use. To ascertain whether app users are progressing through the logic pathway is to have certainty that the app has resulted in a change of habit and maintained changes in behaviour.

Stakeholders communicated that level of app engagement could determine exposure to app content and BCTs. It was suggested that an evaluation of the number of BCTs present within the app may be of use, including an investigation of how many of these have been shown to be effective within the literature:

P10: "…and I mean what you want to do is, not only find out how many BCTs there are, but whether the extent of which what's present agrees with what has been shown to be effective."

Availability of heuristics, such as the ease of conceptualising the amount of sugar via sugar cubes, was suggested as a potential BCT that is present in the Food Scanner app.

5.3.3.2.2 Theme 2: Factors impacting app uptake

Stakeholders expressed the need to learn more about the characteristics of app users, in comparison to non-users. It is common that those who engage with dietary apps have pre-existing concerns regarding the sugar content within their children's food. Those who are less aware of the negative impacts of sugar, would be less likely to download the app. For such reasons, stakeholders expressed the importance of language when first introducing the app to users as this is likely to impact who will download it. This may suggest the importance of embedding DDIs within larger public health campaigns to help facilitate the process:

P4: "I guess, one thing that would be really important is not potentially more important is not, once someone's using the app they're already, they've already got at least some motivation because otherwise they wouldn't use the app because they don't have. Whereas they have to, well they don't have to they can opt out of the child measurement program, so then it, you almost need to take it back a step further and go and think about the language with which you introduce the app to people before they even download it. And that could almost be one of the most important bits of the puzzle. Otherwise, you will only ever get the worried well parents, more or less, downloading it who probably did already know that they really shouldn't be giving their kid a bar of chocolate they should give them a banana instead."

Issues surrounding inapplicability of a dietary app to oneself was flagged as a barrier to app uptake. This may be due to the normalisation of overweight and obesity within particular communities, not feeling any urgency from a health outcomes perspective relating to children's diets, as well as the lack of knowledge to detect overweight and obesity within children. Therefore, exposure to campaigns and knowledge of dietary apps may not be sufficient to promote uptake:

P4: "And it's getting harder cos people can't recognise overweight and obese children because so many children are overweight that their child looks normal, which is also part of the challenge with feedback for the national childhood measurement program, exactly."

Issues surrounding cognitive dissonance were also expressed where people may reject information that makes them feel negative about themselves or find any feedback regarding their child's weight as a criticism rather than a health warning. Therefore, dietary apps need to be introduced in a way which does not trigger rejection of information.

There are also external factors that may prevent app uptake; commercial influences such as Google and Apple design their portals and algorithms to draw attention to particular products within the app market, which may not be in favour of public health. In addition, reviews and ratings on the app store could deter people from downloading an app. Finally, given the Food Scanner app is part of a larger Change4Life campaign, the size of the campaign may have an impact on uptake, especially given it has the credibility that it is provided by the government. It has also been found that when well-known, famous or credible persons endorse an app, levels of app uptake and app engagement increase. High levels of downloads which lead to the number one list for downloads in the app market, creates further app exposure and downloads amongst those who weren't particularly searching for a dietary app:

P2: "If there's an IOS software update or Google, you know, android update, that can have knock-on effects on the app. There will be things that need to be fixed for users to maintain it and because also, regular updates is something else that is there in the app store which, I think, can affect whether or not people, you know, the uptake is, good reviews, if the app is getting buggy and people aren't updating it you'll get worse reviews, you'll get a worse app store rating."

It was said that although the NHS app library is a credible platform, it has a lack of exposure which may dissuade researchers and app developers from going through the application process to put their app on the portal.

5.3.3.2.3 Theme 3: Factors impacting app effectiveness/usefulness

Stakeholders highlighted several factors that may impact on app effectiveness and usefulness. How people get to the intervention is expected to affect whether or not they engage with the intervention (e.g. credibility). If one does not engage with an intervention then any changes in dietary behaviours and health outcomes cannot be expected. It was raised that app engagement should be measured over the long-term to track app use duration alongside insights into how app use changes over time. One stakeholder felt it necessary to understand the reasons that draw people to using a dietary app initially. One participant discussed the importance of learning the circumstances that prevent people from engaging with a dietary app to make healthier lifestyle changes and finding ways to overcome these. App qualities such as ease of use, app features, functionality, accessibility and BCT content can impact app engagement. Oftentimes people may stop using health and fitness apps as they are found to be boring, effortful, or ineffective in changing behaviour. Where some apps may be designed for everyday use, others may lead to behaviour change over the short-term thus leading to early app disuse:

P3: "So, you kinda expect, ideally, overtime people would stop using it, but what you're trying to capture is that they've stopped using it because they've changed their behaviour, not that they've stopped using it because they got bored with it and reverted back to being consciously incompetent."

5.3.3.2.4 Theme 4: Direct impact of app on psychological and behavioural factors

Discussions outlined a number of outcome measures in relating to the Food scanner app. These included weight and nutrition knowledge, behaviour change, food purchasing, sugar consumption, dietary changes, impact of intervention on confidence in consuming healthy food, unintended consequences, and habit formation.

Nutritional guidance is allocated by age group, increasing the difficulty in understanding what a healthy diet is. In addition, people may lack knowledge around why too much food or nutrient intake is bad for health and only decide on making changes after they have got an obesity-related disease rather than preventing disease initially. Parents need knowledge, not just around nutrition, but also the skills to cook nutritious meals, alongside knowledge concerning the consequences of weight gain. One stakeholder felt that measuring knowledge as an outcome may be a more accurate measure of the impacts of the app as it is more easily attributable, given that people have a lot of exposure to other factors that could impact on behaviour:

P1: "It's in the news, it's in the media, people talking about it. So, the easiest way would be just to measure nutrition knowledge before and after". Short-term use of the app should increase confidence in parents/carers, through the delivery of accurate information, around healthy diets and in being able to prepare a nutritionally balanced healthy meal."

A measure of the food that is purchased or the quantity of food purchased due to the use of the app is an important aspect of the evaluation, given that the app works by impacting on what parents buy for their children. Shopping receipts were suggested as a form of food purchasing measure, whilst another stakeholder suggested a greater focus on snack and drink purchases and how they change over app duration, for instance:

P6: "I think purchasing habits would be another massive huge area of (yeah).

P1: Yeah, I don't know how far you can go but you can get shopping receipts, purchasing [?? 51:48].

P7: Yeah, the problem is the they'd only have enough money to buy a little food and you're gonna buy – you can change the knowledge but then that's..

P4: I'm wondering whether you might wanna focus on snack purchases and stuff which is a bit more it's, it's a bit more (P7 yeah) specific isn't it? And also you tend not to then process a snack you just open it and eat it…

P4: Snacks and drinks."

Stakeholders agreed that short-term dietary changes due to the app should be captured. Some stakeholders felt macronutrients should not be measured in isolation (e.g. sugar), and that changes to the overall diet needs to be evaluated, given that compensatory behaviours may often occur alongside reductions in sugar consumption. There was also curiosity as to whether dietary changes would apply more widely to items not scanned through the app. It was expressed that any reductions in sugar or energy consumption would take a considerable time to reflect in changes in weight. Investigations of how dietary intake is projected to health outcomes in the long term was suggested. One stakeholder indicated that confirmation bias may occur where parents may take up healthier behaviours, without particularly using the app, to confirm to themselves that they are a good parent:

> *P5:* *"There's a point on mediator of change where I think confirmation bias plays a role. So, we talked about there's a study on, on bamboo toothbrushes and they're really making impact on environment but, because brush your teeth in the morning, the bamboo brush and you want to confirm that you are a good environmentalist, you go out throughout the day being slightly more environmental. And that's the impact, that actually having a bamboo toothbrush has. Downloading this app is a signal to yourself that I'm a good parent and then you confirm that you're going to be a god parent, even if you're not using the app directly."*

Habit formation was said to occur after visible changes in behaviour have been measured, making it a medium-term outcome. In simplifying the conceptual model, stakeholders suggested that outcomes should be measured up to habit formation whilst using other available evidence in the literature to model forward from that. It was noted that evidence of maintained habits are needed, even after app use has stopped, before assumptions regarding adolescent outcomes and beyond are made. Transitional periods over the life course may be an ideal time to investigate this to begin with, such as the period between primary and secondary school, when a child becomes more independent. In addition to habit formation, stakeholders felt it important to also evaluate the continuation of habits into the long-term, where habits can then be passed onto the next generation.

5.3.3.2.5 Theme 5: Health outcomes

Demonstrating clinical effectiveness, such as changes in weight, was seen as important to stakeholders as it provides evidence that will allow clinicians to promote an app's use. The pathways by which dietary apps prevent childhood obesity also lead to the prevention of health outcomes in the long-term. Reductions in sugar consumption may result in attainment of normal bodyweight and reductions in weight related disease, which may lead to population-level reductions in hospital admissions. In addition, dental problems were seen as an important factor relevant to childhood with strong connections to sugar consumption:

P2: *"We added to ours dental problems, cos it's a health outcome that's very relevant in childhood. Connections very strong so there's evidence."*

One stakeholder suggested an evaluation of the distributional effects of the intervention as opposed to the average effects as this will enable any changes in health outcomes within extreme cases to be captured, resulting in potential health gains. Small differences in weight are important in the long-term, especially small declines across the population. It is expected that children may be gaining weight over the study period, therefore collecting outcomes related to weight gain as opposed to weight loss may be more fitting. Given the difficulty in collecting reliable BMI percentile data on children, any change in weight in the long term will also be difficult to attribute to the app. One stakeholder suggested the advantages of linking intervention outcomes to health data since any changes in weight due to changes in diet may take a couple of years.

In addition to the above, QoL was also considered an important outcome, with proxy measures available to investigate the impact of a dietary intervention. However, there were concerns from stakeholders over the unlikelihood of seeing any changes to QoL given that there are no indications initially to show that children are unwell (depending on the inclusion criteria of the sample). There were mixed opinions on whether QoL was an essential factor to capture within economic evaluations in comparison to alternative measures more sensitive to changes in diet in childhood:

P4: *"I guess the only, the challenge is are you, you're talking to parents not the children but the what you're interested in is the impact of the intervention on the child's consumption. So, it would, you won't be able to capture whether the child feels different which is…*

P6: *There are proxy methods of outcomes, so you could. You could ask quality of life.*

P7: *Exactly.*

I: *I will be including [?? 1:55:53] I am including the child health utility [?? 1:55:58], I'm including that one, I am including that one.*

P6: *But would you expect any change, I mean.*

I: *I'm not expecting any changes.*

P6: *Because otherwise, there's no indication to show that the children are unwell, I mean most of it will all be ones, no problems with anything. So, are you collecting anything else in terms of quality of life?"*

5.3.3.2.6 Theme 6: Impacts of app on the whole family

Stakeholders expressed that dietary apps may have an impact on the whole family, as opposed to the sole app user. Changes in grocery shopping and meal preparation may impact the healthiness of the home environment, which may constitute more than one child. The Food Scanner app can also be considered a shared intervention where the parent is facilitating goal setting and child app engagement. Alternatively, the behaviour change pathway could consist of changes in the parent's behaviour first which is then translated to changes in the child's behaviour through education, modelling or due to changes to the home environment:

P10: "*And the other principle is that this is a family intervention, so the whole family benefits. So, there is going to be a bit of difficulty, you're gonna, I mean that adds to the complexity of the evaluation. But, it's very unlikely that you're going to get successful weight loss in a child, without the whole family changing their dietary behaviours."*

This process may lead to changes in the child's attitudes, beliefs and motivations around healthy diets, alongside maintenance of healthy dietary habits as the child grows older:

P4: "*So, it might be that working through the app like by the time the child's 10, they've got really good habits around healthy snacks and then they go to secondary school and it all gets lost. So, I suppose there's, just thinking about other whether you can track it long enough that you pick up on kind of maintenance of the behaviour a key transition phase that's not that long after the end of the age that your interested in. Because, at that point, kids also get more access to their own money to buy snacks and stuff at school."*

5.3.3.2.7 Theme 7: Wider/indirect app benefits

In addition to the direct effects of DDIs, stakeholders discussed the wider potential impact, or knock-on effects, that a dietary app may have. Wider app benefits include an increased motivation and awareness of macronutrient content within the diet. Improved changes to the diet may increase the salience of other healthier behaviours more generally, such as physical activity. The use of the Food Scanner app could lead to a shift in buying habits or a shift in consumer demands. This may encourage manufacturers and retailers to reformulate the physical availability of lower sugar products in store, leading to a shift to healthier food promoted and marketed, which in effect would lead to a change in dietary intake in people who are not using the app. Other wider app benefits comprised of policy change, political pressure to change policy and policy acceptance:

P5: *"But, if we have child outcomes, parent outcomes and then environmental outcomes, that might be a good way cos we talking about re-formulation and the wider implications of them of the presence of the app. So, if you..*

I: *So, rather than having as a contextual factor should have it so sort of outcome [?? 59:28] ok.*

P5: *I think it might, yeah cos it's, you, it kind of gets messy when you try and put it in. So, I think the 3 main ones would be re-formulation, political pressure to change policy and then inversely, policy acceptance. So, we talked about we, we track people's happiness of government to get involved in their child's weight or children's weight. And it goes up and down and [?? 59:57] be… very, very high."*

One stakeholder voiced that wider app benefits should not be measured until certainty of the app's effectiveness has been established in the short-term.

5.3.3.2.8 Theme 8: Contextual factors impacting app effectiveness

Several contextual factors impacting app effectiveness were raised. These included stress consequences, social networks, inconsistent health messages, cooking skills, and affordability. Stakeholders explained that stress has a great impact on decision making, especially in cases where a dietary app, such as the Food Scanner, requires one to take in novel information. Those in lower socio-demographic groups tend to experience higher stress than those that are not, and stress can be a barrier to taking in new information and therefore changing habits:

P5: *"I think on, on, on the second contextual fact, contextual factors stress seems to me like quite an important one. We talked about inequality in, in social demographics and obesity, the link between the one. There tends to be a much higher level of stress in the lower social demographic groups. Stress' impact on decision-making is, is, is quite profound so, and particularly with this because it's impulse control, it's also about taking in novel information. If you're high stress, you're less likely to change your habits. We're obviously trying to change habits here so, I think that's a considerable contextual factor."*

The need to consider the role of social networks was raised numerous times, including social/socio-political responsibility. One stakeholder described obesity as a contagious illness as it is connected to social network influences. Inconsistent health messages could also impact on behaviour change, such that health messages are constantly updated alongside age-specific guidance creating further barriers to adherence. Stakeholders raised the concern that the Food Scanner app does not provide any assistance on how to cook healthy meals, which could act as a barrier to habit formation. Stakeholders also discussed affordability of healthier food items that could impact on diet. If healthier choices are not made cheaper or promotions are more focused on unhealthy foods, then those engaging with the app will not be able to make the necessary changes to improve their diet if they have limited funds:

P4: "I suppose that thing about treats links into kind of that affordability, because for some people a chocolate bar is a quite affordable way of treating whereas other people can say "oh, we'll go out for the day" that's not an option for everyone so then if you're saying you shouldn't do that as much then what other things [?? 46:20] are there that could be, yeah that's a treat cos [?? 46:25]."

5.3.3.3 Objective 3: Priority outcomes to be captured within evaluations of dietary digital intervention

When investigating priority outcomes to be captured within evaluations of dietary apps, results suggested that changes in dietary behaviour was the most important output, followed by wider changes in the diet (as opposed to investigating one single nutrient alone) and BMI. The continuation of health habits or maintenance of intervention effects was considered the third priority outcome, which was also classified as a long-term outcome (see Table 5 for further priority rankings). One stakeholder felt that short-term outcomes should be seen as a greater priority over long-term outcomes, due to the difficulty in isolating the impact of the intervention on long-term outcomes.

5.3.3.4 Objective 4: Resource pathways and associated costs

Figure 9 depicts outputs produced directly by stakeholders within sub-group discussions (Group A and Group B) in relation to resource pathways and associated costs. Upon further discussion, five themes emerged: 1) stages of app development and maintenance; 2) app-related costs; 3) user costs; 4) societal costs; and 5) impact of app on health and healthcare utilisation.

Table 5. Priority outcomes for evaluation of a dietary digital intervention

Short-term factors	**Ranking***
Change in dietary behaviour (items covered in app and outside of app)	1
Wider changes in diet	2
Awareness of childhood obesity	4
Industry sales of high sugar products	5
Active users	6
Confidence in choices	7
Compensatory behaviour	7
Long-term factors	
BMI	2
Continuation of health habits/maintenance through key phases	3
Quality of life	4
Shift in consumer demand/Policy change	4
Prevention of ill health	5
Healthcare use	5
Cost reduction	7
Dental outcomes	7
Distribution of effects	7

*Ranking: 1=highest, 7=lowest

5.3.3.4.1 Theme 1: Stages of app development and maintenance

It was outlined that apps should be developed with the end-user; understanding user requirements will increase app engagement. To ensure functionality, an app must be regularly maintained. This includes updating app content, updating software so that it continues to be compatible with the latest smartphones and updating look and feel, which includes images and colours that are attractive and current. One stakeholder advised that conversations with commercial providers are needed regarding approximate maintenance costs of keeping an app up to date and attractive. The shelf-life of an app is dependent upon the company undertaking its maintenance and whether the app gets passed on to other agencies.

App maintenance poses an issue for economic analyses, in comparison to drugs which stay constant once they have been produced. Within economic evaluations, short-term app development costs should be considered alongside long-term costs relating to app updates, which are essential to maintain compatibility with software updates and bug fixes:

P2: "Our app developer described it to me as, it was quite a nice analogy, was that people often think of apps as like a nice painting you buy for your house when actually it's a houseplant [OK] and if you don't keep watering it, like, it will die and you'll want to get rid of it. And, so they are, something that I think a lot of people don't consider when developing an app, they think about the costs in the short-term so develop the app. And then as soon as it's released like yeah, you're done. But they haven't costed for what it will, you know, if there's an IOS software update or Google, you know, android update, that can have knock-on effects on the app."

5.3.3.4.2 Theme 2: App-related costs

Several stakeholders believed app development costs should be viewed as sunk costs within analyses. Who should bear the burden of these costs was also raised; it may be more cost-effective if app development came from an academic institution as opposed to a public body that relies on tax money:

P1: "is it worth using tax money to develop something that could be done perhaps better than current methods [yeah]. And more cheaply and without like [yeah] a team of like 40 people [mhm], civil servants to do it, like, [yeah] yeah. That who should bear the burden of the [yeah] cost essentially."

One-off costs may include discovery, where research is conducted into app content, including user needs, user-testing, and actual app development. The Food Scanner app incurs additional costs in relation to nutrition data access. In cases where the data is not bought, this will still incur in-house costs for collecting the data internally.

One stakeholder highlighted the gap within the literature regarding app maintenance cost estimates. Conversations with commercial providers are needed to gain a perspective into the percentage of the original development cost that is spent on annual app updates. This is particularly important if a cost-effectiveness evaluation is taking place over a long-term horizon. Maintenance costs were said to include application program interface, database access, server costs and service level agreements (e.g. for monitoring bugs). Service level agreements do not incur high costs. Agile development costs are optional and could also fall within app maintenance costs. This consists of monitoring and reviewing an app that has been built to see how it can be adapted to fit high priority user needs:

P5: "I suppose on app cost, so we have the discovery which is doing research on to what you should build, then you have dev which is actually building. So, you typically have one agency to do the discovery that would be basically understanding user needs and user stories and then you build the app to fit those needs. So, there's discovery, then you have dev, development, then you have user testing and then you'll have maintenance, you know, discovery, sorry development and user testing are obviously intertwined, well hopefully. Then you have maintenance which you could cover under the API and server costs. Access to the database, this is very specific to food scanners.

I: It could be for the food, well I mean the food scanner is the case study here but.

P5: But yeah, API server costs, database access, access to the database. Service, service legal agreements which is basically just monitoring bugs, so service level agreements.

I: Have you any idea how much the section comes to in terms of cost?

P5: It is..

P4: Easily definable isn't it? As in like, you could work it out.

P5: Yeah, yeah it depends on what, what app you're talking about. Service level agreements are not, not, not significant, not, not very significant in terms of, as a percentage of the total build, it would be like in the sub 10%, significantly less than 5%."

Marketing costs were also flagged as a potential consideration within evaluations, such as app promotions. With regards to the Food Scanner app, one stakeholder explained how PHE have a set budget to focus on the call to action. Usually such a budget would go towards a message-led campaign with a support product which acts as the solution to the health problem. There is difficulty in separating out the costs of the support product from the overall marketing campaign, given that the campaign would be going ahead whether or not the support product exists. Therefore, marketing costs would only contribute a small percentage to overall campaign costs. Another stakeholder suggested that a sensitivity analysis should be conducted within economic evaluations that takes into consideration the "wider picture" in which an app sits, alongside the potential cost of the app alone. One stakeholder also highlighted that the cost going towards the app is the opportunity cost of another message or call to action. Others compared overall app costs to other services which would be far more expensive to roll out (e.g. health screening).

5.3.3.4.3 Theme 3: User costs

Engaging in a dietary app may have unexpected cost consequences for the app user. Given that healthy food is more expensive than nutrient poor foods, any changes in shopping habits due to the app may result in increased costs to the user. There is also the potential of food wastage costs, where the child has a dislike for healthier food alternatives purchased. As a result, parents may try to compromise with their child by rewarding them for consuming a healthier food option, thus incurring additional costs. Other stakeholders suggested happiness costs where the app may make both the child and parent miserable, though no suggestions were provided on how this would be measured. Parent time was also flagged as a potential cost given the time and cognitive commitments involved with using the app to scan products and process the feedback obtained:

P4: "We started then thinking about costs to the parent, so the kind of obvious ones were time, the cost of switching, so there was like the direct cost of if you switch a [2:23:10 CHOCOLATE BAR] tit may cost you less cos a banana is cheaper than a [2:23:14 CHOCOLATE BAR] but if you start buying pistachios it's gonna cost you more. So, it kinda depends on, I don't know overall whether or not it would cost you more or less."

5.3.3.4.4 Theme 4: Societal costs

As well as user-centred costs, costs to society were also flagged. These included parent productivity costs as a result of attending their child's appointments, and time spent using the app. Costs to the education sector were highlighted due to increased outreach of trying to get non-school attenders to attend school. Increased costs to the food sector were also mentioned due to loss of profits from high sugar content, leading to increased marketing. Finally, in the case where an app has been poorly designed due to insufficient funds, stakeholders mentioned lost opportunity costs of deterring people from trying to adopt healthier behaviours:

P1: "I guess healthcare could be a trigger, triggers, ooh I haven't been to the dentist, I don't take my child to the dentist I will now start taking them to the dentist, so. [?? 12:15:03] Dunno, patient, from a dentist or possible a parent if they're not under the NHS or [?? 2:15:12]

P4: Unless you're not in fulltime education.

P6: Cost to the parent.

P4: Cost to the parent in term so of..

P6: In terms of getting the [?? 2:15:23]

P4: Yeah, sort of say time off work potentially, so.

P6: Productivity cost then?"

5.3.3.4.5 Theme 5: Impact of app on health and healthcare utilisation

Stakeholders outlined the importance of considering healthcare resource use within childhood as well as adulthood. Within childhood, healthcare use should be investigated over the short-term, to include dental problems and GP visits. Other stakeholders believed that healthcare use is unlikely to change in the short-term. Changes in healthcare use may depend on sample BMI percentiles (i.e. amongst those with obesity).

Healthcare utilisation could be due to complications in overweight/obesity and noncommunicable diseases such as cardiovascular disease, diabetes, cholesterol, and osteoarthritis. With healthcare resource use comes increased healthcare costs; the use of a dietary app may lead to NHS cost reductions alongside household savings from private dental care. There were also mixed opinions with regards to attributing any changes in healthcare resource use down to the app.

P10: "You want long-term outcomes (yep) of course you're going to be looking at habit formation and all sorts of other things (yep). The use of healthcare resources, all that's very unlikely to change in the short-term and academic. I mean, it depends if you're thinking about morbidly obese children or… what BMI you're thinking about."

Conversely, stakeholders discussed a potential increase in demand for public health services due to the app increasing awareness around diet. Increased support-seeking to live a healthier lifestyle may increase costs to public health and healthcare services. Similarly, the app may increase patient empowerment to access healthcare services due to app-led changes in dietary attitudes and related health issues:

P4: "Is there, just thinking of others, is there something, I think it's probably bit of a long shot actually, but is there something around increasing demand for services? Because if, if I think it is probably unlikely from an app, but if you're making parents more aware of their child's weight and their child's diet, could it lead to increase demand for support from public health services?

P6: Definitely, because that's. I did a bit of research about this and one of the things that like primary care practitioners said was a barrier to them for bringing up issues of weight is the fact once you tell the family, you know, that the child has an issues, what then? Cos normally there's nothing to refer them to.

P4: It's one of the issues with the national child measurement program, you get this letter saying your kids overweight, deal with it."

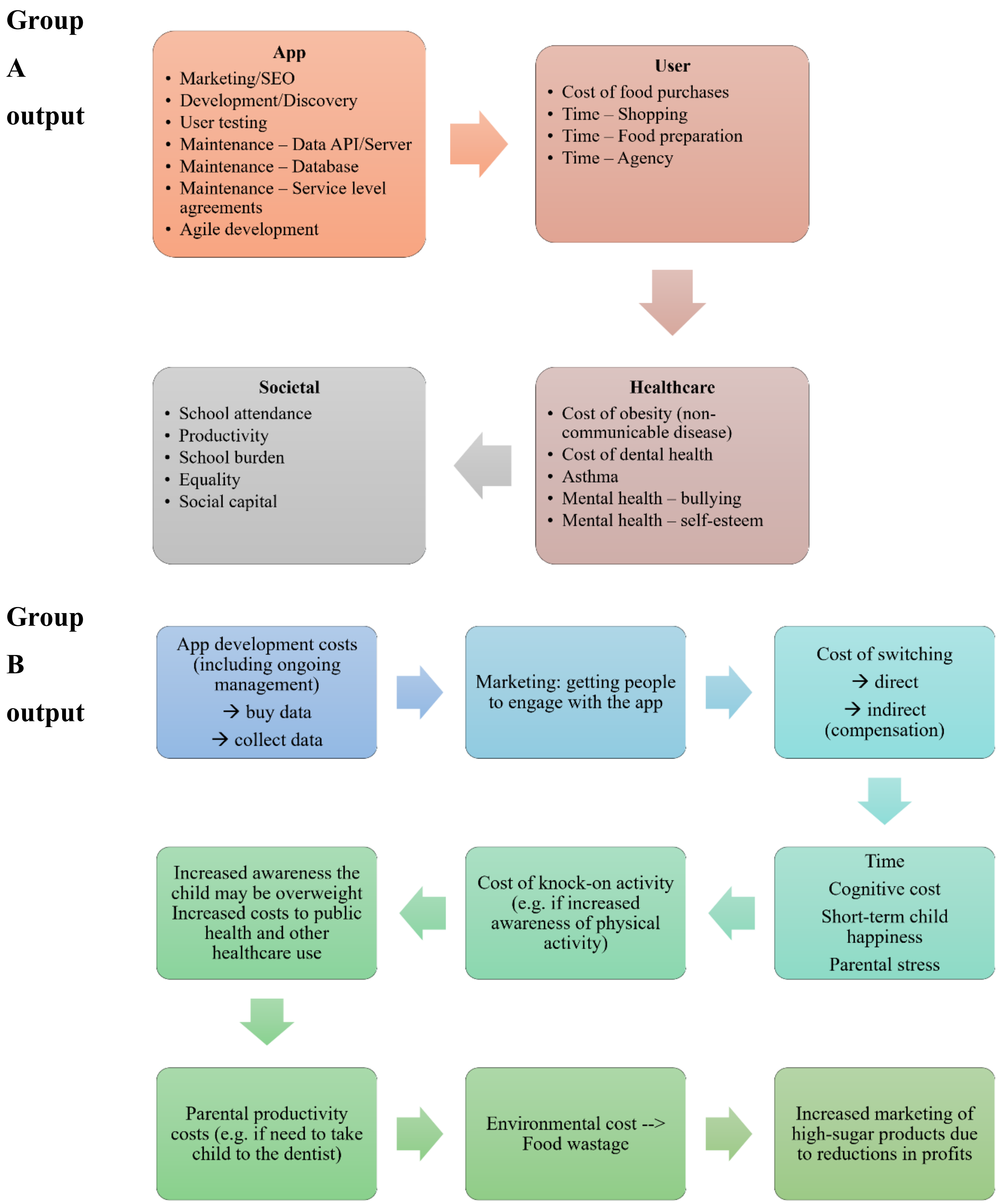


Figure 9. Objective 4 output by stakeholder sub-group: Group A output and Group B output of resource pathways and associated costs

5.3.3.5 Objective 5: Key factors of economic evaluations of dietary digital interventions

Essential and preferable factors of economic evaluations of dietary apps were brainstormed by stakeholders and are presented in Table 6. Upon further discussion, two major themes emerged: 1) considerations for economic evaluations; and 2) considerations by population group of interest.

Table 6. Workshop output of essential and preferable factors to include within an economic evaluation of dietary digital interventions

Essential factors	Preferable factors
General outcomes	
App use*	What is used in the app?
Who is using the app?	App use*
Number of active users	Effect of swaps (e.g. compensatory behaviours)
Is the app reaching those most in need?	Cost of swaps
Purchasing behaviour (e.g. Transactional data on users [sugar/salt/fat])	
Dietary behaviour change (including calorie consumptions)	
Habit formation/Maintenance of behaviour change	
Child and adolescent outcomes	
Weight*	Child quality of life*
Healthcare resource	Short term proxies of long-term chronic conditions (e.g. BMI)*
School attendance	
Well-being	
Quality of life (generic and weight specific; including mental health components)*	
Adult outcomes	

BMI	Parent diet
Healthcare costs	
Resource use (drug use/GP)	
Quality adjusted life years	
Life years	
Productivity	
Short term ill health (e.g. mental health)	
Long term ill health (e.g. cancer)	
Wider societal impacts	
Outcomes by population subgroups	
–Reformulation of HFSS foods	
Policy changes in response to positive dietary changes caused by the Food Scanner app	

*Overlap in opinion between the essential and preferable factors, potentially due to someone's professional background.

5.3.3.5.1 Theme 1: Considerations for economic evaluations

There was some dispute amongst stakeholders regarding the outcomes of interest required within an economic evaluation. One stakeholder felt that the use of desired intervention outcomes within an economic evaluation was sufficient rather than the need to model potential long-term health outcomes. In contrast, another stakeholder expressed that behaviour change does not necessarily lead to further outcomes due to unintended consequences (e.g., intervention changes behaviour but has no other effects in the long-term). Incorporating long-term modelling within pilot and feasibility studies may add extra value to the intervention. It also enables a quantifiable comparison between different apps. In addition, it was highlighted that dietary apps may have small effects. However, as they are wide-reaching, this may lead to large effects on a population level, and low costs per participant, in comparison to a costly intervention with large effects reaching a small proportion:

P1: "So, if we have different types of interventions, some might be quite small effects but cheap and have very high reach and then erm, some have very, quite large effects but *they're very costly and they only reach a small proportion of people who [yeah] can sort of access those [mm]. Erm, balancing those two, erm, I think we can still see with the first type of intervention we could potentially see very large effects just because they are reaching a large proportion of people so a good sense check of whether that's actually true, I think would be both on the sort of population level uptake, is it true that they are reaching more people [mm] than would normally be reached."*

One stakeholder expressed how an economic model of a dietary app should not look dissimilar to a model evaluating a non-digital intervention, given the main mechanism of behaviour change is through information giving. The only major difference to be accounted for is app costs:

P7: *"I'm just trying to think whether, I mean, it's like you're starting from assumption that the models gonna be completely or you want us to tell you whether it could be different. Because I can think like, well that's another kind of information giving intervention why should be any different from any other intervention [?? 2:35:25] apart from the poster specific to the app. But if we have, you know, posters putting up at the grocery store and telling me hey you buy that snack, that's bad for this, this and this reason. And then they wouldn't see much of a difference, apart from the cost of developing the app. So, that's why I'm trying to understand."*

It was agreed that costs relating to app development, optimisation and potentially promotional costs should be incorporated within economic models, as well as healthcare costs. Despite HTA recommendations of a health and social care perspective, evaluating a dietary app constituting part of a mass-media campaign may require a person-centred model, whereby personal impacts or consequences of the intervention to the individual are considered.

There was disagreement around the inclusion of child QoL within an economic evaluation, whereby child BMI percentile was considered an essential outcome to verify behaviour change. An opposing view highlighted that improved QoL is necessary as a condition of app engagement:

P4: *"It was me that put it as preferable to be, mostly it was influenced by the fact that I think the essential is stuff you really need. So, the, it would be really good to have child quality of life, it's just I don't, I don't think, I don't think you need it to say that the app works to impact on BMI. It depends what you're trying to say what the app does.*

P6: *Countering that, the reason why I've put it as essential is because if the app makes kids miserable then there is absolutely no way that anyone's gonna carry on using it."*

Some stakeholders believed that due to the complexity of outcomes, changes in nutrition knowledge would be the simplest factor to measure whilst others believed measuring habit formation was essential. In both cases, existing evidence would be required to model forward from these. Stakeholders expressed the benefit of a model that shows changes in weight, whereby existing models of calorie balance can help acquire BMI estimates from trial dietary data. Others expressed that BMI should not be included within a model if trial outcomes are based on two-year follow-up or less.

5.3.3.5.2 Theme 2: Consideration by population group of interest

Stakeholders acknowledged that although apps may be designed to target the general population, there is a need to have representation of children with overweight or obesity to be able to see some changes in dietary behaviours or BMI. One stakeholder voiced the importance of looking at the distribution, rather than the average, of app effectiveness. This will help make salient whether the app is effective in helping those most in need, and therefore potentially preventing the occurrence of an obesity-related disease. Investigating whether an app is equally effective across different sociodemographic groups was also raised. Interventions should only be treated as population-level if they have been tailored towards subgroups within the population. Usability testing should include people across the spectrum, whilst evaluations should check the uptake and effectiveness across participant groups:

P2: "I think it might be important to look at the distribution as well, because if the app helps child who's very obese, you know, very extreme end, and the families got a lot of other problems going on, if that child then doesn't get diabetes when they're 12, that's a massive health gain and if you can even just, you know, pick up at the very extremes obviously it's t, that might be more important to this then trying to observe a big shift in obesity from quite a sort of small intention. Might be a way of..

I: So, this is under short-term or long-term?

P2: I think it's still long-term, but I think maybe it's, it's not really looking at short-term long-term sorry, I'm probably jumping in but it popped into my head, but looking at not as what's the average effect, what's the population doing, it's more yeah targeted.

P4: It's targeted isn't it? So, and actually I guess your short and your long-term outcomes if you were targeting use of the app to say a population with that were already kind of severely overweight or obese, then it might look very different what you'd track, which is quite interesting."

5.4 Discussion

Stakeholder engagement explored the factors needed to assess DDIs, developed a conceptual model of the decision problem and discussed potential issues and recommendations for their evaluation. The process discussed priority outcomes and cost implications for dietary apps in clinical and economic evaluations. Stakeholder engagement outputs included a revised problem-oriented conceptual model that outlines the pathway between exposure to the Food Scanner app, and long-term health outcomes (see Figure 8). In addition, study findings present insights for the development of evaluations of DDIs, including trial and economic evaluation design, and provides a foundation for economic model development (discussed further in Chapters 7 and 8). Stakeholder discussions generated recommendations for future evaluations (Table 7). Recommendations are not based on a consensus between all stakeholders (e.g. priority ranking task; Table 5); rather they are based on popular opinions. The findings and recommendations of this study have been grouped into four overarching topics: effectiveness evaluations, economic evaluations, app development and future research.

Table 7. Linking recommendations emerging from stakeholder engagement to the evaluation of the Food Scanner app

Topic	Recommendation	Has this been considered or actioned within the thesis?
Objective 1: The role of apps within interventions		
Effectiveness evaluation	• In instances where apps form part of a multicomponent intervention, they should be evaluated individually and as a whole to provide insight into interactive effects between components.	Chapters 6 and 7
Economic evaluation	• Whether an app is required to be used continuously, or over the short-term (enough to form positive dietary habits) may have implications on evaluations. Cost implications may present in instances where there is	Chapters 6 and 7

	dependence on continuous use to lead to behavioural changes. Evaluations should therefore consider reasonable timescales that will allow outcomes to be appropriately captured.	
App development	• The conceptual model produced could provide a form of guidance around the barriers and facilitators to behaviour change, which could aid app development and improvement decisions (e.g. providing nutritional information to aid purchasing decisions with no guidance on how to prepare food is a barrier to behaviour change)	Chapters 6 and 8
Objective 2: The pathways by which dietary apps impact on dietary intake and childhood obesity prevention		
Effectiveness evaluation	• Explore whether discontinued app use is due to behaviour change. This could be investigated through exploring the association between food purchased/consumed between continued/discontinued app users.	Chapters 6 and 8
	• Evaluate the number of BCTs present within an app, including an investigation of effective BCTs, as suggested within the literature.	Chapter 3
	• Measure app engagement. If there are changes in behaviour, but no app engagement, cannot attribute changes to the intervention	Chapter 6
	• Provide evidence of clinical effectiveness to encourage clinicians to promote an app's use.	Chapter 6
	• Investigate the circumstances that prevented people from engaging with an app to make healthier lifestyle changes and find ways to overcome these.	Chapter 6

	• Collecting data on weight loss may not be suitable for children, due to growth and related weight gains over study period.	Not applied
	• Where possible, link intervention outcomes to health data (i.e. data linkage) as any changes in weight due to diet may take years to present within children.	Not applied
	• Measuring knowledge as an outcome may be a more accurate and attributable measure of app impacts.	Chapters 6 and 8
	• Use shopping receipts to verify snack and drink purchases, and measure changes over study period.	Chapter 8
	• Macronutrients should not be measured in isolation and changes to the overall diet need to be evaluated.	Chapter 6
	• Spill-over effects of app outcomes onto other family members need to be accounted for, otherwise may be underplaying the potential (cost) effectiveness of the app.	Chapter 6
	• Wider app benefits (e.g. changes to the food system) should not be measured until certainty of the app's effectiveness has been established.	Not applied
Economic evaluation	• Dental problems are strongly tied to sugar consumption and therefore should be considered within healthcare costs.	Chapter 7
	• HRQoL may not be a suitable measure within prevention studies targeting healthy child populations, where there is no indication of low HRQoL initially. If a child has optimal HRQoL at baseline, then it is unlikely that an intervention will lead to additional improvements. To overcome this,	Not applied

	representative samples are necessary that consist of both extreme and average cases (e.g. BMI percentiles) that may result in initial variability of HRQoL between children.	
	• Investigate how measurements of dietary intake can be projected to health outcomes in the long term, as unlikely to result in weight changes over a trial period.	Chapter 7
	• Need evidence of maintenance of behaviour change (habit formation) before long-term assumptions are made. Use available evidence to model forward from that.	Not applied
	• Transitional periods over the life course may be an ideal time to investigate habit formation.	Not applied
App development	• Be wary of cognitive dissonance and formulate sensitive health messages/app content that will not lead to a negative emotional response, as this may lead to discontinued app use.	Not applied
Future research	• Generate greater insight into the user characteristics of app users, in comparison to non-users.	Chapters 2 and 6
Objective 3: Priority outcomes to be captured within evaluations of dietary digital intervention		
Effectiveness evaluation	• Priority outcomes for evaluations of a dietary mHealth intervention have been generated, which can be consulted when designing evaluation protocols (see Table 5).	Chapters 6 and 7
Objective 4: Resource pathways and associated costs		
Economic evaluation	• Short-term app development costs should be considered alongside long term maintenance costs relating to essential app updates.	Chapter 7

	• Consideration of costs for buying access to data (e.g. nutrition database), or in-house costs of researcher time for collecting data internally.	Not applied
	• Sensitivity analyses should be conducted taking into account additional cost sources and cost estimates of a mobile app (e.g. promotions; campaigns).	Not applied
	• Include childhood costs within the evaluation.	Chapter 7
	• Unlikely to be able to attribute any changes in healthcare resource use to app use. Measuring healthcare use may be more suitable if the sample contained children with overweight or obesity	Not applied
App development	• Develop app with diverse end-users to understand user requirements which may increase app engagement and reduce health inequalities.	Not applied
Future research	• Commercial providers are key stakeholders; engage in discussions to gain a perspective into the percentage of the original development cost that is spent on annual app updates.	Chapter 7
	• Current complex intervention guidance views mutability as an evaluation problem. However, for DHI app mutability is an essential component of sustained effectiveness. Evaluations could support and inform app evolution, whilst additionally monitoring the relationship between app evolution and intended behavioural changes. This requires clear definitions of intended intervention outcomes from the outset.	Chapter 8

Objective 5: Key factors of economic evaluations of dietary digital interventions

Effectiveness evaluation	• Investigate whether app is equally effective across different sociodemographic groups.	Chapter 6 and 8
Economic evaluation	• Essential and preferable factors to include within an economic evaluation of DDIs are outlined in Table 6.	Chapter 5
	• Incorporating long-term modelling within pilot and feasibility studies may add extra value to the evaluation.	Not applied
	• Engaging in a dietary app may have unexpected cost consequences for the app user (e.g., greater costs of healthier foods; mobile data costs to use the app; time costs of engaging with the app). Therefore, a person-centred model may be more suitable than a healthcare perspective.	Chapter 7
	• Utilise a model that ideally shows changes in weight. Adopting the use of existing models of calorie balance can help acquire BMI estimates from trial dietary data.	Not applied
	• Evaluate the distributional effects of the intervention as opposed to the average effects as this will enable any changes in health outcomes within extreme cases to be captured, therefore preventing the occurrence of an obesity-related disease	Not applied

Based upon synthesis of stakeholder discussions, recommendations for evaluating app effectiveness were generated. For instance, apps should be evaluated as standalone interventions, and in the context of a multicomponent intervention. This will help provide perspective into the additive, multiplicative, or even subtractive effects an app may or may not provide to complex interventions. The Sugar Smart app (outdated version of the Food Scanner) had been previously evaluated within the context of the Change4Life campaign (Bradley et al., 2020). Although positive dietary outcomes of the campaign were reported, it is unknown what additive effect the app contributed to these outcomes. Discussions further highlighted that level of app engagement may impact on BCT exposure. Evaluations require an understanding of BCTs in relation to app content (as was discussed within Chapter 3), alongside an understanding of whether discontinued app use is due to successful behavioural changes or failure to engage users. Understanding BCT components within interventions and how they may link to behavioural changes has been highlighted within the literature (Michie et al., 2017).

The conceptual model provides an understanding of the behavioural changes expected from a dietary app. It allows evaluation decisions to be explicit and timescales to be justified. However, the time horizon of evaluations needs to be considered alongside the conceptual model. Some dietary apps, such as the Food Scanner, are not intended for long-term use and focus on small and effective changes in behaviours. An evaluation should therefore not be too ambitious to expect changes outside the boundaries of the app and related BCTs whilst considering priority outcomes specified by stakeholders. Priority outcomes included changes in dietary behaviours (single macronutrient and overall diet), changes in child BMI percentiles and habit formation. Evaluations based on distributions can capture positive effects of interventions which may otherwise be lost when calculating averages. For instance, distributional effects can capture changes in health gains and healthcare cost savings within children with overweight or obesity. These are often adopted through micro-simulation modelling approaches, which models individuals within the population separately, thus preserving heterogeneity (Hayes et al., 2019). The literature suggests modest effects of dietary apps (Islam et al., 2020), sampling methods should therefore include a stratified representation of BMI to capture changes in dietary behaviours. In addition, rarely have studies considered spill-over effects of interventions targeting child outcomes, as was highlighted within Chapter 4. The Food Scanner app in particular targets food purchasing behaviours, which may have dietary implications for a whole household as opposed to a single child. Spill-over effects of health improvement has been previously demonstrated within pupils not participating within an after-school intervention but had interacted with intervention-exposed pupils (De Heer et al., 2011). Similarly, a weight loss intervention targeting children resulted in positive dietary shifts amongst parents (Matthan et al., 2022).

With respect to economic evaluations, long-term modelling was considered a solution in the unavailability of long-term trial data. However, maintenance of behaviour change (i.e., habit formation) needs to be evidenced before long-term assumptions are made. Economic evaluations of dietary apps have yet to consider maintenance of intervention effects, unlike lifestyle interventions (Oosterhoff et al., 2020). Due to low effect sizes emerging from experimental studies (Islam et al., 2020) it is likely that any modest decay in intervention effects will result in no effects. Alternatively, stakeholders recommended that data linkage should be sought as a potential solution that links intervention outcomes to long-term health data.

Data linkage is an emerging area of interest within health research. Datasets can be used to link data across different sectors (e.g. education and healthcare), to explore child outcomes in relation to one another (Imperial College London, 2023). For example, Administrative Data Research UK is developing improved methods for researchers to access public sector data to better inform policy decisions (ADR UK, 2023). The Child Outcomes Research Consortium additionally offers access to routinely collected child mental health and wellbeing data (Child Outcomes Research Consortium, no date). This can be useful when investigating the long-term impacts interventions may have on children's wellbeing. The UK Biobank offers comprehensive health-related patient data, with patient consent, obtained from GPs (UK Biobank, 2023). Data linkage studies have been successfully undertaken. For instance, datasets have been obtained by numerous government agencies to investigate the relationship between child weight status and developmental outcomes (Pearce et al., 2016). On the other hand, if wanting to track long-term BMI changes in children, linking intervention data to the National Child Measurement Programme (NCMP) may be feasible (Firman et al., 2019). Recently, through data linkage child-reported survey responses were linked to child Free School Meal status (obtained via the Secure Anonymised Information Linkage [SAIL] Databank). This was used to investigate how school closures during COVID-19 impacted child health (e.g. dietary intake) and wellbeing by level of deprivation (James et al., 2021). Although data linkage methods are growing in popularity, they are also challenging. For instance, identifying matches through unique identifiers can lead to either missed matches or false matches (analogous to Type I and II errors) (Mayer and Stockdale, 2021). It can additionally be a time-consuming process. For instance, in James et al. (2021), demographic data was initially separated from outcome data before being sent to the NHS Wales Informatics Service, whilst outcomes data was sent to SAIL. The datasets were then joined through a unique anonymous linking field. Data linkage can also lead to ethical considerations, including the handling and processing of personal and sensitive data. The representativeness of the sample is also dependent on characteristics of individuals who are likely, or not likely, to consent (Mansfield et al., 2020). Matching individuals between datasets is an additional challenge, especially in cases where unique identifiers are different (Mansfield et al., 2020). Finally, it is associated with problems of using observational data to assess causality. So, although data linkage offers the opportunity to gather additional data on study participants without creating an extra burden to participants, it is a time and resource intensive process on behalf of researchers.

This study contributed to discussions around resource pathways and associated costs, which is currently lacking within DDI literature. These included healthcare costs, such as dental, that are more likely to present within a paediatric population. Concerns regarding the attribution of healthcare resource use to app use were stated in instances where overweight and obesity were not represented within the sample. Likewise, stakeholders flagged HRQoL measures as unsuitable within prevention studies that have no indicators of unwell children. This contradicts current guidance on the inclusion of preference-based utility measures within economic evaluations (National Institute for Health and Care Excellence, 2013). Costs involving nutritional data access, which is a typical feature within dietary apps, and app marketing costs were also suggested. In addition to this, discussions included the development cycle of an app, which could facilitate cost estimates. The application of sensitivity analyses within evaluations could explore cost ranges in situations where there is uncertainty. The current study further extends the discussions relating to development and maintenance costs outlined in McNamee et al. (2016).

Barriers and facilitators to app uptake, engagement and behaviour change need to be considered when developing dietary apps. These factors have been outlined within Chapter 2 of the thesis. However, the conceptual model demonstrates the pathways by which a dietary app leads to behavioural changes in addition to the contextual factors impeding on this. Evaluations should be conducted targeting an app's intended audience. Hard to reach and socioeconomically disadvantaged groups need to be engaged within conversations (e.g. co-design methods) to strengthen an app's potential and reduce health inequalities. Discussions with stakeholders did not lead to the definition of groups of interest relating to the Food Scanner app. However, PHE's social marketing strategy has aimed to reduce health inequalities, provide simple health messaging to tackle low health literacy, alongside provision of free and interactive resources to enable those in lower socioeconomic positions to engage and benefit (Public Health England, 2017c).

Recommendations for future research were suggested. As outlined within Chapter 2, individuals most motivated to change their behaviour are more likely to engage with dietary interventions (Schmied et al., 2023). As such greater insight into the characteristics of non-users may help develop appropriate promotional material that nudges less motivated individuals into downloading and using a dietary app. For example, promoting the 10,000 Step Australia Program through a social media campaign led to a substantial increase in app downloads (Rayward et al., 2019). However, downloads did not result in app usage, suggesting that more personalised advertisements may be needed (e.g. as part of a workplace initiative with a completion date).

There is often difficulty in accessing data (e.g. app costs) by government or commercial agencies, as opposed to apps developed by academic institutions (Kalita et al., 2022). Cost estimates form crucial parameters within economic evaluations; engaging commercial providers within discussions could help generate estimates of app costs. Resource pathway outputs from the current study can be used to facilitate such discussions. Taking on these recommendations, a Freedom of Information (FOI) request was sent to PHE enquiring about the costs involved throughout the Change4Life Food Scanner app's lifecycle. This is further discussed within Chapter 7 where the economic impact of the Food Scanner app is explored.

Stakeholders highlighted the need for credible portals which allow access to credible DHIs. Despite the need to develop, or raise awareness, of such platforms (e.g. NHS apps library), there was no discussion concerning the definition or characteristics of a high quality app and credibility standards of evidence, apart from the inclusion of BCTs. There has been ample research into the assessment of app quality. Validated app quality measures have been developed, such as the mobile application rating scales (MARS) which is an app quality rating tool (Terhorst et al., 2020). The MARS assesses engagement, functionality, aesthetics, and information quality of an app. It has been used extensively within mHealth research and has suggested moderate quality of currently available apps (Schoeppe et al., 2017, Bardus et al., 2016, Zarnowiecki et al., 2020). On the other hand, although standards currently exist for preventative research (Gottfredson et al., 2015), the generalisability onto DDI evaluations may be inhibited given the complexity of DDI evaluations. NICE have developed an evidence standards framework for digital health technologies (National Institute for Health and Care Excellence, 2019). Standards include the incorporation of intended user group acceptability in the design process, consideration of health inequalities, defining the level of expert involvement, and transparency around the creation of reliable health messages. Standards additionally included the provision of evidence to support a DDI's (cost) effectiveness and generalisability of such evidence onto real-world settings. Despite these standards, challenges with current evaluation methods have recently been outlined alongside a call for pragmatic and innovative approaches to generate convincing and timely evidence (Guo et al., 2020).

This chapter has addressed several priority topics and gaps within the literature. For instance, the current study has explored how to incorporate economic factors into intervention design (McNamee et al., 2016), which will be discussed in further detail within Chapters 6 and 7. Previous research has also suggested a need to critically review existing economic evaluations of DHIs (McNamee et al., 2016). Although a systematic review was conducted in Chapter 4, it did not capture any economic evaluations of dietary apps, which inspired the involvement of stakeholders to fill a crucial gap within the literature. The current chapter has also considered the complexity of the Change4Life Food Scanner app and the implications this has for existing economic approaches. Resource pathways and associated costs across the development cycle were also explored. The latter two advancements have previously been suggested as avenues for future research (Michie et al., 2017).

This chapter used guidance from Squires' Framework for developing the structure of public health economic models (Squires et al., 2016). The framework outlines four phases in the methods to developing conceptual models. Phase A aligns the framework with the decision-making process. Like a study protocol, this phase considers approaches to evidence searching, modes of stakeholder engagement, alongside an overview of time and resources available to complete study tasks. Aspects of this phase were executed in the planning of empirical studies within this thesis. Phase B involves identifying relevant stakeholders who can use their expertise to make judgments on model structure. Actors in the system were involved within stakeholder engagement (i.e., clinical and methods experts) alongside system owners (e.g., Public Health England representative of the Change4Life Food Scanner app). Phase C involves developing a problem-oriented conceptual model and describing current resource pathways, which was the main objective of this chapter. Phase D of the framework includes reviewing existing economic evaluations, determining the model boundary and level of detail, alongside choosing an appropriate model type. To address this, Chapter 4 conducted a systematic review of economic evaluations and modelling studies of childhood obesity prevention dietary interventions. Essential factors to consider when creating economic models were also generated within the current chapter. However, more stakeholder consultations are needed to finalise the level of detail within the design-oriented model structure which would form the basis of a mathematical model. Outputs generated within this thesis could help support the development of the model, including recommendations for model development (Chapter 4; Table 3), stakeholder recommendations for evaluations (Chapter 5; Table 7), and pilot and feasibility study outcomes (Chapters 6 and 7).

The methods applied within this study had several limitations. In contrast to traditional qualitative research guidance, data saturation was not met. Planning and executing stakeholder engagement was a very time-consuming task. Although involvement of the general public and healthcare professionals is encouraged within stakeholder consultations (Roberts et al., 2012), the researcher did not have capacity to run multiple stakeholder engagement workshops tailored towards different groups. In fact, stakeholders without a background in health economics were less involved within discussions pertaining to economic evaluations. This reflects the difficulty in engaging diverse audiences in discussions around complex topics. To overcome this anticipated obstacle, a discussion document was circulated ahead of the workshop and interviews. In addition, the updated conceptual model was sent to all stakeholders to ensure that their expert views had been incorporated. The diversity of stakeholder backgrounds led to a dispute over which factors were essential for an economic model, thus generating a longer list of essential factors than preferable factors. In addition, there was a lot of divergent and unclear views expressed around cost inclusions and resource pathways, demonstrating a lack of consensus on how costs of DDIs should be measured. This is addressed within Chapter 7, where costs relating to the Food Scanner app are explored further. Furthermore, the methods by which recommendations for evaluations were synthesised did not offer a formal analysis to address divergent viewpoints. Considering time constraints and a limited stakeholder sample, Delphi methods may be a cost-efficient approach to elicit opinions of stakeholders within future consultation processes (Dalkey, 1969). Delphi surveys present individual judgements to stakeholders which can be rated by level of importance or agreeability (Frew and Breheny, 2019). Responses can then be grouped to derive a consensus viewpoint across decision makers and experts. Aspects of the Delphi survey method were adopted within the stakeholder workshop, such as the priority ranking exercise (see Table 5). Delphi methods may be better suited within future stakeholder sessions to reach final judgments, while also recognising and accommodating divergent opinions. In addition, Squires et al. (2016) suggested that economic model development is an iterative process that requires stakeholder consultations throughout the process in order to maintain model transparency, validity and credibility. As such, a next step for future research would be to involve stakeholders in the development of an economic model based on the essential factors outlined (i.e. determining the model boundary). Development of economic models are further discussed within Chapters 7 and 8 of the thesis.

Despite the limitations outlined above, the stakeholder workshop generated a positive response. Seven feedback forms were completed; most stakeholders felt that the session workload and time allocated to individual tasks was "just right". All stakeholders rated the facilitator as either good or very good at explaining the objectives of each task. In addition, all stakeholders were either satisfied or very satisfied with the stakeholder engagement event and thought it was well organised. Finally, all stakeholders found the programme relevant to their interests as well as the diversity of backgrounds amongst attendees.

5.4.1 Conclusions

Engaging stakeholders for the conceptual modelling of a DDI has been an invaluable contribution to the thesis. This work has generated a conceptual model that can be adopted and adapted to help inform research aims, designs and methods. In addition, given the scarcity of research guidance around the development and evaluation of dietary apps, this chapter provides useful discussion of issues relating to the evaluation of dietary apps alongside recommendations for practice. This chapter has also informed the evaluation approach of the Food Scanner app (Chapters 6 and 7), which will generate data parameters that could contribute to the design of an economic model. This will be discussed further within Chapter 8 of the thesis.

6. Evaluating the Change4Life Food Scanner app in Reducing Children's Energy and Sugar Intake: a Randomised Pilot and Feasibility Study

Previous chapters have provided a foundation of understanding relating to dietary digital interventions. Chapter 2 provided an overview of BCTs relating to dietary mobile apps, factors impacting app engagement, current evidence in relation to dietary app effectiveness and associated study designs. Chapter 3 identified BCT occurrence and content within the Change4Life Food Scanner app and concluded that the Food Scanner app is a theoretically grounded intervention though effectiveness data is required to verify outcomes. Through stakeholder discussions (Chapter 5), a deeper understanding of the Food Scanner app's pathway towards obesity prevention was mapped. Recommendations were outlined for evaluations of DDIs, which included study procedures and measures alongside considerations for the interpretation of findings. This chapter integrates findings from previous chapters to guide the development of an evaluation of the Change4Life Food Scanner app, a complex intervention, whilst bearing in mind the complexity of the food system as outlined within Chapter 1. This chapter is currently in preparation for submission to a peer-reviewed journal.

6.1 Background

In the UK, children are not meeting their recommended daily fruit and vegetable intake. In 2018, only 18% of 5-15 year olds consumed the recommended five daily portions of F&V, whereas 53% consumed less than 3 portions a day (NHS Digital, 2020). Data from the National Diet and Nutrition Survey has suggested an overconsumption of saturated fat, sugar and salt than is recommended (Beverley et al., 2020). Sugary soft drinks, cakes, biscuits and breakfast cereals, are causing children aged 4-10 to consume almost double their daily sugar limits (Public Health England, 2018a). Unless children's diets improve, over 50% of the UK population is predicted to be obese by 2050 (McPherson et al., 2007).

Over the past decade, there has been an increased focus on the use of mobile applications to improve dietary intake and prevent weight gain. Dietary apps boast numerous advantages; they are easily accessible to smartphone users, free and can be frequently updated to improve services offered. However, the evaluation of dietary app-based interventions is complex. Given that dietary apps are still an emerging area of research, we are only just developing an understanding of who engages with dietary apps (Ernsting et al., 2017), the factors that impact on their engagement (Perski et al., 2017), and whether app engagement leads to positive behavioural changes and improvements in dietary intake (Falkenhain et al., 2022, West et al., 2017). These concepts have been discussed within the literature overview in Chapter 2.

In summary of the findings from the narrative review (Chapter 2), pilot RCTs have often been a popular choice of study design when investigating the effectiveness of dietary apps in improving children's dietary outcomes via parental behaviour change (Nyström et al., 2017, Nollen et al., 2014). This is not surprising given the uncertainty surrounding evaluation methods pertaining to complex DDIs, as discussed within Chapter 5, which is a relatively new and developing area of research (Michie et al., 2017, Skivington et al., 2021). Studies have also highlighted the difficulties in achieving sustained intervention effects (Delisle Nyström et al., 2018, Pearson et al., 2022, Vázquez-Paz et al., 2022), which may be due to difficulties in maintaining long-term app engagement (Pearson et al., 2022, Lin and Mâsse, 2021). This is particularly the case when assessing anthropometric outcomes in comparison to dietary outcomes (Nyström et al., 2017, Bonvicini et al., 2022, Yau et al., 2022b). Despite mixed-evidence regarding the effectiveness of dietary apps in leading to behavioural changes, evidence has suggested positive changes in psychological predictors of behaviour change (Vázquez-Paz et al., 2022, West et al., 2017). Despite these findings, there is still a lack of studies exploring the clinical and economic effectiveness of standalone, as opposed to multicomponent, DDIs targeting child outcomes.

The Change4Life Food Scanner app was designed to support household food purchasing behaviours. The app was first released by PHE as part of a wider campaign (Public Health England, 2017c). The campaign aimed to improve children's diets through raising awareness on the fat, sugar and salt content within everyday popular foods. The Food Scanner app provides feedback on the nutritional content of barcode-scanned packaged foods in a variety of visual formats, which has been discussed comprehensively within Chapters 1 and 3. The provision of information pictorially, or through concrete images, has been found to be an effective strategy to improve dietary choices (Adams et al., 2014, Scapin et al., 2021). Not only does this method facilitate participant understanding of the nutritional content within foods and beverages, but also induces an element of disgust, leading to positive behavioural changes (Miller et al., 2022).

An earlier version of the Food Scanner app (previously known as the 'Sugar Smart' app) was evaluated as part of the wider Change4Life Sugar Smart mass-media campaign (Bradley et al., 2020). The six-week campaign included TV and billboard advertising, a mobile app, and the distribution of resources to children via schools. Outcomes of the study suggested a 2% reduction in sugar intake post-intervention, though this effect was not sustained at 12-month follow-up. Despite a reduction in sugar intake, compensatory behaviours occurred; there was an increase in fat and energy intake. When asked to provide feedback on the Sugar Smart app, qualitative findings suggested that the app was useful and fun for child involvement, the use of sugar cubes were an appropriate measure to display information, the app helped food purchasing decisions and prompted discussions around food within households. Despite these positive evaluation outcomes, there are several study limitations worth flagging. Families who have previously shown interest in Change4Life campaigns were recruited to participate in the study. As such, the sample may already be motivated to change their behaviour and engage with campaign material. The study also did not include a control condition; therefore, it cannot be concluded whether reductions in sugar consumption was due to the campaign. Finally, given that the evaluation was focused on the Change4Life Sugar Smart campaign in general, the contribution of the app in reducing sugar consumption cannot be ascertained, as data on app engagement was not collected.

The Food Scanner app has undergone a series of major updates to design and content features since its initial release. Chapter 3 investigated BCT content within the Food Scanner app and explored how BCT content evolved with app updates (Mahdi et al., 2022b). Findings suggested that the Food Scanner app has the theoretical underpinning of a potentially effective intervention. However, a formal evaluation is necessary to understand whether app content and related BCTs is sufficient in leading to changes in dietary behaviours.

Although the Food Scanner app has been available on the app market since 2017, no study to date has investigated its effectiveness in improving children's sugar or dietary intake. Though the Food Scanner app communicates nutritional information on packaged foods using visual images, the effectiveness of such images has not previously been investigated within controlled trials within applied settings. In addition, there are a lack of studies that have conducted independent evaluations of pre-existing apps available on the app market as standalone dietary interventions, or those developed by Government agencies. The evaluation of complex interventions in complex settings can be a challenging task. Chapter 5 sought the expertise of stakeholders within the fields of childhood obesity, digital interventions, and health economics to advise on the appropriate methods to adopt within evaluations of dietary mobile applications. It was raised that app development and maintenance costs can be substantial, as will be explored further within Chapter 7, emphasising the importance of understanding the cost-effectiveness of dietary apps in light of scarce resources. Recommendations were put forward in relation to intervention effectiveness evaluations, economic evaluations, app development and future research. The adoption of evaluation recommendations outlined within Chapter 5 will be highlighted throughout this chapter.

To address the gap within the literature, a pilot RCT was conducted to test the feasibility and acceptability of evaluating the Change4Life Food Scanner app in reducing children's sugar and energy consumption over a 3-month trial period. An economic component of the Food Scanner app evaluation is additionally explored within Chapter 7. Understanding effectiveness outcomes of the app will contribute to economic evaluations by enabling cost-effectiveness estimations to be deduced. The primary objective was to, (1) assess the feasibility and acceptability of evaluating the Food Scanner app; and (2) inform design considerations for a subsequent RCT, such as effect size estimates. In addition, secondary objectives were to, (1) investigate whether there was a reduction in child sugar consumption and overall energy intake between baseline, 1-month and 3-month follow up, between participants in the intervention and control arms; (2) explore app engagement over trial duration; and (3) explore differences in psychosocial outcomes between study conditions.

6.2 Methods

6.2.1 Study design and setting

This was a 3-month non-blinded between-subject pilot RCT and feasibility study, with 1:1 allocation ratio to both intervention and control arms. Upon consenting and completing sociodemographics, participants completed 3-day food diaries at baseline followed by a baseline survey. Participants randomised into the intervention arm then received contextual nutrition guidance with a prompt to download and engage with the Change4Life Food Scanner app. Those randomised into the control arm did not receive any additional information. Food diaries were additionally completed at 1-month follow-up (1MFU) and 3-month follow-up (3MFU), alongside an additional survey at 3MFU. The 3MFU survey included open and closed-ended questions covering aspects of acceptability relating to study methods, food diaries, and the Food Scanner app. Those in the intervention arm additionally completed fortnightly app engagement measures.

Recruitment was focused on Yorkshire and the Humber (Y&H), United Kingdom. This was decided to maintain some control over the variability, and individual differences between participants that may not be possible with national recruitment. In addition, the prevalence of overweight and obesity is higher in Y&H in comparison to the England national average (NHS Digital, 2021), has one of the highest prevalence of overweight and obesity in England, deeming it a region in need of intervention.

The trial was registered on the Open Science Framework (https://osf.io/62hzt/). Ethical approval was obtained by the University of Sheffield Research Ethics Committee (026380) in August 2019. The study and reporting of the study adhered to CONSORT for pilot and feasibility studies (Eldridge et al., 2016).

6.2.2 Development of study materials

Patient and public involvement (PPI) contributed advisory and consultation input regarding methods and study procedures. A Parent Governors group, which was originally formed as part of the Born in Bradford project (Born in Bradford, 2023), were engaged in two PPI sessions. Five PPI participants were present, all of whom were parents of 7-11 year old children, and were diverse in ethnic background. The first PPI session consisted of a 45-minute discussion on study procedures and outcome measures (see Appendix 11 for an outline of the discussion schedule and feedback obtained). The second PPI session lasted 20 minutes and included discussions around the appropriateness of study materials, including information sheets, consent forms and intervention exposure. Study material was appropriately adjusted to reflect the feedback obtained by parent governors.

Cognitive debriefing was conducted before the roll out of the main pilot and feasibility study. Cognitive debriefing is a structured interview technique that ensures all study materials, instructions and survey questions are interpreted as intended, in line with research objectives (York Health Economics Consortium, 2016). Study materials were piloted with five volunteers through semi-structured interviews and in line with ethical approval. Volunteers were asked to go through materials and explain what they thought the questions meant, whether the questions made sense, and if they had any feedback on how to improve the wording of questions so that they are easier to understand. Amendments to study materials were made in accordance with feedback.

6.2.3 Participant recruitment and randomisation

Sample size calculations are not usually required when conducting pilot studies (Eldridge et al., 2016), however it is advised that the sample size is large enough to provide information on the factors under investigation. Viechtbauer et al. (2015) formulated an online calculator for sample size calculations of pilot studies. This tool was designed to provide a sample size estimate that will be sufficient to identify any unforeseen problems within the trial methods. At a 95% confidence interval, and a probability of 0.01 and 0.05 of a problem manifesting, the estimated sample sizes are 298 and 58, respectively. Given this, I aimed to recruit 120 participants, in addition to a 20% attrition rate, totalling to 144 participants (72 in each study arm). This was seen as sufficiently large to detect major problems with study methods, and feasible within resource and time constraints.

Participants were eligible to take part in the study if they met the following inclusion criteria:

- Parent of a primary school child, aged 4-11 years old.
- Lived in Yorkshire and the Humber.
- Owned a smartphone.
- Had access to the internet inside and outside the home.
- Had enough data storage (at least 100mb) on smartphone.
- Had availability to participate and engage in the study for three consecutive months.
- Were an active grocery shopper for the household *or* involved in decisions over children's food.
- Their grocery shopping was dominantly undertaken in a grocery store/supermarket and not online.

Participants were excluded from the study if:

- They were currently using the Change4Life Food Scanner app.

- Had a child with a health condition with special dietary requirements that could confound outcomes.

Upon consenting to participate, participants were randomly allocated into a control or intervention arm using a pre-generated randomisation sequence developed through Microsoft Excel. A randomisation sequence of 50 was produced at first, which was followed by 20 sequences per block thereafter (a total of 4 blocks). Researcher blindness to condition allocation was not possible, as distribution of study materials depended on this.

6.2.4 Intervention and Control

Although the study aimed to investigate the impact of the Change4Life Food Scanner app on children's dietary intake through parental behaviour change, participants were presented with a cover story in order to not bias self-reported food intake (Robinson et al., 2014). Therefore, participants were invited to take part in a study investigating "parental attitudes towards dietary online tools" and were informed that some participants may be required to download and engage with apps (see Appendix 12).

After completion of baseline measures, participants allocated to the intervention arm were presented with nutrition guidance targeting 4-11 year old children obtained from the Change4Life webpages. This provided a relevant context to then instruct participants to download the Food Scanner app onto their smartphone, and to use the app to make smarter choices when grocery shopping (see Appendix 13). Participants were presented with a validation question to ensure that they read the materials, and downloaded the app ("Please open the app. What is the background colour of the starting page?"). As the study aimed to evaluate a publicly available dietary app, prompting of app use was minimised to not impact the generalisability of results. Those in the control group did not receive any dietary guidance and were merely informed at the end of the survey that they would shortly receive weblinks via email to complete 3-day food diaries.

6.2.5 Measures

Appendix 14 outlines a comprehensive list of measures alongside response options for baseline and follow-up surveys.

6.2.5.1 Sociodemographics

Data on child age and sex, alongside parent ethnic background, educational attainment, household income and number of people living in the household were collected. Data on household income was used to group participants according to the Index of Multiple Deprivation (Department for Work and Pensions, 2022).

6.2.5.2 Anthropometrics

Self-reported child and parent height and weight were collected alongside sociodemographic data. Despite underreporting of body weights in self-reported data (Akinbami and Ogden, 2009, Nyholm et al., 2007) it was not considered feasible within the timescales of this project to collect data objectively. However, research has suggested a high positive correlation between self-reported and measured height and weight in children (Rios-Leyvraz et al., 2022). Height and weight measurements were collected to enable calculations of BMI percentiles in children for the exploration of data by weight status (independent variable), rather than to treat BMI percentiles as a study outcome (dependent variable). Erroneously, child date of birth was not collected which disenabled BMI percentile calculations. Although child weight was an essential factor to consider within evaluations as suggested within Chapter 5, stakeholders did not believe that changes in weight can be expected from short follow-up periods, which was the case within this feasibility study.

6.2.5.3 Dietary assessment

Three-day food diaries of child food intake were completed by participating parents. This included two weekdays and one weekend day. Participants were asked to complete all three food diaries over 7 days. To determine the best method to capture dietary intake, best practice guidelines were followed for dietary assessment in health research (Cade et al., 2017). These offer a list of considerations when selecting an appropriate dietary assessment tool. Objective methods of dietary assessment, such as doubly labelled water, were ruled as unfeasible for the given budget, timescales and subjects of interest. Myfood24® was selected as the most effective and efficient method for addressing the research aims and timescales, in comparison to other self-reported methods, such as the Food Frequency Questionnaire (see Appendix 15 for a review of best practice guidelines for dietary assessment in health research). Myfood24® is a validated user-friendly online dietary assessment tool (Wark et al., 2018). Participants can search for food items for breakfast, lunch, dinner and snacks, whereby suggestions are also made for commonly missed items. Features are also in place to recognise food items from common spelling mistakes, selection of portion sizes through pictorial aid, and a recipe builder where participants can save recipes for commonly cooked foods. As well as this, nutrient analysis is undertaken on behalf of the researcher by myfood24®, which increases its appeal as a highly efficient tool for both researchers and participants, under time-constraints (Hutchesson et al., 2015). It is worth noting however that the validation study was not an independent review; the study team had conflicting interests and included the director of myfood24® alongside shareholders. Although a full nutrient analysis was provided by myfood24®, measures of sugar (g) and energy intake (kcal) were of interest to address the aims of this study and follow stakeholder recommendations (Chapter 5) to not measure macronutrients in isolation.

6.2.5.4 Predictors of behaviour change

A number of psychological predictors of behaviour change were investigated and survey development was mostly informed by the COM-B model (Michie et al., 2011). The COM-B model considers three main factors: capability, opportunity and motivation, which in combination lead to behaviour change. The measure of capability included psychological capability, knowledge and actual skills (physical capability); opportunity referred to social opportunities to change behaviour; and motivation consisted of both automatic and reflective (i.e. intentions). How the COM-B relates to the Change4Life Food Scanner app's development and content has been outlined in Chapters 1 and 3. In most cases, response options were provided in a 5-point Likert-scale format ranging from high to low agreeability, however response options varied across questions (see Appendix 14 for a comprehensive overview of survey questions alongside response options). Questions relating to the COM-B model were informed by the literature (Stevely et al., 2018).

Capability was measured through numerous methods. Physical (skills-based) capability investigated parents' ability to track their child's sugar intake (Stevely et al., 2018). On the other hand, psychological capability investigated participants' difficulty in sticking to sugar guidelines ("How easy or difficult do you find it to limit your child's sugar intake to the amounts recommended in the above guidelines?"), alongside their current nutrition knowledge (e.g., "What do you think is the daily-recommended sugar intake for your child's age, in grams?"). Knowledge is seen to precede behaviour change constructs such as attitudes but is not intrinsically a source of change (Baranowski et al., 2003). On the other hand, the COM-B model postulates that knowledge can increase capability which could enable behavioural changes (Michie et al., 2011). Participants were asked to rate their own knowledge, and were asked nutrition-based questions, alongside interpretation of food labels. This was seen as an important factor to consider by stakeholders within Chapter 5, given the Food Scanner app is designed to provide information in the use of nutritional food labels and the sugar content found within products. Examples of applied knowledge questions relating to the interpretation of food labels include, "these are nutritional labels taken from real cereals. If you want to have 100g of this cereal, which of these two options has less sugar? Please consider all information provided", and "this is a nutritional label taken from a popular chocolate flavoured drink available in most supermarkets. Approximately how many sugar cubes do you think are in this chocolate drink based on the information provided".

Opportunity to change behaviour investigated whether one's lifestyle made it easy or difficult to limit their child's sugar intake ("how easy or difficult do you think your lifestyle makes it for you to limit your child's sugar intake to the above guidelines, a day?"). This was further investigated at 3MFU; participants were asked if they knew where to seek advice or information on how to cut down their child's sugar consumption.

To test motivation to change behaviour, items assessing parents' current concerns over children's sugar intake ("how concerned, if at all, are you about your child consuming more sugar than what is recommended?"), alongside their desire to stick to recommended guidelines ("to what extent do you want to keep your child's sugar consumption within recommended guidelines?"), their current intentions ("to what extent do you intend to keep your child's sugar consumption within recommended guidelines?") and actual attempts of doing so ("to what extent are you actively trying to reduce your child's sugar intake?"). The use of nutritional food labels ("do you look at food labels when buying food?", "does nutritional information on food labels affect your shopping choices?") alongside previous use of dietary apps were also investigated to shed insight into dietary motivations based on previous behaviours.

Separate to the COM-B model, questions pertaining to attitudes and perceived behavioural control (PBC) of child sugar intake were also investigated, all of which are strong predictors of behaviour change in accordance with the theory of planned behaviour (Ajzen and Madden, 1986). Response options relating to attitudes ranged from (1) strongly agree – (5) strongly disagree, or (1) extremely important – (5) not at all important. In relation to PBC, response options ranged from (1) almost total control – (5) no control at all. Perceptions of eating habits ((1) very unhealthy – (5) very healthy; (1) strongly agree – (5) strongly disagree) and child weight status (underweight, healthy weight, overweight, obese) were evaluated based on the theoretical stages of change model (Prochaska and DiClemente, 1983).

6.2.5.5 Physical activity

Self-reported measures of moderate intensity physical activity frequency were collected at baseline only (Carroll et al., 2017). Physical activity was incorporated within the feasibility study to provide further description of child characteristics and behaviours. In addition, physical activity forms an integral component of the energy balance equation, and ought to be controlled within analyses investigating impacts of interventions on dietary behaviours within full-scale trials. When asked about the frequency of moderate intensity physical activity, response options ranged from (1) daily to (5) never. Open-ended responses allowed participants to indicate average time in minutes their child was engaged in moderate intensity physical activity on weekdays and weekends.

6.2.5.6 Economic impacts

Participants were asked to complete a parent-proxy of a short validated paediatric HRQoL instrument known as the CHU9D (Stevens, 2010, Ratcliffe et al., 2016). The measure consists of nine dimensions (worried, sad, pain, tired, annoyed, schoolwork/homework, sleep, daily routine, and ability to join in activities) with five response options (least to most severe).

For purposes of an economic evaluation, data was captured on healthcare resource use in the last 3 months (including number of times and total length of time per contact) (Cottrell et al., 2018); school absenteeism due to a health problem (Powell et al., 2013); and workplace absenteeism due to child's health (Beecham and Knapp, 2001). Further details pertaining to these measures, alongside economic outcomes, are further explored within Chapter 7 (Mahdi et al., 2023).

6.2.5.7 External policy confounders

Five questions measured participant exposure to external policy confounders that may have had an impact on their behaviour during the time of the study. This was asked to provide an understanding of the wider food system and how the external policy context affects parental feeding practices. Questions included, "has the introduction of the sugar tax led you to buy different drinks for the household?", "has the introduction of the sugar tax reduced your child's sugar intake?" and, "do you currently use Change4Life resources?". Response options ranged from always (1) – never (5). Participants were additionally asked about their level of familiarity with Change4Life and to also rate their level of agreeability with the following statement, "existing public health campaigns and messages have helped me improve my child's diet" ((1) strongly agree – (5) strongly disagree).

6.2.5.8 Impact of the Coronavirus pandemic

In March 2020, 10-weeks into study recruitment, the UK Government imposed a national lockdown, advising against all but essential travel, school closures and social distancing requirements due to the Coronavirus (COVID-19) outbreak. As such, this became a potential major confounder for trial outcomes and measures were introduced to account for the impact of COVID-19 on lifestyle changes. Recent research reported increased food intake amongst an adult sample during the COVID-19 lockdown (Buckland et al., 2021), whilst a meta-analysis observed increased weight gain and obesity prevalence in children during the first year of the pandemic (Anderson et al., 2023). Measures enquiring about changes in behaviour in response to COVID-19 included changes in the child's diet; ability to make healthier food choices for one's child; food purchasing behaviour; types of food bought; participation in the study; ability to scan barcodes using the Food Scanner app (intervention only), and the Food

Scanner app's ability to support healthier food choices during the lockdown (intervention only). Participants were also asked to rate their agreeability with several statements relating to the potential impacts of the COVID-19 lockdown on the child's dietary behaviours. In addition, participants were asked to rate the extent to which the lifestyle changes imposed by the Government due to COVID-19 had affected food purchasing behaviours, in comparison to before the lockdown. Whilst some questions were informed from Buckland et al. (2021), others were produced de novo.

6.2.5.9 Study feasibility, acceptability and sustainability

Study feasibility was informed by the literature. Recruitment and retention rates included numbers who: accessed the participant information sheet (PIS), started completing the consent form, consented, were in the study at 1MFU and 3MFU, completed food diaries (baseline, 1MFU and 3MFU), and completed surveys (baseline and 3MFU) (Reale et al., 2018, Chai et al., 2021). Study compliance was assessed by asking, "were you able to complete all requested study tasks?" (4-point Likert: completed all the tasks – completed very few of the tasks). Delivery of intervention components was assessed through number of participants that downloaded the Food Scanner app, the number of participants who used the app at least once, and number of participants who had previous exposure to the Food Scanner app (Sutherland et al., 2019b). Intervention arm participants were asked to report on their app engagement fortnightly. Measures assessed the number of days in which the app was used, and the average time spent using the app, which were used to calculate total app engagement time (minutes). Participants were also asked to report the number of items scanned every two weeks. Measurements of app engagement and reasons for disengagement were recommended by stakeholders within Chapter 5.

Study acceptability was assessed at the end of the trial, where participants were asked to feedback on their study experience, informed by previous work (Reale et al., 2018, Sutherland et al., 2019b). Closed-ended questions enquired about the extent to which the study was easy to complete, time consuming/demanding, whether receiving reminders to complete food diaries and surveys were helpful, and whether participants were able to complete all requested study tasks. Five response options were provided ranging from high agreeability to low agreeability. Open-ended questions allowed participants to elaborate on what prevented them from completing all study tasks, whether there was anything the study team could have done to keep them more engaged in the study, and whether there were any additional comments not covered within the survey.

Participants were also asked whether food diaries affected what their child ate or what they had recorded, adapted from Buckland et al. (2019). Participants were asked to rate their level of agreeability ((1) strongly agree – (5) strongly disagree) to the following statements: "I did not report everything my child ate", "I changed what my child actually ate to make it easier to record", "it had no effect on what my child ate", "it was easy to use", "I found it too much work".

Study sustainability was also assessed (Reale et al., 2018). Participants were asked whether they would be willing to continue participation for 9 more months, if this study was extended to a 12-month trial ((1) definitely yes – (5) definitely no).

Participants in the intervention condition were asked to provide feedback on their experiences with using the Food Scanner app. Questions were adapted from previous studies and assessed app likeability (West et al., 2017) and usefulness ("how often did the Food Scanner app help you choose to buy different foods or drinks?"). In addition, usefulness of sugar cube images displayed via the app were also assessed ("how useful did you find the sugar cube images shown in the app?"; "how easy to understand were the sugar cube images shown in the app?"; "how useful would it be to have those sugar cube images printed on food packages, as part of the nutritional label?") (Neal et al., 2017). Based on the COM-B model, participants' capability of making healthy food choices after using the Food Scanner app was also assessed ("how much do you think you know about making healthy food choices after using the Food Scanner app?" (Méjean et al., 2013); "with the Food Scanner app, I find nutritional labels hard to understand" (Méjean et al., 2013); "using the app has increased my ability to reduce the number of high sugar snacks that my child eats" (West et al., 2017); "using the app has increased my ability to make healthier food choices for my child"). Considering cost implications may act as a barrier to long-term behaviour change, the financial impacts of using the app was also explored, as has been done within previous research (Sutherland et al., 2021).

Results for cost implications are outlined in Chapter 7. As indicated in Chapter 3, in June 2020, the Food Scanner app underwent a major update, which led to changes in both its content, design features and use of BCT (Mahdi et al., 2022b). An additional question was included to assess participant exposure to the app update and whether participants felt it had improved their engagement with the app.

Open-ended questions formed a qualitative aspect of data collection, given that time constraints prevented the adoption of focus groups and/or interviews, which is recommended when evaluating complex interventions (Skivington et al., 2021) and within pilot and feasibility studies to help address research questions (O'Cathain et al., 2015, Aschbrenner et al., 2022). These items provided insight into users' perceptions of the app and their suggestions for improvements. Specifically, respondents were asked to provide feedback on what they liked/disliked about the app, and how the app can be improved to: make it more attractive to use, help increase use, and help support healthier diets. Finally, participants were asked if anything prevented them from using the app, which was suggested by stakeholders within Chapter 5.

6.2.5.10 Study withdrawal feedback

Participants who dropped out from the study were sent a short Qualtrics survey regarding reasons for drop out. This included a multiple-answer checklist of potential reasons for discontinued participation and an open-ended question asking for suggestions on how to keep participants more engaged in the study.

6.2.6 Study Procedure

A flowchart of the study procedure is presented in Figure 10.

6.2.6.1 Recruitment

A brief invitation email or online post introducing the research study, as well as incentive for participation, was circulated through primary schools, community centres, social media, online recruitment websites and University of Sheffield mailing lists twice. A gesture of good will was offered to primary schools and community centres in the form of a workshop on healthy eating behaviours, covering the importance of sugar reduction and interpretation of nutritional labels on packaged foods. Recruitment took place between January 2020-June

2020, with a six week pause during March/April 2020 due to COVID-19.

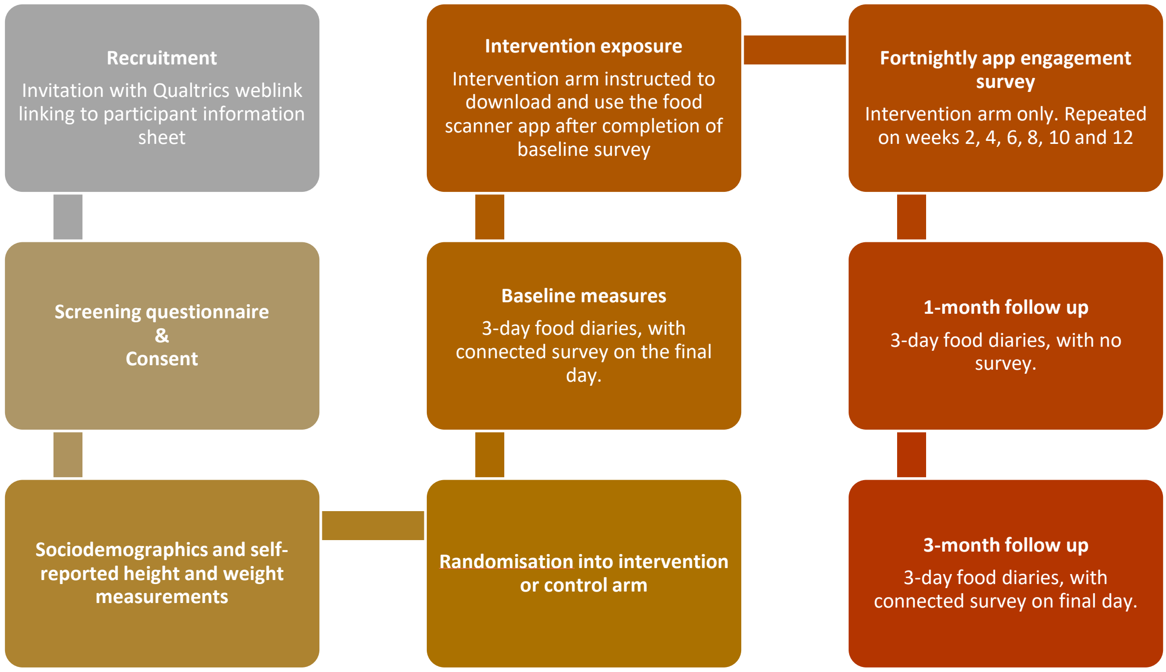


Figure 10. Flowchart of pilot and feasibility study procedure

Emails were sent to 88 primary schools in Sheffield and one primary school in Leeds. Responses were received from 11 schools, of which four agreed to circulate details of the study to parents (circulation of study details by text message, social media, flyers, and/or email). A halt on school-based advertisements and recruitment was placed when the COVID-19 national lockdown came into effect in March 2020. Recruitment also took place through various social media platform, including Twitter and Facebook. The study was advertised on 11 Facebook groups dedicated to parents in Y&H.

The initial study invitation contained a weblink which directed prospective participants onto a Qualtrics page with detailed study information (see Appendix 12). Individuals were screened for eligibility and those successful proceeded to complete an online consent form. Upon consenting, participants completed sociodemographic and anthropometric measures and provided their contact details. This was followed by randomisation into study condition.

6.2.6.2 Baseline and follow-up measures

Participants were sent an invitation email to complete three food diaries over a 7-day period, with a unique link for each food diary day. Alongside this, participants were sent a text message to alert them that an email was sent. If food diaries were not submitted, reminders were sent. Guidance on how to complete food diaries was accessible through the myfood24® website. Parents were encouraged to complete diaries with help from their child. Upon submission of the third food diary, participants were taken onto a Qualtrics webpage where additional survey questions relating to psychological determinants of dietary behaviours were asked. The Qualtrics survey was manually sent to participants who did not complete the 3rd food diary within the required time. Those previously randomised into the intervention arm were then exposed to the intervention and asked to download and use the Food Scanner app. Those randomised into the control arm did not see any additional information after survey completion.

Two weeks after baseline measures were collected, participants in the intervention arm were asked about their engagement with the Food Scanner app in the previous two weeks. This process was repeated fortnightly. When participants did not respond, follow up attempts were made via email and short message service.

Four weeks after treatment exposure (week 5 since baseline), participants were sent an email with an invitation, consisting of unique links, to complete three-day food diaries on myfood24®. Reminders to complete food diaries were sent to participants if food diaries were not submitted.

Twelve weeks after treatment exposure (week 13 since baseline), participants were sent another email with an invitation to complete three-day food diaries. After completion of the third food diary, participants were redirected to Qualtrics to complete a follow-up survey. The survey included the same measures as baseline, in addition to questions relating to external policy influencers, impacts of COVID-19, and study acceptability, feasibility and sustainability measures. In addition, those in the intervention arm were asked to complete app engagement measures and to provide their feedback on their experiences of using the Food Scanner app. Reminders were sent to participants to encourage them to complete food diaries. All participants were thanked for their participation in the study.

6.2.6.3 Participant retention and study withdrawal

Participants received a maximum of two reminders per survey or diary entry. Participants were also informed by short message service that they had been sent an email with food diary links. In addition, as a form of encouragement participants were contacted when they were half-way through the study and contacted again 1 week before their 3-month follow-up to alert them that they had one week left until they received their next, and final, set of food diaries. Participants in the control condition received a £30 voucher, and those in the intervention arm received a £35 voucher upon study completion for participant time. In addition, for every food diary submission, participants were entered into a prize draw for a Virgin Experience Days gift card worth £150. If participants did not complete the 3-month trial, they did not receive a gift voucher, as outlined within the PIS. However, all participants who contributed to food diaries, irrespective of completing the study or not, were entered into the prize draw.

Participants who had not been responsive to food diary entries, survey completion requests and reminders were sent an email acknowledging their study withdrawal, whilst requesting they complete a short survey providing reasons for their withdrawal. Those completing the survey were entered into a prize draw for a chance to win a £25 Love2Shop voucher.

6.2.7 Statistical analyses

Statistical analysis was conducted on IBM SPSS Statistics 15. Average energy (kcal) and sugar (g) intake of completed food diaries were calculated for baseline, one-month and three-month follow up. Skewness and Kurtosis tests were undertaken to check for normality, alongside z-scores. Extreme data points (i.e. outliers) were removed ahead of analysis in instances where z-scores were above 3 standard deviations (Howell et al., 1998). This was applied for dietary, physical activity and app engagement data, and did not exceed more than 2 exclusions per variable. Complete case analysis was the primary method of analysis. Descriptive statistics (Mean [±SD] and percentages) were carried out on participant characteristics and survey measures and compared between control and intervention conditions. Data from 5-point Likert scales were transformed (and reverse coded where necessary) into 3-point scales representing low, medium and high agreeability outcomes. This was carried out to ease interpretation, comparison and reporting of outcomes within- and between-groups. Given this is a pilot and feasibility study, statistical analysis explored mean differences and confidence intervals. Preliminary inferential statistics were conducted at the 5% significance level for exploratory purposes only. Though the notion of hypothesis testing is a contentious issue within the reporting of pilot and feasibility studies as they are usually underpowered to detect statistical significance (Thabane et al., 2010). However, this is a commonly adopted method by researchers (Shanyinde et al., 2011) and one which was undertaken within this evaluation. Paired samples t-tests were conducted to explore differences in psychosocial outcomes between baseline and 3-month follow-up. A mixed design Analysis of Variance explored the preliminary efficacy of the Food Scanner app on energy (kcal) and sugar (g) intake, and to obtain effect size estimates, at 1-month and 3-month follow-up. As the study was not powered to detect significant differences, no covariates were imputed into the model. Mean differences in dietary intake between intervention and control arms were also explored using independent samples t-tests.

Multiple imputation (MI), using Monte Carlo simulation techniques (Rubin, 1987), was conducted as a sensitivity analysis for sugar and energy intake outcomes at baseline and 3MFU only, as a method to manage and explore missing data, using STATA SE 15. As missing data was assumed missing at random (MAR), the Gaussian normal regression imputation method was performed, alongside condition, age and gender as auxiliary variables. As MI relies on complete cases of auxiliary variables, those with missing sociodemographic data were removed from the dataset (n=10). The average of all imputations was calculated to obtain a single result per variable. Independent samples t-tests, as described above, were repeated to test for significance between mean differences.

Analysis of open-ended responses was analysed using qualitative methods of thematic analysis. Thematic analysis provides the researcher with the main themes, or patterns, emerging from responses, organised hierarchically. Utilising a grounded theory approach, codes were derived based on what emerges from responses. Codes were grouped into themes, rather than categorising responses into pre-defined themes informed by the literature (Braun and Clarke, 2006). Data was interpreted and linked back to support or help understand quantitative outcomes.

6.3 Results

6.3.1 Participant recruitment and retention

In total, 201 potential participants accessed the Qualtrics webpage to the PIS. Of these, 29 did not provide consent, 26 did not provide an email address and 20 did not pass the eligibility criteria. The remaining sample consisted of 126 parents, of which 62 were allocated to the intervention arm and 64 to the control arm. Participants were recruited via Facebook (n=54; 42.9%), University of Sheffield mailing list (n=23, 18.3%) and via their family and friends (n=15, 11.9%). The remainder of participants did not provide any information (n=34, 27%).

The first baseline food diary was completed by 87 of 126 (69%) parents (control: n=43; intervention: n=44). As such, 39 parents did not complete the first food diary, and were considered dropouts from the beginning. All 3 food diaries were completed by 77 of 126 (61%) participants at baseline, 51 (40%) participants at 1MFU (61 [48%] completed at least one food diary) and 52 (41%) participants at 3MFU (66 [52%] completed at least one food diary). The baseline survey was completed by 79 of 126 (63%) parents (control: n=39; intervention: n=40). Finally, 64 of 126 (51%) participants completed the final 3MFU survey (control: n=35; intervention: n=29), and 62 (49%) dropped out. For the CONSORT flowchart, see Figure 11.

6.3.2 Sociodemographics

Amongst study completers (n=64), the mean age of the children was 6.94 ±2.19 years (54.8% female). Approximately 80% of the parental sample was Caucasian, of which 71% had completed higher education, and approximately half were from the two least deprived income quintiles. In regard to the child sample, there was 55% males within the intervention arm and 36% in the control. Additionally, 24% of children in the intervention arm were in the two most deprived income quintiles in comparison to 17% in the control arm. Table 8 outlines baseline characteristics of randomised participants, and Table 9 outlines the distribution of demographics of study completers within the intervention and control arms.

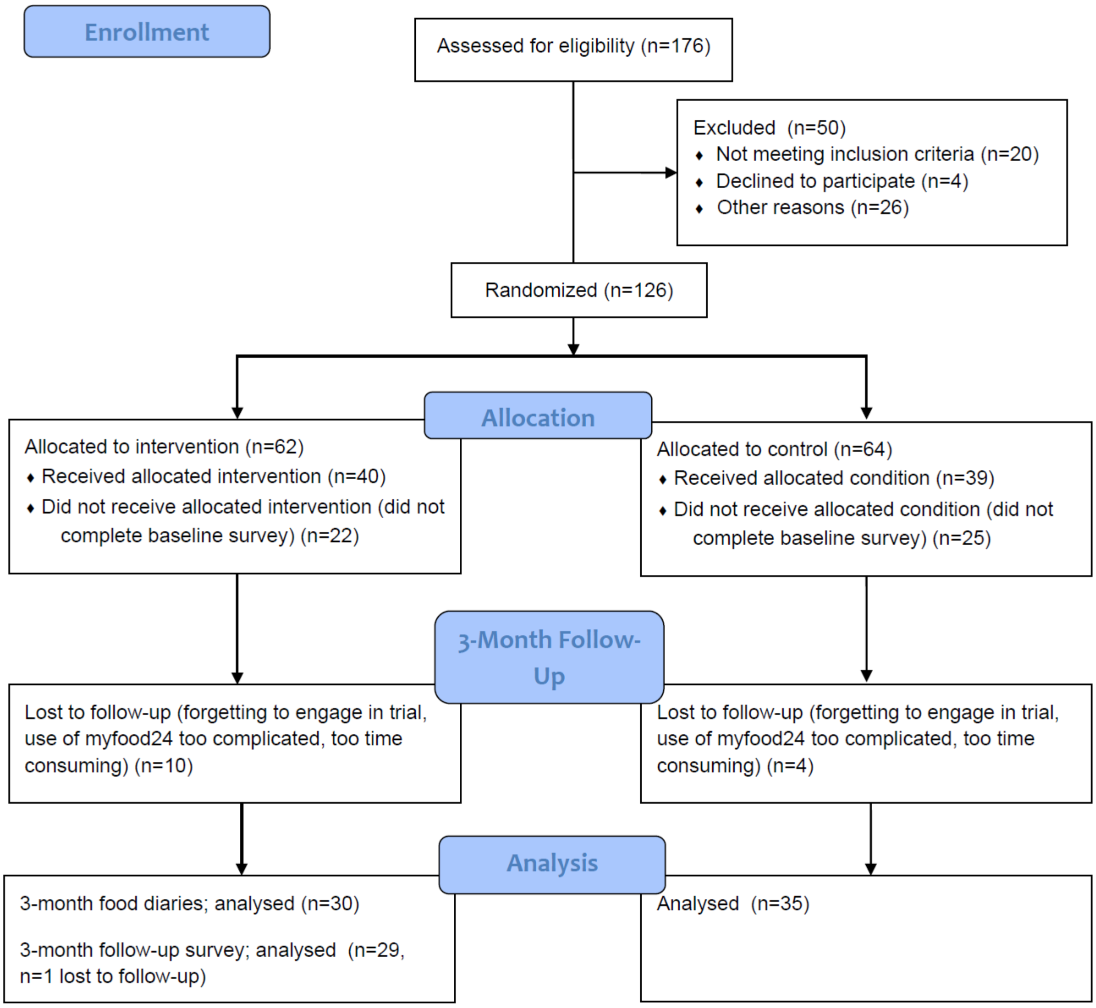


Figure 11. CONSORT flow chart for the Change4Life Food Scanner app pilot and feasibility trial.

Table 8. Baseline characteristics of randomised participants

		All	Intervention	Control
N		126	62	64
Missing cases		12[a]	7[b]	5[c]
Child age (years)	Mean (SD)	6.81 (2.04)	6.77 (1.77)	6.85 (2.28)
Child sex	N (%) Female	60 (52)	26 (46)	34 (57)
	N (%) Male	56 (48)	30 (54)	26 (43)
Parent Ethnicity	N (%) White British	81 (71)	41 (75)	40 (68)
	N (%) White other	9 (8)	5 (9)	4 (7)
	N (%) Asian	11 (10)	4 (7)	7 (12)
	N (%) Mixed White and Black	4 (4)	3 (6)	1 (2)
	N (%) Other	9 (8)	2 (4)	7 (12)
Parent Education	N (%) Higher education [d]	79 (69)	39 (71)	40 (68)
	N (%) Other	35 (31)	16 (29)	19 (32)
Household Income (quintiles)	N (%) Q1 – most deprived	16 (13)	10 (16)	6 (9)
	N (%) Q2	5 (4)	2 (3.2)	3 (5)
	N (%) Q3	16 (13)	6 (10)	10 (16)

	N (%) Q4	28 (22)	14 (23)	14 (22)
	N (%) Q5 – least deprived	40 (32)	18 (29)	22 (34)
	N (%) Unknown [e]	21 (17)	12 (19)	9 (14)
Household size	N (%) 2	10 (9)	6 (11)	4 (7)
	N (%) 3	32 (28)	9 (11)	23 (39)
	N (%) 4	53 (47)	33 (60)	20 (34)
	N (%) 5	14 (12)	4 (7)	10 (17)
	N (%) Other	5 (4)	3 (5)	2 (3)

N.B. Percentages rounded up to 0 decimal places.
[a] 10 missing cases for variables: age, sex
[b] 6 missing cases for variables: age, sex
[c] 4 missing cases for variables: age, sex
[d] Defined as higher education qualification below degree level, degree level qualification, or a Masters/PhD or equivalent
[e] Includes missing and unknown cases

Table 9. Demographics of study completers

		Total n = 64	**Intervention** n = 29	**Control** [a] n = 35
Child age (years)	Mean (±SD)	6.94 (±2.19)	6.8 (±1.99)	7.09 (±2.38)
Child sex	N (%) Female	34 (55)	13 (45)	21 (64)
	N (%) Male	28 (45)	16 (55)	12 (36)

Parent Ethnicity	N (%) White British	42 (68)	20 (69)	22 (67)
	N (%) White other	6 (10)	4 (14)	2 (6)
	N (%) Asian	3 (5)	2 (7)	1 (3)
	N (%) Mixed White and Black	3 (5)	2 (7)	1 (3)
	N (%) Other	8 (13)	1 (3)	7 (21)
Parent Education	N (%) Higher education [b]	44 (71)	21 (72)	23 (70)
	N (%) Other	18 (29)	8 (28)	10 (30)
Household Income (quintiles)	N (%) Q1 – most deprived	8 (13)	5 (17)	3 (9)
	N (%) Q2	5 (8)	2 (7)	3 (9)
	N (%) Q3	7 (11)	3 (10)	4 (11)
	N (%) Q4	13 (20)	5 (17)	8 (23)
	N (%) Q5 – least deprived	23 (36)	11 (38)	12 (34)
	N (%) Unknown	8 (13)	3 (10)	5 (14)

N.B. Percentages rounded up to 0 decimal places.
[a] Two missing cases for gender, education and ethnicity.
[b] Defined as higher education qualification below degree level, degree level qualification, or a Masters/PhD or equivalent

6.3.3 Feasibility and acceptability

Study compliance was explored. In relation to food diary completion, 58 of 77 (75%) respondents who completed all 3 food diaries, completed them within 7 days. At 1MFU, 45 of 52 (87%) respondents completed food diaries within 7 days, and at 3MFU 49 of 56 (88%) respondents completed food diaries within 7 days. Out of the 40 participants that were exposed to the intervention, 6 (15%) did not download the Food Scanner app. Among study completers, only one participant in the intervention arm did not use the Food Scanner app at least once throughout the study.

Table 10 outlines results relating to feasibility and acceptability measures. Amongst all study completers, 48 of 64 (76%) reported completing all study tasks, whereas 13 (21%) completed most tasks. When participants were asked to elaborate on what prevented them from completing all study tasks, issues surrounding time, forgetfulness, personal or family illness, work demands, going on holiday, COVID-19-related difficulties, and issues with using myfood24®, were reported. For example, in relation to work demands, one respondent said, “I am a busy NHS worker who has worked more over the previous few months due to the COVID pandemic”. One respondent highlighted difficulty engaging with the Food Scanner app during the pandemic, “time consuming with COVID as went back to work and shopping was a rush and didn’t allow me extensive time to scan food and use the app or fill in diaries”. Despite this, only 10 of 64 (16%) parents felt that participating in the study was too time consuming.

Food diary acceptability was explored further (see Table 10). Quantitative outcomes suggested that 44 of 64 (69%) respondents found myfood24® easy to use, whilst 17 (27%) found it too much work, exemplified by one respondent reporting, “food diary was onerous, mainly because it didn’t always have all options (particularly Aldi brand foods) and was difficult to complete on a mobile phone”. Pearson’s Chi-Square suggested no significant differences in food diary acceptability ratings between the intervention and control arms. The majority of participants (n=55, 87%) disagreed with the statement, “I did not report everything my child ate”, X^2 (2, N = 63) = 0.915, p = 0.633. When asked whether they had changed what their child ate to make it easier to record, 53 (83%) reported disagreement, X^2 (2, N = 64) = 4.872, p = 0.088. Finally, 44 (69%) reported agreement that food diaries did not affect what their child ate, X^2 (2, N = 64) = 2.092, p = 0.351.

Study acceptability was investigated at 3MFU (see Table 10). In general, the study was considered acceptable, whilst Pearson's Chi-Square suggested no significant differences in study acceptability ratings between the intervention and control arms. Amongst study completers, 51 (80%) felt that the study was easy to complete, X^2 (2, N = 64) = 4.046, p = 0.132, and 62 (97%) felt that task completion reminders were helpful, X^2 (1, N = 64) = 0.018, p = 0.892.

How to keep participants more engaged throughout the study was explored. Although most respondents provided no suggestions, 6 themes emerged from those that did (presented in *italics)*. Participants were required to complete food diaries on the day of consumption; however some participants preferred to choose the day of *food diary completion* ("being able to complete the food diaries retrospectively would have been helpful"). A few participants suggested that *myfood24® improvements* needed to be made. This included the myfood24® database ("My son has a plant-based diet and it was often very difficult to find the exact things that he eats…"), alongside reminders to submit food diaries ("perhaps when a diary is partially completed but not yet submitted a reminder to ask you to submit would have been useful"). In addition, given this was a study focusing on child outcomes, one participant suggested that children should be more actively involved by providing a *task for the child* ("maybe have something for the child themselves to do"). *Greater monetary incentive* was additionally voiced, whereby some participants felt that what was offered was not sufficient for the time and effort required to complete study tasks, whilst others voiced that willingness for continued participation was dependent upon incentive offered ("£30 seems a bit low in hindsight for the participation and time committed", "I'd happily continue with the study subject to reward"). Finally, *transparency around study tasks and objectives* was suggested. Respondents did not feel that there was enough transparency around how long the study tasks would take, and the time commitments involved ("the person who recommended it said it would be quite short"). Despite the above, *positive feedback* reflecting study acceptability was provided ("enjoyed documenting with my child, good engagement with him").

6.3.4 Sustainability

If the study was extended to a 12-month follow-up, 45 of 62 (73%) participants reported that they would be willing to continue with the study for a further 9 months (see Table 10).

Pearson's Chi-Square suggested no significant differences in sustainability responses between the intervention and control arms, X^2 (2, N = 62) = 1.278, p = 0.528.

Table 10. Feasibility and acceptability of study procedures, n (%)

Measure	n	High agreeability	Medium agreeability	Low agreeability
Study procedures				
Study was easy to complete?[a]	64	51 (80)	8 (13)	5 (8)
Participating in the study was time consuming/demanding? [b]	64	10 (16)	23 (36)	31 (48)
Receiving reminders to complete food diaries and surveys was helpful? [c]	64	62 (97)	2 (3)	0 (0)
All requested study tasks were completed? [d]	63	48 (76)	13 (21)	2 (3)
Food diaries [c]				
I did not report everything my child ate	63	1 (2)	7 (11)	55 (87)
I changed what my child actually ate to	64	6 (9)	5 (8)	53 (83)

make it easier to record				
It had no effect on what my child ate	64	44 (69)	11 (17)	9 (14)
It was easy to use	64	44 (69)	11 (17)	9 (14)
I found it too much work	64	17 (27)	15 (23)	32 (50)
Sustainability				
Willing to continue with study for 9 more months if the study was extended to a 12-month follow-up [e]	62	45 (73)	11 (18)	6 (10)

[a] Original response options were: extremely easy, somewhat easy, neither easy nor difficult, somewhat difficult, extremely difficult.
[b] Original response options were: a great deal, a lot, a moderate amount, a little, none at all.
[c] Original response options were: strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, strongly disagree
[d] Original response options were: completed all tasks, completed the majority of the tasks, completed a fair amount of the tasks, completed very few of the tasks.
[e] Original response options were: definitely yes, probably yes, might or might not, probably not, definitely not.

6.3.5 Study withdrawal

Out of 62 dropouts, 6 completed the study withdrawal survey. Three respondents found the use of myfood24® too complicated to log food diaries, 2 found study tasks too time consuming, 2 kept forgetting to complete food diaries, 2 did not feel that the gift voucher offered was enough compensation and 1 was facing technical issues. Open-ended responses suggested that myfood24® was not suitable for logging vegan diets and that it was difficult finding the exact foods consumed on the myfood24® database, especially when logging recipes (see Appendix 16 for open-ended feedback).

6.3.6 Preliminary effects of the intervention

6.3.6.1 App engagement

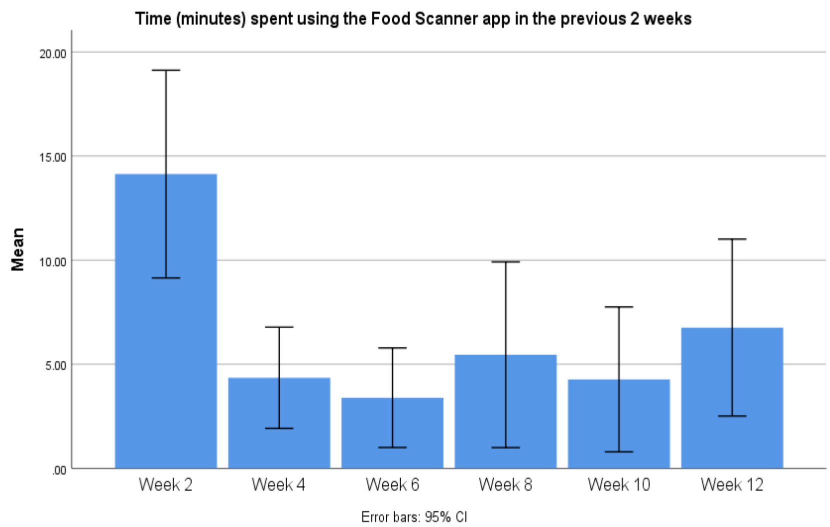
Results indicated that average app engagement (minutes) decreased over time. During the first two weeks of exposure to the Food Scanner app, participants (n=34) reported an average engagement time of 14.1 minutes (±14.7) per two weeks. At 12 weeks, participants (n=29) reported approximately 6.8 minutes (±11.6) of app engagement in the previous two weeks. In between, app engagement time varied (see Figure 12, panel a). Number of items scanned fortnightly suggested a gradual decrease in app engagement over the trial period (see Figure 12, panel b). Participants reported an average of 11 scanned items (±20.5) during the first 2 weeks of app exposure (week 2), and 3 scanned items (±4.6) in the final 2 weeks of the trial (week 12).

6.3.6.2 Predictors of behaviour change

Predictors of behaviour change at baseline and 3MFU are reported in Table 11. Generally, there was little change in outcomes between baseline and follow-up. Trends in the data are described below.

Within the intervention condition psychological capability reduced between baseline and 3MFU; 70% of participants reported an ability to make healthy food choices at baseline vs. 41% at 3MFU. This occurred despite greater, yet modest, ease in understanding nutritional labels (40% had difficulty understanding FOP labels at baseline vs 28% at 3MFU), and greater tracking of child sugar consumption (physical capability; 23% had low nutritional tracking at baseline, in comparison to 7% at 3MFU). Within the control condition, participants reported slightly greater difficulty in understanding nutritional labels at 3MFU (39% at baseline vs 60% at 3MFU), and greater tracking of child sugar consumption (29% had low nutritional tracking at baseline in comparison to 17% at 3MFU). When asked what the daily-recommended sugar intake (g) for one's child's age, only 5 of 40 (12.5%) intervention participants at baseline answered correctly, whilst 24 participants (60%) were unsure. At 3MFU, 5 of 29 (17%) answered correctly, whilst 48% underestimated the daily-recommended sugar intake. Amongst study completers only, 3 of 29 (10%) answered correctly at baseline, and 5 of 29 (17%) answered correctly at 3MFU. Similarly, only 6 of 38 (16%) control participants answered correctly at baseline, whilst 17 participants (45%) were unsure. At 3MFU, 9 of 34 (26.5%) answered correctly. Amongst study completers, 6 of 32 (19%) answered correctly at baseline, and 8 of 32 (25%) answered correctly at 3MFU.

A



B

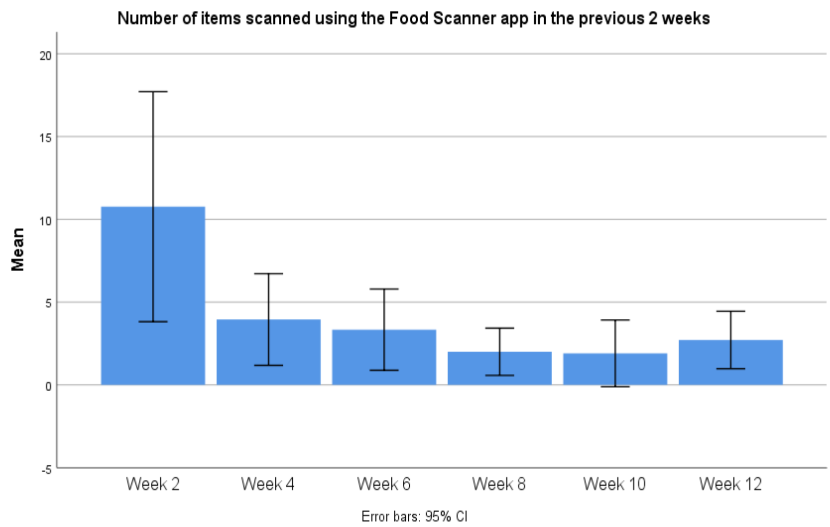


Figure 12. Self-reported Food Scanner app engagement over the 12-week trial period (n=34). A Time (minutes) spent using the Food Scanner app in the previous 2 weeks. B Number of items scanned using the Food Scanner app in the previous 2 weeks.

A total score out of 3 was calculated for applied knowledge questions (0 = no answers correct; 3 = all answers correct). At baseline, 11 of 22 (50%) intervention participants answered correctly on one question, whilst 6 of 22 (27%) participants answered correctly on 2 questions. Amongst the control condition, 5 of 21 (24%) answered correctly on one question, and 13 of 21 (62%) answered correctly on two questions. At follow-up, 7 of 28 (25%) intervention participants got 0 questions correct, 12 (43%) got 1 question correct, and 8 (29%) got 2 questions correction. Amongst the control condition, 9 of 34 (27%) got 0 questions correct, 11 (32%) got 1 question correct and 12 (35%) got 2 questions correct. The remainder got all 3 questions correct. Repeated measures t-tests among study completers indicated an average score (out of 3) of 1.3 (±0.9) at baseline and 1.1 (±0.9) at 3MFU, $t(13) = 0.41$, $p = 0.34$, within the intervention arm (n=14). The control arm (n=17) had an average score of 1.6 (±0.9) at baseline and 1.2 (±1.0) at 3MFU, $t(16) = 1.93$, $p = 0.04$.

In exploring opportunities for behaviour change, results within the intervention condition suggested an increased difficulty of limiting children's sugar intake to recommended guidelines between baseline and 3MFU. Results also indicated an increased want (automatic motivation), but a decreased intention (reflective motivation), to keep their child's sugar consumption within recommended guidelines at 3MFU in comparison to baseline. No observable differences were present within the control condition for either opportunities or motivations. Results also suggested that 28% of respondents within the intervention arm, in contrast to 46% within the control arm, regularly looked at food labels when buying food at baseline. In addition, 18% of participants in the intervention arm reported that nutritional information on food labels affected their shopping choices, in comparison to 36% in the control arm at baseline. Moreover, 43 of 78 (55%) participants indicated no previous engagement with dietary apps at baseline, whilst 4 of 78 (5%) indicated previous use of the Change4Life Sugar Smart app, an older version of the Food Scanner app.

There were minimal changes in attitudes between baseline and 3MFU within both intervention and control conditions. On the other hand, when investigating changes in PBC, both conditions had decreased levels of control over child's sugar consumption at 3MFU in comparison to baseline (% participants with high control over child's sugar consumption; intervention: 78% [baseline] vs. 68% [3MFU]; control: 85% [baseline] vs. 69% [3MFU].:

Mean differences between baseline and follow-up were investigated separately for intervention and control conditions. T-tests suggested no significant differences or shifts in psychosocial outcomes over time in either condition (see Appendix 17).

Perceived eating habits and perceived child weight status were only collected at baseline. Most of the respondents within both the intervention condition (73%) and the control condition (67%) had medium agreeability that their child's diet is healthy. The majority of all participants believed that they should improve their child's eating habits (see Table 5). In addition, results suggested that amongst responders, 75 of 79 (95%) parents believed their child was healthy weight, whilst 2 (3%) were reportedly underweight, and 2 (3%) were reportedly overweight.

6.3.6.3 Anthropometric and dietary outcomes

Parent reported height and weight measurements were collected at baseline only. Results found that 78 of 126 (62%) participants reported their child's height, whilst 64 (51%) reported their child's weight. This resulted in 58 (46%) complete height and weight data points.

Energy (kcal) and sugar intake (g) outcomes within- and between groups are reported in Table 12 and are based on study completers only. At 1MFU, energy intake reduced by -102.4 kcal (95% CI: -284.5; 79.7) in the intervention group, and -185.7 (95% CI: -307.8; -63.6) in the control group, in comparison to baseline. At 3MFU, energy intake reduced by -157 (95% CI: -301; -13) in the intervention group, and -175.2 (95% CI: -316; -34.4) in the control group, in comparison to baseline. This resulted in a non-significant mean difference in energy intake of 83 (95% CI: -122.8; 289.4) at 1MFU, and 18 (95% CI: -180; 216.5) at 3MFU between the intervention and control conditions, with a greater reduction within the control condition.

Table 11. Comparison of psychological predictors of behaviour change between intervention and control arms, n (%)

Question	Baseline agreeability			3-month follow-up agreeability		
	High	**Medium**	**Low**	**High**	**Medium**	**Low**
Attitudes						
It is important for me that my family eat a healthy diet? [a]						
Intervention (base, n=40; 3MFU, n=29)	35 (88)	5 (13)	0	24 (83)	5 (17)	0
Control (base, n=39; 3MFU, n=35)	33 (85)	6 (15)	0	30 (86)	5 (14)	0
Having too much sugar leads to disease						
Intervention (base, n=40; 3MFU, n=29)	33 (83)	6 (15)	1 (3)	27 (93)	2 (7)	0
Control (base, n=39; 3MFU, n=35)	36 (92)	3 (8)	0	33 (94)	1 (3)	1 (3)
When buying food, snacks or drinks for my child, it is important to pay attention to the amount of sugar it contains						
Intervention (base, n=40; 3MFU, n=29)	31 (78)	7 (18)	2 (5)	25 (86)	3 (10)	1 (3)
Control (base, n=39; 3MFU, n=35)	35 (90)	4 (10)	0	34 (97)	1 (3)	0

Question	Baseline agreeability			3-month follow-up agreeability		
	High	**Medium**	**Low**	**High**	**Medium**	**Low**
For my child to be healthy, I need to be careful how much saturated fat my child eats						
Intervention (base, n=40; 3MFU, n=29)	34 (85)	4 (10)	2 (5)	22 (76)	6 (21)	1 (3)
Control (base, n=39; 3MFU, n=35)	30 (77)	8 (21)	1 (3)	29 (83)	5 (14)	1 (3)
For my child to be healthy, I need to be careful how much sugar my child eats						
Intervention (base, n=40; 3MFU, n=29)	40 (100)	0	0	27 (93)	1 (3)	1 (3)
Control (base, n=39; 3MFU, n=35)	39 (100)	0	0	34 (97)	1 (3)	0
For my child to be healthy, I need to be careful how many calories my child eats						
Intervention (base, n=40; 3MFU, n=29)	17 (43)	18 (45)	5 (13)	10 (35)	9 (31)	10 (34)
Control (base, n=39; 3MFU, n=34)	17 (44)	9 (23)	13 (33)	20 (59)	6 (18)	8 (24)
Perceived eating habits						

Question	Baseline agreeability			3-month follow-up agreeability		
	High	**Medium**	**Low**	**High**	**Medium**	**Low**
"My child's diet is healthy?" [c]						
Intervention (base, n=40)	5 (13)	29 (73)	6 (15)	--	--	--
Control (base, n=39)	4 (10)	26 (67)	9 (23)	--	--	--
"*I should improve my child's eating habit"* [c]						
Intervention (base, n=40)	27 (68)	7 (18)	6 (15)	--	--	--
Control (base, n=39)	26 (67)	6 (15)	7 (18)	--	--	--
Perceived behavioural control						
I have control over my child's sugar consumption? [a]						
Intervention (base, n=40; 3MFU, n=28)	31 (78)	9 (23)	0	19 (68)	9 (32)	0
Control (base, n=39; 3MFU, n=35)	33 (85)	6 (15)	0	24 (69)	11 (31)	0
COM-B measures: Physical capability						

Question	Baseline agreeability			3-month follow-up agreeability		
	High	**Medium**	**Low**	**High**	**Medium**	**Low**
I often keep track of how much sugar my child eats or drinks each day? [a]						
Intervention (base, n=40; 3MFU, n=29)	15 (38)	16 (40)	9 (23)	10 (35)	17 (59)	2 (7)
Control (base, n=38; 3MFU, n=35)	15 (40)	12 (32)	11 (29)	18 (51)	11 (31)	6 (17)
COM-B measures: Psychological capability						
I find it easy to limit my child's sugar intake to the amounts recommended in the above guidelines? [a]						
Intervention (base, n=40; 3MFU, n=29)	9 (23)	7 (18)	24 (60)	7 (24)	3 (10)	19 (66)
Control (base, n=38; 3MFU, n=35)	14 (37)	6 (16)	18 (47)	14 (40)	4 (11)	17 (49)
I know a lot about making healthy food choices? [a b]						
Intervention (base, n=40; 3MFU, n=29)	28 (70)	12 (30)	0	12 (41)	16 (55)	1 (3)
Control (base, n=39; 3MFU, n=35)	26 (67)	13 (33)	0	22 (63)	13 (37)	0
"Too much sugar intake for my child increases their risk of obesity"						

Question	Baseline agreeability			3-month follow-up agreeability		
	High	Medium	Low	High	Medium	Low
Intervention (base, n=40; 3MFU, n=29)	39 (98)	1 (3)	0	29 (100)	0	0
Control (base, n=39; 3MFU, n=35)	39 (100)	0	0	34 (97)	1 (3)	0
"*Nutritional labels are hard to understand*" [b]						
Intervention (base, n=40; 3MFU, n=29)	16 (40)	10 (25)	14 (35)	8 (28)	8 (28)	13 (45)
Control (base, n=39; 3MFU, n=35)	15 (39)	11 (28)	13 (33)	21 (60)	6 (17)	8 (23)
COM-B measures: Automatic motivation						
I am concerned about my child consuming more sugar than what is recommended? [a]						
Intervention (base, n=40; 3MFU, n=29)	10 (25)	28 (70)	2 (5)	8 (28)	19 (66)	2 (7)
Control (base, n=38; 3MFU, n=35)	10 (26)	22 (58)	6 (16)	10 (29)	17 (49)	8 (23)
I want to keep my child's sugar consumption within recommended guidelines? [a]						
Intervention (base, n=40; 3MFU, n=29)	20 (50)	19 (48)	1 (3)	18 (62)	10 (34)	1 (3)

Question	Baseline agreeability			3-month follow-up agreeability		
	High	Medium	Low	High	Medium	Low
Control (base, n=38; 3MFU, n=35)	29 (76)	9 (24)	0	26 (74)	9 (26)	0
COM-B measures: Reflective motivation						
I intend to keep my child's sugar consumption within recommended guidelines? [a]						
Intervention (base, n=40; 3MFU, n=29)	32 (80)	7 (18)	1 (3)	20 (69)	8 (28)	1 (3)
Control (base, n=38; 3MFU, n=35)	34 (89)	3 (8)	1 (3)	31 (89)	3 (9)	1 (3)
I am actively trying to reduce my child's sugar intake? [a]						
Intervention (base, n=40; 3MFU, n=29)	15 (38)	23 (58)	2 (5)	13 (45)	13 (45)	3 (10)
Control (base, n=38; 3MFU, n=35)	18 (47)	18 (47)	2 (5)	16 (46)	16 (46)	3 (9)
I look at food labels when buying food? [a c]						
Intervention (base, n=40)	11 (28)	27 (68)	2 (5)	--	--	--
Control (base, n=39)	18 (46)	20 (51)	1 (3)	--	--	--

Question	Baseline agreeability			3-month follow-up agreeability		
	High	**Medium**	**Low**	**High**	**Medium**	**Low**
Nutritional information on food labels affects my shopping choices? [a c]						
Intervention (base, n=40)	7 (18)	28 (70)	5 (13)	--	--	--
Control (base, n=39)	14 (36)	25 (64)	0	--	--	--
COM-B measures: Social opportunity						
My lifestyle makes it easy for me to limit my child's sugar intake to the above guidelines, a day? [a]						
Intervention (base, n=40; 3MFU, n=29)	15 (38)	10 (25)	15 (38)	9 (31)	5 (17)	15 (52)
Control (base, n=38; 3MFU, n=35)	20 (53)	11 (29)	7 (18)	19 (54)	10 (29)	6 (17)
If I wanted advice or information on how to cut down on my child's sugar consumption, I know where to go? [a]						
Intervention (3MFU, n=29)	--	--	--	20 (69)	4 (14)	5 (17)
Control (3MFU, n=35)	--	--	--	26 (74)	2 (6)	7 (20)

[a] Measures have been reworded for ease of interpretation against 3-point agreeability outcomes. Original questions are presented in Appendix 14.

Question	**Baseline agreeability**			**3-month follow-up agreeability**		
	High	**Medium**	**Low**	**High**	**Medium**	**Low**

[b] At 3-month follow up, the question was presented in the context of the Food Scanner app, for those in the intervention arm.
[c] only measured at baseline.

Similar results were observed with sugar intake. At 1MFU, sugar intake reduced by 1.4 (95% CI: -12.6; 15.4) in the intervention group, and -8.9 (95% CI: -14.8; -2.9) in the control group. At 3MFU, sugar intake reduced by -1.3 (95% CI: -12.8; 10.2) in the intervention group, and -11.2 (95% CI: -18.5; -3.9) in the control group. This resulted in a non-significant mean difference in sugar intake of 10 (95% CI: -3; 23) at 1MFU, and 10 (95% CI: -3; 23) at 3MFU between conditions, with a greater reduction within the control condition.

A 2x2 mixed model ANOVA was conducted, with study condition as a between-subjects factor (intervention vs. control) and time as a within-subjects factor (baseline vs. 1MFU and 3MFU). The analysis revealed a within-subjects main effect of energy intake over time at 1MFU, $F(1, 58) = 7.827$, $p = .007$, $\eta_p^2 = .119$, and at 3MFU, $F(1, 63) = 11.204$, $p < .001$, $\eta_p^2 = .151$, suggesting that irrespective of study condition, energy intake was significantly greater at baseline than follow-up. The analysis also revealed a between-subjects main effect of condition at 1MFU, $F(1, 58) = 7.860$, $p =.007$, $\eta_p^2 = .119$, and 3MFU, $F(1, 63) = 6.143$, $p <=.016$, $\eta_p^2 = .089$, whereby the intervention arm consumed more calories than the control arm irrespective of time. No interaction between condition and energy intake over time was found at 1MFU, $F(1, 58) = .654$, $p=.422$, $\eta_p^2 = .011$, or 3MFU, $F(1, 63) = .034$, $p=.855$, $\eta_p^2 = .001$.

When investigating sugar intake, the analysis revealed no within-subjects main effect over time at 1MFU, $F(1, 57) = 1.275$, $p = .264$, $\eta_p^2 = .022$, and 3MFU, $F(1, 61) = 3.760$, $p = .057$, $\eta_p^2 = .058$. There was also no between-subjects main effect of condition at 1MFU, $F(1, 57) = .963$, $p =.331$, $\eta_p^2 = .017$, and 3MFU, $F(1, 61) = 2.523$, $p =.117$, $\eta_p^2 = .04$. Finally, there was no interaction between condition and sugar intake over time at 1MFU, $F(1, 57) = 2.383$, $p=.128$, $\eta_p^2 = .040$, and 3MFU, $F(1, 61) = 2.380$, $p=.128$, $\eta_p^2 = .038$.

Multiple imputation was conducted on baseline and 3MFU outcomes for energy (kcal) and sugar (g) intake. For energy intake, 40 imputations were conducted, whilst 50 imputations were conducted for sugar intake. Differences in energy intake suggested an average energy intake of 1619 kcal (±400.8) at baseline within the intervention group (n=56), and 1534 kcal (±413.6) within the control group (n=60). At 3MFU, there was an average energy intake of 1610 kcal (±330.4) within the intervention group, and 1379 kcal (±226.9) within the control group. This resulted in a significant mean difference of 147 kcal (95% CI: 6.6; 288) between the intervention and control conditions, $t(114) = 2.1$, $p = .04$, with a greater reduction within the control arm. Results also found an average sugar intake of 78g (±22.9) at baseline within the intervention group (n=56), and 78g (±25) within the control group (n=60). At 3MFU, there was an average sugar intake of 82g (±25.6) within the intervention group, and 63g (±19.2) within the control group. This resulted in a significant mean difference in sugar intake of 18g (95% CI: 8.9; 28.1) between the intervention and control conditions, $t(114) = 3.8$, $p<.001$, with a greater reduction within the control arm.

6.3.7 Intervention and study feedback

Those in the intervention condition were asked to feedback on the acceptability of the Change4Life Food Scanner app. The use of sugar cube images was considered easy to understand by 25 of 28 (89%) participants, however were only found to be useful by 16 (57%) participants. In addition, 24 (86%) reported that it would be useful to have such sugar cube images printed on food packages as part of the nutritional label. Despite the positive feedback regarding the app and its features, 20 (71%) participants reported that the app did not help them improve their food purchasing behaviours.

When asked to feedback on their likeability of the Food Scanner app, 16 of 28 (57%) participants thought the app was helpful, 24 (86%) thought the app was easy to use, 14 (50%) enjoyed using the app, 17 (61%) liked the app, and 18 (64%) said that they would recommend the app to others.

When asked to feedback on their perceptions of the effectiveness of the Food Scanner app in improving dietary behaviours, 16 of 28 (57%) reported that using the app increased their ability to reduce the number of high sugar snacks their child ate, and that the app increased their ability to make healthier food choices for their child. On the other hand, open-ended responses suggested barriers to changing behaviour, including the provision of less healthy diets when being looked after by grandparents ("I can see I offer my child a better diet when I can personally prepare and choose what he is eating. On two days a week he is looked after by grandparents who do tend to give him more unhealthy food choices as it is easier"), and COVID-19 placing difficulty on dietary behaviour changes ("I've found the study very insightful. I'm thinking more about what they eat. However, our current restrictions make it harder to take action"). One respondent flagged that the survey did not ask what changes participants made to their diets since using the Food Scanner app ("There has been nowhere to report what changes we did make?").

Table 12. Mean differences (±SD) in energy (kcal) and sugar (g) intake between baseline and follow-up

Outcome	**Intervention**			**Control** [a]			**Total mean difference (95% CI)**
	Baseline	**1 month**	**Difference (95% CI)** [b]	**Baseline**	**1 month**	**Difference (95% CI)**	
Energy (kcal)	1772.7 (±404.8)	1670.3 (±338.4)	-102.4 (-284.5; 79.7)	1568.1 (±459.2)	1382.4 (±329.6)	-185.7 (-307.8; -63.6)	83.3 (-122.8; 289.4)
Sugar (g)	77.1 (±21.5)	78.4 (±33.4)	1.4 (-12.6; 15.4)	76.2 (±24.1)	67.3 (±25.6)	-8.9 (-14.8; -2.9)	10.2 (-3.0; 23.5)
	Baseline	**3 months**	**Difference** [c]	**Baseline**	**3 months**	**Difference**	
Energy (kcal)	1763.2 (±421.8)	1606.2 (±445.7)	-157.0 (-301.0; -12.0)	1552.1 (±470.8)	1376.9 (±277.7)	-175.1(-316.0; -34.4)	18.2 (-180.1; 216.5)

Sugar (g)	80.1 (±25.8)	78.9 (±33.0)	-1.3 (-12.8; 10.2)	75.5 (±23.4)	64.3 (±25.9)	-11.2 (-18.4; -3.9)	9.9 (-2.9; 22.7)

N.B. Data is based on complete case analysis, after the removal of outliers 3 standard deviations from the mean.
[a] Energy, n= 35; sugars, n=25 for both 1-month and 3-month follow-up
[b] Energy, n= 25; sugars, n=24
[c] Energy, n= 30; sugars, n=28

Common to all apps on the app market, the Food Scanner app underwent a major update in June 2020, resulting in changes in design and features. Participants were therefore asked whether they had noticed any changes or updates in the Food Scanner app in the past 3 month, of which 2 of 10 participants responded yes. Participants that had experienced an app update were asked whether the latest update improved their engagement with the app, of which both participants answered, ‘a little/a moderate amount’.

Open-ended questions asked participants within the intervention arm to feedback on their experiences of using the Food Scanner app, to outline barriers to app engagement alongside recommendations for app improvements. Eight themes emerged (presented in italics; see Table 13 for themes, codes and supporting quotations). There was generally a lot of positive feedback with regards to the app. Some participants found the app helpful in providing feedback on nutritional information. However, others voiced that the app was not suitable for those who cook, provides elementary level nutrition information, and that they as individuals rely on FOP nutrition labels (*app usefulness*). Other parents voiced that the app’s barcode scanner needed to be improved to recognise more items, that a product search feature should be included alongside better storage of popular scanned items (*better product recognition*). Similarly, it was suggested that improvements be made to the structure/display of nutritional information (e.g., displaying information amount per serving, or attaching information provided via the app on FOP nutritional labels), alongside low sugar food swap suggestions and methods to improve monitoring of behavioural changes. On the other hand, one participant valued that the app signposted to external resources to help further aid dietary choices (*information provision and monitoring*). Although the majority of participants found the app to be aesthetically pleasing and eye-catching, a few recalled that the colour-scheme was not aesthetically pleasing and that more positive reinforcement through encouraging language was needed (*presentation*). In addition, several parents reported that access to incentives would increase their use of the app, such as reward systems, prize incentives and money off vouchers (*rewards and incentives*). Other participants suggested that the app be more personalised through incorporation of individual targets alongside sharing outcomes on social media (*personalisation*), and to also be more child-friendly and engage children directly (*promote child involvement*). Finally, several participants voiced that the app was easy, quick, and fun to use. Others found it inconvenient to use in supermarkets, especially during COVID-19 where there was a need to disinfect items regularly. Some considered the app time-consuming to use, especially when meals had to be prepared quickly. In addition, due to busy lifestyles, participants often forgot about the app which prevented its use, emphasising the need for in-app daily reminders to prompt app use. Issues surrounding the use of too much phone memory was also raised (*convenience and practicality)*. A comprehensive overview of codes and participant quotes can be found within Appendix 16.

6.3.8 External confounding variables

Child physical activity was parent-reported at baseline. Those in the intervention condition (n=39) reported an average of 75 weekday minutes (±40.7), though this was subject to the removal of one outlier (600 minutes of typical weekday physical activity, 6SD above the mean), and 116 weekend minutes (±68.2) of physical activity. Those in the control arm (n=37) reported an average of 86 weekday (±53.4) and 107 weekend (±66.7) minutes of physical activity. Weekday and weekend days combined suggest similar physical activity levels between groups.

At 3MFU, participants were asked whether the introduction of the sugar tax led to changes in beverage purchasing behaviours; 64% of the sample (n=64) answered 'never' and 25% agreed that it had impacted on their behaviour to some extent. Similarly, when asked whether the introduction of the sugar tax reduced their child's sugar intake, 66% of the sample responded 'never', whereas 25% reported a reduction in sugar intake to some extent. One respondent provided feedback at the end of the study that open-ended responses were needed to clarify choice of answers ("I don't think the sugar tax questions were worded correctly because they didn't give a chance to explain the responses. Sugar was removed from some products to avoid the sugar tax (Ribena we are looking at you) and replaced with artificial sweeteners… so you could say that the sugar tax has influenced that behaviour but not in the way that the question was worded to measure").

Table 13. Thematic analysis of Change4Life Food Scanner app open-ended feedback

Theme	Codes	Quote
App usefulness	● Helpful feedback of nutritional information ● No added value ● Assumes lack of nutrition knowledge ● App assumes ample time to scan products ● App does not consider meal prepping and shopping list ● App only useful before changes made ● Don't need to continuously use app ● App isn't useful for personal grocery choices ● Not useful for those that cook ● Limited usefulness and information provision ● Not useful for those providing balanced diet	"Easy to use and understand broke down nutritional labels into comprehensible information allowing informed and healthy decisions" "The app assumes that you don't know much about child nutrition in the first place. As a parent I regularly meal plan and write a shopping list I don't just wander round the supermarket scanning random items. The app also assumes you have ample time to wander round when in reality I like to spend the least amount of time shopping." "Not sure. Once you know the content of a product you don't need to scan it again. It was very useful at first but once we'd made changes we didn't need it as much." "I think it is aimed at parents who only buy ready made food for their children. It is not helpful for parents who cook from scratch. It also assumes that you know very little about basic nutrition. For example I know a can of Coke is unhealthy and

	• Does not address fussy eaters • Does not consider other important macronutrients • Limit to app use • Don't need to use it	contains several cubes of sugar, I don't need an app to tell me. I wouldn't bother to scan several to see which had the least amount of sugar, I just wouldn't buy it in the first place. I didn't use the app after a while as it didn't give me any further information."
Better product recognition	• Not everything scanned recognised • Embed search features • Section on popular scanned items	"Better range of goods recognised" "Maybe search for an item rather than having to scan" "Include more items"
Information provision and monitoring	• Resources • Display information by serving • Improve display of information presented • Make information attached to food labels • Health behaviour progress chart • Score items scanned • Swap ideas • Recipe ideas	"I liked the link to the change to life website for the nhs recipes" "have the amount per serving" "Don't use the app, make it attached to the food label." "A chart to show positive changes to see progress" "examples of healthy treats advertised on it" "Recipe ideas? Like alternatives for birthday party treats that have less sugar in?"

Presentation	● Aesthetically pleasing ● Tone/Preachy ● Simple colours ● Colour clashes impact concentration ● Simple encouraging terms	"It was very easy to scan products and see their information. It was bright and interested my daughter too." "simple encouraging terms" "less colour clashes makes it hard to concentrate" "simpler colours"
Rewards and incentives	● Money off vouchers ● Rewards system ● Gamification ● Access to incentives for healthier products	"Incentives- money off vouchers, rewards system, make into a game to get children involved in making food choices" "Possibly incentives for parents that otherwise may choose cheaper options like potential discount and money accumulators" "Give free healthy food for using the app."
Child involvement	● Chart to log child's progress ● More child-friendly	"engage children directly to integrate with daily life" "Maybe a chart to log a child's progress when they've made swaps."
Personalisation	● Individual targets ● Link with social media	"provide individual targets" "Maybe link with social media"

Convenience and practicality	● Ease and speed of use ● Fun ● Inconvenient ● Use less phone memory ● Time consuming ● Daily reminders ● Forgot ● COVID-19 impacting diets ● COVID-19 impacting use	"It was easy to use and handy to have on my mobile so when I was in a shop I could use it to decide which was a healthier choice of product." "use less memory" "Too time consuming" "Its difficult to get the app out in shops and start scanning everything before making a purchase." "I have to prepare food quickly so didn't have time" "disinfecting phone" "daily reminders to use it" "I often forgot about the app"

When asked to report on their familiarity with the Change4Life campaign, 6% of the sample reported no familiarity, 50% of the sample reported some familiarity, and 44% reported high familiarity with the campaign. Despite this, 33% of the sample claimed to not currently use Change4Life resources, 52% sometimes use such resources, and 15% of the sample use Change4Life resources frequently. When asked whether existing public health campaigns and messages have helped to improve their child's diet, 31% of the sample agreed to some extent, whereas 25% did not agree and 14% were not aware of any public health campaigns or messages.

As this study was disrupted by COVID-19, participants were asked a series of questions relating to the impacts of COVID-19 on their child's diet (see Appendix 18). The majority of participants agreed that COVID-19 affected food purchasing behaviour (51%), led their child to eat more snacks than they did before (61%), eat more home cooked meals (76%), and spend more money on food (72%). Most participants disagreed that COVID-19 led to an increase in take-out food consumption (59%). When asked whether COVID-19, or any other events, affected responses or engagement in the trial, 48 (76.2%) of respondents answered no. When asked whether there were any other factors that may have had an influence over child sugar consumption in the last 3 months, 53 of 64 (83%) said no. For those that responded yes, open-ended responses were grouped into 3 themes. It was found that *lockdown demands caused time constraints*, whereby one participant reported, "life became hectic going back to work and home-schooling so had difficulty completing all tasks", whilst another similarly said, "second survey was pandemic peak–- we struggled to fit in the surveys also". Results also suggested that the pandemic had resulted in changes to individuals' dietary behaviours (*changes to diet)*. One respondent reported, "only in the first few weeks of lockdown when I couldn't buy my usual groceries." Another respondent referred back to lockdown and school closures, "because at school her food intake would be very different". Finally, being *out of routine* during the pandemic was found to affect engagement with the trial; one respondent reported, "being at home has increased snack consumption".

6.4 Discussion

The current study set out to investigate the feasibility and acceptability of evaluating the Change4Life Food Scanner app in reducing children's energy and sugar intake at 1-month and 3-month follow-up. The study additionally aimed to explore app engagement and changes in psychosocial outcomes over the study period. High drop-out rates have challenged the feasibility of the study; modifications to study design and methods may be warranted to maximise study completion. Despite the large drop-out rate, the study was considered feasible, acceptable, and sustainable amongst study completers. However, the Food Scanner app was not found to be effective in shifting parental psychological predictors of behaviour change to be more favourable. Neither was the app effective, in comparison to a control condition, in reducing energy (kcal) or sugar (g) intake amongst children via parental behaviour change. When missing data was managed through MI, results suggested significant reductions in energy and sugar intake in the control arm, in comparison to the intervention arm, over the trial period. These results are in contrast to the findings from Chapter 3, whereby the Food Scanner app was found to consist of a range of effective BCTs (Mahdi et al., 2022b), and having followed evaluation recommendations put forth by stakeholders within Chapter 5. How these findings relate and integrate with one another will be discussed within Chapter 8. The discussion below will specifically focus on the outcomes of this chapter.

Study feasibility was investigated through numerous methods. Only 63% of individuals who accessed the Qualtrics webpage participated in the study, demonstrating a high conversion rate. A large proportion of prospective participants did not provide an email address despite completing consenting procedures. This may have been due to a lack of realisation that ongoing engagement and correspondence with the researcher was necessary. Unfortunately, recruitment to trials have been found to be more challenging than recruitment to cross-sectional surveys (Treweek et al., 2018). Participant recruitment and retention suggested an almost 30% attrition immediately after consenting procedures, and a further 20% drop out at 3MFU. Similar attrition rates have been reported within mHealth interventions, calling for improved strategies to retain participants (Meyerowitz-Katz et al., 2020, Sousa et al., 2020, Jakob et al., 2022). Although a greater sample of control participants completed the study, in comparison to the intervention condition, a greater proportion of those randomised into the intervention condition dropped out before intervention exposure. Therefore, it cannot be assumed that intervention condition demands led to a greater dropout rate. Insufficient participation incentives and inability to commit to the completion of food diaries using myfood24® were reported within the study withdrawal survey. In addition, as the study was disrupted by COVID-19, the pandemic may have interfered with participant availability and willingness to commit to a 3-month trial and associated tasks. COVID-19 has been reported to have disrupted research trials, recruitment, and clinical outcomes (Sathian et al., 2020), as well as impacting children's dietary behaviours (Campbell and Wood, 2021, Farello et al., 2022), data completeness and participant retention (Jose et al., 2022). Incentivisation approaches and behavioural insights may help counter participant attrition within a full-scale trial.

Amongst completers, the study and intervention were rated positively and were considered acceptable. Task completion reminders were rated highly given that respondents reported forgetfulness as a common reason behind late or absent submissions. Given the small sample size of the feasibility study, I was able to manually send out task completion reminders in response to participant progress. A full-scale trial would benefit from a more cost and time-efficient automated approach. Although most respondents found the use of myfood24® acceptable, a third of the sample found it too time consuming and difficult to use. Issues raised included accessibility of the platform via mobile phone, and lack of representation of vegan diets on myfood24®. Although myfood24® is currently smartphone-friendly, it was still within the optimisation phases during the feasibility study, unbeknownst to the researcher. Moreover, although myfood24® boasts the largest food database in comparison to its competitors (myfood24, 2022), it left many participants feeling overwhelmed. Such indicators are important when choosing a suitable platform to log food diaries. A third of respondents also reported that food diaries affected what their child ate. Monitoring of behaviours, such as with food diaries, is a BCT and can alone contribute to positive behavioural changes and improvements in diets (Zepeda and Deal, 2008). Inclusion of a control condition accounted for this confounder within the trial.

Preliminary effects of the intervention on dietary outcomes were assessed. Findings suggested that the Change4Life Food Scanner app was not effective in reducing energy or sugar intake in comparison to a control condition. Although there were noticeable reductions in intake at follow-up in comparison to baseline within both conditions, reductions were larger, albeit nonsignificant, in the control arm. Given the small sample size, inferential statistics were conducted for exploratory purposes as opposed to reaching definitive conclusions. Effect size estimates, based on partial eta-squared, of the *condition x intake over time* interaction also suggested no to little effect of the intervention. Multiple imputation for the handling of missing data found significant differences at 3MFU, whereby the intervention arm consumed significantly more energy (kcal) and sugar (g) than the control arm. Evidence regarding the effectiveness of DDIs suggest potential modest effects (Langarizadeh et al., 2021, Yau et al., 2022b, Bonvicini et al., 2022, Islam et al., 2020). Study findings are complementary to a natural experiment that explored the effectiveness of the Change4Life campaign, which included an older version of the Food Scanner app. The authors reported that the campaign led to reductions in children's sugar consumption at 6-weeks (end of campaign), but not 12-months follow-up (Bradley et al., 2020). However, Bradley et al. (2020) did not include a control comparator to determine if reductions were due to the campaign. The results of this chapter suggested reductions in food intake in both control and intervention arms, highlighting the importance of control comparators within evaluations of complex interventions. Chapter 3 also investigated the BCTs adopted within the Food Scanner app (Mahdi et al., 2022b). The app used a variety of BCTs from various domains with evidence of effectiveness within obesity prevention and dietary interventions. However, the use and effectiveness of BCTs within lifestyle/behavioural interventions may not translate to app-based interventions. Further discussion in relation to the mismatch between BCT mapping (Chapter 3) and feasibility study outcomes, alongside the implications and areas for future research, will be discussed in Chapter 8.

The Change4Life Food Scanner did not lead to improved dietary outcomes and led to greater reported food intake within the intervention arm. Potential reasons include a higher percentage of males within the intervention arm. Nutritionally, males require greater energy intake than females (NHS, 2021) which may partially explain differences in dietary measures at baseline between groups. Unfortunately, due to the small sample size sex was not included within analyses as a covariate. The lack of engagement with the Food Scanner app may have also contributed to the absence of intervention effects. Firstly, results suggested a general decline in app engagement, both in time spent using the app and the number of items scanned, throughout the study period. These findings are reflective of existing mHealth research (Sutherland et al., 2019b, Schoeppe et al., 2016, Vaghefi and Tulu, 2019, Russell et al., 2018). An RCT examined the effects of a stand-alone dietary app in reducing discretionary foods packed within lunchboxes (Pearson et al., 2022). Gradual engagement drop-off was observed despite the inclusion of recommended app features. Secondly, given that average engagement time with the Food Scanner app was relatively low, participants may not have been exposed to all features and BCTs necessary to promote behavioural changes (Gilliland et al., 2015, Villinger et al., 2019). Participant feedback suggested that the app may have limited use once nutritional feedback has been provided on usual items purchased. It has been previously noted that behaviour change may not require sustained engagement and that level of engagement may differ between individuals (Michie et al., 2017). Finally, app engagement measures relied on self-reported retrospective memory recall, which may have impaired accuracy or led to recall bias (National Cancer Institute, no date). The integration of data collection methods from mobile apps directly has been recommended (Murray et al., 2016). However, the feasibility study was an independent evaluation so data could not be directly collected via the app.

Psychological predictors of behaviour change may explain modestly higher dietary intake within the intervention arm. Those in the control arm opted for more health-conscious behaviours at baseline, such as regularly relying on food labels to make food purchasing decisions. These results are complemented by outcomes of the applied knowledge questions, whereby control participants performed better than intervention participants at both baseline and 3MFU. Therefore, it is possible that control participants were initially more motivated than intervention participants to adopt healthier eating habits. Monitoring dietary intake is also a demand characteristic that may lead to changes in behaviour (Robinson et al., 2014). Control participants reported increased tracking (physical capability) of child sugar consumption between baseline and 3MFU, more so than intervention participants. As the control condition was initially more nutritionally aware and motivated, the self-monitoring nature of food diaries may have acted as an unintended intervention with positive effects (Michie et al., 2009). Alternatively, results also suggested decreased levels of knowledge in making healthy food choices within the intervention arm. These counterintuitive results may have been due to a bias in dropouts, where those with more nutrition awareness have opted out of the study due to a lack of perceived benefits (Messier et al., 2010). This was additionally supported by participant feedback where a lack of additional app benefits or new information was a reason for disengagement. If this was the case, then the sample of study completers within the intervention arm may have lacked the nutritional knowledge to implement changes to their child's diet (Romanos-Nanclares et al., 2018), resulting in a lack of intervention effects. This is further supported within assessments of applied nutrition knowledge, where participants in both control and intervention conditions performed worse at follow-up than they did at baseline, despite questions opting for the same format and style.

Small sample sizes may have contributed to the lack of intervention effects. Large sample sizes offer improved average accuracy and greater generalisability of study findings (Biau et al., 2008). Multiple imputation outcomes demonstrate potential significant differences in study outcomes with greater sample sizes. Greater attrition in the intervention arm may have been due to low incentivisation in relation to study demands or participant fatigue (Khadjesari et al., 2011). This highlights issues around selecting a suitable control condition, that has comparable study demands to the intervention condition (Murray et al., 2016). Differences in demands between intervention and control conditions may have also impacted the quality of data received between groups (Freisling et al., 2015). Finally, Murray et al. (2016) highlighted the risk of the comparator arm seeking resources from elsewhere, especially when dietary mobile interventions are free and accessible to the public. As such, all participants were asked about external confounders at 3MFU to account for such a risk.

Choice of outcome measures may have restricted observation of intervention effects. Participants in the intervention arm were not asked to report changes made to their food purchases and/or diets after using the Food Scanner app. This was raised by one study participant and may suggest that although the intervention was not superior to a control condition based on average data, changes may have been made to food purchases that could be impactful at a population level (Cleghorn et al., 2019). A full-scale trial ought to consider changes in food purchasing choices to capture direct impacts of the Food Scanner app. Consideration of food purchasing along the pathway to behaviour change has been outlined within the conceptual model in Chapter 5.

COVID-19 and associated lockdown was an unforeseen confounder of the feasibility study. An amendment to the 3MFU survey explored the potential impacts of COVID-19 on children's diets and study participation. Study findings suggested that most children's diets had been reportedly impacted by the pandemic, including parental food purchasing behaviours and greater snacking. Similar findings suggested that 48% of UK-based adults had increased food intake during the COVID-19 lockdown (Buckland et al., 2021). Research outside the UK has shown a significant increase in sugary drink consumption amongst Italian children with obesity before and 3-weeks into the lockdown (Pietrobelli et al., 2020), as well as increased purchasing of ultra-processed cupboard staples amongst American families (Skerritt et al., 2020). This study's preliminary findings may not be generalisable to a non-pandemic context or when conducting a full-scale trial.

App design and content may impact on app engagement thus effectiveness in improving dietary outcomes (Perski et al., 2017), highlighting the need to consider the pathway leading to behaviour change outlined within the conceptual model (Chapter 5). Most respondents liked the app and thought it was helpful. However, the app did not reportedly impact on people's food shopping choices. This may have been due to several reasons. Firstly, the app did not recognise barcode scanned items from more affordable supermarkets. This is a fundamental design flaw given that the app was designed to target those within lower socioeconomic positions and help bridge health inequalities. More people are now living in poverty and experiencing food insecurity due to the UK cost of living crisis (The Food Foundation, 2022, Bisdounis, 2022). The cost of living crisis has also increased consumer shopping at more affordable supermarkets than before (Farooqui, 2022). Barcode scanner detection of foods within more affordable supermarkets may widen the app's reach, increase engagement, and thus become more effective. In addition, respondents highlighted that the app was somewhat burdensome to use. During COVID-19, hand sanitisation and sanitisation of inanimate objects became usual practices among the public to decrease virus transmission. Due to this, individuals may not have been fully engaged with the app whilst grocery shopping. Use of the Food Scanner app would have also increased time spent in-store, led to greater contact with unnecessary products and increased risk of infection.

There are several implications for app improvement and future research. Reformulation of FOP nutritional labels may reduce the burden of using the Food Scanner app. This could include images of sugar cubes or teaspoons so that the public, not confined to using the app, can benefit from easy-to-interpret nutritional information (Lilo and West, 2022, Bleich et al., 2014, Billich et al., 2018). The use of the app is also restricted to the availability of a product's barcode, which is unavailable on online grocery or package free shopping. To overcome this, the app could include an item search feature allowing access product information in the absence of a product barcode, as suggested by participants. This would increase app-use inclusivity through broadening the app's reach to online grocery shoppers and would also help those who pre-plan their shopping lists and meals for the week ahead. In addition, the incorporation of incentives such as access to money-off vouchers for healthier products was recommended. This suggested improvement highlights that although the app provides information on the nutritional content of foods consumed, it does not offer a solution to the barriers (e.g. greater costs) of purchasing healthier alternatives (Goudie and Hughes, 2022). Participant recommendations for app improvements have been on par with findings from a recent systematic review on the influences of app uptake and engagement (Szinay et al., 2020). The provision of health information, statistical information on progress, reminders, reduction of cognitive loads and self-monitoring features increased capability to change behaviour. App-personalisation, social networking and professional support was also believed to increase opportunities to change behaviour. Finally, available rewards were identified as increasing motivation to change behaviour.

The current study has provided rich data on various aspects of the Change4Life Food Scanner app and the feasibility of the current evaluation approach. In addition, the inclusion of open-ended responses provided useful insights into how individuals engaged with the app and the study. Study procedures were informed from stakeholder engagement outputs outlined in Chapter 5, whilst PPI engagement allowed opinions of the target population to be considered. This helped shape the framing of survey questions and materials, choice of incentives, and recruitment strategies. However, some suggestions put forward by PPI were oblivious to demand characteristics, such as playing on parents' concerns regarding children's sugar intake to aid recruitment, and logistical difficulties in their administration, such as objective measurements of height and weight (see Appendix 11).

The speed in which apps are updated in comparison to the publication of findings is considered a problem within evaluations of DDIs (Murray et al., 2016). As discussed within Chapter 5, and will be discussed further within Chapter 8, evaluations of complex interventions need to embrace the evolutionary nature of DDIs and embed these considerations within study designs and methods. This will enable generalisability of study findings onto real-world settings. In addition, the evolution of an app is essential to user engagement. As such, evaluations ought to be adaptable to app developments, in addition to the theories of behaviour change underpinning these developments. The evaluation approach undertaken within this study can be useful for the implementation of future evaluations, whilst the findings can help inform the development and improvement of dietary apps. The implications of the evolution of an app on evaluation approaches will be further discussed within Chapter 8.

High drop-out rates, resulting in a small sample size, resulted in several additional limitations. Firstly, the representativeness of the study population is questionable. Study samples within feasibility studies are not expected to be representative of the study population, but rather the outcomes of this research can bring awareness of precautions to consider within a full-scale trial. For example, recruitment success by recruitment method can tailor more sophisticated recruitment strategies. Secondly, acceptability and sustainability of study procedures are biased towards study completers. Although study withdrawal feedback was obtained by a minority of participant dropouts, further insight into study acceptability amongst dropouts may be warranted, although difficult to acquire. To account for high attrition and missing data, MI was carried out to explore whether this had an impact on study findings. Finally, covariates, and biases in study completers were previously discussed, including sex and psychological predictors of behaviour change. This satisfies stakeholder recommendations in generating greater insight into app user characteristics (Chapter 5). Due to the small sample size, the study was not sufficiently powered to account for potential covariates within analyses, which may have led to different statistical outcomes. Small sample sizes also meant that it was not possible to generate additional comparisons of characteristics between users and non-users of the app, nor a comparison of app effects by sociodemographic groups, as recommended within Chapter 5.

Collection of height and weight measurements were recommended by stakeholders within Chapter 5. This was not investigated within the study due to high levels of missing data, and difficulties faced computing BMI z-scores. Erroneously, data pertaining to child date of birth was not collected, alongside height and weight, which is necessary when computing BMI percentiles. In addition, the absence of BMI percentiles meant that outliers in relation to energy and sugar intake could not be explained. This therefore limits our ability to explore whether the Food Scanner app was more effective among children with overweight or obesity (Singhal et al., 2021). In addition, differences in baseline BMI percentiles between conditions would need to be controlled within full-scale trials, given the relationship between weight and dietary intake (Pérez-Escamilla et al., 2012). Parent perceptions of child weight status was collected. However, results suggested that only 2 children within the sample were reportedly overweight, which is not a sufficient sample size to draw observations. Research has additionally suggested that parents often misperceive their overweight children as healthy weight, highlighting the inaccuracies relating to self-reported weight status data (Rietmeijer-Mentink et al., 2013). A full-scale trial may consider additional analyses by weight status, in which case maximising the reporting of height and weight measurements would need to be explored. The implications of not collecting height and weight measurements will be discussed further in Chapter 8.

Dietary data was self-reported, as opposed to being objectively measured. Although the collection of food diary data is a common approach adopted within trials, research has suggested an increased risk of underreporting true intake (Wark et al., 2018), which may possibly explain differences in intake between intervention and control arms. Alongside administrative limitations in collecting child data, there was no capacity to integrate additional methods to verify self-reported food diaries, such as wearable cameras or the use of food images (O'Loughlin et al., 2013, Harrington et al., 2021). The feasibility study additionally included self-generated measures of applied nutrition knowledge, in addition to those outlined within section 6.2.5.4 which tested participant's actual knowledge and ability to interpret FOP nutritional information (see Appendix 14). Participants performed worse at follow-up than baseline, across both conditions. In both cases, most respondents (over 70%) were able to answer at least one nutrition knowledge correctly out of three. Validated measures when assessing nutrition knowledge should ideally be adopted within trials (Kliemann et al., 2016). This is further discussed within Chapter 8. Finally, the evaluation did not opt for the use of a validated app engagement or evaluation measure as they were not considered fit for purpose (Usability.gov, no date). Since DDI evaluations are interested in the suitability of apps in improving dietary behaviours and outcomes (Vázquez-Paz et al., 2022), the development of a validated tool targeting dietary apps may be necessary to feedback on the app's usability and functionality (Ahmed et al., 2020). The development and use of an applicable validated measure would allow the comparability of outcomes relating to the Food Scanner with other competing dietary mobile interventions.

6.5 Conclusions

The approach undertaken to evaluate the Change4Life Food Scanner app in reducing children's energy and sugar intake was feasible. Almost all participants randomised into the intervention arm engaged with the app at least once, and the majority of participants completed most study tasks. High attrition rates and low recruitment numbers are similar to previous studies, however, may have been additionally impacted due to COVID-19. Study procedures and measures were considered acceptable based on participant feedback, however there was some reservations over the use of myfood24® for logging food diaries as it was considered too time consuming. Finally, the intervention was considered sustainable to evaluate whereby most study completers expressed preparedness to continue for a 12-month trial. The analysis did not offer evidence of Food Scanner app effectiveness for improving children's diets in comparison to a control condition at both 1-month and 3-month follow-up. However, the small sample size and COVID-19 disruptions cautions the overinterpretation of inferential statistics.

The Food Scanner app continues to be updated with new content by the Department of Health and Social Care (Digital). Study findings, suggesting minimal to no effects of the intervention, highlight the need to incorporate rigorous comparative evaluation into the developmental cycle of the app. Such a comparative evaluation would benefit from a large scale and randomised design to cope with the level of potential confounding in the food system. Findings from this study, such as effect sizes generated from the ANOVA, could help assist a power calculation to determine sample size estimates. Open-ended responses provided invaluable insights into participants' experiences with the app. A future trial ought to adopt a mixed-methods approach to allow for in-depth discussion around user experiences. This study has also provided useful participant recommendations to improve the Food Scanner app, the behaviour change theory underpinning the app, and the barriers within the system disenabling its use. These recommendations have complemented and verified pathways generated within the conceptual model (Chapter 5). Findings could aid public health campaigns and policy teams to revise the app's content and accessibility issues to help maximise its use, raise awareness around food and nutrition, and improve children's diets.

Preliminary findings from the current study have suggested that the Food Scanner app is not effective in improving dietary choices. Recommendations for evaluations outlined in Chapter 5 highlighted the need to consider the costs involved in the development and maintenance of such apps. Chapter 7 aims to investigate the economic and health impacts of the Change4Life Food Scanner app, whilst taking recommendations from stakeholder engagement outcomes (Chapter 5).

7. Economic and Health Impacts of the Change4Life Food Scanner App: Findings from a Randomised Pilot and Feasibility Study

In continuation from the previous chapter, the current chapter explores the feasibility of collecting and evaluating data relating to the economic and health impacts of the Food Scanner app. Outcomes of the systematic review (Chapter 4) highlighted the lack of economic evaluations of dietary mobile applications. The systematic review further informed the selection of measures and guided the choice of economic evaluation given time and resource constraints. Stakeholder engagement for the conceptual modelling of a dietary app (Chapter 5) highlighted the importance of cost data in relation to the app, alongside distal and proximal outcomes of interest. The outcomes of this chapter have been published (Mahdi, S., Buckland, N. J. and Chilcott, J. (2023) 'Economic and health impacts of the Change4Life Food Scanner app: Findings from a randomized pilot and feasibility study', *Frontiers in Nutrition, 10*, pp. 1125542. DOI: https://doi.org/10.3389/fnut.2023.1125542). This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY) and the copyright therefore belongs to the authors. It has been reproduced, with the permission of all co-authors, for the purposes of this thesis.

7.1 Introduction

Childhood overweight and obesity is a growing public health problem. Childhood obesity increases the risk of noncommunicable diseases, such as asthma, sleep apnoea, musculoskeletal problems, and psychological problems (Bass and Eneli, 2015). This creates a greater demand for healthcare resource use, therefore negatively impacting on limited healthcare budgets. Direct medical costs of obesity are estimated at £6.1billion to the UK NHS (Public Health England, 2017a), and $14 billion in the United States (Cawley, 2010, Trasande and Chatterjee, 2009). The rising trends in overweight and obesity has been associated with the growing availability of high density and nutritionally poor foods (Ritchie and Roser, 2017).

The use of smartphones has grown extensively. Recent figures suggest that 88% of the UK online adult population engage with mobile applications (Ofcom, 2021), whilst over half of US smartphone users have used a health app (Krebs and Duncan, 2015). Mobile apps have demonstrable beneficial impacts on weight reduction and dietary choices (Marcolino et al., 2018), whilst offering flexibility in their administration and use. They have the potential to reach diverse populations at low cost and may be provided by public health agencies as a public good. As such, there has been a growing number of dietary interventions delivered via smartphone apps (Tate et al., 2013, Barlow and Ohlemeyer, 2006). Despite being deemed a cost-effective method to deliver dietary interventions (Iribarren et al., 2017), few studies have considered economic outcomes within their analyses, with little guidance available to aid this process. As such, it has been flagged that further research is needed on how best to integrate economic factors into intervention design (McNamee et al., 2016).

Unlike conventional healthcare interventions (e.g., pharmaceutical), mobile apps have their own methodological issues within evaluations, therefore require specific guidance to aid cost-effectiveness analyses (McNamee et al., 2016, Michie et al., 2017, Gomes et al., 2022, Murray et al., 2016, National Institute for Health and Care Excellence, 2019). Current recommendations for practice have included implications for resource use and benefit measurement pertaining to app evolvement (Gomes et al., 2022), including development, implementation, and updates up to eventual obsolescence (Michie et al., 2017); intervention costs based on study sample size or potential population reach (Gomes et al., 2022); extended health benefits such as spill-over effects of the intervention onto social networks (Gomes et al., 2022); and non-health care impacts such as productivity (Gomes et al., 2022). Given this, cost per QALY within economic analysis have been deemed unlikely to capture health and non-health impacts of mHealth interventions. Instead, cost-consequence analysis, where a clear breakdown of costs and various benefits, has been recommended (Gomes et al., 2022, National Institute for Health and Care Excellence, 2019). This allows decision makers to use only the relevant aspects of this breakdown for their own local contexts.

Since the search strategy of the systematic review was conducted within Chapter 4, economic evaluations of DDIs have started to emerge. The SWAP-IT trial aimed to reduce energy-dense foods packed in lunchboxes. The intervention included an mHealth component which provided support on healthy lunchbox preparation to parents of primary school children in Australia (Sutherland et al., 2019b). The intervention adopted the use of an existing school app to communicate health promotion messages via push-notifications to support packing of healthy lunchboxes. Non-app components included the dissemination of resources to parents alongside lunchbox nutrition guidelines. Within a trial-based economic evaluation, costs relating to the mHealth component only included graphic design revisions and liaison time. Overall the intervention was deemed cost-effective at reducing energy intake from energy-dense, poor nutrient foods (Brown et al., 2021). Similarly, LifeLab Plus targets improvements in dietary behaviours in adolescents in the UK. The multicomponent intervention included education modules, training for teachers, and an interactive mobile app component with gaming features. A Markov model was developed to estimate the costs, benefits and cost-effectiveness of the intervention in comparison to usual schooling (Kalita et al., 2022). The model assumed that intervention effects were sustained for four years, and then diminished to no effect over 10 years. The European Quality of Life 5 Dimensions 3 Level was used to estimate QoL outcomes. App costs were incorporated as capital costs and assumed to last 10 years. App maintenance costs were also assumed at 25% of the development cost per year. Intervention effects were estimated based on best available evidence from the literature deeming the intervention cost-effective in accordance with the UK reference case (National Institute for Clinical Excellence, 2013). In addition, a recent systematic review of DDIs concluded that mHealth interventions that are not cost-effective in the short-term may likely be cost-effective in the long-term due to cost-offsets and wider user reach (Law et al., 2022).

Feasibility studies can provide insights into the suitability of study designs, methodological approaches, and economic outcomes (Kipping et al., 2019). The HelpMeDoIt RCT tested the feasibility and acceptability of evaluating a mobile dietary app designed for weight loss amongst adults with overweight and obesity through mobilising social networks (Simpson et al., 2020a). Data collected for economic evaluation included NHS resource use, participant-borne costs (e.g., grocery shopping), interventions costs, HRQoL and capability wellbeing. App development and maintenance costs were valued, alongside quotes for future app maintenance (Simpson et al., 2020b). This is an important consideration given that app design and software features need to be regularly updated to maintain user engagement and app function (Michie et al., 2017). Although the study was not powered to detect significant changes, the intervention had potential to be effective, with modest decreases in BMI and sedentary time within the intervention group, thus generating moderate effect sizes.

Evaluations of health promotion apps are lacking (Tully et al., 2021). Little is known regarding whether the Change4Life Food Scanner app is cost-effective in improving dietary behaviours. To inform the evaluation of the Change4Life Food Scanner app and to subsequently design a mathematical economic model, an understanding of feasible short-term and long-term outcomes need to be investigated (see Chapter 5). This can then provide insights into the relationship between economic evaluations alongside trials within long term modelling to predict long term outcomes. The aims of this study were to (1) explore the feasibility of collecting cost and outcome data when evaluating the cost-effectiveness of the Food Scanner app; and (2) investigate whether RCTs offer a feasible approach to assessing whether the Food Scanner app is cost-effective in improving dietary choices. This was achieved through a multi-step process which firstly involved the engagement of stakeholders to design a conceptual model (Chapter 5, Figure 8) that would then inform the parameters of the feasibility study.

7.2 Methods

7.2.1 Pilot and feasibility study

Outcomes from the stakeholder engagement and conceptual model (Chapter 5) were used to inform trial design. The study was conducted as part of a pilot RCT, which tested the feasibility, acceptability, and sustainability of evaluating the Change4Life Food Scanner app in reducing overall energy intake and sugar consumption in 4–11-year-old children through parental behaviour change (Chapter 6). Information relating to the pilot and feasibility study design, study procedures and methods, participants and recruitment, and intervention and control conditions can be reviewed in Chapter 6. The current chapter extends Chapter 6, and reports the feasibility of collecting economic outcomes of the Food Scanner app for the purposes of cost-effectiveness analysis.

7.2.2 Economic study and statistical methods

This study undertook a healthcare perspective with aspects of societal impacts to address the generalisable issues of feasibility pertaining to both. A cost-consequence analysis was conducted which has been recommended for the evaluation of digital products (Office for

Health Improvement and Disparities, 2020, National Institute for Health and Care Excellence, 2019). These consisted of healthcare resource use and associated costs, school absence, workplace absenteeism, and HRQoL measures. Statistical analysis was carried out on STATA/SE 15.1. Resource questions were adapted from a number of surveys identified from the Database of Instruments for Resource Use Measurement (Database of Instruments for Resource Use Measurement, 2023). Permissions were obtained from the copyright holders of original surveys.

The conceptual model identified potential distal and proximal outcomes of the Food Scanner app, with economic modelling providing linkage. Both distal and proximal outcomes were investigated within this study to assess the feasibility of using such measures within a future cost-utility and/or cost-effectiveness analysis of the Food Scanner app.

As this is a feasibility study, and therefore not powered to detect significant differences, descriptive statistics were conducted only, and inferential statistics are not reported.

7.2.2.1 Study and intervention costs

Most study costs were related to the completion of food diaries using myfood24®. Costs relating to the production of resources and materials (e.g. time spent producing recruitment flyers) were not included in cost estimates as they were considered sunk costs (a cost spent that cannot be reversed). Costs associated with the distribution of physical resources, including trial promotion material, was also not included as the schools and community centre recruitment was cancelled due to COVID-19 lockdown measures. This also meant that the trial incurred cost losses incurred by printing and postage services of materials that were not distributed to parents due to lockdown measures.

Separate to trial data, costs relating to the development and maintenance of the Change4Life Food Scanner app were explored, as recommended by stakeholders within Chapter 5. Dialogue was exchanged with a research associate and mobile app developer at Sheffield Hallam University in February 2020. The aims of the dialogue were to expand knowledge concerning app development and maintenance costs outlined within Chapter 5. It was narrated that costs depend on app features, the technology implemented (native app, built for a specific platform, or hybrid app, same as a native app but with a web browser embedded within) alongside whether there is a need for a server infrastructure to store data remotely or perform heavy computational requests. It was also recalled that Progressive Web Apps are often quicker and cheaper to develop if the purpose of the app is relatively simple and single featured and avoids the need to host it on an app store. App-store presence incurs a cost (£79/year for iOS and £25 indefinitely for android). Maintenance of an app varies on new updates of device software that could potentially break the app and bug fixes found once the app is released. There are free tools that can capture app crashes, audience statistics and push out remote push notifications to the apps for monitoring and engagement, such as Google-owned Firebase. This allows a developer to observe the performance of an app and adjust it to satisfy the user experience. Developers can also access demographic data that is collected by Google via Firebase. On the other hand, if an app is developed natively, a team of developers would be required to accommodate the coding language and skills required. Developers are expected to maintain an app for software annually. It is often the case that clients are charged with a yearly invoice, with a breakdown of costs, based on staff hours to complete each customer requirement. There is also an issue of "technical debt" whereby the coding language becomes outdated, and therefore needs to be maintained to preserve app functionality. Some apps have running contracts comprising of minor and major releases over a lifetime, usually consisting of bug fixes and app improvements. To be approved on the app market, an app needs to be uploaded onto a server which incurs further costs. Due to variability in app content and features, examples of app development and maintenance costs by app complexity could not be provided.

A FOI request was submitted to Public Health England in October 2020 enquiring about the total costs of the Change4Life campaign, as well as development and maintenance costs of the Change4Life Food Scanner app. This was submitted to estimate intervention costs as data was not available publicly. Access to such data would allow us to conduct more accurate cost-effectiveness analyses going forward and would allow the estimation of the mean cost per user (Gomes et al., 2022). A response was received in December 2020 outlining total marketing costs associated with the Change4Life campaign. In addition, to gain insight into the cost per download, the Change4Life Food Scanner app webpages were consulted for number of downloads for both Google Play (Google Play, 2022) and the Apple App store (Apple App Store, 2022).

7.2.2.2 Health Related Quality of Life

Participants completed the CHU9D instrument, a short validated paediatric HRQoL instrument (Stevens, 2010, Ratcliffe et al., 2016). This is a preference-based measure designed for self-completion by 7–17-year-olds and proxy completion for younger age groups (The University of Sheffield, 2023). Given that parents were the ones participating in the trial, the parent proxy version was utilised. The instrument consists of nine dimensions: worried, sad, pain, tired, annoyed, schoolwork/homework, sleep, daily routine, and ability to join in activities. Each dimension consists of five response options ranging from the least severe option (e.g. my child does not feel worried/sad/tired today) to most severe (e.g. my child feels very worried/sad/tired today). Parents are asked to decide which option represents their child best on the day of completion. Overall HRQoL scores were calculated based on survey responses ranging from 9 (least severe) to 45 (most severe). Utility values (value or preference that the population gives to a particular health state) were calculated through the use of UK adult preference weights (i.e. utility values were based on UK adult preferences), with scores possibly ranging from 0.33 (worst health) to 1 (perfect health) (Stevens, 2012, Stevens, 2008). Utility values were then used to calculate QALYs using the trapezium rule (area under the curve) (Whitehead and Ali, 2010). Although stakeholders (Chapter 5) did not expect to see any changes in HRQoL measures within a 3-month intervention period, the CHU9D was used to assess the feasibility of collecting HRQoL measures when evaluating a dietary mobile app.

7.2.2.3 Child Healthcare Use

Current evidence indicates increased healthcare use and hospital admissions (Jones Nielsen et al., 2013) and costs amongst children with overweight and obesity (Breitfelder et al., 2011). As such, this study tested the feasibility of collecting self-reported healthcare resource usage as a basis for measuring healthcare costs. Participants were asked to report healthcare services used in the last 3 months including number of visits and total length of time per contact (Cottrell et al., 2018). These questions were included in order to assess incremental effects of the Food Scanner app on short term health resource use. Healthcare resource costs, including GP, nurse, dental, hospital inpatient and hospital outpatient were estimated using 2021 Personal Social Services Research Unit (PSSRU) costs (Jones and Burns, 2021). The National Schedule of NHS Costs (year 2019/2020) was used to estimate accident and emergency costs (NHS England, 2021). See Table 14 for healthcare cost data and assumptions.

7.2.2.4 Productivity and personal financial losses

Societal perspectives include costs which matter to society, such as workplace productivity losses and personal financial losses. Outcome measures considered school absenteeism in the past 3 months due to a health problem (Powell et al., 2013) and workplace absenteeism in the past 3 months due to child's health (Beecham and Knapp, 2001). Productivity losses were estimated by multiplying days off work due to child health by median daily rate of £108.20, based on the Sheffield median weekly income (Office for National Statistics, 2020). As suggested by stakeholders in Chapter 5, increases in grocery shopping expenditure can be an unintended consequence of dietary interventions (Jensen and Poulsen, 2013, Saulle et al., 2013) given that healthier foods are more costly than less healthier alternatives (Rao et al., 2013, Kern et al., 2017). To determine whether a full investigation into grocery expenditure is warranted in a full-scale trial, participants in the intervention arm were asked at 3MFU, "using the Food Scanner app has led me to spend… a lot less/slightly less/the same/slightly more/a lot more… on groceries".

Table 14. Healthcare resource costs and assumptions

Resource	Cost (£)	Unit	Assumption
GP consultation	3.70	Minute	GP costs were estimated at £3.70 per minute of patient contact, including qualification costs. This excluded direct care staff costs as the majority of the trial ran during COVID-19, and the majority of GP consultations had become via telephone.
Nurse	0.733	Minute	Nurse costs were estimated at 73.3p per minute of patient contact (based on £44 per hour). Costs included qualifications.

Hospital inpatient	827	Visit	Inpatient costs are not calculated by time. Costs were available for non-elective short and long stays. Given that only one respondent had an inpatient stay which lasted less than 24 hours, it was considered a short stay.
Hospital outpatient	137	Visit	Outpatient attendance was not available by minutes or hours, but rather having occurred or not, despite this information being collected from participants. Given that no further details were collected regarding the nature of the outpatient visit, a weighted average cost of all outpatient attendances was selected.
Accident & Emergency (A&E)	182	Visit	Accident and emergency costs were sourced through the National Schedule of NHS Costs 2019-2020 for NHS trusts and NHS foundation trusts. Data was not collected on the reason for the A&E visit, and whether participants were admitted, if they had any investigations or treatments. Therefore, a weighed mean average of all A&E visits was selected, accounting to £182 per unit.
Non-routine dental	3.28	Minute	Dental costs were estimated at £3.28 per minute of patient contact (based on £197 per hour of patient contact). Data on the nature of the appointment was not collected therefore whether any dental procedures were carried out can not be ascertained.

NB. All costs were sourced through the PSSRU 2021 Database, unless otherwise stated.

7.2.2.5 Sensitivity Analysis and Handling of Missing Data

It is not unusual for cost data to be right skewed or follow a gamma distribution, as opposed to a normal distribution. This is due to the majority of the population being in good health, therefore incurring minimal healthcare costs (Thompson and Barber, 2000). Standard deviation z-scores were explored for healthcare and workplace absenteeism cost data (i.e., productivity costs). Extreme data points, interpreted as those 5 standard deviations from the mean, were removed from the analysis, as part of a sensitivity analysis.

In addition to complete case analysis, MI was also conducted as part of a sensitivity measure. It allowed exploration of the feasibility of using such approaches when evaluating the economic impacts of a dietary app, especially when retention rates could impact on the completeness of data.

MI methods were adopted using Monte Carlo simulation techniques (Rubin, 1987). The Gaussian normal regression imputation method was conducted, where data was assumed MAR. Sociodemographic data with complete cases were selected as auxiliary variables for MI purposes. These included: condition, child age, child sex, ethnicity, location, education, household income and household size. Therefore, participants with missing sociodemographic data were removed from the dataset for MI purposes (n=12). These respondents did not report any school absences, workplace absenteeism or healthcare resource use that could lead to noticeable changes in total costs and mean differences.

Variables considered for MI included QALYs (calculated from CHU9D outcomes), healthcare resource costs, workplace absenteeism due to child's health, and school absenteeism, all at baseline and 3 month follow up. All these variables had between 35-50% missing data. The percentage of missing cases per variable determined the number of imputations per variable (White et al., 2011). Additional imputations were conducted in cases where the Fraction of Missing Information percentage was above the number of imputations. A single result per case was calculated based on the average value of imputations per variable. MI was favoured over other missing data handling techniques as it considers the variance between and within variables and reduces chances of biased estimates which often arise in other methods (Jakobsen et al., 2017).

7.3 Results

7.3.1 Study costs

The total cost of the feasibility study was £4666.29 in year 2020 (Table 15). The average cost was calculated at £36.05 (2020) per participant (n=126). The cost almost doubles to £70.98 (2020) per participant when numbers are based on study completers (n=64).

Table 15. Feasibility trial costs

Item	Cost
Myfood24® – 2 year access + participant entries	£1810
Incentives – gift vouchers (intervention)	£1015
Incentives – gift vouchers (control)	£1050
Incentives – withdrawal survey voucher	£25
Incentives – prize draw (Virgin Experience Days Gift card) + shipping	£154.99
Mobile sim card	£44.90
Social media advertising	£419
Call for Participants advertising	£24
Print and postage services	£123.40
TOTAL	**£4666.29**

7.3.2 Intervention related costs

Data from Google play shows that the Change4Life Food Scanner app has achieved over 500,000 downloads to date (Google Play, 2022). This information is not available on the Apple app store. Outcomes from the FOI request noted that PHE agrees to a fixed rate for services, but no further information or breakdown of costs was provided regarding development and maintenance costs. The FOI request was therefore unsuccessful in gaining the information necessary for a comprehensive CCA. On the other hand, PHE confirmed they had run two Change4Life campaigns in 2017 encouraging healthy eating for children and families, to the value of £3.5 million in paid media activity. As part of these campaigns, consumers were encouraged to download the 'Be Food Smart' app (as the Food Scanner app was then called) to find out how much sugar, fat and salt were in a range of popular products, and to help consumers choose healthier options. PHE further confirmed that they do not hold any information on the ROI for the Change4Life campaign, or the Food Scanner app. As I was unable to retrieve specific app-related costs, cost per download could not be quantified.

When investigating the financial consequences of using the app, 20 out of 28 participants (71%) reported that using the Food Scanner app led them to spend the same amount on groceries. Whereas 7 participants (25%) reported that using the app led them to spend slightly more on groceries. Only one participant reported spending less on groceries after using the app (4%).

7.3.3 Health related quality of life

A total of 78 (62%) participants completed CHU9D measures at baseline, and 63 (50%) completed these measures at follow up. One participant was removed from analysis at 3 month follow up due to missing data. This resulted in 62 complete cases across baseline and follow up. Very few problems were reported in children's HRQoL. The median response was mostly rated as 1 (least severe option) across baseline and follow-up for both intervention and control conditions. In addition, the total mean HRQoL score within the intervention arm was 13.61 (±3.52) at baseline and 13.14 (±4.36) at 3MFU. Similarly, within the control arm, the total mean was 13 (±3.38) at baseline and 12.41 (±3.38) at 3MFU (see Appendix 19). Mean utilities within the intervention arm was 0.89 (±0.08) at baseline and 0.89 (±0.10) at 3MFU. Within the control arm mean utilities were 0.90 (±0.08) at baseline and 0.91 (±0.08) at 3MFU.

Table 16 outlines mean differences (±SD) between baseline and follow-up across conditions. The mean difference (SD) for the total CHU9D score at follow-up was -0.46 (±4.56) for the intervention arm and -0.59 (±4.05) for the control arm. When CHU9D scores were converted into utilities, the mean difference between 3MFU and baseline was 0.01 (±0.10) for the intervention arm, and 0.01 (±0.09) for the control arm. Differences less than 0.03 are not considered clinically meaningful according to Drummond's rule of thumb (Drummond, 2001), which has been adopted within similar studies (Furber and Segal, 2015, Hayes et al., 2023). This resulted in 0.22 QALYs for children in the intervention arm (SD=0.019, 95% CI: 0.22; 0.23) and 0.23 QALYs (SD=0.02, 95% CI: 0.22; 0.23) in the control arm over the 3-month period of the study. This amounted to a mean reduction in QALYs between groups over the trial period of -0.004 (SD= 0.02, 95% CI: -0.01; 0.01).

7.3.4 Child healthcare use

Parents reported more frequent healthcare resource use over the 3 months prior to baseline compared to the 3-month study period within both study arms (see Table 17). GP services were most frequently reported. There was greater healthcare resource use and associated costs at baseline compared to follow-up in both study arms. There was a £1684.30 decrease in healthcare costs at follow-up in the intervention arm, and £782.31 decrease in the control arm over the 3-month study period. As outlined in Table 16, mean difference (SD) between baseline and follow-up child health-care costs was -£52.56 (95% CI: -138.83; 33.71) for the intervention arm (n=26) and -£21.79 (95% CI: -53.48; 9.90) for the control arm (n=32). This amounted to a mean reduction between groups over the data collection period of -£30.77 (SD=230.97; 95% CI: -113.80; 52.26).

Table 16. Costs (£) and consequences in intervention and control groups

Costs and consequences	Intervention	Control
Child healthcare costs (£)		
N	26	32
Mean difference (SD) between baseline and follow-up	-52.56 (213.59)	-21.79 (87.91)
95% CI	-138.83; 33.71	-53.48; 9.90
Health Related Quality of Life score [a]		
N	28	34
Mean difference (SD) between baseline and follow up	-0.46 (4.56)	-0.59 (4.05)
95% CI	-2.23; 1.30	-2.00; 0.83
Utility score		
N	28	34

Mean difference (SD) between baseline and follow up	0.01 (0.10)	0.01 (0.09)
95% CI	-0.03; 0.05	-0.02; 0.05
Quality Adjusted Life Years		
N	28	34
Mean (SD) between baseline and follow up	0.22 (0.02)	0.23 (0.02)
95% CI	0.22; 0.23	0.22; 0.23
School absenteeism		
N	29	32
Mean difference (SD) between baseline and follow-up	-0.36 (1.25)	-0.55 (1.36)
95% CI	-0.84; 0.11	-1.04; -0.06
Workplace productivity due to child's health (£)		
N	27	34
Mean difference (SD) between baseline and follow-up	-80.15 (235.52)	-15.91 (54.15)
95% CI	-173.32; 13.02	-34.81; 2.98

[a] Based on the Child Health Utility 9 Dimension instrument.

Table 17. Total healthcare resource use and associated costs (95% CI)

Healthcare resource	Intervention		Control	
	Baseline (n=38)	Follow up (n=28)	Baseline (n=37)	Follow up (n=33)
Healthcare resource use (minutes) †				
GP	85 (28.15; 141.85)	20 (-7.76; 47.76)	75 (10.42; 139.58)	32 (1.64; 62.36)
Nurse	0	0	15 (-7.02; 37.02)	5 (-4.99; 14.99)
Hospital inpatient	840 (-832.65; 2512.65)	0	0	0
Hospital outpatient	55 (-21.77; 131.77)	25 (-10.43; 60.43)	45 (-21.06; 111.06)	40 (-22.63; 102.63)
A&E	60 (-59.50; 179.50)	0	625 (-569.70; 1819.70)	0
Non-routine dental	80 (4.89; 155.11)	90 (-34.88; 214.88)	51 (-4.52; 106.52)	15 (-7.08; 37.08)
Total	1120 (-665.56; 2905.56)	135 (4.19; 265.81)	811 (-402.66; 2024.66)	92 (16.06; 167.94)
Healthcare resource use (visits) †				

Hospital inpatient	1 (-0.99; 2.99)	0	0	0
Hospital outpatient	2 (-0.78; 4.78)	2 (-0.78; 4.78)	2 (-0.78; 4.78)	2 (-0.78; 4.78)
A&E	1 (-0.99; 2.99)	0	2 (-0.78; 4.78)	0
Healthcare resource costs, £ §				
GP	388.5 (99.52; 677.48)	74 (-28.71; 176.71)	277.5 (38.55; 516.45)	192.4 (-16.53; 401.33)
Nurse	0	0	18.33 (-11.58; 48.24)	0
Hospital inpatient	827 (-819.77; 2473.77)	0	0	0
Hospital outpatient	274 (-106.82; 654.82)	274 (-106.20; 654.20)	274 (-106.55; 654.55)	274 (-107.44; 655.44)
A&E	182 (-180.48; 544.48)	0	364 (-141.66; 869.66)	0
Non-routine dental	656 (-328.39; 1640.39)	295.2 (-114.41; 704.81)	364.08 (-144.47; 872.63)	49.2 (-23.22; 121.62)

Total	2327.50 (94.62; 4560.38)	643.20 (69.90; 1216.50)	1297.91 (368.14; 2227.69)	515.60 (6.58; 1024.62)

† Calculated as the sum of the number of visits x average appointment time per participant
§ Calculated as healthcare resource use x cost of healthcare service (see Table 14). In cases where healthcare visits are valued per unit costs, this was quantified by number of visits x healthcare service cost.

7.3.5 Productivity and personal financial losses

Total days off school due to ill health, and consequential parent time off work, over the past 3-months was reported (see Table 18). Over the trial period, there was a reduction of 20 days off work in the intervention arm, and a reduction of 6 days off work in the control arm. Baseline absenteeism cost amounted to £2272.20 within the intervention arm, and £649.20 within the control arm. At 3MFU, workplace absenteeism costs amounted to £108.20 in the intervention arm and £0 in the control arm.

Based on complete case analysis, mean difference between baseline and follow-up school absenteeism was -0.36 (95% CI: -0.84; 0.11) per child for the intervention arm (n=29) and -0.55 (95% CI: -1.04; -0.06) for the control arm (n=32). This amounted to a mean difference reduction of -£80.15 (95% CI: -173.32; 13.02) in workplace productivity losses within the intervention arm and -£15.91 (95% CI: -34.81; 2.98) in the control arm per participant. This resulted in a mean difference reduction of -£64.24 (SD=241.66, 95% CI: -147.54; 19.07) between study arms at follow up.

7.3.6 Sensitivity analysis

Two data points were removed from the analysis due to *z*-scores greater than 5. Mean differences (SD) between baseline and follow-up child healthcare costs were -£14.28 (95% CI: -50.89; 22.33) for the intervention arm (n=25) and -£21.84 (95% CI: -53.55; 9.87) for the control arm (n=32). This amounted to a mean difference between groups over the data collection period of £7.56 (SD=124.91; 95% CI: -39.66; 54.70). There was a mean reduction (SD) between baseline and follow-up workplace productivity costs of -£41.62 (95% CI: -92.70; 9.47) for the intervention arm (n=26) and -£15.88 (95% CI: -34.74; 2.98) for the control arm (n=34). This amounted to a mean difference between groups over the data collection period of -£25.73 (SD=137.54; 95% CI: -73.98; 22.51).

Table 18. Productivity losses

Absenteeism and associated costs	Intervention		Control	
	Baseline (n=40)	**Follow up (n=27)**	**Baseline (n=38)**	**Follow up (n=35)**
Child total days off school due to ill health	14.5	4	19.5	0
Parent total time off work due to child health	21	1	6	0
Parent productivity costs (£)†	2272.20	108.20	649.20	0

† Cost of paid time off work due to child's health (total days off by median daily rate £108.20 based on Sheffield median weekly rates).

The number of missing observations that were accounted for within MI ranged between 39-42 at baseline, and 54-55 at 3-month follow up. The dataset comprised of 114 complete observations after MI (intervention: n=55; control: n=59). Appendix 20 provides a breakdown of totals and means of MI outcomes. Mean differences between baseline and follow-up of MI cost and consequence outcomes are outlined in Appendix 21. In summary, mean differences between study conditions over the study period led to a mean decrease in healthcare resource costs by -£12.95 (SD=163.92, 95% CI: -55.49; 29.59), workplace productivity cost reduction of -£36.72 (SD=174.12, 95% CI: -81.74; 8.31), and a mean reduction in QALYs by -0.01 (SD=0.02, 95% CI: 0.00; 0.01, see Appendix 21).

7.4 Discussion

This pilot study investigated the feasibility of collecting and evaluating cost-effectiveness measures to help inform the development of a full-scale trial evaluating the Change4Life Food Scanner app. This is the first study, to my knowledge, to assess the cost and associated consequences of a UK Government dietary app. All analyses should be interpreted in terms of feasibility. Complete case analysis suggested a reduction in healthcare resource costs, school absence and workplace productivity losses, and a modest increase in utilities, at follow-up, for both intervention and control arms. When mean differences were compared between groups, there was a greater reduction in both healthcare expenditures and productivity losses in the intervention arm, alongside a modest reduction in QALYs. Similar findings were apparent within multiple imputation. These findings suggest that the Food Scanner app may have the potential to be cost-saving from a healthcare and societal perspective, however a larger sample size is needed to test for significance between-groups

The observed effects confirm that the time horizon of the study was short for the outcomes under investigation. As highlighted within Chapter 5, overweight and obesity alongside healthcare and societal consequences are long-term trajectory issues to which changes are unlikely to be observed within a 3-month feasibility study. As recommended by stakeholders, the presence of a long-term economic model would provide the basis for making predictions about the long-term impact of short-term changes observed in this study and a full-scale trial (see Chapter 5 Table 7 for additional recommendations for economic evaluations of DDIs). A full-scale trial with at least a 12-month follow-up period may be necessary to allow for any short- (e.g., diet) and medium-term (e.g., body weight and HRQoL) impacts of the intervention to be captured, which may not be reliably captured within shorter follow-up periods. A 12-month follow-up could additionally ascertain habit formation as suggested within Chapter 5.

Economic evaluations alongside trials involve an analysis of trial costs. The costs of running the feasibility study amounted to £36.05 per participant, based on the number of consenting participants. However, costs per participant almost doubled when the average is based on study completers. Alongside sample size calculations, such costings will provide an estimate on the funding requirements of a full-scale trial. Calculation of study costs could be used to inform a full pre-trial model analysis to calculate the expected net benefit of a full trial design and whether this is positive or negative. However, to achieve this, intervention costs estimates would be needed alongside a long-term impact model. The latest MRC guidance on the evaluation of complex interventions has suggested that economic modelling could be adopted within feasibility studies to verify whether the predicted benefits of the intervention justify both intervention costs and that of any future research (i.e., expected value of perfect information [EVPI] analysis) (Skivington et al., 2021). This could help determine whether the implementation of a full-scale trial is beneficial.

The current study was unable to account for costs relating to the development and maintenance of the Change4Life Food Scanner app. Although the inclusion of such costs within economic evaluations was recommended by stakeholders within Chapter 5, attempts to access this information were unsuccessful. This was partly due to the costs of the app being intertwined with the costs of running the broader Change4Life campaign. In addition, there is a lack of information in the public domain regarding total number of previous and current app installs. There is a misconception that apps are a low-cost approach to achieving public health outcomes (Iribarren et al., 2017). Whilst the cost per download is low, and some apps are available for free to the user, the costs of development and ongoing maintenance, as well as the program or campaign in which they are embedded, are substantial (Michie et al., 2017). For example, Kalita et al. evaluated a multicomponent intervention that included a dietary app component (Kalita et al., 2022). App development costs (expert estimation) was estimated at £324,000, for an app duration of 10 years, in addition to 5 years of development time. Maintenance costs were assumed to be 25% of app development costs, amounting to £16,200. On the other hand, Tully et al. estimated app development costs at approximately €11,000, whilst maintenance costs were estimated at approximately €2000 (15-20% of app development costs). Additional costs were also flagged, such as cloud data storage) (Tully et al., 2021).

Alongside substantial app costs, there is difficulty in demonstrating intervention effects. This includes short-term intervention effects, which are both small and difficult to measure, as well as long-term effects, due to difficulty in providing validated approaches to predicting long term outcomes, as has been demonstrated and discussed within Chapter 4 (Mahdi et al., 2022a). Therefore, economic evaluation is imperative to gain estimates of long-term outcomes that otherwise would not be possible. Given the difficulties in external evaluation, and more importantly in light of accepted frameworks for evaluation of complex interventions in complex settings (Skivington et al., 2021), economic evaluations and long-term modelling should be embedded within programs. However, further transparency and research is needed exploring app development and maintenance costs by intervention complexity and features to guide evaluations. Such research may consider the inclusion of app developers as key stakeholders within discussions whereby a map of the app development journey can be mapped out alongside cost estimates. However, it is also likely that the size of app development companies and location may impact on cost of services. Such data will help guide the estimation of app-related costs in the absence of data and should be utilized alongside a series of sensitivity analyses.

App promotion is a necessary driver to maximize app uptake and therefore has the potential to increase cost-effectiveness of app-based interventions (Michie et al., 2017). Given that the Food Scanner app was initially released as part of a multi-media national campaign comprising of billboard and TV-based advertisements, as well as resources for schools (Bradley et al., 2020), calculations of app-related costs may become entangled with Change4Life promotion material and general campaign costs. Cost-effectiveness of app promotion has been previously investigated within evaluations. A conceptual model was produced to reflect the likely population of New Zealand that would download a promoted weight loss app and use it at least once. Results suggested that smartphone app promotion costs amounted to NZ $2,883,000 over one year, resulting in small health gains and borderline cost-effectiveness at a population level. However, the model did not factor in app use by those not exposed to the mass media campaign, as well as duration and quality of app engagement (Cleghorn et al., 2019, Jones et al., 2022). In the case of the Food Scanner app, costs associated with the Change4Life campaign in general were available only. Using these cost-estimates within cost-effectiveness analysis of the Food Scanner app risks overestimating costs involved in relation to the intervention received. Given that the Food Scanner app is freely available on the app market, individuals may engage with the app without having been exposed to, or engaged with, any of the other campaign material. Although the Food Scanner app can be considered as a standalone intervention, it is ultimately a component within a larger complex intervention (or campaign) operating in a complex obesity system. Ideally, complex interventions alongside their components should be evaluated individually and in conjunction to gain insight into the active ingredients leading to changes in behaviour (Craig et al., 2008, Skivington et al., 2021).

Healthcare resource use, and associated costs, were reported throughout the trial period. Results suggested a greater reduction in healthcare expenditure within the intervention arm. We cannot ascertain whether such changes were due to intervention exposure given the high variation within the short-term follow-up of the intervention. Furthermore, potential impacts on healthcare consequent on health changes are more likely to be distal as suggested within the conceptual model and stakeholder discussions within Chapter 5.

The running of the trial was impacted by COVID-19. The pandemic resulted in decreased population A&E attendance (McConkey and Wyatt, 2020), and decreased outpatient services (Bottle et al., 2022), therefore it is possible that these impacts may underlie the reductions in healthcare uptake observed. The number of missing data for healthcare resource use measures were similar to other outcomes obtained within the trial. Although these measures were considered feasible, assumptions were made when costing the use of healthcare resources, given the ample costing options available on the National Schedule of NHS Costs 2019-2020 for NHS trusts and NHS foundation trusts, especially for A&E and inpatient services (NHS England, 2021). Although stakeholders within Chapter 5 recommended the inclusion of childhood costs within economic evaluations, this was not considered a priority outcome in comparison to dietary outcomes and maintenance of intervention effects. There was scepticism surrounding the attribution of healthcare resource use to app use, unless the sample had good representation of those with overweight/obesity. Similarly, recommendations put forth from the critical appraisal in Chapter 4 also suggested that utility outcomes should be explored by weight status across sociodemographic groups. However, as outlined within Chapter 6, BMI percentiles were not incorporated within the analysis due to data unavailability, and the sample was too small to consider subgroup analyses.

The CHU9D instrument was considered a feasible HRQoL measure for the purposes of the trial. Given the current study was only 3 months, I did not expect to see any considerable change in CHU9D outcomes, as was evidenced within study findings and also highlighted previously by stakeholders within Chapter 5. Results suggested some worsening of HRQoL outcomes, though minimal, within the intervention group at follow-up. Given that COVID-19 was a study confounder, the pandemic may have impacted negatively on child outcomes and mental health (Thomas et al., 2022b). On the other hand, the lack of variability in CHU9D responses could suggest that the CHU9D is not sensitive enough to detect changes in HRQoL in a predominantly healthy sample. For example, a systematic review investigating utility values for childhood obesity interventions found very small but significant differences by child weight status (Brown et al., 2018). A longer study follow-up period, with a larger sample size, would help provide clarity regarding the CHU9D's suitability, particularly if the intervention were to result in improvements in dietary choices. Critical appraisal of methods undertaken within cost-effectiveness studies in Chapter 4, highlighted the lack of economic evaluations alongside trials that considered child HRQoL using preference-based outcome measures. As such, the inclusion of childhood benefits when modelling the medium- and long-term impact of interventions was suggested, alongside improved assessment tools to enable the detection of changes in HRQoL among healthy children. HRQoL was also considered an essential factor to consider within economic evaluations, highlighted by stakeholders in Chapter 5. Stakeholders also suggested the inclusion of wellbeing outcomes. As discussed within Chapter 4, wellbeing may be better suited than HRQoL measures within a child sample with no previous or reported health conditions. However, wellbeing measures were not included within trial measures to not overburden participants.

School absence and parental productivity losses were seen as essential factors to consider within economic evaluations in Chapter 5. However, findings from the critical appraisal in Chapter 4 highlighted a lack of evaluations that had considered school absences, and child healthcare resource use. Current findings within this chapter have suggested a reduction in productivity losses at follow up, in both condition arms. These results are aligned with school absence data. Measures did not account for whether time off work was taken as paid (annual leave) or unpaid leave. This ought to be considered in future revisions of trial measures, as it may risk overestimating productivity losses. Future revisions of this measure should also consider workplace absenteeism for both parents as opposed to the participating parent only, to account for differences in how responsibilities are divided within households. A recent review on the use of productivity loss instruments has recommended the use of the institute for Medical Technology Assessment Productivity Cost Questionnaire to capture absenteeism, presenteeism and unpaid work over a 4 week recall period (Hubens et al., 2021); which has been previously advised for increased recall precision (Severens et al., 2000). In addition, given that recruitment specifically took place in Y&H, differences in median weekly wages by geographic region was not incorporated within costing assumptions. However, this may be necessary within a full-scale trial should recruitment be expanded to the UK more generally.

Dietary interventions may risk unintended economic consequences, which may act as a barrier to continued engagement or dietary behaviour change (Saulle et al., 2013). Approximately a quarter of the sample in the intervention arm reported having spent slightly more on groceries due to their use of the Food Scanner app. This is similar to previous research that aimed to improve the healthiness of children's lunchboxes, however resulted in a non-significant increase in the cost of packed lunches at follow-up (Sutherland et al., 2019b). Given that a small proportion of individuals within the intervention arm reported increased grocery expenditures due to the 3-month trial, future measures within a full-scale trial ought to quantify these findings, for example through the collection of shopping receipts. This method has previously been used to monitor food purchasing behaviours (Monsivais et al., 2013). Food expenditure was only measured within the intervention arm; therefore, it cannot be verified whether similar consequences were present within the control arm. This is important to consider, as results outlined within Chapter 6 suggested reduced energy and sugar intake at follow-up within both intervention and control arms. In addition, as flagged by one participant within Chapter 6, those in the intervention arm were not asked to report the dietary changes made due to using the Food Scanner app. Therefore, it cannot be concluded that the increase in food expenditure was due to healthier food swaps. A full-scale trial may consider measuring food expenditure for both study conditions. A full-scale trial also ought to incorporate an evaluation of the types of foods consumed with respect to food-based dietary guidelines (e.g., 5Aday and the Eatwell guide) as indicators of improved diet.

Sensitivity analyses were conducted within the trial. Removal of outliers, or extreme data points, for cost data resulted in smaller mean differences between intervention and control arms over the trial period, in comparison to complete case analysis. Results suggested greater productivity cost-savings within the intervention arm, as was the case within complete case analysis. However, after sensitivity analysis greater healthcare resource cost savings were found within the control arm, which was not the case within complete case analysis. Excluding outliers has demonstrated an impact on cost data. A future trial protocol should consider how outliers are to be interpreted and how extreme cost items should be handled. Previous research has adopted bootstrapping techniques, which reduces the impact of highly skewed data and extreme data points (Reilly et al., 2015). Alternatively, the 95th percentile of the overall sample's baseline and follow-up costs have also been used to determine cost outliers (Smith et al., 2022).

The current evaluation has considered a broad range of economic measures which were considered feasible and explored multiple imputation methods for missing data handling. However, the study did have several limitations. Opportunity costs for lost time for using the Food Scanner app was not accounted for. Given that data on time spent engaging with the app was collected, opportunity costs could have potentially been quantified. However, there would have been uncertainty regarding appropriate costing units. Another limitation involved the considerable amount of missing data, amounting to approximately 50% due to the high dropout rate early in the trial (before randomisation exposure). Despite this, the sample size was still within the suggested range for pilot and feasibility studies (Sim and Lewis, 2012, Julious, 2005). However, there were considerable differences in baseline reported outcomes for healthcare resource use and parent time off work due to child health between study arms. It cannot be established whether differences in baseline characteristics may be driving differences in outcomes at follow up, as opposed to the intervention. It is necessary that participant retention methods are considered for a full-scale trial, alongside efforts to over-recruit participants to account for a high drop out.

7.5 Conclusions

This pilot and feasibility study exploring the economic and health impacts of the Change4Life Food Scanner app adds to the modest yet growing literature on the cost-effectiveness of mHealth dietary interventions. This is currently an under-researched area, given the development and evaluation of DDIs has only started to emerge over the past decade. As such, the consideration of appropriate economic outcome measures, in addition to clinical outcomes, is necessary within feasibility studies before they are implemented in large-scale trials. Study results suggested that outcomes under investigation were feasible, though may require some revisions to best capture accurate data, such as parent productivity losses and the quantification of grocery expenditure. The use of an RCT study design was also considered feasible to investigate the study question. However, given the nature of complex interventions within complex food systems (Butland et al., 2007), such designs may need to be supplemented with qualitative data collection to help explain the relationships between intervention exposure and outcomes of interest (Ariss and Nasr, 2022). This is further discussed within Chapter 8. In addition, in cases where missing data cannot be prevented, multiple imputation methods were considered a successful approach to handle missing data whilst considering both within- and between-participant variability. However, further research is warranted into the effectiveness of DDIs and their related costs.

The systematic review in Chapter 4 did not identify any economic evaluations of DDIs. As such, the current Chapter has contributed to the limited literature and has outlined potential methods that can be adopted within economic evaluations alongside trials. Unfortunately, due to data, time-horizon, and sample size constraints, not all recommendations for economic evaluations outlined within Chapter 4 could be implemented. Nevertheless, recommendations emerging from Chapter 5 provided direction on suitable methods to adopt within the economic evaluation of the Food Scanner app, alongside considerations for interpretation. Findings from this current chapter need to be interpreted alongside preliminary app effectiveness data outlined within Chapter 6. Chapter 8 will integrate findings presented with previous chapters to reach clear learning points and key contributions to the literature.

8. Discussion

This thesis has investigated suitable methods for evaluating the effectiveness and cost-effectiveness of dietary digital interventions in improving 4-11 year old children's dietary intake, with a particular focus on the Change4Life Food Scanner app, a dietary mobile application. To address the thesis aims, the thesis has adopted a cyclical structure whereby the outcomes of preceding chapters have informed methods of proceeding chapters, whilst the outcomes of proceeding chapters have been used to reflect on the recommendations of previous chapters. This final discussion integrates the findings of each chapter to provide a summary of overall thesis outcomes and implications, alongside suggestions for future research. To do this, firstly a summary of thesis aims will be presented. Secondly, a summary will be provided of each chapter's aims and main findings in isolation and integration with others. Thirdly, main findings will be integrated into themes and discussed considering the broader literature. Fourthly, overall strengths and limitations of the thesis will be considered. Finally, recommendations for policy and future research will be presented.

8.1 Summary of thesis aims

The Change4Life Food Scanner app provides families with engaging feedback on the nutritional content of packaged foods (Google Play, 2022). However, few formal evaluations have explored whether public funds are being invested efficiently (Bradley et al., 2020). Effectiveness of dietary apps rely on successful app engagement (Perski et al., 2017), which is determined by several factors, discussed within Chapters 2 and 3. DDIs are complex interventions meaning careful consideration is required when planning evaluations (Skivington et al., 2021), though very little guidance is available (Michie et al., 2017, McNamee et al., 2016, Murray et al., 2016). As such, the aims of this thesis were to develop a framework (i.e. discussion of methods and recommendations) for evaluating DDIs (particularly mobile apps) in improving children's dietary intake. This firstly included developing an understanding of the design and content of dietary mobile apps and their impacts on user engagement and app effectiveness (Chapter 2 and 3). Secondly, recommendations were generated for evaluating DDIs based on current issues (Chapters 4 and 5). Thirdly, taking on previous recommendations, a pilot and feasibility study was conducted to explore the effectiveness and cost-effectiveness of the Food Scanner app in reducing children's sugar and energy intake (Chapters 6 and 7). Finally, as will be discussed within the current chapter, the framework adopted for evaluating DDIs will be evaluated and amended considering the findings from, and experiences of, conducting a pilot and feasibility study.

8.2 Summary and integration of main findings

8.2.1 A narrative review of dietary digital interventions (Chapter 2)

A narrative review of DDIs was conducted exploring factors impacting app engagement, psychological predictors of behaviour change, and effectiveness of dietary and nutritional labelling apps. Findings from Chapter 2 have highlighted the complexity involved when evaluating the effectiveness of dietary apps. Factors impacting on app engagement included app design, content, and features, and choice of BCTs. On the other hand, level of app engagement was found to predict app effectiveness (i.e. behaviour change). Mobile apps have the potential to change behaviours, but this depends on the user's motivation and whether it is used as a standalone intervention or as part of a multicomponent intervention. Multicomponent interventions are more effective than standalone interventions. This chapter highlighted the importance of dissecting the Food Scanner app's content and features, as this is an essential component of the evaluation process and formed the basis of Chapter 3.

8.2.2 An assessment of behaviour change techniques in two versions of a dietary mobile application (Chapter 3)

BCT mapping has become a popular method in the evaluation of DDIs, as demonstrated within Chapter 2. Studies have attempted to understand how BCT content may be interlinked with app quality ratings (Davis and Ellis, 2019, Schoeppe et al., 2017) and app effectiveness (Villinger et al., 2019, Webb Girard et al., 2020). Following a similar pursuit and methodology, a content analysis of BCTs was conducted to understand the Food Scanner app's intended mechanism of behaviour change and how BCT content evolves with app updates. Whilst BCT mapping is commonly undertaken within DDIs, investigating BCT evolution with app updates, and the mapping of BCT near-misses, provides a novel contribution to the literature. The outdated version of the app (v1.6) was initially evaluated within the pilot and feasibility study (Chapters 6 and 7), before a minority of participants were exposed to an app update (v2.0) in June 2020 prior to completion of the 3MFU survey. This version of the app contained BCTs ‘goal setting (behaviour)’, ‘feedback on behaviour’, ‘social support (unspecified)’, ‘instruction on how to perform behaviour’, ‘salience of consequences’, ‘prompts/cues’ and ‘credible source’. These were also present within the updated version. The outdated version also featured the additional BCT ‘behaviour substitution’ and was comparatively less BCT intensive in terms of content and occurrence in comparison to the updated version. The BCT content of the Food Scanner app resembles that of existing dietary apps and incorporates BCTs which have previously been found to be effective.

Chapter 3 has provided insight into (1) how behaviour change theory applies to app content, (2) whether an intervention could be effective (in instances where it contains effective BCTs), and (3) how BCT content evolves with app developments, both in quantity and frequency of occurrence. Findings also demonstrated that as an app evolves, so does the theory underpinning the app, which may have implications on evaluations. This will be discussed in further detail within section 8.3.4. App evolution is a natural process within an app’s lifecycle, yet this is considered a challenge within evaluations (Michie et al., 2017), and questions whether apps are based on a central theory. For instance, Chapter 3 suggested that 7 BCTs are consistently present between outdated and updated versions of the Food Scanner app. Whether app content and related features are maintained or discarded may be determined by user feedback during user testing (Mueller et al., 2022, Adil, 2023).

8.2.3 Methods for the economic evaluation of obesity prevention dietary interventions in children: A systematic review and critical appraisal of the evidence (Chapter 4)

Chapter 2 highlighted the current evidence relating to dietary app engagement, predictors of behaviour change, and app effectiveness, whilst Chapter 3 identified the BCTs residing within the Food Scanner app. The next step investigated how to evaluate dietary apps given their complexity as demonstrated within previous chapters. A systematic review and critical appraisal were carried out exploring the methods used to conduct economic evaluations of dietary interventions in children and adolescents, including long-term modelling, and to make recommendations to assist health economists in the design and reporting of such evaluations. Four overarching methodological challenges were identified within the systematic review (Chapter 4). These include modelling long-term impact of interventions, measuring and valuing health outcomes, cost inclusions and equity considerations. Variability in methods used to predict, measure and value long-term benefits in adulthood from short-term clinical outcomes in childhood was evident across studies. Key recommendations to improve the design and analysis of future economic evaluations was this review's original contribution to the literature. This included the consideration of weight regain and diminishing intervention effects within future projections (i.e., maintenance of intervention effects); exploration of wider intervention benefits not restricted to QoL outcomes; and inclusion of parental or caregiver opportunity costs. Other issues flagged included the exclusion of modelled benefits pertaining to spill-over effects of interventions onto other family members, the exclusion of school absenteeism and associated parental workplace absenteeism, alongside the lack of inclusion of child health outcomes.

At the time in which the systematic review was conducted, only one evaluation of a DDI was identified. The lack of evaluations prevented the acquisition of useful guidance to support the evaluation framework of the Food Scanner app. However, the systematic review consisted of a critical appraisal of existing economic evaluations and models, and generated recommendations for improved economic analyses. Findings from the systematic review shaped the discussions and research questions within stakeholder engagement (Chapter 5) and informed the development of the draft (pre-stakeholder engagement) conceptual model. The systematic review additionally informed the evaluation within Chapter 7 including choice of outcome measures. Given the lack of consideration of child HRQoL, school absence and child healthcare resource use within evaluations, Chapter 7 explored the feasibility of their inclusion.

8.2.4 Stakeholder engagement for the conceptual modelling of a dietary digital intervention (Chapter 5)

Stakeholder engagement explored potential causal pathways by which a dietary app leads to childhood obesity prevention through the development of a POCM. A POCM provides a broad overview of the system in which a decision problem exists, ensuring that the problem is fully understood. This is different to programme theory, which explains the theory of how an intervention operates, and different to logic models, which link intervention components to expected outcomes. A first draft conceptual model was based on findings from Chapters 2, 3 and 4, and was further developed with input from stakeholders. The conceptual model provided insights into resource pathways and cost considerations alongside essential and preferable factors that should be measured within evaluations of DDIs. Potential issues and recommendations for evaluating the effectiveness and cost-effectiveness of dietary apps were also discussed. Stakeholders highlighted the complexity in evaluating the Change4Life Food Scanner app. Priority outcomes comprised of short-term changes in dietary behaviours, long-term BMI, long-term maintenance of health habits, prevention of ill-health and QoL, with an emphasis on the family unit. App-related costs were split into software, content and updating the 'look and feel' of an app. App marketing costs were also advised, given that user uptake is dependent on this. Suggested healthcare costs covered costs of obesity, dental health, and mental health, whereas societal costs included school attendance and productivity. Recommendations put forth by stakeholders on evaluation approaches of dietary mobile apps is an original contribution to the literature.

Outputs of the stakeholder engagement included recommendations for evaluations. Stakeholders flagged factors which may not be suitable to measure within feasibility studies with short time horizons (e.g., economic impacts). Consequences of doing so have been outlined within Chapter 7, section 8.2.6 and 8.3.2. In addition, stakeholder engagement reconfirmed some of the arguments posed within Chapter 4, including the importance of establishing maintenance of intervention effects (i.e., habit formation) when projecting long-term outcomes, and the likelihood of family spill-over effects within interventions targeting child outcomes.

8.2.5 Evaluating the Change4Life Food Scanner app in reducing children's energy and sugar intake: a randomised pilot and feasibility study (Chapter 6)

Research is needed to develop appropriate methods for evaluating DDIs. Chapters 2-5 built a foundation for the design of a pilot RCT. Chapter 6 investigated the feasibility and acceptability of evaluating the effectiveness of the Food Scanner app in reducing children's energy and sugar intake at 1MFU and 3MFU. Recommendations from stakeholder engagement (Chapter 5) were incorporated within study methods. Studies within the narrative review (Chapter 2) helped develop survey questions. Outcomes of BCT mapping (Chapter 3) provided an understanding of the app’s content and features, which aided in contextualising study outcomes.

Most participants who completed the study reported that it was easy to complete and found task completion reminders helpful. However, some reported that using myfood24® for food diary completion was too much work. Preliminary analyses suggested no significant intervention effects of the Change4Life Food Scanner app and no significant changes in psychological predictors of behaviour change. App engagement (minutes) also decreased throughout the study. There was high acceptability amongst participants for the app’s use of sugar cube images, though most participants had low acceptability of the app for aiding food purchasing decisions. App improvement suggestions included healthier substitute recommendations, and access to discounts for healthier alternatives. Most study completers were also willing to continue with the study for a 12-month trial. Findings from this research can inform design parameters for any full-scale trial and help inform the development and continuous improvement of dietary apps. Methods adopted within the study were also considered both acceptable and feasible, despite an initial high attrition rate. This chapter has provided numerous contributions to the literature. It has provided preliminary insights into the effectiveness of the Change4Life Food Scanner app, explored the feasibility of methods undertaken within an evaluation of the app, and has provided recommendations for future evaluations and app developments.

Chapter 6 outcomes have improved understanding of the use of BCTs (Chapter 3), as well as the conceptual model (Chapter 5). Understanding the theory potentially underpinning the Food Scanner app (Chapter 3) has helped develop appropriate outcome measures. It additionally allowed participants to voice their app likes and dislikes through open-ended questions. Outcomes additionally underlined the gaps for improvements which could be addressed through BCT revision (i.e., participants have provided suggestions for app improvement; which BCTs can be adopted to help address these suggestions? Is there reliable evidence to suggest that these new BCTs have a history of being effective?).

BCT mapping (Chapter 3) suggested that the Food Scanner app should lead to positive outcomes as it consisted of ‘effective’ BCTs. However, preliminary results from the pilot RCT did not support evidence for app effectiveness. In returning to the conceptual model within Chapter 5, several plausible reasons become apparent for these contradictory findings. Firstly, perhaps the BCTs adopted within the Food Scanner app have not been found to work optimally within complex interventions, child outcomes, or health promotion-based interventions (Webb Girard et al., 2020, Wehling et al., 2020). Secondly, it is possible that the content produced to deliver BCTs was not satisfactory enough (i.e. BCTs were not delivered optimally). Thirdly, the BCT taxonomy may not be developed sufficiently to allow for generalisability of BCT effectiveness at the intervention level. If a specific BCT has been present in numerous effective interventions, it does not mean that all such interventions containing that BCT will be effective. This is discussed further in section 8.3.3. Fourthly, participants may not have engaged sufficiently with the app to have been exposed to BCTs. This questions whether future evaluations should monitor app content exposure through self-reported methods (e.g., tick box exercise of whether they had seen a variety of different app content). This method has been adopted within studies and could explain the relationship between engagement and BCT exposure (Perski et al., 2020). Further exploration of factors impacting on the effectiveness of DDIs are discussed within section 8.3.1.

Chapter 6 findings have helped support, or finetune, recommendations placed by stakeholders within Chapter 5. For instance, knowledge was seen as an essential factor to measure, but many participants did not correctly answer applied knowledge-related questions generated by the researcher (see Appendix 14). How applied knowledge is assessed is important, and whether knowledge measured is likely to change from using the app. Whilst reflecting on the Food Scanner app's features, the app provides individuals with the "answers", rather than proactively "teaching" or providing users with skills around nutritional content. For instance, once an item is scanned (e.g. chocolate bar), the app will feedback that the product contains high amounts of sugars, with a visual representation in sugar cubes. It does not feedback on how to interpret sugar in grams, or how to interpret FOP nutrition labels. Knowledge can still be gained through using the app however, such as knowledge that chocolate bars contain a lot of sugar, or knowledge that a chocolate bar contains more sugar than tea biscuits (per 100g). Therefore, knowledge assessed needs to be directly related to the knowledge taught through the app.

Stakeholders within Chapter 5 recommended that reasons for discontinued app use should be explored. However, the pilot RCT highlights difficulties in establishing discontinued app use. As shown in Figure 12, app use over time is not a linear process, and it involves periods of increased or decreased engagement (Michie et al., 2017). Therefore, there is a need for future research to establish a criterion for app engagement and discontinued app use. What prevents people from engaging with dietary apps and methods to overcome these were also recommended by stakeholders. However, the feasibility study highlights the complexity within the system that may prevent individuals from engaging with an app, such as personal lifestyle barriers, issues with the actual app, or issues with the wider system making it difficult to change dietary choices (see section 8.3.1 for further discussion). In addition, there are problems obtaining study feedback from dropouts. This includes potentially biased assessment of study acceptability alongside difficulty in re-engaging and learning from dropouts regarding study design issues. Therefore, although it may be relatively straightforward to investigate the barriers to engagement, it is certainly more challenging to overcome them.

Finally, the pilot RCT broadened understanding of the conceptual model. Preliminary results suggested no changes in outcomes from the very start of the conceptual model; there were no changes in knowledge, psychological predictors of behaviour change, nor dietary outcomes. Long-term changes within the model cannot be expected when there is no evidence to support intervention effects early on. Intervention content and/or app engagement also needs to be reviewed in greater detail to understand what is preventing positive shifts in parental mediators of change, and child dietary outcomes.

8.2.6 Economic and health impacts of the Change4Life Food Scanner app (Chapter 7)

The conceptual model (Chapter 5) highlighted that long-term impacts of successful DDIs should lead to positive economic and health outcomes. Chapter 7 therefore builds on from Chapter 6 and investigated the feasibility and acceptability of evaluating health outcomes in children and economic effectiveness of the Food Scanner app through a cost-consequence analysis. Chapter 7 used data from the pilot RCT and is a continuation of the evaluation presented in Chapter 6. The development of measures within Chapter 7 was informed by systematic review findings (Chapter 4). This included the lack of childhood obesity prevention studies measuring child outcomes (school absence, child HRQoL, child healthcare resource use) and parent productivity costs. Evaluation methods and interpretation of study data was additionally informed by stakeholder recommendations (Chapter 5). Given the lack of cost-effectiveness studies of DDIs targeting child outcomes, this formed an original contribution to the literature. Descriptive statistics indicated mean reductions in utilities, healthcare costs, and workplace productivity losses within the intervention arms compared to the control arm over the 3-month period. Similar findings were apparent after multiple imputation. The exploration of distal outcomes over a short follow-up period may explain modest mean differences between study arms. COVID-19 may have also confounded healthcare resource data. Although measures adopted were deemed feasible, the study highlighted difficulties in obtaining data on app development and maintenance costs. Economic modelling was flagged as essential for predicting long-term outcomes that may not be reliably captured over the short-term. Care must therefore be taken to not overinterpret associations between healthcare costs and intervention exposure over the 3-month trial period. Given that Chapters 6 and 7 are different dimensions of the same study, any confounders, covariates and study limitations highlighted within one chapter, will equally affect the other.

The pilot and feasibility study did not offer support that the Food Scanner app was effective in improving dietary intake based on preliminary outcomes. Therefore, we cannot expect any noticeable changes in HRQoL or healthcare resource use. It would be erroneous to attribute any changes in HRQoL or healthcare resource use to intervention exposure in the absence of effectiveness data. This is additionally flagged within Chapter 5, whereby stakeholders advised that evidence of habit formation is needed before long-term assumptions can be made. Although the duration of the feasibility study (3 months) was considered a shortcoming of the study design, it is unlikely that a longer follow-up period would have yielded different results. In accordance with the conceptual model in Chapter 5 (Figure 8), if the Food Scanner app did not demonstrate improved dietary outcomes in relation to a control comparator over the short-term (i.e. 3-month trial period), it is unlikely that favourable outcomes will be demonstrated in the long-term (e.g. 12 months +). Similarly, if there are no indications of intervention effects in the short- or long-term, then it is unlikely that any changes in short- or long-term healthcare resource use or HRQoL can be reduced to the intervention.

Chapters 5 and 7 have demonstrated the complexity around the inclusion of reliable cost estimates within economic evaluations of DDIs. For instance, Chapter 4 denotes that intervention costs often consider staff time and materials needed to implement an intervention. Such costings are relatively easy to locate as they often have a fixed value market price. However, app costs vary across apps (depending on complexity of the app), and the hours taken to develop it. Costs can also vary depending on the company, the company's expertise and location (e.g., London-based business may have higher hourly rates than international or North of England businesses) (Bailey, 2018).

8.3 Integration of study findings: arising themes across chapters

Upon integrating the main findings presented throughout this thesis, four overarching themes have emerged that have been topics of discussion throughout chapters:

1. Factors impacting cost-effectiveness of dietary mobile interventions.
2. Economic modelling in the absence of data.
3. Development of app content and BCTs.
4. App evolution within evaluation frameworks.

Each theme will be discussed in further detail below, integrating the findings across chapters and placing them within the context of the broader literature.

8.3.1 Factors impacting cost-effectiveness of dietary mobile interventions

The Food Scanner app may not offer a cost-effective approach to improving children's sugar and energy intake in isolation. Rather, the app may be better placed within a multicomponent intervention aimed at achieving a food system shift. Although the evaluation approach and choice of outcome measures were informed by Chapter 2-5 findings, there was no indication of preliminary effects on any of the outcomes investigated within the feasibility study. This means that a) the app may be ineffective when evaluated as a standalone intervention within a trial-based study design and b) it would be difficult to make recommendations on power calculations in considering a subsequent study size. It was also established that dietary apps in general, as well as the Change4Life social marketing campaign, incur substantial costs (Chapter 7). Based on preliminary findings, version 1.6 of the Food Scanner app did not demonstrate cost-effectiveness. As those receiving the intervention had poorer, albeit non-significant, dietary outcomes than those in the control condition, it could be suggested that the control condition is dominant (more effective, less costly) over the intervention condition.

Although this thesis has not evidenced the effectiveness of the Food Scanner app, public health campaigns promoting the use of DDIs still have potential to improve health behaviours despite the mix in evidence (Mizdrak et al., 2020, Cleghorn et al., 2019). Research in New Zealand has investigated whether government mass media campaigns are cost-effective use of public funds. Results suggested that promoting physical activity apps was unlikely to lead to improved health outcomes (Mizdrak et al., 2020). Similarly, a systematic review investigated the effectiveness of digital communication strategies by community-serving agencies in promoting healthy behaviours. Findings suggested that digital media campaigns did not improve health behaviours, despite high levels of acceptability and engagement (Eppes et al., 2023). On the other hand, mass media promotion of weight loss apps generated small health gains resulting in borderline cost-effectiveness outcomes for the total population (Cleghorn et al., 2019). It was concluded that greater app uptake may be needed to improve cost-effectiveness outcomes, such as through health worker recommendations. In other literature, weight loss apps have been found to be effective amongst adults with overweight or obesity, including sustained behavioural changes over 12 months (Chew et al., 2022). This highlights that dietary apps may not result in mean behaviour changes at a population level. Therefore, an investigation into targeted population effects by weight status may be warranted.

According to theories of behaviour change, psychological predictors predict intentions and actual changes in behaviours (Ajzen and Madden, 1986). Preliminary analyses within the feasibility study (Chapter 6) did not evidence changes in psychological predictors over the study period, despite the Food Scanner app comprising of evidence-based BCTs. Low user engagement with the app may be a barrier to BCT exposure, thus intervention effectiveness. Alternatively, the methods used to deliver BCTs (i.e. app features and content) may not be optimal in changing behaviour. For example, unlike many nutrition-related apps targeting children, the Food Scanner app did not embed gamification features (Brown et al., 2022), nor did it include information about health consequences (Mahdi et al., 2022b), which has been found to be a popular BCT within commercial apps (Brown et al., 2022). In addition, the Food Scanner app does not provide any customisability or personalisation to tailor goals and aspects of positive reinforcement to the individual, which can result in more significant impacts in improving dietary outcomes (Chen et al., 2020). As such, although BCTs are present (Mahdi et al., 2022b), there may be a sense of user disengagement due to a lack of personal relevance (Melcher et al., 2022).

Chapter 5 developed a conceptual model outlining the pathway between the Food Scanner app and health outcomes (Figure 8). Contextual factors that may inhibit app engagement were flagged. These include person-level barriers alongside broader system-level barriers. Discussions within Chapters 6 and 7 also flagged barriers to behaviour change within the wider food system, highlighting the need for a whole-systems approach when tackling issues relating to childhood obesity prevention. For example, affordability of mobile data in the absence of Wi-Fi may inhibit app use within supermarkets, thus creating further inequalities. Policies surrounding prescribing of mobile applications by health practitioners may be supplemented by the provision of mobile data credit. To my knowledge, no studies have explored the impact of mobile credit supplementation on engagement with mobile applications and health outcomes. Open-ended responses within the feasibility study additionally reported that the app consumed too much phone memory, which may be a barrier to use if not supported by appropriate smartphone specification. Despite the popularity and use of smartphones, access to Wi-Fi, mobile data and phone memory can be costly and unaffordable to those within deprived socioeconomic backgrounds (Faith, 2018). App developments may consider the logistics of offline use to overcome such issues.

App engagement decreased throughout the trial period (Chapter 6). App engagement may not have been sufficient to lead to behavioural changes, despite the app being rated positively (Chapter 6). However, what is considered as sufficient app engagement is arbitrary and can differ between individuals and apps (Yardley et al., 2016). It was not possible to determine whether the lack of behavioural changes was due to a lack of quantity or quality of app engagement, and therefore lack of exposure to BCTs, or not. An RCT investigated the effectiveness of a digital lifestyle app on gestational weight gain and diet quality (Henriksson et al., 2022). App engagement, in the form of registration of self-monitoring data, was associated with diet quality and lower gestational weight gain. Though, engagement in the form of app sessions and page views was not. Different types of user engagement could therefore have different effects on health outcomes (Henriksson et al., 2022). However, barriers to app engagement could prevent successful behaviour change and dietary improvements. A barrier to engagement within the feasibility study related to forgetfulness (Chapter 6), whereby push notifications were suggested as an app improvement. Research has suggested that push notifications within DDIs led to increased app engagement in the short term (Freyne et al., 2017).

The Change4Life Food Scanner app may not provide a cost-effective population-level intervention. This raises concerns whether the limited public health budget is being utilised efficiently to support improvements in dietary outcomes. However, the app may not be designed to create shifts in behaviours in isolation, but rather support behaviour change in the face of a complex system with multiple interacting policies. Dietary apps may operate more optimally in conjunction with environmental changes that enable behavioural changes, as suggested by stakeholders (Chapter 5) and reflected within the conceptual model (Figure 8). For example, the Food Scanner app may have attracted greater interest and downloads when it was promoted as part of a wider Change4Life campaign, especially when celebrity figures were used to support campaign messages (Steed, 2017). Modified versions of the app have often been promoted with annual Change4Life campaigns focusing on specific health message. For example, a Change4Life campaign promoting healthier snacking in children ("100 calorie snacks, 2 a day max"), had conjured support from supermarkets to aid in the promotion of the campaign. In addition, the campaign messages were broadly advertised across different media outlets (Public Health England, 2018b). Despite this, an investigation of parent awareness and perceptions of the campaign suggested no clear evidence of healthier snacking behaviours (Day et al., 2022). Participant reported barriers to campaign effectiveness included the lack of availability, promotion, display, and choice of healthier snack options within supermarkets. Ultimately, there are environmental factors beyond the scope of the app (or the broader campaign) that may impede effectiveness such as access to and affordability of healthier swaps. This was also supported in the feasibility study (Chapter 6), whereby participants' app improvement recommendations included access to vouchers for healthier substitutes. Cost barriers have become more prevalent with recent economic hardships faced within the UK, such as the cost of living crisis, alongside rocketing inflation rates which have almost doubled the cost of everyday foods on offer (Sustain, 2023). Due to the ongoing financial crisis more people are living in poverty and are struggling to access nutritious meals (Goudie, 2022). As a result, the UK Government has delayed the restriction of multibuy promotional offers of HFSS foods (Department of Health and Social Care, 2022a). Delaying this policy implementation promotes the consumption of HFSS foods, which may act as an obstacle to the effectiveness of dietary interventions.

A single intervention (such as the Food Scanner app) may not be sufficient to improve children's diets. A food system shift is needed, where policies and interventions work alongside one another, complement and interact with each other (Doherty et al., 2022). For the Food Scanner app to be potentially effective, the food system needs to be a facilitator, not a disruptor, to behavioural changes. Economic models could potentially explore the interacting effect that food policies, including the Food Scanner app, have upon each other and on long-term health outcomes. Research has previously suggested that adopting whole-systems approaches within modelling leads to more favourable projected health outcomes, as opposed to modelling policy scenarios in isolation (Orr et al., 2016, Roberts et al., 2019).

8.3.2 Economic modelling in the absence of data

With insufficient evidence to support short term app effects, the economic modelling of long-term outcomes of the Food Scanner app would be redundant. Time horizons are important for evaluations as they can impact outcome measures and provide a more realistic time frame for changes to occur. For instance, studies within the systematic review (Chapter 4) often lasted a year. Whilst research exploring child utilities has often found minimal differences between child weight status categories (Tan et al., 2018, Eminson et al., 2018). This suggests that although the 3-month time horizon was undoubtedly short, it's also probable that HRQoL outcomes would have been similar with longer follow-up periods.

The duration of the feasibility study, alongside the impact of COVID-19, may not have been sufficient to detect changes in dietary outcomes. Interventions of longer durations (6 months – 2 years) are more likely to result in sustained behavioural changes (Black et al., 2017). A value of information (VOI) analysis can determine whether a full-scale trial is warranted based on feasibility study outcomes (as discussed in Chapter 7). This takes into consideration the expected opportunity cost of a decision error (i.e., financial repercussions of making the wrong decision of funding an intervention that may not in fact be cost-effective). A calculation of the population EVPI estimates maximum funding that should be allocated to eliminate decision uncertainty. If the EVPI is less than the projected cost of a full-scale trial, then further evaluation of the Food Scanner app may be dismissed. A systematic review found that adaptive e-learning, to improve dietary behaviours, was not cost-effective in comparison to dietary advice delivered by a healthcare professional. EVPI analysis found that costs substantially exceeded a willingness-to-pay threshold of £20-30k per additional QALY. It was recommended that no further trials are implemented until more theoretical work is conducted exploring characteristics relating to the target population, target behaviour, content and delivery of the intervention (Harris et al., 2011).

Outcomes of the systematic review did not identify any evaluations of DDIs, despite a comprehensive search strategy. The lack of available studies to support DDI evaluations and model development suggests a gap within the literature. Despite this, recommendations and guidance on designing and undertaking health economic studies of DHIs have been developed (McNamee et al., 2016, National Institute for Health and Care Excellence, 2019), though not specific to dietary apps and child outcomes. Undertaking economic evaluations of DDIs can provide insight into cost-effectiveness estimations, and how model structures and assumptions have been developed and compare to mainstream interventions.

Outcomes from the systematic review (Chapter 4) can be used to adapt existing model structures to evaluate mobile applications. Adaptations could adopt recommendations suggested by stakeholders, such as the inclusion of essential parameters of interest (Chapter 5). The lack of available data hindered the development and economic modelling of the Food Scanner app. To generate long-term outcomes, short-term effectiveness data was required. Given the Food Scanner app had not been previously evaluated, preliminary efficacy data was generated through a pilot and feasibility study (Chapters 6 and 7). Effect sizes generated from the study (Chapter 6) could estimate the sample size for a full-scale trial and accompanying economic evaluation. Alternatively, preliminary modelling could be carried out following on from feasibility study findings, as has been advised within MRC guidance on evaluating complex interventions, aiding decisions on whether to proceed to a full-scale evaluation (Skivington et al., 2021). Due to obstacles around gathering cost data, as was established within Chapter 7, cost estimates within sensitivity analyses could provide insight into varying cost-effectiveness outcomes (Briggs et al., 1994). Such outcomes could be useful when informing decisions on maximum app development costs.

Stakeholders' recommendations shaped the choice of measures within the feasibility study (Chapter 7). For example, dental problems are closely tied to sugar consumption (Hong et al., 2018), and is the primary reason for hospital admissions in children, costing the NHS £205million (British Dental Association, 2023). Despite this, dental problems were rarely flagged as a healthcare cost within the systematic review. Unfortunately, due to the short 3MFU period long-term projections of health outcomes, such as healthcare resource use and HRQoL, could not be fully explored. To include these effects long term models of the relationship between free sugar intake and dental problems would be required (Davidson et al., 2021, Jevdjevic et al., 2021). In fact, stakeholders were sceptical of any relationship occurring between the Food Scanner app and healthcare resource use. This was confirmed within Chapter 7, where there was a minimal difference in average healthcare resource use between study conditions. Understanding the distribution of healthcare resource cost data in relation to child BMI-percentiles may provide insights into the relationship between weight status, app exposure, and health outcomes. Recently, a retrospective analysis of data from DDI users to support intermittent fasting was conducted (Valinskas et al., 2023). Adults with obesity who had engaged highly with the app had lost significantly more weight than non-active users. Given this, distributional effects of the Food Scanner app based on engagement and weight status may be required within a full-scale trial.

Changes in BMI are a medium-term outcome that cannot be reliably investigated within a short 3MFU period. In the absence of BMI data, existing energy balance equations could be used to estimate long-term projections from energy intake data. However few studies, as identified within Chapter 4, have modelled short and long-term HRQoL and mortality impacts from dietary intake. Te Velde et al. (2011) modelled intervention effects based on grams of F&V consumption. On the other hand, Haby et al. (2006) used a two-step process using data from energy intake. An energy imbalance was calculated by a comparison of reductions in core and non-core food intake. Validated coefficients were then used to model the impact on changes in weight (Swinburn et al., 2006). In addition, Hall et al. (2013) developed a quantitative mathematical model to predict childhood body weight based on changes in energy intake, whilst Power et al. (1997) examined the relations between child and adult BMI based on the 1958 British birth cohort.

8.3.3 Development of app content and BCTs

An original contribution of this thesis relates to the specification of app improvements and system-level barriers that may inhibit app engagement and app effectiveness. In addition, this thesis has highlighted current issues with the BCTTv1 and recommendations for the expansion of the taxonomy which will be discussed below.

Programme theory was investigated within Chapter 3 through a BCT mapping exercise of the Food Scanner app using the BCTTv1. This process highlighted instances of ‘near-misses’, where insufficient evidence prevented the mapping of BCTs. Near-missed BCTs included ‘information about social and environmental consequences’ (v1.6), ‘social reward’ (v2.0), and ‘behavioural practice’ (v1.6 and v2.0). The inclusion of such BCTs could have improved the content of the Food Scanner app and delivered a more effective and engaging intervention. In fact, mapping “near-misses” is a novel approach that has not been previously discussed within the literature or outlined within the taxonomy (Michie et al., 2013). Extensions of the BCT taxonomy ought to include the identification of near-misses; app content can then be improved through stronger connection to behaviour change theory. The taxonomy could also benefit from setting thresholds for what can be categorised as a BCT. Additional extensions to the BCTTv1 could include further research into the conditions, groups, settings and delivery platforms in which BCTs are found to be effective. This will allow informed decision making relating to BCTs when developing interventions. For instance, the Food Scanner app contained BCTs that had high effectiveness ratios within weight loss interventions or those targeting young adults (Ashton et al., 2020). However, such findings may not be transferrable, and therefore such BCTs may not work optimally within public health mass media campaigns targeting child outcomes.

The conceptual model highlighted the importance of incorporating evidence based BCTs within DDIs. How BCTs are delivered through the choice of app content and how they interact with one another could impact outcomes. In addition, how BCTs are used could determine whether an app is used continuously (which is often the case with monitoring and tracking-based apps) or over a short period of time. To improve the choice of relevant BCTs that are fit for purpose, and to better guide researchers when developing interventions, the BCT framework may benefit from embedding explicit information regarding the pros and cons of different BCTs (e.g., a classification system).

Where individuals shop for food could be a barrier to app engagement. This was highlighted within the conceptual model and verified within the pilot and feasibility study. Participants reported that not all food items scanned were recognised, particularly in more affordable supermarkets. From an app development perspective, a more comprehensive food database is required for the app to work more optimally, with an emphasis on accurate health messaging. Although this will likely incur further costs, it would enable greater reach among lower socioeconomic groups who may benefit most from the app. In fact, some respondents reported that portion size feedback or feedback for multipacks was incorrect. Previous research has similarly found that nutritional content conveyed within apps is inaccurate

(Maringer et al., 2019). In addition, a review of commercial apps targeting children has also found inaccuracies in dietary guideline recommendations (Brown et al., 2022).

8.3.4 App evolution within evaluation frameworks

Since the trial was conducted, the Food Scanner app has been through two major updates. The first major update was investigated in Chapter 3 through a BCT mapping exercise. Findings demonstrated that a newer version of the app encompassed more BCTs in comparison to the version under evaluation within the feasibility study (Chapters 6 and 7). The second major update occurred in December 2022 whereby the app underwent rebranding and is now known as the NHS Food Scanner app. The latest version of the app contains new content and features and has coincidentally incorporated improvements that were suggested by trial participants (Chapter 6). For example, the app now includes healthier swap suggestions, which has been the main feature of the latest update (version 3.6.3; last updated 19th December 2022) and tagline of the 2022 campaign, "Scan, Swipe, Swap!" (Department of Health and Social Care, 2022b). Experimental studies have demonstrated that healthier swaps are an effective method to reduce calories from saturated fat (Koutoukidis et al., 2019) and support healthy purchase behaviours (Jansen et al., 2021). The NHS Food Scanner has also included a social norms aspects whereby users can indicate when a swap has been made to earn badges and inspire others. Social norms theory postulates that perceptions of others' behaviour influences our own (Ajzen and Fishbein, 2005), and has been demonstrated as effective for influencing dietary choices within behaviour change research (Dempsey et al., 2018, Spadine and Patterson, 2022, Pelletier et al., 2014). For instance, Hammami et al. (2023) have reported that a vegetarian social norm, in the form of a person immediately ahead in queue, increased uptake of vegetarian meals within a workplace canteen. It is unknown whether the inclusion of these new app features within the Food Scanner app would have any effects on engagement and dietary behaviours. However, recent research has found that social influence and social support are determining factors of app use (Cho et al., 2021).

Throughout the process of monitoring the evolution of BCTs within the Food Scanner app, a number of phases relating to BCT and app evolution have emerged. The first phase relates to changes in the content of how BCTs are delivered (i.e. BCTs are the same, but the content of how they are delivered changes). This can include modifications to current content, or the introduction of new content. The second phase may lead to changes in the use of BCTs, whether through inclusion of new BCTs or omission of old BCTs. The third phase may include a paradigm change, where the underlying theory to support the delivery of the intervention can shift. This would lead to substantial changes and reforms to app aims, behavioural targets and accompanying content and related BCTs.

With frequent app updates, routine BCT mapping of app content as part of the evaluation process may not be sustainable. Perhaps evaluations need to focus on the central theory behind the app, and ask key questions in relation to, "what is the end goal of the app?", and "what are the intermediate outcomes that will help one reach that end goal?". These have been mapped out within the conceptual model in Chapter 5. Outcome measures should then be tailored to address the extent to which users have reached these end goals. The COM-B model could be utilised to ensure all aspects of desired outcomes are captured. Similar to psychological therapies, whereby patients are regularly asked to complete repeat psychometric measures throughout the course of their treatment (Kotronoulas et al., 2014), regular measurement of app effects throughout an app's lifecycle could identify progress in reaching desired outcomes. Regular data points can determine how app updates lead to improvements in behavioural outcomes, whilst using a consistent methodology. Qualitative data can complement quantitative routine findings.

Interrupted time series analyses methods could be adopted to analyse the long-term data acquired from app evaluations (Bernal et al., 2017). A time series is a continuous sequence of observations from population data, usually taken repeatedly at equal intervals. ITS is used to retrospectively analyse public health policies and regulations where population-level health outcome data is available over a defined period. It is an ideal method for the evaluation of natural experiments conducted within a real-world setting. To conduct ITS, it is necessary to know the exact date in which an intervention was enforced. Population-level outcomes, such as sugar consumption or BMI, can be tracked over a sufficient period both before and after the implementation of the intervention to be able to establish changes in trends over time. Trends in outcomes are usually "interrupted" after the introduction of the intervention. It has been advised that ITS would work optimally in situations where outcomes are likely to change relatively quickly after the introduction of a policy change (Bernal et al., 2017). Although this revised evaluation framework proposes an integration of app evolution within evaluation methods, it may be difficult to retain participants for a long period of time, though this is usually the case within cohort studies (Teague et al., 2018). In instances where demands placed on participants can become burdensome, compensation for time, or payment, may be necessary (Elfeky et al., 2020).

Current evaluation methods were considered feasible and acceptable for implementation within any full-scale trial of a dietary app. However, current evaluation methods come with their own set of challenges (see Chapter 6 and 7). For instance, the suitability of conducting an RCT to assess the effectiveness of the Food Scanner app may be questionable (Michie et al., 2017, McNamee et al., 2016), given regular app updates and improvements to app features. Murray et al. (2016) published guidance to help support those undertaking RCTs of DHIs. It was advised that RCTs should be undertaken only once the DHI can be implemented with high fidelity and likely to lead to meaningful benefits. It was additionally advised that a clear causal model needed to be defined, and that internal validity of RCTs needed to be improved (e.g., participant retention). On the other hand, real world evaluation methods may be better suited to the evaluation of dietary apps (Ariss and Nasr, 2022). Real world evaluations appreciate that the world is complex and continuously changing, therefore linear evaluation approaches may not be ideal. Within real world evaluations, a range of approaches are adopted; rather than merely investigating whether an intervention works, a diversity of perspectives is sought to understand what interventions work for whom, why, how and under what conditions. Unlike RCT approaches that seek a definite outcome, real world evaluations gather diverse perceptions, through qualitative approaches and co-created participatory engagement with a range of stakeholders (Patton, 2011, Patton, 2018). In fact, app development and associated evaluations should be an iterative process that involves the end-user throughout every stage of the cycle (Murray et al., 2016). An integration of quick quasi-experimental approaches into an app's lifecycle, alongside qualitative insights into the app's shortcomings and suggested improvements, could detect whether the app is fit for purpose (McNamee et al., 2016, Michie et al., 2017). Co-creation methods could steer researchers and developers in the right direction and inform app content and features. Real world evaluation, as a way to incorporate holistic approaches, is growing in popularity when evaluating complex interventions within complex systems (Bryant et al., 2023, Skivington et al., 2021). Embedding qualitative elements within quantitative RCT designs can generate greater insights and context to results obtained (Creswell and Clark, 2017). Unfortunately, due to time constraints a traditional mixed-methods research design was not pursued within the feasibility study (Chapters 6 and 7). However, as qualitative approaches are an essential component of- and added value to- complex intervention evaluations, elements of the mixed methods approach were incorporated within the feasibility study. Respondents were asked open-ended questions assessing their experiences of engaging with the feasibility study and using the Food Scanner app, allowing for key uncertainties in study outcomes to be addressed (Skivington et al., 2021).

The Change4Life Food Scanner app is a complex intervention. The current thesis has addressed issues of rigor and efficiency in evaluating DDIs and has applied the recommendations for future research outlined by Murray et al. (2016). For example, specification and classification of the Food Scanner app through BCT mapping was undertaken to understand the app's active components (Chapter 3). Stakeholder engagement was undertaken to establish a causal model, alongside short-term proxy outcomes, when measuring the effectiveness of the Food Scanner app (Chapter 5). The current thesis additionally conducted a pilot and feasibility study to help provide insight into whether more intensive research is warranted relating to the evaluation of a government-app (Chapters 6 and 7). The pilot study explored methods to retain participants (e.g., study task reminders; Chapter 6), and explored multiple imputations methods for missing data management, to help overcome the biases that may arise during the data collection period (Chapters 6 and 7). The thesis has additionally applied MRC guidance on evaluating complex interventions (Skivington et al., 2021). For example, developing programme theory at the beginning of research projects, is considered best practice, and was conducted within Chapter 3 of this thesis. Secondly, engagement with stakeholders was carried out both when building a conceptual model, and through PPI engagement to advise on feasibility study materials. Stakeholder engagement was useful for the co-development of the conceptual model alongside overcoming obstacles to evaluation and implementation. Unfortunately, aspects of intervention refinement could not be executed as the researcher had no control over app content and design decisions. Cost-consequence analysis has been advised for complex intervention evaluations in comparison to cost-utility analysis, as was conducted within Chapter 7, as this provides decision makers with a comprehensive overview of health and non-health costs and benefits across different sectors (Skivington et al., 2021, National Institute for Health and Care Excellence, 2019). In conclusion, although the feasibility study opted for an RCT study design, the mixed methods utilised throughout this thesis have considered evaluation approaches of complex interventions wherever it was possible to do so. Although RCTs can be a feasible method to evaluate DDIs, they do not offer iterative processes to support ongoing app developments and improvements.

8.4 Thesis strengths and limitations

This thesis has generated original contributions to the literature and strengthened existing knowledge. However, there are several strengths and limitations that warrant discussion that have not been previously discussed within individual chapters.

A key strength of the thesis has included the diversity in research methods adopted alongside study designs, which has allowed the thesis aim to be explored through various perspectives. Chapter 3 conducted a content analysis of BCTs allowing predictions surrounding app effects. As it was not possible to access information regarding the development process of the app by PHE, we cannot ascertain whether the theory underpinning BCTs was applied to determine the development of the app. However, identification of BCTs can help explain a theory that justifies app content. A comprehensive systematic review of economic evaluations and critical appraisal of the evidence led to recommendations for future economic evaluations and modelling studies relating to dietary interventions for childhood obesity prevention (Chapter 4). Qualitative methods through stakeholder engagement were used to understand how the Food Scanner app can lead to behaviour changes, while also contributing to understanding evaluation approaches and considerations (Chapter 5). A mixed-methods pilot RCT was conducted exploring the feasibility and acceptability of evaluating the effectiveness and cost-effectiveness of the Change4Life Food Scanner app, generating preliminary data on intervention effects of dietary intake (Chapter 6), and economic outcomes (Chapter 7), alongside open-ended responses relating to study experiences and app feedback (Chapter 6). Qualitative components of the evaluation allow questions to be answered in greater depth, complement quantitative findings and provide greater insight into research questions (Creswell and Clark, 2017). In addition, the multidisciplinary nature of this thesis has merged perspectives from different disciplines, including psychology, public health, health economics and decision sciences. This has enabled critical thinking and the ability to address research questions more holistically as opposed to a single viewpoint (Choi and Pak, 2006).

This thesis follows a structure whereby the outcomes of preceding chapters have informed methods of proceeding chapters. However, this was not always possible. Unfortunately, it was not feasible to implement all recommendations put forth by stakeholders (Chapter 5) within the evaluation of the Change4Life Food Scanner app. Some recommendations were beyond the scope of this thesis, such as preliminary long-term modelling using pilot and feasibility outcomes. Other recommendations were directly linked to app development and app improvements; as the Food Scanner app is government-funded and developed, the researcher had no control over design decisions. However, the outcomes of this thesis could help inform any future developments of the app. In addition to this, the APEASE criteria, which forms part of the BCW framework to achieving behaviour change, can be used to assess and evaluate the appropriateness of current or future app developments (West et al., 2019). The APEASE criteria explores whether the proposed intervention is: (1) acceptable to key stakeholders (acceptability); (2) sustainable and scalable to implement (practicability); (3) effective in achieving policy objectives, reaching target groups and size of effect (effectiveness); (4) affordable with regards to app development and maintenance costs and offers a ROI (affordability); (5) likely to lead to unintended adverse or beneficial consequences (side-effects); (6) decreasing the gap in health inequalities (equity).

Measurement of clinical effectiveness was also recommended. Although self-reported height and weight measures were collected within the trial, child date of birth was not, preventing the calculation of BMI percentiles. The evaluation of distributional effects of the interventions in relation to BMI percentiles was therefore not possible, despite stakeholder recommendations (Chapter 5). In addition, methods to deal with outliers appeared as an issue during data analysis (Chapters 6 and 7) though this was not discussed among stakeholders. Outliers relating to dietary intake and healthcare resource costs were removed from the analysis, based on 3 (dietary intake) or 5 (costs) standard deviations over the mean. As child BMI percentile data was unavailable, there was insufficient data to determine whether outliers were justifiable (e.g., due to an error in reporting) or associated with child BMI percentiles (data unavailable). If outliers were associated with higher BMI percentiles, their removal would have restricted individual variability in dietary changes within the dataset, and the dataset may have become more representative of expected outcomes within healthy weight children only.

Participant sample size was also a barrier to additional analyses, such the investigation of app effectiveness across SES groups and ethnicity. In fact, equity considerations are considered integral components of evaluations (Round and Paulden, 2018, International Health Economics Association, 2023). The Food Scanner app was designed to reduce health inequalities through the provision of a free and accessible tool (Public Health England, 2017c). A full-scale trial would need representation from deprived populations to enable an assessment of app effectiveness across various SES groups. Although the recruitment strategy aimed to target schools within deprived areas, this was impacted by the COVID-19 lockdown. Given that approximately 80% of study completers within the feasibility study (Chapters 6 and 7) were of White ethnicity, and only 20% were within the most deprived household income quintiles (Q1 and Q2), the study sample underrepresented groups that may have benefited most from using the Food Scanner app. Underrepresented groups within samples is commonly flagged as a limitation within research. In fact, generalisability and external validity are common issues within research due to over representation of White, Educated, Industrialised, Rich, and Democratic (WEIRD) populations (Henrich et al., 2010). As such, improved strategies to increase recruitment of underrepresented groups need to be adopted. These could include snowball sampling methods where early participants can refer their friends to participate (Webber-Ritchey et al., 2021), tailoring advertisements to people of interest, and having fair and attractive incentives, such as payment per survey as opposed to delayed payment after study completion (Langer et al., 2021). Suggestions for participant retention could include a trial period of conducting research-based activities, such as completion of 3 food diaries over 7 days, and observing level of compliance, before a decision is made whether a participant is suitable for the study (Langer et al., 2021).

Stakeholders provided recommendations on the choice of outcome measures. Firstly, nutrition knowledge was a recommended measurement of intervention effects. Questions relating to self-perceived knowledge and actual (applied) knowledge were included within trial outcomes. Measurement of actual knowledge was self-generated and focused on the interpretation of FOP nutritional labels. This resulted in a high level of inaccurate responses across both the intervention (Food Scanner app exposure) and control arms. Although cognitive debriefing was conducted ahead of study roll-out (see section 6.2.2) to ensure that questions were interpreted as intended, it is possible that questions created were too difficult for the general population. Question difficulty was not assessed via cognitive debriefing, as this method does not expect participants to complete study measures, but rather tests whether they have understood the questions posed. Conducting pilot and feasibility studies to ensure study materials are suitable and feasible is therefore important. A validated measure of nutrition knowledge should instead be adopted within a large-scale trial. For example, the General Nutrition Knowledge Questionnaire is a validated measure of nutrition knowledge (Kliemann et al., 2016). However, at 88 items the questionnaire was deemed too exhaustive to include within the feasibility study. Condensed validated measures may be more appropriate to include within existing evaluation frameworks. For example, this could include questions targeting food groups and nutrient content, and the interpretation of food labels (Kliemann et al., 2016). Within the feasibility study, macronutrients were not measured in isolation (Chapter 6). The Food Scanner app did not lead to reductions in either sugar intake or overall energy intake. Due to sample size limitations, further exploration of compensatory behaviours was not deemed appropriate, despite being identified as an issue within the design phase of the pilot and feasibility study (Chapter 5). Collection of shopping receipts (Gustafson et al., 2019) or shopping data (Wu et al., 2022) was similarly considered to verify household food purchases, however in doing so would have generated an additional workload at a time where there was no extra capacity. Similarly, the inclusion of spill-over effects (Chapters 4 and 5) was considered through the collection of parent food diary entries. However, there were concerns regarding participant fatigue and cost implications for additional myfood24® data entries.

Objective data collection methods were not utilised within this thesis as they were not considered feasible within a time constrained project. Although under-reporting is a constant issue within self-reported dietary data, myfood24® was found to be no worse than its competitors (Wark et al., 2018). In fact, myfood24® has many advantages over its competitors which have previously been outlined within Chapter 6 and Appendix 15. On the other hand, objective data collection has advantages and disadvantages compared to self-reported methods (Jahedi and Méndez, 2014). Although they are known to increase the accuracy of data collected, they also incur greater costs, administrative and ethical barriers, and can be more burdensome to participants (Illner et al., 2012). For example, appointments with participants and their children may be needed for height and weight measurements. Although this could have been feasible within a small-scale pilot study, it would certainly lead to planning and organisational complications within a full-scale trial. Although the feasibility study was completely digital, it had poor retention numbers. The inclusion of in-person commitments may dissuade individuals from participating in the study from the outset, which was a primary reason for not pursuing researcher-obtained height and weight measurements. Other reasons for not pursuing this approach related to researcher capacity and travel-related cost implications. Furthermore, as the feasibility study was disrupted by COVID-19, height and weight measurements would not have been possible. Alternative solutions could include data linkage approaches through linking participant data with NHS data or NCMP data. However, these would have resulted in ethical considerations, a need to involve NHS ethics committees and can be a time consuming and difficult process to gain approvals and access (Stalker et al., 2004).

Challenges faced throughout this thesis also related to study recruitment (Chapters 5-7). Stakeholders were dominantly from an academic background. Although there was potential for greater diversity, several factors interfered with recruitment success. Reasons for non-participation included unavailability, sickness leave, work demands/competing priorities, commute time, and maternity leave. Some individuals had initially accepted the invitation but later declined due to university strikes, whilst others accepted to participate in a phone interview with no further contact, or their availability surpassed the data collection period. Recruitment difficulties were also encountered within the pilot and feasibility study. This was particularly the case within school recruitment methods and gaining access to staff with authority. In addition, COVID-19 and associated lockdown disrupted recruitment arrangements on several occasions. This included the distribution of 500 flyers to parents via children's school bags, alongside advertisement and recruitment agreements arranged with community and leisure centres. Having relied solely on online recruitment methods after the COVID-19 lockdown was introduced, issues surrounding the appropriateness of recruitment given the current climate was questioned. Unfortunately, the success and associated costs of recruiting via primary schools and other community settings could not be determined, and therefore cannot be factored in projected costs of a full-scale trial.

8.5 Future work

Each empirical chapter within this thesis has made original contributions to the literature. However, further work is needed to advance the research of DDI evaluations targeting child outcomes. Previous chapters have highlighted avenues of future research in relation to their findings. This section will highlight additional areas of future work that may be required following on from integrated thesis outcomes.

Research dissemination is an area of future work that helps transform study outputs into outcomes. So far, findings have been disseminated within national and international conferences (see Dissemination and Doctoral Development section of the thesis). Findings from Chapters 5-7 have outlined suggested app improvements and barriers within the system impeding on app effects. Some of these improvements have already been implemented within the latest version of the Food Scanner app, suggesting their relevance. A strategy is needed to disseminate thesis outcomes. Currently, this research has received some media attention within a nutrition science website (van Hal, 2023), rather than mainstream news outlets. A press release of study outcomes could be organised to create further media attention. Other strategies may rely on current networks to establish connections with the research and development team currently working on the NHS Food Scanner app, where research outputs alongside recommendations for future app developments can be presented. Throughout the early phases of developing the methodology relating to this thesis, multiple conversations were had with the PHE marketing team regarding the Food Scanner app and its history alongside its intended mechanism of behaviour change. A representative from PHE additionally attended the stakeholder engagement session (Chapter 5), and the revised conceptual model was also sent to the PHE marketing team.

The outcomes of the pilot and feasibility study have provided insights into participant attrition rates and effect sizes. These factors are needed to calculate sample size estimates for a full-scale trial alongside estimates of study costs to inform grant proposals. A full-scale trial would evaluate the latest version of the app. This may require BCT mapping to be repeated to gain an understanding of how theory can support the development of app content (irrespective of whether app content was in fact driven by behaviour change theory). Findings from Chapter 3 have suggested that the evolution of an app is supported by increased BCT presence, whether through greater prominence of a single BCT (e.g. adding more content and app features that contain the same BCT), or through the inclusion of additional BCTs that were not present before. The inclusion of additional BCTs has been reported to increase physical activity app ratings, and perceived app impact (Davis and Ellis, 2019). However, further research ought to explore the impacts of BCT quantity (i.e. number of different BCTs) and BCT frequency (i.e. number of times same BCT presented within app content) on behavioural outcomes. Collaborations with the Department of Health and Social Care (Digital) could help manage trial timings in relation to Food Scanner app updates and broader Better Health, Healthier Families campaigns, the new rebranding of Change4Life (NHS, no date). A full-scale trial may require modifications to the study protocol to accommodate for larger sample sizes. For example, rather than sending study task reminders to participants manually, automated methods need to be explored to decrease researcher burden. In addition, amendments to outcome measures may be necessary, such as the inclusion of validated knowledge measures and parental dietary outcomes. Objective data collection should also be explored to account for limitations within self-reported methods. Real world evaluation approaches may also be integrated within the full-scale trial through qualitative interviews of app user experiences.

Future research should focus on the development of a design-oriented economic model. Currently, this thesis has provided insight into the causal chain from theory (i.e., BCT mapping) to short-term and long-term health outcomes. However, continuation of stakeholder engagement is necessary to help identify the parameters and related data that could support model design. Currently, findings from the systematic review (Chapter 4) have provided a starting point in relation to the identification of key parameters relating to obesity prevention models. Examples of such parameters include probability of adult weight status by child weight status, incidence of weight-related health conditions, annual mortality rates, health state values/utilities for the general population and by disease incidence, and costs relating to diseases (Wyatt et al., 2018). Outcomes of the feasibility study have provided insight into app engagement, and dietary and HRQoL outcomes. Stakeholder engagement has supported discussions around building an economic model, providing suggestions for essential factors to consider across time horizons, whilst also highlighting current gaps within the literature that may be a barrier to model design. However, given the pilot and feasibility study was underpowered, a full-scale trial with a longer time horizon may be necessary to achieve more definite effectiveness and clinical outcomes that could be used within the model. Using energy balance models, and childhood to adulthood BMI trajectories, dietary and BMI data could be used to predict long-term adult outcomes, whilst factoring in covariates such as demographics (Kenney et al., 2019, Oosterhoff et al., 2020). As discussed within Chapter 4, such models often assume maintenance of intervention effects, which oftentimes can overpredict the cost-effectiveness of interventions. Additional research is needed to explore the maintenance of DDI effects, or this can be accounted for within sensitivity analyses guided by previously adopted annual depreciation rates (Coffield et al., 2019). Parameters linking disease outcomes to adult BMI could be obtained from existing research and models (Ekwaru et al., 2017, Wyatt et al., 2018). However, there has been a lack of consideration within models linking child BMI to adverse health outcomes (Chapter 4), despite available evidence to support this association (Tiffin et al., 2011, Sahoo et al., 2015). In addition, an economic model may consider including a one-off app cost, rather than calculating a cost per user, as the number of users will not impact app development and maintenance costs (i.e., a public good). As difficulties were encountered in accessing cost data, evaluations may need to rely on expert estimations (Oosterhoff et al., 2020). Finally, further research would be necessary to investigate the impact of the Food Scanner app across various subgroups, to enable measurement of equity within economic models.

Some of the wider outcomes generated within this thesis have the potential to be impactful. In relation to discussions around FOP nutritional labels covered within Chapters 1 and 2, Chapter 6 outcomes suggested that most study completers agreed that supplementing FOP nutritional labels with images of sugar cubes would be helpful (Chapter 6). This can help policy makers make decisions on cost-effective policies to raise awareness of the nutritional content within food, without dependence on the Food Scanner app. However, beliefs do not always translate into action, and although most participants believed sugar cube images on FOP labels will be helpful, it does not mean they actually will be (McDermott et al., 2015). Therefore, an investigation on the (cost) effectiveness of improved FOP labelling policies is warranted in comparison to current FOP labelling and the Food Scanner app.

8.6 Conclusions

There is a lack of guidance surrounding the evaluation of DDIs targeting child outcomes. This PhD sought to identify the challenges in assessing effectiveness and cost-effectiveness of DDIs in improving children's dietary intake through an evaluation of the Change4Life Food Scanner app. This was conducted through a 3-step process: (1) develop an understanding of dietary mobile apps and their mechanisms of behaviour change, (2) explore methodological approaches to evaluating app-based interventions within a child population, and (3) implement an evaluation of the Change4Life Food Scanner app. This research suggested that DDIs are complex interventions that often reside within multicomponent interventions within complex settings. App effectiveness is highly dependent upon app engagement, which is a result of BCTs, app content and design features, in addition to user characteristics, and internal and external barriers to app use. The BCT content of the Food Scanner app was found to resemble that of other dietary apps and incorporates several BCTs which have previously been found to be effective. Guidance was sought on how to evaluate DDIs targeting child outcomes. The systematic review demonstrated variability in methods used to predict, measure and value long-term benefits in adulthood from short-term clinical outcomes in childhood. This led to the development of key recommendations to improve the design and analysis of future economic evaluations. Given the lack of studies evaluating DDIs, stakeholder engagement was conducted. This led to the development of a conceptual model alongside recommendations for the evaluation of DDIs. Stakeholder recommendations were implemented through a pilot study investigating the feasibility of evaluating the Change4Life Food Scanner app in reducing children's sugar and energy intake. Findings suggested that although study procedures were acceptable by participants, there was a high attrition rate suggesting a low acceptability of the Food Scanner app in practice. In addition, although the feasibility study was underpowered to detect significant differences, preliminary analyses suggested no indication that the Food Scanner app improved children's dietary intake and therefore preventing childhood obesity. The feasibility study also highlighted the difficulties in obtaining data on app development and maintenance costs, as well as the importance of economic modelling to predict long-term outcomes that may not be reliably captured over the short-term, such as HRQoL and healthcare resource use.

Integrated thesis findings have suggested that the Food Scanner app may not single handedly offer a cost-effective approach to improving children's sugar and energy intake. Rather, the potential barriers identified throughout this thesis indicate that a food system shift is required to assist changes in dietary behaviours. It is possible that dietary apps may be more effective within the context of such a shift. It is also possible that dietary apps may be more effective within the context of a multicomponent intervention, or in the case of the Food Scanner, it may be more effective within the broader Change4Life campaign. However, there is little evidence to suggest that previous campaigns lead to positive or sustained changes in dietary behaviours (Day et al., 2022). Whilst this may be the case, the thesis generated design considerations for future developments of the Food Scanner app and/or other dietary apps, which may help increase app effectiveness. Additional thesis findings highlighted the difficulty in obtaining long-term data of DDI effects and resource costs which may be overcome through economic modelling. The thesis provided recommendations of essential and preferable factors within evaluations, resource pathways and related costs, as well as suggestions of model structures based on systematic review findings. Finally, this thesis has suggested that RCTs are a feasible method to evaluate dietary mobile applications, though may not be the most optimal approach. Evaluations ought to embrace the evolving nature of apps, rather than consider these an obstacle to overcome. For example, iterative evaluation approaches may be more suitable to support ongoing app developments and improvements.

Regular and frequent collection of outcome measures could also help track how app developments correlate with user psychological and behavioural outcomes.

The findings of this thesis are original and extend the current literature. Firstly, they can be used to aid developments and improvements in dietary mobile apps targeting child outcomes. Secondly, they can provide additional insights into the evolution and effectiveness of BCTs that support app developments. Thirdly, this thesis can help inform the establishment of additional policy initiatives to support dietary behaviours, such as tackling system barriers to app engagement and effectiveness. Finally, the findings can support future methods and evaluation developments, including economic modelling, pertaining to dietary mobile apps.

Appendix 1: Principles of Health Economics

Economic evaluation methods	
Cost-minimisation analysis	Comparison of cost outcomes only. Note this is only valid where non inferiority or equivalence of treatment effects is demonstrated.
Cost-effectiveness analysis	Uses natural units (e.g. blood pressure, BMI, life years, etc) rather than QALYs as the measure of benefit. Calculates the cost per unit in the chosen outcome measure. ICERs can be calculated by dividing the additional costs by additional effects. Empirical measures of benefits may be sensitive to changes due to treatment, however self-reported measures may be dependent upon validity of the questionnaire and its sensitivity to changes in desired outcome.
Cost-utility analysis	Uses health-related utilities (not disease specific) as the measure of benefit. This includes, QALYs, DALYs, and HYEs. Outcomes originally measured using HRQoL measures, which are then converted to health-related utilities.
Cost-benefit analysis	Benefits are valued in monetary terms (including both health and non-health benefits). It compares the differences between incremental benefits and the incremental costs of a new intervention in comparison to an existing one If the net social benefit is positive (above the value of 0), then the new intervention is deemed economically attractive.
Quality Adjusted Life Year (QALY)	Generic health measure used to assess the effectiveness/benefits of an intervention. It is a measure that combines both quality and length of life. QALYs can be derived from a number of preference-based measures. A QALYs is measured on a scale from 0 (dead) to 1(perfect health) to describe a given health

	state. Any value lower than 0 represents states that are considered "worse than dead". These measures are also referred to as preference-based measures should preferences for health outcomes be obtained from society, thus providing "utility scores". QALYs can be used as a universal measure of benefit that allows easier comparison of different interventions and treatments within different areas of interest.
Willingness to Pay (WTP) threshold	Society's willingness to pay for a QALY gain. NICE accepts treatments that have an ICER between £20-£30k. Thresholds will help determine if an ICER for a given treatment is acceptable and should be adopted.
Incremental Cost Effectiveness Ratio (ICER)	Comparative analysis of costs and effects. This usually compares a new treatment with a control comparator or usual practice. In cases where there are multiple treatments being compared against each other, treatment options are to be aligned by decrementing health benefits (QALYs). Incremental cost and benefits are calculated between each intervention and the one preceding it in benefit. An ICER is calculated by: (Cost of new intervention – cost of standard intervention) / (QALY of new intervention – QALY of standard intervention)
Dominance	When one intervention dominates the other, it is more effective and less costly, and lies within the South East quadrant of the cost-effectiveness plane. When one intervention is dominated by another, it is less effective and more costly, and lies within the North West of the cost-effectiveness plane. Most interventions lie in the North East quadrant, where they are more effective and more costly.

Net Monetary Benefit	An alternative way to calculating cost-effectiveness, rather through an ICER calculation, is through net monetary benefit: (WTP threshold x QALY) – cost. When multiple interventions are being compared, rather than conducting an incremental analysis, the net monetary benefit of each intervention can be calculated, and the intervention with the highest net benefit is the most cost-effective.
Cost Effectiveness Acceptability Curve (CEAC)	A figure that portrays the probability (y-axis) that an intervention will be cost-effective at a given threshold (x-axis)
Opportunity cost	Resources are scarce, therefore budget allocation should be directed at treatments or interventions that will maximise wellbeing. However, spending money on one treatment means that a sacrifice is made in terms of a lost opportunity elsewhere (benefits are forgone from not allocating the budget to a different treatment option/treatment options are given up due to funding going elsewhere).
Economic models	
Decision trees	A decision process that is broken down into a tree-like structure, requires a sequence of decisions to be made with a small number of possible decision outcomes. At every chance node (specific events as a consequence of the strategic choice) there is a probability of an event occurring or not. These form a chain of events that follow on from one another. Every event has a probability of occurring (or not), along with associated costs and utilities. Decision trees are useful when events occur over a short time period (therefore not suitable to use for lifetime horizons), though movement through the tree is primarily driven by events and is not time explicit.

Markov models	A decision problem, or a health condition, is characterised by a set of health states and transition probabilities. At every cycle individuals within the cohort either stay in their current health state or transition to another health state. Transition probabilities are time-variant and time is controlled in discrete cycles. Markov models are suitable for progressive diseases where risk is ongoing and events may occur more than once and death is always the final state. Although Markov models usually deal with a homogenous cohort of individuals (all assumed to be the same), Markov microsimulations deal with individual patients or individuals and can account for baseline characteristics and individual differences. Such characteristics would therefore result in more accurate transition probabilities specific to particular individuals.
Time horizon	Time in which the intervention under investigation is being evaluated/the time over which cost and benefit data is applicable.
Healthcare perspective	Effectiveness of interventions under investigation fall within the NHS and social care budget. This will reflect upon the costs to be included within the economic evaluation.
Societal perspective	Considers the impact of the intervention on the society as a whole. This will not only include intervention costs, but will also include the indirect costs associated with the provision of the intervention. For example, this may include productivity costs (impact of sickness of absenteeism/presenteeism and how this may impact negatively on the economy); informal carer time (sick individuals would require caring for, and an individual's time should be valued); future unrelated medical costs; and other opportunity costs (e.g. value of

	time taken to participate in intervention or receive treatment). Sensitivity analyses ought to be conducted using different cost data sources and/or different costs, should a societal perspective be adopted
Discounting	Discounting allows for differential timing. As a society, we prefer to incur costs in the future rather than now. Future costs and benefits are discounted to reflect a present value. This is applied by multiplying costs and benefits by a weighing factor, or discount rate, so that when costs are compared over a long-term time horizon, it will be as if they all occurred at the same time. In the UK, a discount rate of 3.5% is most commonly used.
Sensitivity analysis	There are many sources of uncertainty when conducting an economic evaluation. Sensitivity analysis allows one to change the values of input parameters and test how sensitive the ICER is to those changes. One-way sensitivity analysis is when one parameter input is changed at a time and the ICER is re-calculated. If a decision changes of whether to accept or reject a new intervention due to changes in one parameter this signifies that the ICER is not robust. Two-way sensitivity analysis simultaneously varies the values of two key parameters, which are typically correlated.
Probabilistic Sensitivity Analysis (PSA)	Parameters in the model are entered as probability distributions. Through Monte Carlo simulation, values are randomly sampled from each distribution and cost and benefit outcomes are recorded. This is conducted at least 1000 times and mean costs and QALYs are derived.

Appendix 2: Behaviour Change Techniques Identified in the Change4Life Food Scanner App

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
<u>1.1 Goal Setting (Behaviour)</u> *Set or agree on a goal defined in terms of the behaviour to be achieved* **Domain 1: Goals and Planning**	✓	✓	1. When first opening the app, the following is displayed: "Find out what's in your food and get tips to make your family healthier", with a barcode scanner feature above. 2. After scanning a food item: "Can you find a healthier snack?"	1. "Find good choice badges – You'll see these when you scan healthier food and drinks. How many will you find?" This feature sets a challenge to find good choice badges and therefore a goal is set to find them.
<u>2.2 Feedback on behaviour</u> *Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. form, frequency, duration, intensity)*	✓	✓	1. Traffic Lights 2. Visual depiction of sugar cube equivalents; saturated fat is portrayed in slabs; salt is portrayed in sachets 3. Calorie content 4. Sugar, salt and fat content	1. Scan history displays 20 previous scans displaying the name and traffic lights for each product scans, allows user to see what they have previously scanned. 2 . Visual Depiction of

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	**Updated Version (v2.0)**
Domain 2: Feedback and Monitoring			5. Phrases in response to scans such as: *"Peanut butter has a surprising amount of sat fat and salt. Spread thinly"; "This choice makes a great start to the day. Enjoy it with fresh fruit"; "This is high in sugar. Look for low sugar swaps with more greens".* 6. Further Feedback from traffic lights: Users can click on a traffic light where further feedback is provided. E.g. "This is high in sat fat. Look for a reduced fat version"; "This is high in sugar. Look for low sugar swaps with more greens". 7. 'View previous scans' feature	sugar/fat/salt content 3. Calorie information 4. Traffic lights 5. Virtual reality element (for items with orange or red traffic lights there is a virtual reality animation that demonstrates how much sugar/sat fat/salt is in the item) 6. Low badges – these are shown for products with low amounts of sugar/sat fat/salt. 7. Woah badges - "Woah, that's a lot!" badges are shown when the amount of sugar, sat fat or salt is more than the app can display within the reveal screen: this is 232g of sugar, 175g of sat fat and

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
				50g of salt. Scan feedback per pack, per portion, per 100g (different presentation styles). Tells you how many grams of sugar, sat fat, salt and calories is in each of these. Tells you what the equivalent amount is in sugar cubes, saturated fat slabs and salt sachets.
3.1 Social Support (Unspecified) *Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for*	✓	✓	1. Feedback upon scanning: "This choc is high in sugar and fat! Can you find a healthier snack?"; "Ek, this breakfast choice contains lots of sugar, saturated fat and salt"; "Sugar Alert – look at that sugar, we should have less than 7 cubes of	1.Refer user to external resources for extra information and support on healthy eating: links to "more ideas for healthy eating"; "Change4life website".

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	**Updated Version (v2.0)**
performance of the behaviour **Domain 3: Social Support**			sugar a day"; "sat fat find – look at all those grams of sat fat, we should have less than 28 a day"; "Woohoo! This choice makes a great start to the day. Enjoy it with fresh fruit". 2. Feature of the link to more ideas (ideas of healthier alternatives, prompt to sub a high salt/sugar/fat item for a healthier) 3. Feature of the link to further information on traffic lights	
4.1 Instruction on how to perform behaviour * *Advise or agree on how to perform the behaviour (includes 'Skills training')*	✓	✓	1. On the instruction section of the app, 'scan your food and drink and find out what's inside' (instruction on how to use the app) 2. Feedback Upon Scanning: "Peanut	Instruction is given in the 'more info' section of the app concerning how to use the app: 1. "What's inside? Scan the barcode to see what's inside your

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
Domain 4: Shaping Knowledge			butter has a surprising amount of sat fat and salt. Spread thinly" (how to consume peanut butter in a healthier way)	food and drink" 2. "Let them loose: See the sugar, saturated fat and salt inside your food and drink come to life" 3. "Find good choice badges: You'll see these when you scan healthier food and drinks. How many will you find?". It also explains how to use the traffic lights and the meaning of the badges. 4. How to use this app feature 5. "Scan" - "Scan a barcode"
<u>5.2 Salience of consequences</u> *Use methods specifically designed to emphasise the*	✓	✓	1. Once items are scanned, feedback is provided in a number of different ways: Visually – sugar is portrayed	Use of method specifically designed to emphasise consequences making them more

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
consequences of performing the behaviour with the aim of making them more memorable (goes beyond informing about consequences) **Domain 5: Natural Consequences**			in quantity of sugar cube equivalents; saturated fat is portrayed in slabs; salt is portrayed in sachets. This is a memorable way of showing how much sugar/sat fat/salt is in the item and allows the user to visualise the content and understand the content in terms that are more relevant to them e.g. sachets of salt rather than grams of salt.	memorable (e.g. animations and imagery presented in relatable terms; rather than just grams of sugar the equivalent is presented as cubes of sugar). 1. Scan feedback: tells you what the equivalent amount is in sugar cubes, saturated fat slabs and salt sachets 2. Let them loose, How much is that: -Animations of sugar cubes/sat fat slabs/salt sachets attacking or overwhelming green person -Image of blue figure dragging bucket, tips it to release the sugar cubes, they start moving and

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
				surround him. He falls on the ground and the bucket drops on his head. -Image of blue figure leaning on closed umbrella. Looks up surprised and opens umbrella up, to then see loads of slabs of fat falling from the sky. He then looks at them whilst they're on the floor in shock/disgust. -Blue man running frantically away from a load of sugar cubes or sachets of salt in which he slips and falls on his back. The sugar cubes/sachets catch up. Salt sachets start pouring out all the salt content beside him, whilst he is lying

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
				unconscious on his back with an upside down mouth/frown. -Blue man leaning on umbrella and starts raining salt on him. Looks at the puddle of salt in shock/disgust/unhappy.
5.3 Information about social and environmental consequences *Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour* **Domain 5: Natural Consequences**		✓	n/a	Generalised nutritional information given on the item that is scanned, information is 'unspecified' and applicable to all 1.Virtual Reality display of sugar/sat fat/salt content 2. Visual display of sugar/sat fat/salt content

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	**Updated Version (v2.0)**
<u>5.6 Information about emotional consequences</u> *Provide information (e.g. written, verbal, visual) about emotional consequences of performing the behaviour* *Note: consequences can be related to emotional health disorders (e.g. depression, anxiety) and/or states of mind (e.g. low mood, stress)* **Domain 5: Natural Consequences**		✓	n/a	1. Virtual Reality display of content: -Image of blue figure leaning on closed umbrella. Looks up surprised and opens umbrella up, to then see loads of slabs of fat falling from the sky. He then looks at them whilst they're on the floor in shock/disgust. -Blue man running frantically away from a load of sugar cubes or sachets of salt in which he slips and falls on his back. The sugar cubes/sachets catch up. Salt sachets start pouring out all the salt content beside him, whilst he is lying unconscious (?) on his back with an

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
				upside down mouth/frown. -Blue man leaning on umbrella and starts raining salt on him. Looks at the puddle of salt in shock/disgust/unhappy. 2. “This product contains naturally occurring sugars. You don’t need to worry about the sugar in plain milks, as this isn’t added sugar”

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
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* **Domain 7: Associations**	✓	✓	1. Low Badges 2. Sugar/fat/salt alerts with text: 'sugar alert' *Eek! This cereal is high in sugar and contains a surprising amount of salt!*	1. 'Woah that's a lot' badge: appears when there is too much sugar/sat fat/salt content in the food to be able to display on the screen i.e. food with very high content. Badge is red, designed like a stop road sign and surrounded by sugar cubes/fat slabs/salt sachets with angry faces 2. Low badges: badges are awarded when an item with a low sugar/sat fat/salt content is scanned, reinforces successfully finding and scanning a 'green' item 3. Traffic lights

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	**Updated Version (v2.0)**
<u>8.2 Behavioural Substitution</u> *Prompt Substitution of the unwanted or neutral behaviour* **Domain 8: Repetition and Substitution**	✓		1. Feedback is provided regarding the item scanned, with messages pertaining specifically to the high amount of sugar/sat fat/salt within the product: - "This choc is high in sugar and fat! Can you find a healthier snack?" Prompt to substitute for a healthier snack (i.e. unwanted behaviour for wanted behaviour) - "This is high in sugar. Look for low sugar swaps with more greens" 2. Feature of the link to more ideas (ideas of healthier alternatives, prompt to substitute a high salt/sugar/fat item for a healthier	n/a

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	**Updated Version (v2.0)**
			alternative)	
<u>9.1 Credible Source</u> *Present verbal or visual communication from a credible source in favour of or against the behaviour* **Domain 9: Comparison of outcomes**	✓	✓	1.Delivery of intervention/app is by PHE in general, who are a credible source, under the "Change4Life" campaign	1. Delivery of intervention/app is by PHE in general, who are a credible source, under the "Change4Life" campaign
<u>10.4 Social reward</u> *Arrange verbal or non-verbal reward if and only if there has been effort and/or progress in performing the behaviour (includes 'Positive reinforcement')*		✓	n/a	1. Low Badges: Badges are awarded when an item with a low sugar/sat fat/salt content is scanned; reinforces successfully finding and scanning a 'green' item 2. 'High five, let's celebrate', celebration animation: upon

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
Domain 10: Reward and Threat				scanning an all green item the screen comes up with a 'happy' green person and a message that reads "High-Five, Go go green! This is low in sugar, sat fat and salt. Go go green!" 3D Feature of green man on a podium dancing and celebrating with confetti under a banner that reads 'high-five, go go green!' with images of green man celebrating and offering high fives.
<u>10.5 Social Incentive</u> *Inform that a verbal or non-verbal reward will be delivered if and only if there has been effort and/or progress in performing the behaviour*		✓	n/a	1. 'Good Choice' badges feature: the feature of the thumbs up on the badge indicating a positive action (social praise for finding good choice item). User is informed that if effort is put in to find good

BCT, definition and Domain	Present in Outdated Version	Present in Updated Version	Evidence	
			Outdated Version (v1.6)	Updated Version (v2.0)
Domain 10: Reward and Threat				choice options and then scan them, they will find a good choice badge.

NB. BCTs have been coded for both app engagement and improved dietary choices.
* BCT targeted app engagement only
† BCT targeted dietary choices only

Appendix 3: Medline Search Strategy

#	Searches	Search type	PICOS
1	(kindergarten or elementary or pre-school or childhood or children or child* or teen* or adolescen* or kid* or parent or parents or youth or youths or girls or boys or "young person" or "young people").ti,ab.	Search term	Population
2	(portion* or purchas* or consum* or sugar* or energy or calorie or calori* or food* or snack* or beverage* or "fast food" or "junk food" or drink or drinks or SSB or soda or sodas or sugar-sweetened or "meal size" or macronutrient* or fruit* or vegetable* or fat or fibre or salt or nutrition* or diet*).ti,ab.	Search term	Intervention
3	("body fat" or obese or obesity or adiposity or "body composition" or overweight or weight or BMI or "body mass index").ti,ab.	Search term	Outcome
4	("health utility index" or "economic model*" or "economic evaluat*" or cost or "cost benefit*" or cost-benefit* or "cost utilit*" or cost-utilit* or "cost effective*" or cost-effective* or "economic analys*" or economic-analys* or "quality adjusted life year*" or "quality-adjusted life year*" or QALY or "disability adjusted life year*" or "disability-adjusted life year*" or DALY or "life years gained").ti,ab.	Search term	Study design
5	adolescent/ or child/	MeSH term	
6	Pediatric Obesity/pc [Prevention & Control]	MeSH term	
7	body weight changes/ or weight gain/ or weight loss/	MeSH term	
8	Healthy Diet/	MeSH term	
9	Energy Intake/ph [Physiology]	MeSH term	
10	models, economic/	MeSH term	
11	cost-benefit analysis/	MeSH term	
12	1 or 5		
13	3 or 6 or 7		

14	2 or 8 or 9
15	13 or 14
16	4 or 10 or 11
17	12 and 15 and 16
18	limit 17 to (english language and humans and "all child (0 to 18 years)" and (classical article or clinical study or clinical trial, all or clinical trial or controlled clinical trial or evaluation studies or government publications or guideline or journal article or meta analysis or observational study or pragmatic clinical trial or randomized controlled trial or "review" or systematic reviews) and last 18 years)

Appendix 4: Quality Appraisal Summary Data

		Responses: Yes (Y), No (N), Not clear (NC), Not applicable (NA)	TOTAL N (%)			
			Y	**N**	**NC**	**NA**
	BMJ 35 item checklist					
Study Design	1	The research question is stated	26 (100)	0	0	0
	2	The economic importance of the research question is stated	24 (92)	2 (8)	0	0
	3	The viewpoint(s) of the analysis are clearly stated and justified	24 (92)	2 (8)	0	0
	4	The rationale for choosing the alternative programmes or interventions compared is stated	15 (58)	10 (38)	1 (4)	0
	5	The alternatives being compared are clearly described	23 (88)	3 (12)	0	0
	6	The form of economic evaluation used is stated	25 (96)	0	1 (4)	0
	7	The choice of form of economic evaluation is justified in relation to the questions addressed	24 (92)	2 (8)	0	0
Data collection	8	The source(s) of effectiveness estimates used are stated	26 (100)	0	0	0
	9	Details of the design and results of effectiveness study are given (if based on a single study)	21 (81)	2 (8)	0	3 (11)
	10	Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies)	2 (8)	1 (4)	0	23 (88)

	11	The primary outcome measure(s) for the economic evaluation are clearly stated	26 (100)	0	0	0
	12	Methods to value health states and other benefits are stated	16 (61)	0	1 (4)	9 (35)
	13	Details of the subjects from whom valuations were obtained are given	15 (58)	11 (42)	0	0
	14	Productivity changes (if included) are reported separately	3 (11)	2 (8)	0	21 (81)
	15	The relevance of productivity changes to the study question is discussed	5 (19)	17 (65)	0	4 (15)
	16	Quantities of resources are reported separately from their unit costs	13 (50)	13 (50)	0	0
	17	Methods for the estimation of quantities and unit costs are described	22 (85)	4 (15)	0	0
	18	Currency and price data are recorded	26 (100)	0	0	0
	19	Details of currency of price adjustments for inflation or currency conversion are given	9 (35)	17 (65)	0	0
	20	Details of any model used are given	13 (50)	0	0	13 (50)
	21	The choice of model used and the key parameters on which it is based are justified	12 (46)	1 (4)	0	13 (50)
Analysis and interpretation of results	22	Time horizon of costs and benefits is stated	24 (92)	1 (4)	1 (4)	0
	23	The discount rate(s) is stated	19 (73)	4 (15)	0	3 (12)
	24	The choice of rate(s) is justified	9 (35)	7 (27)	0	10 (38)
	25	An explanation is given if costs or benefits are not discounted	3 (12)	2 (8)	0	21 (81)

	26	Details of statistical tests and confidence intervals are given for stochastic data	11 (42)	9 (35)	0	6 (23)
	27	The approach to sensitivity analysis is given	24 (92)	2 (8)	0	0
	28	The choice of variables for sensitivity analysis is justified	15 (58)	9 (35)	0	2 (8)
	29	The ranges over which the variables are varied are stated	18 (69)	7 (27)	0	1 (4)
	30	Relevant alternatives are compared	24 (92)	2 (8)	0	0
	31	Incremental analysis is reported	22 (85)	4 (15)	0	0
	32	Major outcomes are presented in a dissaggregated as well as aggregated form	24 (92)	2 (8)	0	0
	33	The answer to the study question is given	25 (96)	1 (4)	0	0
	34	Conclusions follow from the data reported	24 (92)	2 (8)	0	0
	35	Conclusions are accompanied by the appropriate caveats	24 (92)	2 (8)	0	0
	Phillips et al. (2004) - Modelling studies only					
Structural assumptions	S4	Are the structural assumptions transparent and justified?	13 (50)	0	0	13 (50)
		Are the structural assumptions reasonable given the overall objective, perspective and scope of the model?	12 (46)	1 (4)	0	13 (50)
Model type	S6	Is the chosen model type appropriate given the decision problem and	13 (50)	0	0	13 (50)

		specified causal relationships within the model?				
Time horizon	S7	Is the time horizon of the model sufficient to reflect all important differences between options?	11 (42)	3 (12)	0	12 (46)
		Are the time horizon of the model, the duration of treatment and the duration of treatment effect described and justified?	9 (35)	5 (19)	0	12 (46)
		Has a lifetime horizon been used? If not, has a shorter time horizon been justified?	12 (46)	2 (8)	0	12 (46)
Disease states/ pathways	S8	Do the disease states (state transition model) or the pathways (decision tree model) reflect the underlying biological process of the disease in question and the impact of interventions?	11 (42)	1 (4)	0	14 (54)
Cycle length	S9	Is the cycle length defined and justified in terms of the natural history of disease?	2 (8)	8 (31)	8 (31)	8 (31)
	Paediatric Quality Appraisal Questionnaire					
Cost and Resource use	17	Are opportunity costs of lost time (productivity costs) for parents and informal caregivers measured when required?	5 (19)	18 (69)	0	3 (12)
Outcomes	28	Are school/day-care absences taken into consideration?	1 (4)	25 (96)	0	0

N.B. Total percentages may not equal 100% due to rounding.

Appendix 5: Quality Appraisal of Individual Studies

	Question Number	***Adab et al. 2018***	***An et al. 2018***	***Beets et al. 2018***	***Brown et al. 2007***	***Brown et al. 2021***	***Coffield et al. 2019***	***Conesa et al. 2018***	***Ekwaru et al. 2017***	***Graziose et al. 2017***	***Haby et al. 2006 &***	***Kenney et al. 2019***	***Kesztyus et al. 2013***	***Kesztyus et al. 2017***	***Ladapo et al. 2016***	***McAuley et al. 2010***	***Mernagh et al. 2010***	***Moodie et al. 2010***	***Oosterhoff et al. 2020***	***Reeves et al. 2021***	***Reilly et al. 2018***	***Rush et al. 2014***	***te Velde et al. 2011***	***Vieira et al. 2019***	***Wang et al. 2008***	***Wang et al. 2003***	***Wyatt et al. 2018***
	***BMJ 35 item checklist* Responses: Yes (Y), No (N), Not clear (NC), Not applicable (NA)**																										
Study Design	1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	2	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y
	3	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	4	Y	Y	Y	Y	Y	N	Y	N	N	Y	Y	N	Y	N	N	NC	Y	Y	Y	Y	N	Y	N	N	N	Y
	5	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	6	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NC	Y	Y	Y	Y	Y	Y	Y	Y	Y

	7	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
Data collection	8	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	9	Y	Y	Y	Y	Y	Y	Y	N	Y	NA	N	Y	Y	Y	Y	NA	Y	Y	Y	Y	Y	NA	Y	Y	Y	Y
	10	NA	NA	NA	NA	NA	NA	NA	NA	NA	Y	NA	NA	NA	NA	NA	N	NA	NA	NA	NA	NA	Y	NA	NA	NA	NA
	11	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	12	Y	Y	NA	Y	NA	Y	NA	Y	Y	Y	Y	NA	NA	NA	Y	Y	Y	Y	NA	NA	NC	Y	Y	NA	Y	Y
	13	Y	N	N	Y	Y	N	N	Y	Y	N	N	Y	Y	Y	Y	N	N	Y	Y	Y	N	Y	Y	N	N	Y
	14	NA	Y	NA	N	NA	N	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Y	NA	NA	NA	NA	NA	NA	Y	NA
	15	N	N	NA	N	N	Y	NA	N	N	Y	N	NA	N	NA	N	N	N	Y	N	N	Y	N	N	N	Y	N

	16	N	Y	N	Y	N	N	N	N	Y	N	N	Y	Y	Y	Y	N	N	Y	Y	N	N	N	Y	Y	Y	Y
	17	Y	Y	Y	Y	Y	Y	N	N	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y
	18	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	19	Y	Y	N	N	N	Y	N	Y	N	N	N	N	N	N	N	Y	Y	Y	N	N	N	Y	N	Y	N	N
	20	NA	Y	NA	Y	NA	NA	NA	Y	Y	Y	Y	NA	NA	NA	NA	Y	Y	Y	NA	NA	Y	Y	NA	NA	Y	Y
	21	NA	Y	NA	Y	NA	NA	NA	Y	Y	Y	N	NA	NA	NA	NA	Y	Y	Y	NA	NA	Y	Y	NA	NA	Y	Y
Analysis and interpretation of results	22	Y	Y	NC	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	23	Y	Y	N	Y	NA	Y	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	NA	Y	Y	Y	NA	N	Y	Y
	24	N	Y	NA	N	NA	Y	NA	N	Y	Y	N	NA	NA	NA	N	N	Y	Y	NA	NA	Y	Y	NA	NA	N	Y
	25	NA	Y	N	NA	NA	NA	NA	NA	NA	NA	NA	Y	Y	N	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

26	Y	N	N	Y	Y	N	Y	N	Y	Y	Y	NA	NA	NA	NA	N	Y	Y	Y	N	NA	N	N	NA	Y	N
27	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
28	Y	N	NA	N	N	Y	N	N	N	Y	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	N	NA	Y	Y	Y
29	Y	Y	NA	Y	N	Y	N	Y	Y	N	N	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y
30	Y	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
31	Y	Y	Y	N	Y	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
32	Y	N	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
33	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
34	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y
35	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
Phillips et al. (2004) - Modelling studies only																										

Structural assumptions	S4	NA	Y	NA	Y	NA	NA	NA	Y	Y	Y	Y	NA	NA	NA	NA	Y	Y	Y	NA	NA	Y	Y	NA	NA	Y	Y
		NA	N	NA	Y	NA	NA	NA	Y	Y	Y	Y	NA	NA	NA	NA	Y	Y	Y	NA	NA	Y	Y	NA	NA	Y	Y
Model type	S6	NA	Y	NA	Y	NA	NA	NA	Y	Y	Y	Y	NA	NA	NA	NA	Y	Y	Y	NA	NA	Y	Y	NA	NA	Y	Y
Time horizon	S7	NA	Y	NA	Y	NA	Y	NA	Y	N	Y	Y	NA	NA	NA	NA	Y	Y	Y	NA	NA	Y	Y	NA	NA	N	N
		NA	Y	NA	N	NA	Y	NA	Y	N	N	Y	NA	NA	NA	NA	Y	N	Y	NA	NA	Y	Y	NA	NA	N	Y
		NA	Y	NA	Y	NA	Y	NA	Y	N	Y	Y	NA	NA	NA	NA	Y	Y	Y	NA	NA	Y	Y	NA	NA	N	Y
Disease states/ pathways	S8	NA	N	NA	Y	NA	NA	NA	Y	Y	Y	NA	NA	NA	NA	NA	Y	Y	Y	NA	NA	Y	Y	NA	NA	Y	Y
Cycle length	S9	NA	N	NA	N	NA	NA	NA	NC	N	N	NA	NA	NA	NA	NA	Y	NC	N	NA	NA	N	N	NA	NA	N	Y

Paediatric Quality Appraisal Questionnaire

Cost and Resource use	17	Y	NA	N	N	N	Y	N	N	N	Y	N	N	N	N	N	N	Y	Y	N	NA	NA	N	N	N	N	N
Outcomes	28	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N

Responses: Yes (Y), No (N), Not clear (NC), Not applicable (NA)

See Appendix 4 Quality Appraisal Summary Data for full questions/criteria alongside question numbers

Appendix 6: Characteristics of Intervention Studies

Author (year)	Study design; duration (reference)	Intervention; components	Sample; population; age group	Outcome measures	Key results
Adab et al. (2018)	Cluster RCT; 12 months	WAVES trial; healthy eating, physical activity, parental engagement, signposting.	N=2462 (baseline); primary schools in West Midlands, UK; 5-6 year olds	BMI-z (UK 1990 reference curves), WC, skinfold thickness, %BF, dietary intake, quality of life (CHU9D)	Not significant; mean BMI-z difference between control and intervention arms at 18 months = -0.027 (95% CI = -0.137 to 0.083)
An et al. (2018)	Quasi experimental study; 4 years (Schwartz et al., 2016)	Promote plain water consumption; installation of water dispensers.	N=1,065,562 (baseline); public elementary schools, New York; kindergarten to 8^{th} grade	BMI	Significant BMI-z reduction of 0.025 in boys (95% CI = -0.038 to -0.011). Significant BMI-z reduction of 0.022 in

					girls (95% CI= -0.035 to -0.008). Risk reduction of childhood overweight by 0.9% among boys (95% CI= 0.015 to 0.003) and 0.6% among girls (95% CI= 0.011 to 0.000).
Beets et al. (2018)	RCT with one-year delayed treatment group; 2 years (Beets et al., 2017)	After school programme; serves healthy foods and encourages physical activity	N=2663 (baseline); after school programmes, South Carolina; 5-12 years	Foods and beverages served	Increased number of days/week for servings of fruits/veg: 0.6 vs 1.7 (delayed group), 0.6 vs 4.4 (immediate group), OR=3.8, 95% CI=1.45 to 9.95.

					SSBs: 1.2 vs 0.2 (delayed group), 3.2 vs 0 (immediate group), OR=0.05, 95% CI=0.02 to 0.13. Desserts: 2.9 vs 0.6 immediate group), OR=0.1, 95% CI=0.03 to 0.33.
Brown et al. (2007)*	Untreated, matched control group design with repeated dependent pretest and posttest samples; quasi experimental design; 4 years (Coleman et al., 2005)	CATCH programme; nutrition and physical activity embedded within curriculum, family involvement	N=896 (baseline); elementary schools, El Paso, Texas; 8-11 years	Risk of overweight or obesity using BMI percentiles (+85th or +95th), percentage of fat and sodium in school lunches, physical activity.	No effect of CATCH on anthropometry Girls: Rate of increased overweight risk in CATCH schools significantly lower (2%) to controls (13%). Boys: Rate of increased

					overweight risk significantly lower (1%) in CATCH schools compared to controls (9%).
Brown et al. (2021)	2x2 factorial cluster randomised controlled trial; 10 weeks (Sutherland et al., 2019b)	SWAP IT intervention; encouraged parents to swap lunchbox discretionary food items to healthier alternatives through a school communication app, educational component	N=778 (baseline intervention), N=991 (baseline control); primary schools, New South Wales, Australia; 5-12 years	Items packed in lunchbox (mean kJ), mean total and percent energy from foods that align with Australian Dietary Guidelines and discretionary food items.	Reduction in total energy from school lunchbox: -131.61 kJ, CI = -317.26, 54.05, p = 0.16; reduction in energy from discretionary foods: -211.61 kJ, CI = -426.16, 2.95, p = 0.05; increase in energy from healthier everyday food: 83.13 kJ, CI = 2.65, 163.61, p = 0.04

Coffield et al. (2019)*	Non-randomised controlled trial; 2 years (Economos et al., 2013)	Shape Up Sommerville (SUS); Diet and PA, whole-system approach targeting school (e.g. school food service), home (e.g. parent education) and community (e.g. "approved" restaurants) environments	N=1028; schools, home and community, Massachusetts, USA; grades 1-3.	BMI-z from height and weight.	BMI-z intervention relative to controls: -0.057 (95% CI: -0.08, -0.04) Self-reported BMI of intervention parents, relative to control group: -0.411 (95% CI: -0.725, -0.097)
Conesa et al. (2018)	Randomised, parallel, controlled primary school-based obesity prevention intervention; 28 months (Tarro et al., 2014)	Educacio en Alimentacio (EdAI) program; educational activities promoting nutrition	N=2350; primary schools, Catalonia, Spain; 7-8 years	Prevalence of obesity (primary), changes in BMI z-score, WC and incidence & remission of excess weight (secondary)	Obesity prevalence decreased by 2.02% in intervention group and increased by 0.44% in control group. Boys: 4.39% difference in obesity

					prevalence (95% CI: 3.48 – 5.30%, p = .01). Intervention boys had sig. reduction of −0.24 units in the BMI z-score compared with the control group. Girls: no sig. differences
Ekwaru et al. (2017)	Observational; 2 years (Fung et al., 2012)	The Alberta Project Promoting active Living and healthy Eating in Schools (APPLE); nutrition and physical activity, parental engagement	N=7850; elementary schools, Alberta, Canada; grade 5 (~10 years)	BMI, dietary intake (FFQ), physical activity	Sig difference in changes in calorie intake (mean -212kcal, 95% CI: -315 to -109) of APPLE students compared to control. 2.2% reduction in obesity prevalence between 2008-2010

					among APPLE schools compared to 2.8% increase in control. APPLE Schools estimated to reduce odds of obesity over normal weight by 0.723 times per year (OR = 0.723, 95%CI: 0.553 to 0.946).
Graziose et al. (2017)	Cluster RCT; 1 year	Food, Health & Choices (FHC) program; curriculum embedded lessons on nutrition, physical activity	N=769; elementary schools, New York; 10-11 years	BMI	4% fewer boys and 2.4% fewer girls were with overweight/obesity compared with 1.3% more boys and 1.3% fewer girls in the control condition.

		and reducing screen time.			Adjusted odds ratio for boys = 0.17 (p=.04); for girls = 0.25 (p=.1)
Haby et al. (2006) - benefits & Carter et al. (2009) - costs	Multiple interventions evaluated separately: Non-RCT; 2 years (Tamir et al., 1990) Quasi-experimental; 3 years (Manios et al., 1999) Cluster RCT; 1 school year (James et al., 2004) RCT; 2 weeks (Gorn and Goldberg, 1982)†	Keep your body healthy programme; nutrition and physical activity classroom teaching, parental involvement (Tamir et al., 1990) Nutrition and physical activity classroom teaching (Manios et al., 1999)	N=829; primary schools, Jerusalem; first graders (6 years) (Tamir et al., 1990) N= 5681; primary schools, Crete, Greece; first grade (6 years) (Manios et al., 1999) N=644; junior schools, Christchurch, Southwest England;	BMI, dietary habits, BP, fasting total cholesterol, high density lipoproteins, triglycerides (Tamir et al., 1990) 3-day food diary, BMI (Manios et al., 1999) 3-day food diary, BMI (James et al., 2004) Drink and snack choices (Gorn and Goldberg, 1982)	BMI residual difference between intervention and control groups = 0.76 (p<.01) (Tamir et al., 1990) 1.1 units significant increase in BMI in controls compared to intervention group; no sig. difference in energy consumption (Manios et al., 1999) Reduction of carbonated drink

	Christchurch obesity prevention project (CHOPPS); classes discouraging fizzy drink consumption (James et al., 2004)	7-11 years (James et al., 2004)		consumption in intervention group, mean difference = 0.7; 95% CI=0.1 to 0.3; decrease in overweight/obesity prevalence in intervention, mean difference = 7.7%; 95% CI = 2.2% to 13.1% (James et al., 2004)
	Controlling TV advertisements to moderate sugar intake and a balanced diet (Gorn and Goldberg, 1982)	N=288; youth camp, Quebec, Canada; 5-8 years (Gorn and Goldberg, 1982)		Sig. effect of treatment on children's drink choice and proportion of fruit selected (Gorn and Goldberg, 1982)

Kenney et al. (2019)	An et al. (as above)	An et al. (as above)	An et al. (as above)	An et al. (as above)	An et al. (as above)
Kesztyus et al. (2013)	Cluster-randomised trial; 1 year	URMEL-ICE intervention; SSB consumption (nutrition), physical activity and media use through classroom teaching and parental engagement.	N=1810; primary schools, Ulm and Gunzburg, Germany; 7 years (average)	Parental BMI, child BMI, WC, WtHR	No statistically significant effect of intervention on BMI; Unadjusted RR for incident overweight at follow-up was 0.66 (95% CI: 0.39 to 1.14) (intervention group). Sig. effect on waist circumference (-0.85 (95% CI: -1.59 to -0.12).
Kesztyüs et al. (2017)	Cluster RCT; 1 year	Join the Healthy Boat intervention; SSB consumption (nutrition), physical activity	N=1968; primary schools, Baden-Wurttemberg, Germany; grades 1-4	BMI, WC, WtHR.	Sig. effect of intervention on BMI percentile (mean 0.45, p = 0.038) but reduced to non-sig.

		and media use through classroom teaching and parental engagement.			when controlling for baseline BMI
Ladapo et al. (2016)	RCT; 5 weeks (Bogart et al., 2014)	Students for Nutrition and eXercise (SNaX); promotion of healthy foods and physical activity.	N=5299; public middle schools, Los Angeles; grades 6-8	Portions of fruit and vegetables served. Number of free/reduced-price lunches served. Number of full price lunches served. Number of all lunches served. Number of snacks sold.	Increased fruit servings in intervention compared to control from pre to during intervention (0.07, (SD=0.03) $p<0.01$); no sig diff in veg. Sig diff in snack sales (-0.03 (SD=0.01), $p<0.01$)
McAuley et al. (2010)*	Non randomized Controlled intervention; 2 years (Taylor et al., 2006)	A Pilot Programme for Lifestyle and Exercise	N=469; communities and primary schools,	BMI, BMI z-score, WC, Dietary intake (FFQ), Physical activity	BMI z-score was significantly lower in intervention relative to control

		(APPLE); nutrition through free fruit provision, water filters, and classroom teaching, and physical activity.	Otago, New Zealand; 5-11 years		children by 0.26 units (95% CI = 0.21-0.32) at 2 years and weight z-score by 0.18 units (95% CI = 0.13-0.22). Overweight (%): 0.88% increase in control relative to intervention group (95% CI: 0.69 – 1.14).
Mernagh et al. (2010)	McAuley et al. (as above) Moodie et al. (as above) Cluster-RCT; 2 years (Foster et al., 2008)	APPLE (as above) Be Active Eat Well (as above) School Nutrition Policy Initiative (SNPI); nutrition education and school policy	APPLE (as above) Be Active Eat Well (as above) N=1349, primary schools, Philadelphia, USA;	APPLE (as above) Be Active Eat Well (as above) BMI, dietary intake (FFQ), physical activity and sedentary	APPLE (as above) Be Active Eat Well (as above) Overweight prevalence at baseline and 2 year follow up:

	implementation (removal of SSBs and unhealthy snacks from vending machines and cafeterias), social marketing and parent outreach (Foster et al., 2008).	grades 4-6 (Foster et al., 2008)	behaviours (Foster et al., 2008)	Control: 15.89%; 20% Intervention: 16.28%; 14.61% OR: 0.65 (95% CI: 0.54 to 0.79) P<.001 Overweight incidence: OR=0.67 (95% CI: 0.47 to 0.96), p=.03 No significant changes in obesity prevalence and incidence. No sig. diff in BMI, total energy, fat and F&V consumption between groups at 2 year follow up (Foster et al., 2008)

Moodie et al. (2013)*	Quasi-experimental non-randomized trial; 3 years (Sanigorski et al., 2008)	Be Active Eat Well programme; nutrition (SSB, energy dense snacks and F&V), physical activity and reduction of television viewing.	N=2184; primary schools, Colac, Australia; 4-12 years	BMI, BMI z-score, WC, WtHR, self-reported physical activity and dietary intake.	Intervention group compared to control: showed lower increase in BMI scores -0.28 (95% CI: -0.7 to 0.15); had lower increases in WC -3.14 (95% CI: -5.07 to -1.22); BMI Z scores -0.11 (95% CI: -0.21 to -0.01); WtHR -0.02 (95% CI: -0.03 to -0.004)
Oosterhoff et al. (2020)	Longitudinal quasi-experimental trial; 2 years (Bartelink et al., 2019)	Healthy Primary School of the Future (HPSF; diet and PA) vs. Physical Activity Schools (PAS; PA	N = 1676, n = 661 (controls), n = 537 (HPSF), n= 478 (PAS); primary schools,	BMI z-score, hip and waist circumference	Compared to control schools: HPSF: − 0.21 kg/m2 [95% CI: − 0.38; −0.05] PAS: − 0.17 kg/m2

		only); healthy morning snacks and healthy lunches, structured sports, play and creative activities.	Netherlands; 4-12 years		[95% CI: −0.33; 0.00] Effects by SES (HPSF vs controls): Low SES: -0.103 (95% CI: -0.22, -0.02) Middle SES: -0.049 (95% CI: -0.16; 0.06) High SES: -0.063 (95% CI: -0.18; 0.05).
Reeves et al. (2021)	Single blinded parallel group RCT	Munch and Move (state-wide obesity prevention programme); access to a web-based menu planning and	N = 27 (intervention services), N=27 (controls services); Daycare services, New South Wales,	Provision of recommended number of serves for each of the following food groups per child per day over a 1-week period:	Mean number of guideline compliant food groups: Relative effect size 0.26; 95% CI: -0.61, 1.14; p=0.55

		decision-support tool, online resources, online reminders and feedback.	Australia; 3-6 years.	(1) vegetables and legumes/beans (two serves) (2) fruit (one serve) (3) whole grain cereals, foods and breads (two serves) (4) lean meat and poultry, fish, eggs, tofu, seeds and legumes (3/4 serve) (5) milk, yoghurt, cheese and alternatives (one serve) (6) no 'discretionary' foods that are high in energy and low in nutrients (zero serves).	Sig. increase in servings of fruits in intervention: 0.21; 95% CI: 0.02, 0.4; p=0.03 Sig. reduction in mean number of times per week discretionary foods provided: -0.33; 95% CI -0.54, -0.11; p=0.003.
Reilly et al. (2018)	RCT; 12-14 months (high intensity intervention)	Support offered in different levels of	High intensity: N=35	Proportion of canteen menus that (i) did not	Policy adherent school canteen

	(Wolfenden et al., 2017), 9 months (medium intensity intervention) (Nathan et al., 2016), 12 months (low intensity intervention) (Yoong et al., 2016)	intensity to promote Government roll out of healthy canteen policy: 50% of menu to be 'green' (healthier foods), limit availability of 'amber' and restrict sale of 'red' (poor nutritional value). SSB sale ban in schools. High intensity: support, provision of tools, performance monitoring and	(intervention), N=35 (control). Medium intensity: N=28 (intervention), N=25 (control). Low intensity: N=36(intervention), N=36 (control). Primary Schools, New South Wales, Australia, 5-12 years.	contain items restricted for sale (red/banned); (ii) healthy canteen items (green) represented more than 50% of listed menu items.	menu, compared to controls: High intensity: RR=14.41; 95% CI: 2.08, 99.97; p=<0.001 Medium intensity: RR=4.29; 95% CI: 1.04, 17.68; p=0.02 Low intensity: RR=4.44; 95% CI: 0.65, 30.11; p=0.06

	feedback, bi-monthly school visits. Medium intensity: **:** as high-intensity but text-message based support. Two support contacts per school term. Low intensity: canteen menu audits with provision of feedback via written report or telephone call		

		each school term (4x).			
Rush et al. (2014)	Longitudinal Randomized controlled trial; 2 years (Rush et al., 2011, Rush et al., 2012)	Project Energize; healthy eating and physical activity.	N=192 intervention schools (124 control schools (2004) and 62 schools (2006); primary schools, Waikato District, New Zealand; 6-8 years ("younger children") and 9-11 years ("older children")	BMI, WC, BP, Fitness Body composition Healthy eating habits and physical activity questionnaire	2006 control data comparison: median BMI difference 0.504 kg/m2 (90% CI: -0.435 to -0.663) 2004 BMI comparison: -0.551 kg/m2 (90% CI: -0.456 to -0.789)
Te Velde et al. (2011)	Cluster randomized trial; 2 years (Tak et al., 2009, Te Velde et al., 2008)	Pro children; provision of healthy foods, curriculum activities, parental involvement (Te Velde et al., 2008)	N=735 (Te Velde et al., 2008) N=771; (Tak et al., 2009) primary schools, Netherlands; 5th grade (10 years)	F&V consumption	Intervention group consumed 28.7g/day more F&V than control (95% CI= -12.8;70.1) (Te Velde et al., 2008).

		Schoolgruiten; free fruit/veg, curriculum-based knowledge and skill development (Tak et al., 2009)			Intervention group consumed 17.4g/day more F&V than control (95% CI= -0.9;35.6).(Tak et al., 2009) Neither statistically significant.
Vieira and Carvalho (2019)	Non-RCT	Planning Health in School Programme; 8x45 minute learning modules to improve diet and F&V intake, increase PA and reduce TV viewing; 10 months.	N=219 (intervention), N=230 (controls); primary schools, Trofa municipality, Porto, Portugal; 10-14 years	Height, weight, WC, BMI, WHtR, FFQ	BMI: Intervention (mean=0.12, SD=0.94) vs control (mean=0.21, SD=1.01); p=0.35 WC: Intervention (mean=-0.38, SD=2.81) vs control (mean=0.3, SD=2.98); p=0.015 WHtR: Intervention (mean=-0.01, SD=0.02) vs control

					(mean=-0.008, SD=0.02); p=0.002 Less soft drink consumption from 0.7 to 0.5 servings/day in intervention group (p=0.043)
Wang et al. (2008)	RCT; 3 years (Yin et al., 2005)	FitKid project; after school programme, healthy snacking, physical activity, discouraging sedentary behaviours.	N=890; elementary schools, Augusta, Georgia, USA; 3rd graders	Reduction in %BF, BMI, WC	At least 40% of after school sessions reduced %BF by 0.76% (95% CI: -1.42 to -0.09) compared with control.
Wang et al. (2003)	Randomized controlled trial; 2 years (Gortmaker et al., 1999)	Planet Health; nutrition, physical activity and television viewing, incorporated	N=1560; middle schools, Boston, Massachusetts; grades 6-7	BMI and tricep-skinfold	Intervention: Obesity prevalence declined from 23.6% to 20.4% during the

		within interdisciplinary curriculum.			two-year intervention. Controls: Obesity prevalence increased from 21.5% to 23.7%. Obesity prevalence sig. reduced in intervention girls compared to controls (OR=0.47, 95% CI: 0.24 to 0.93, p=0.03).
Wyatt et al. (2018)	Cluster RCT; 3 school terms	Healthy Lifestyles Programme (HeLP); SSB consumption, healthy and unhealthy snacks, physical activity	N=1324; state primary and junior schools, Devon, UK; year 5 students	BMI-z at 24 months (primary) BMI-z at 18 months, WC-z, %BF-z, % children classified as underweight/healthy weight/overweight/obese	BMI-z at 24months: -0.02 (95% CI: -0.09 to 0.05; p=0.567) WC-z: -0.05 (95% CI: -0.23 to 0.13) %BF: -0.03 (95% CI: -0.61 to 0.55)

	and screen time, classroom teaching and activities.	

Abbreviations: BF, body fat; BMI, Body Mass Index; BP, blood pressure; CHU9D, Child Health Utility Index 9-dimensions; CI, Confidence intervals; FFQ, food frequency questionnaire; F&V, Fruit and Veg; HPSF, healthy primary school of the future; kilojoule, kJ; kcal, kilocalorie; OR, odds ratio; PA, physical activity; PAS, physical activity school; RCT, randomised controlled trial; RR, relative risk; SES, socioeconomic status; SSB, sugar sweetened beverages; WC, waist circumference; WtHR, waist to height ratio

*intervention based in community and school setting

†intervention based in youth camp setting

Appendix 7: Long-term Modelling Methods of Cost and Benefit Outcomes in Economic Modelling Studies

Study	Methods	Databases utilised
An et al. (2018)	Each Markov cycle exposed subjects to an age and sex-specific risk of death. Survivors gain a year of life and corresponding costs should they be with overweight/obesity. Simulation ends when all subjects die. Probability parameters of an overweight child to become an adult with overweight/obesity were obtained from the literature. The model assumed that economic costs of overweight/obesity begin to accumulate from age 35. Normal distributions were assigned to all parameters.	Age and sex specific risk of death parameters obtained from the United States Life Tables, 2011. Nationally representative health survey data (Finkelstein et al.,; Dor et al.,; Tsai et al.) obtained per capita annual medical costs associated with adult overweight and obesity. Adjusted for inflation based on the Consumer Price Index issued by the US Bureau of Labor Statistics. National Health and Nutrition Examination Survey – prevalence of adult overweight/obesity. National Centre for Education Statistics – total number of public and private schools in the

		United States, including 2015 enrolment figures.
Brown et al. (2007)	**Intervention outcomes:** childhood obesity cases averted based on obesity status at 11 years → predict obesity cases averted at 25-29 years → predict obesity cases averted at 40-64 → include intervention costs → include medical costs averted at 40-64 years (and estimated labour productivity costs averted) based on obesity cases averted → estimate QALYs and calculate cost-effectiveness ratio (CER), or estimate net benefit. Poisson regression was used to estimate number of lost sick days for individuals with and without obesity. Life expectancy and mortality by gender was calculated for 40 year olds with and without obesity who died before turning 65. U.S. Department of Labour, Bureau of Labor Statistics Population Survey Data was used to place value on sick days averted. **Lifetime obesity progression model** - predicted adulthood obesity based on child overweight. This model requires the following information: number of participants at follow up; proportion of at-risk/overweight in grades three and five in the control and intervention arms separately; probability of obesity at 21-29 years conditional on being at-risk, with obesity, not at-risk, without	Lifetime obesity progression model: probabilities estimated by linking **1992, 1987, 1982 NHANES I Epidemiological Follow up Study (NHEFS)** data with the original **1975 National Health and Nutrition Examination Survey (NHANES) I** data. QALYs = **2002 NHIS survey questions** on self-reported health and activity limitations. Life tables by Peeters et al. (2003) used to project life expectancy at 40. **Medical cost parameters:** NHANES III - estimate costs for hyper-tension, hypercholesterolemia, type 2 diabetes, cardiovascular disease and stroke covering age period of 35 years - death.

	obesity at 11 years; probability of obesity at 40 years conditional on being with obesity and without obesity at 20-29 years.	**Indirect costs** calculated using 2002 National Health Interview Survey data.
Coffield et al. (2019)	Capital expenditures were annuitized at a 3% rate with a 10 year lifespan, and future benefits were discounted at an annual 3% rate. Costs were adjusted to 2014 USD using either the Center for Medicare Studies' Health Care Expenditure Price Index or the Consumer Price Index. Intervention effect size depreciated by 2.62% annually (calculated based on estimation of a "breakeven" depreciation rate where costs remain equal to the program's estimated benefits). Healthcare cost estimation: based on changes in BMI z-score (children) or BMI (parents) changes using the Medical Expenditure Panel Surveys (MEPS). Twenty age-specific samples were created to reflect estimated costs by age (child) or age-group (parent) over the 10-year horizon. Regressions tested for significant associations between healthcare costs and BMI changes at each age sample controlling for socioeconomic and demographic covariates. Healthcare costs averted were only considered for significant associations. Productivity loss averted were estimated annually for parents only, based on number of sickness-related missed workdays associated with a 1-point BMI change; parent population-wide treatment effect; and median wage estimates of the MEPS sample.	Center for Medicare Studies Health Care Expenditure Price Index (healthcare cost adjustments only)

Ekwaru et al. (2017)	Markov model based on 10 cohorts of students who pass through grade 5 over a ten-year period. The model assumed that pupils' body weight status predicted their adult body weight, which determined their risk of weight-related diseases and quality of life. It was assumed that the lifestyle changes developed in the two intervention years would continue on for 8 more years. The model included 43 states - three weight categories (normal weight, overweight, obese) and 13 chronic diseases with links to weight status, no-chronic disease state and the dead state. Disease states included: diabetes, hypertension, asthma, osteoarthritis, stroke, coronary heart disease (CHD), kidney cancer, pancreatic cancer, colorectal cancer, breast cancer, endometrial cancer, ovarian cancer, and gallbladder cancer). A multinomial logistic regression model was used to fit data from these cohorts, based on 3 independent variables (sex, weight status and age at a given time point), and outcome variables (weight status in the next assessment (every 2 years). Parameter estimates of the fitted multinomial logistic regression were used in the Markov model to obtain sex and age specific weight status transition probabilities.	**Weight status transition probabilities**: National Population Health Survey (NPHS) (follows 12 year old children and older); National Longitudinal Survey of Children and Youth (NLSCY) that follows children under 12 years of age. **Probabilities of developing chronic diseases**: published studies on incidence rates of chronic diseases, effects of weight status on incidence rates (Guh et al., 2009) and weight status distributions from Statistics Canada 2010. Mortality probabilities: Canadian life table.

	Conditional probability of dying given weight and chronic disease status: Canadian Life Table used to extract mortality hazards by sex and age based on the general Canadian Population, as well as the effects of weight status and chronic disease on all-cause mortality (weight status distribution and prevalence of chronic diseases were considered). At each cycle (age), mortality hazard was estimated based on sex, age and weight status (Mortality hazard obtained from life tables X (Relative Risk of dying for weight status given sex and age / the sum of the proportion of people in a particular weight status given their sex and age multiplied by the relative risk of dying for a particular weight status given sex and age). For every year lived with excess weight/obesity/chronic disease, there was an assigned decrement in health utility scores.	
Graziose et al. (2017)	Quantification of benefits based on QALYs. A hypothetical model population of fifth grade students with a distribution of observable demographic characteristics and weight status was taken from publicly available data. Trial effectiveness data was used to estimate reduction in obesity at age 10 years for males and female. Childhood-to-adulthood BMI trajectories were used to estimate adult obesity prevalence. QALYs were estimated based on existing data taken from Muennig et al.	**Obesity progression model** used to estimate number of cases of adult obesity averted due to the intervention. **Childhood-to-adulthood BMI trajectories** from Goldhaber-Robert et al (2013).

	Medical costs averted were obtained from Finkelstein et al. A CER was calculated to include medical costs associated with obesity averted.	
Haby et al. (2006) - benefits & Carter et al. (2009) - costs	Where interventions have gathered behavioural outcomes rather than anthropometric outcomes, the relationship between behaviour change, energy balance and BMI was modelled: 1) determine changes in energy consumed from behaviour change. 2) model impact on changes in child weight – 10% change in energy balance resulted in 4.5% change in body weight (95% CI= 3.8; 5.1). 3) model DALYs saved as a difference in mortality and morbidity outcomes, in 5 year increments, by sex, due to intervention effects which may result to changes in age-specific BMI distribution over the lifetime, in comparison to a control, through the use of life tables. 4) calculated Potential Impact Fraction (PIF) which is the proportional change in expected disease/death attributable to intervention/control condition. This is used to determine the impact of change in BMI distribution of mortality and morbidity (9 diseases considered). Relative risk estimates for 30-44 year olds were also applied to the 25-29 age group. 5) Reduction in obesity related costs were calculated using the same methods as DALYs saved.	**Australian 1995 National Survey** (NNS95) – 5-19 y/o used as cohort of children for the model; weight and energy density of total diet was used to determine energy imbalance from behaviour change; mean changes in weight were translated to mean changes in BMI, assuming constant height. **Victorian Burden of Disease Study** – years of life lived for disease-related disability. **Australian Institute of Health and Welfare** – used to calculate cost offsets.

Kenney et al. (2019)	CHOICES microsimulation model was used to estimate costs, population reach, water intake, health outcomes and health care cost savings related to childhood obesity over a 10-year time horizon from 2015 to 2025. The model simulates individuals in the US population to project how children's individual growth trajectories would shift after exposure to the intervention, and how that would impact on health and health care costs. Growth trajectories were estimated based on data on demographic characteristics, growth, health behaviours and obesity risk from multiple national datasets. The model was used to estimate the expected reductions in BMI and number of cases of childhood obesity prevented after 10 years. Annual health care cost savings were estimated based on published estimates of healthcare costs associated with child and adult obesity.	Labour costs – Bureau of Labor Statistics (45.56% fringe rate) US Census; The American Community Survey; The National Survey of Children's Health The National Health and Nutrition Examination Survey; The Early Childhood Longitudinal Study-kindergarten cohort; The Behavioral Risk Factor Surveillance system
Mernagh et al. (2010)	Control arm of economic model: simulation to estimate BMI of 10,000 individuals for each ethnic group, for each age between 2-75 years. Each individual was categorised as healthy weight, with overweight or with obesity. The impact of the intervention on mean BMI was subtracted for each simulated individual → this produces a new intervention cohort of 10,000 individuals. Probabilities (expected incidence) of staying in good health or contracting one of 14 obesity-related chronic illnesses was applied to the model at each yearly control group cycle, by age (using Dutch data due to unavailability of New Zealand data).	**New Zealand life tables** – mortality estimated in each yearly cycle. **Statistics New Zealand (2009) National Population Estimates** – mortality rate data **Mittman et al. (1999)** – utility weights.

	Incidence estimates applied to those 20 years+. Utility weights (sourced from the literature) were applied to health states representing average quality of life over the duration of the illness. Utility weights were not applied to BMI categories. Intervention effects were applied to a five-year timeframe (where follow up was not that long, the last follow up effect size was carried forward). Reduction in BMI (intervention effect) relative to controls would decay by 1% per annum after 5 years within the economic model.	**New Zealand Ministry of Health (2004)** – annual health care costs by age and gender – on-going health care costs for healthy weight individuals. **Baal et al. (2008)** – cost of illness data for chronic disease. Ratio applied to estimate incremental cost of chronic illness for New Zealand population.
Moodie et al. (2013)	**BMI to DALYs**: Reduction in BMI was converted to DALYs saved using the ACE-Obesity model. DALYs averted were calculated as the difference in future morbidity and mortality between intervention and control groups. PIFs were used to calculate the impact of the change in BMI on expected disease or death. Diseases considered in the model: ischaemic heart disease, ischaemic stroke, hypertensive heart disease, type 2 diabetes, osteoarthritis, endometrial cancer, colon cancer, postmenopausal breast cancer and kidney cancer.	2001 population epidemiology and disease cost data.

	The Markov Model takes the cohort of children (aged 5-19) and follows them in five-year increments in separate gender groups, until 100 years of age (or death). The intervention was modelled at a national level for one year. It was assumed that the intervention would be taken up by 10% of Australian Primary Schools.	
Oosterhoff et al. (2020)	Modelling started from age 4 – lifetime (distinguished between childhood/adolescence 4-20 years and adulthood). Lifetime health and cost impacts were modelled through changes in BMI. Intervention effects were relayed onto a BMI trajectory (extrapolated BMI values up to age 20 years). School day extended to 30 mins per day, 4 days a week. School absenteeism considered as productivity indicator for children (excess missed school days associated with overweight/obesity obtained from the literature). HRQoL weights and healthcare costs (GP and specialist visits) by child weight status obtained from literature. Costs and QALYs calculated for each age cohort between 4-12 years and then aggregated to represent Dutch 4-12 year olds in a school cohort. RIVM Chronic Disease Model was used to project effects from 20 years of age up to	**Lehnert et al. (2014)** - Productivity losses by weight category **Dutch Burden of Disease Study (Melse et al., 2000)** - Adult Utility weights Child utility weights – literature **Dutch Cost of Illness Study (Slobbe et al., 2006)** - Health resource use and costs: **Zorginstituut Nederland (2015)** - Productivity and healthcare costs

100 (lifetime). Markov model approach; prevalence, incidence and mortality of chronic diseases based on changes in risk factors and weight category (normal weight, overweight and obesity). Considers diseases during life years gained. Diseases included: myocardial infarction, angina pectoris, chronic heart failure, stroke, renal, colorectal, breast, prostate, and endometrium cancer, diabetes mellitus, hip and knee arthritis, and low back pain. The model also considers the risk of secondary diseases due to primary diseases (independent of weight). Model also considers diseases due to ageing (independent of weight). This included: chronic obstructive pulmonary disease, lung, stomach, esophagus, larynx, bladder, pancreas, and oral cavity cancer.

Presence of disease determined utilities obtained from the Dutch Burden of Disease Study. Health state utilities for overweight and obesity are not included. Gains in HRQoL is based on decreases in prevalence of disease and not from weight loss. Healthcare costs were estimated based on the Dutch Cost of Illness Study.

Productivity losses – relation between weight category in adulthood and number of annual sick leave days from work, calculated up to 67 years of age (retirement).

Equity efficiency impact plane, displaying trade-offs between cost-effectiveness and health equity.

	Controls: Assumed BMI changes only due to growth.	
Rush et al. (2014)	The economic model was adapted from Health Research Council of New Zealand (2010). Intervention costs were offset against life-time obesity health treatment costs averted.	New Zealand Ministry of Health 2006/2007 population survey data – used to obtain population BMI data.
	The model estimates QALY increase given obesity-related health conditions averted.	New Zealand life tables and Dutch data on relative risks of disease incidence and mortality conditional on BMI.
	Intervention costs and effects were extrapolated for a lifetime → these were translated onto New Zealand population BMI distributions. In each year of age (2-75), the population is categorised as either normal weight, with overweight or with obesity by fitting a lognormal distribution to mean BMI and standard errors using population survey data.	
	The model tracks risk and projects prevalence of 14 obesity-related diseases and full health, along with associated costs and health benefits (life years and preference-based utility weights).	
	Each health state is associated with a preference-based utility.	

	An intervention is modelled by how it shifts the distribution of BMI in both males and females in the general and Maori populations, using data from intervention effects on BMI. A 1% decay in intervention effects was applied after first 5 years of the intervention. The intervention was modelled by applying observed change in median BMI to the relevant comparison cohort for both general and Maori populations.	
Te Velde et al. (2011)	Epidemiological modelling was used to estimate future health effects of increased fruit and veg intake. The modelling procedure involved, 1) estimation of the effect of the intervention on fruit and veg consumption at 2 years; 2) translating consumption effects into changes in health outcomes → the model compares a reference population (general Dutch population) to an identical intervention population where the amount of fruit and veg consumed can be changed (according to the intervention effects). Mean intake of F&V (g/day) were fit to a Gamma distribution (higher mean for intervention conditions). Intervention consumptions levels at follow up were extrapolated over a lifetime using 30% of intervention effects to track effects from young adulthood to late adulthood.	**National Food Consumption Survey 2003** – provides F&V consumption data for the Dutch reference population covering ages 19-30 years. **WHO Comparative Risk Assessment** exercise – relative risk estimates. **GP registries** – incidence data **Netherlands National Institute for Public Health and Environment 2000** – incidence and mortality estimates for general population.

	Disease incidence due to F&V intake was quantified via PIFs (changes in incidence due to changes in exposure) using a given formula. Disease incidence in the intervention population was calculated from PIFs and incidence in general population.	**DisMod II tool** – enforces consistency between different epidemiological data.
	The model did not account for incidence and mortality rates from causes other than the diseases included. The model accounts for incidence and mortality in the intervention population separately for men and women, whereby life expectancy and disability-adjusted life expectancy is calculated.	**Dutch disability weights** – used to estimate HRQoL lost due to disease (weights are based on severity levels, therefore used estimates of the distribution by the National Institute for Public Health and the Environment to get average disability weight for each disease).
	ICER and NMB was calculated with and without inclusion of lifetime healthcare costs.	Costs of disease (Slobbe et al., 2006)
	Each intervention was compared to a "No intervention" scenario, as well as against each other.	
Wang et al. (2003)	Cost effectiveness ratio was calculated as a ratio of net intervention costs to total QALYs saved by the intervention. Net benefit was calculated as costs averted by the intervention minus intervention costs. Analysis was undertaken for females only as no significant reduction in prevalence of overweight was found amongst boys.	**Cases of adulthood overweight prevented**: Estimates taken from Whitaker et al. (1997) to predict overweight in 21-29 year olds from 1-17 year olds. **NHANES I Epidemiological Follow-up Study** (EFS) - probability of 21-29 year old women with a BMI >27.3 kg/m2 becoming

Base case analysis: 1) estimation of intervention costs; 2) translating observed overweight reduction at 14 years onto overweight prevented at 40 years through the development of a two-stage overweight progression model; 3) estimation of medical care costs averted, QALYs saved, and productivity costs averted, per case of adulthood overweight prevented; 4) calculation of cost effectiveness ratio and net benefit of the intervention. **Overweight progression model (decision tree):** Students were separated into groups with and without obesity for the intervention and a hypothetical no intervention condition, at 14 years. They were further classified as overweight or not at 40 years. By comparing expected number of adulthood overweight cases by age 40 between the two conditions, an estimation of overweight cases prevented by the intervention was calculated. **Medical costs averted in years 40-65 years for the following conditions**: Coronary heart disease, hypertension, diabetes, symptomatic gallstones, and osteoarthritis. Medical costs averted = \$4132 (\$2229 moderately overweight - \$5325 severely overweight).	overweight by 40 years (defined as BMI >25kg/m2) and probability of non-overweight 21-29 year old becoming overweight by age 40. **Medical costs averted:** incidence-based analysis from Gorsky et al. (1996) – direct health care and medication costs associated with women at 40 years and maintained overweight to age 65 years. **QALYs saved**: Healthy People 2000 years of healthy life (YHL) measure (developed by National Centre for Health Statistics) and 1990 National Health Interview Survey (NHIS). **Costs of lost productivity**: 1990 NHIS of the Health Promotion and Disease Prevention sample person file used to estimate average work absenteeism in 40-64 year old women by BMI status.

	QALYs saved per case of adulthood overweight prevented: calculated mean years of healthy life (YHL) scores by BMI and combined these with the life expectancy estimates, through linear regression techniques, to calculate QALYs for overweight and non-overweight women.	**Bureau of Labour Statistics** used to calculate median weekly earnings of the nation in 1996. 35-54 year old women, median earnings = $468 per week; $93.6 a day, and $25272 per year.
Wyatt et al. (2018)	Exeter Obesity Model – a two stage economic model: predicted adult weight status from participant weight status at follow up (age 11-12 years); then predicted future weight-related health outcomes as a consequence of predicted adult weight, through a Markov model approach. Weight-related health outcomes included were type 2 diabetes, chronic heart disease, stroke and colorectal cancer. Each model cycle was 1 year. Adults entered the model as either healthy weight, with overweight or with obesity (disease free). At each cycle year, adults have a probability of either remaining in an event-free state, develop a weight-related disease state, or death. Each cycle comes with an annual mortality risk for event-free and disease-specific mortality for disease states. Costs for disease states (treatment costs) were applied and inflated/uprated to 2014/2015 where necessary.	**Unit Costs for Health and Social Care** – unit costs for staff inputs **Power et al. 1997** – UK longitudinal study tracking 7 year olds until 33 years; used to predict adult weight status from intervention outcomes. **UK Office for National Statistics** – all-cause mortality risk **Health State values to derive QALYs** obtained from a literature search.

Appendix 8: Adjusted Parameters within Sensitivity Analysis

Parameter	Examples
Intervention implementation costs	• Price substitutions using different data sources (Ladapo et al., 2016). • Increasing or decreasing costs by a set percentage (Rush et al., 2014, Te Velde et al., 2011, Mernagh et al., 2010, Oosterhoff et al., 2020). • Comparator costs varied (Wang et al., 2008). • Teacher wages varied to test intervention implementation at different locations (Wang et al., 2003). • Salary costs (Wyatt et al., 2018, Reilly et al., 2018). • Inclusion of sunk costs (one-off bulk cost for intervention development) (Adab et al., 2018, Conesa et al., 2018, Oosterhoff et al., 2020). • 95% confidence intervals associated with costs used to get lower and upper bounds of economic analysis estimates (Reeves et al., 2021, Coffield et al., 2019).
Opportunity costs	• Included opportunity costs of time taken from parents (e.g. work days lost) (Adab et al., 2018, Wang et al., 2003). • Ratio of school absenteeism/sick leave days days for overweight and obesity vs. normal weight varied +/- 20% (Oosterhoff et al., 2020).
Medical costs	• Medical costs obtained from different source (Wang et al., 2003, Brown et al., 2007, Graziose et al., 2017). • Ratio of healthcare costs for overweight and obesity vs. normal weight varied +/- 20% (Oosterhoff et al., 2020).
Intervention effectiveness parameters (Haby et al., 2006, Kesztyüs et al., 2017, Kesztyus et al., 2013, McAuley et	• Influence of intervention effect (BMI) rate of decay on economic model results (no decay, 5% and 10% after Year 5 of model) (Mernagh et al., 2010). • Treatment effect size reductions of 0% to 10% in one-unit increments (Coffield et al., 2019).

al., 2010, Wyatt et al., 2018, Mernagh et al., 2010, Kenney et al., 2019, Oosterhoff et al., 2020, Coffield et al., 2019, Ekwaru et al., 2017)	• Intervention effectiveness varied by 10% and 20% higher and lower effects on the incidence rate (Kesztyüs et al., 2017). • Intervention effects using 20% higher and lower effectiveness values (Oosterhoff et al., 2020, Kesztyus et al., 2013). • Effect maintenance scenarios (constant effects that decrease after end of exposure; increasing effects during exposure that decrease after; increasing effects) (Oosterhoff et al., 2020). • Intervention effects decline with simulation time (Ekwaru et al., 2017, Graziose et al., 2017, Rush et al., 2014, Te Velde et al., 2011). • More conservative estimates of effectiveness (Kenney et al., 2019).
Intervention benefits	• Values placed on QALYs/DALYs (Graziose et al., 2017, Te Velde et al., 2011, Wang et al., 2003, Oosterhoff et al., 2020).
Intervention benefit reach	• Number of people in the sample to receive intervention benefits (e.g. 50% of children to receive benefits) (Adab et al., 2018, Moodie et al., 2013). • Intervention reach when projecting outcomes reflects intervention uptake in study (Kenney et al., 2019). • Intervention uptake decreased by 5%, 10% and 25% amongst people in 9^{th} and 10^{th} deciles of deprivation (Mernagh et al., 2010). • % population relapse (Graziose et al., 2017). • Intervention only benefits certain demographic groups (Graziose et al., 2017, Oosterhoff et al., 2020).
Discount rate	• Ranged from 0-5% (Ekwaru et al., 2017, Rush et al., 2014, Te Velde et al., 2011, Wang et al., 2003). • Ranged from 0-6% (Graziose et al., 2017, An et al., 2018). • Ranged from 0-10% (Mernagh et al., 2010).

Appendix 9: Description of Draft Problem-Oriented Conceptual Model

The model begins with the provision of the Food Scanner app, which comprises of seven BCTs through which behaviour is shaped. However, the success of the Food Scanner app is highly dependent upon a number of contextual factors.

Contextual factors: Access to a smartphone and the internet, considering the app does not function offline, as well as the availability of app features and the quality, functionality and perceived acceptability of the app are all essential factors that determine app engagement (Matthews et al., 2017). Lieffers et al. (2018) conducted qualitative interviews whereby participants voiced a number of concerns that hindered app use, including slow running, crashes, and freezes. It was suggested that user motivation to change behaviour was essential to effectively use the app, considering app use and adherence required considerable effort. Similarly, Flaherty et al. (2018) had suggested the importance of user motivation and app design as a predictor of app engagement and proposed that both app engagement and app functionality in combination led to app acceptability.

Mediators of change: BCTs and their contextual factors lead to positive behaviour change through mediating factors. User motivation and app use is a bidirectional relationship, whereby each has an effect on the other (West et al., 2017). Through app engagement, users' motivation to reduce child sugar consumption increases, and the components of the app may help improve user self-efficacy to carry out the desired behaviour. In addition, through app engagement parental nutrition knowledge may increase, which could help lead to changes in cognitions when making food choices (Golan and Weizman, 2001). Baranowski et al. (2003) suggested that knowledge is best integrated into a larger conceptual framework, but it within itself is insufficient to lead to behaviour change, except amongst the "right" people. Acquisition of knowledge can help change attitudes and intentions towards a behaviour, dependent upon additional factors such as illness concerns and perceived risk. Baranowski and colleagues further discussed key theories of behaviour change including the Health Belief Model (HBM) and the Theory of Planned Behaviour (TPB). The former postulates that the primary motivation to change behaviour is through a combination of perceived susceptibility and severity (perceived threat) as well as perceived benefits and barriers. In combination with self-efficacy (the belief that one is able to carry out the behaviour) and cues to action (a trigger that prompts behaviour, e.g. components of the Food Scanner app), does the likelihood of engaging in health-promoting behaviour (reduction of sugar consumption) increase (Janz et al., 2002). The latter proposes that behaviour change is through a combination of one's attitude towards, and extent to which they value, behavioural outcomes, subjective norms (perceived social pressure of carrying out that behaviour) and perceived behavioural control (perception of ease or difficulty in carrying out the behaviour). These three constructs in turn predict one's intention to carry out the behaviour, which then predicts behaviour change (Ajzen and Madden, 1986).

Mediators of change consist of app engagement, nutritional knowledge and psychological predictors of behaviour change. Although contextual factors associated with these are mostly relevant to app engagement, sociodemographic factors can moderate the relationship between BCTs and all mediators of change. Menezes et al. (2018) assessed the food environment and its impact on a healthy diet. Location of food store (proximity), type of food store and accessibility (e.g. opening hours) all had an impact on consumers' nutrition environment and consequently nutritional intake. A number of studies had also acknowledged the importance of a user's situation in determining app engagement (Lieffers et al., 2018, Matthews et al., 2017). Parental time availability may facilitate or hinder app engagement, despite the presence of positive psychological predictors. Individual personal characteristics (sociodemographics) may not only determine whether an individual is likely to use an app, but it may also predispose the extent of nutritional knowledge, attitudes and other psychological predictors on behavioural outcomes (Carroll et al., 2017, Davison and Birch, 2001). Cross-sectional research conducted by Parmenter and colleagues found a significant decline in knowledge of dietary recommendations and diet-related diseases with lower educational level and SES (Parmenter et al., 2000).

Intermediate outcomes: Within the model, habit formation, healthiness of home environment and changes in purchased items have been included. Golan and Weizman (2001) noted that purchasing healthy foods helps create an environment within the home for healthy habits, which could lead to changes in child weight status. Similarly, it was also suggested that the formation of healthy habits precedes weight loss and improved health (Matthews et al., 2017). Sisnowski et al. (2017) developed a model depicting assumed pathways from a number of policy interventions to health outcomes. Changes in consumer awareness and nutritional knowledge, where nutritional labelling is concerned, led to changes in purchased items. This would lead to changes in overall nutritional intake through changes in frequency and caloric value of purchases. The environment or context in which individuals live may affect behaviour. It was suggested that availability, affordability and attractiveness of healthy foods in comparison to energy-dense foods determined dietary intake (Baranowski et al., 2003). Similarly, Menezes et al. (2018) found that better access to healthy foods was positively associated with F&V intake, even whilst accounting for individual-level characteristics such as income and self-efficacy. Learned food preferences or existing habits are found to act as barriers to adopting new health behaviours (Schwartz et al., 2017) and one's eating context, such as national festivities (Schoeller, 2014) may also act as barriers to intermediate outcomes (Lieffers et al., 2018).

Intermediate outcomes lead to behaviour change outcomes. This has been conceptualised in a multi-step process whereby intermediate outcomes first lead to reduction in sugar consumption. However, whether this successfully leads to a reduction in energy intake may be determined by compensatory behaviours involving consumption of alternative foods (Sisnowski et al., 2017, Schwartz et al., 2017). Successful reduction in energy intake is then thought to simultaneously impact on body weight, though this may be more likely with longer-term follow up, and may also positively impact on health related quality and quantity of life (John et al., 2012). Though the literature has suggested that energy intake and HRQoL to be a bi-directional relationship (Cameron et al., 2012), this is outside the boundaries of the model and has not been included. Excess body weight could lead to changes in diet-related disease incidence (Sisnowski et al., 2017) and both of these factors can directly impact on QALYs. However, as discussed in Chapter 4, a measurement of QALYs through the use of preference-based measures may not be suitable for younger children, as they generally would not be facing diet-related detrimental health conditions, as these manifest later in life. As such, there may be a delay in the observation of any health benefits. Alongside the Food Scanner app, there may be other public health policies that may affect people's food choices and subsequent health outcomes (Sisnowski et al., 2017, Matthews et al., 2017). However, if baseline data is obtained along with the assumption that no new regulations are introduced after baseline, existence of other policies should not interfere with study results. However, there may be interactions between existing policies and intervention components of the Food Scanner app. For instance, the implementation of a sugar tax may decrease the likelihood of a parent purchasing a SSB for their child; however seeing that the SSB has a high sugar cube content may strengthen this association. In addition, school policies may be enablers or barriers to a healthy diet and energy intake, where parents have lesser control over what their children eat should they opt for school-lunches (Schwartz et al., 2017). Despite the above, it is not atypical for models to rely to some extent on an assumption that variable exposures (e.g. context) in the past are reasonable predictors of the future.

Appendix 10: An Overview of Themes and Codes Emerging from Stakeholder Discussions alongside Supporting Evidence

Theme	Code	Example
Objective 1: What is the role of apps within interventions?		
Understanding what is meant by digital app-based intervention	• Defining digital intervention • Defining complexity • Defining digital • Evolving digital health interventions • Dietary apps as interventions • Terminology • App content	"So, I guess I would see an intervention, aside from the app thing, as something that disrupts our influences and natural kind of, someone's natural or current behaviour. So, an app could be an intervention or a kind of state, you know, kind of putting out social norm statements could be an intervention and maybe it's on a sliding scale where some of those are quite simple and then they get more complex as you add in more components." (P4) "It's something that you, you want it to intervene so it has, you know, you're expecting something to change as a result of it. It's focused on health, so it's reasonable to expect health outcomes which comes on to your evaluation question. And it's using digital technology." (P10)
Reflections around the Food Scanner app	• How app works • App shortcomings • App improvements • App purpose • Timeframe	"So, if you have an app, so say this, the food scanner is, is the aim of the app that people just constantly, every single time, for the rest of their lives, when they go to the shops they have to scan it to get an idea of the sugar? Or is it, say, they use it for about a month and by doing that for about a month they get a much clearer idea about how much sugar is in

		different types of food [mhm]? And if they then have that knowledge, they no longer need to be using the app." (P11) "Yeah, so changes in dietary behaviour I suppose to your point is it that, that the shops that are covered the, the items of food that are covered in the app versus the items that are covered outside of the app. Cos we know that this audience eats out quite often that's a major contributor and this app is not affecting that, well not directly affecting it but arguably because of the shift in mind-set or attitude towards healthy, healthy eating might indirectly affect it." (P5)
App within a wider context	• App within complex system • App content interaction • Evaluating complex intervention components separately • Exposure to intervention complexity on outcomes • Understanding the role of an app within complex intervention	"Yeah, I think I'd agree with, with food scanner apps they are useful, they're informative and they work for some purpose but if, in the greater sense, say healthier choices aren't made cheaper or promotions are more on your healthier foods than your unhealthier foods, then someone could scan something see a product that's healthier but if that is more expensive and they don't have those funds, they're not gonna make that change. So, I think yes, it's, it can be useful as an independent intervention whether it's effective as an independent intervention I, I don't know. I think it is, it has to be part of, it's always with obesity, has to be part of a wider, a larger thing yeah." (P4)

		"So I think, you know, if you think of the Change4Life as 1 enormous intervention, you need to look at the effectiveness of each of the individual components, whether that's the broad mass media campaign about Change4Life or like, as a whole, the Change4Life app for physical activity, the Change4Life app for dietary assessment. So I think its, there's no one way to do it, it's not like do all of it or just do this [yep], I think you sort of need to do both [mm]" (P11)
App reaching the public	• Credible app promotion • Awareness of credible apps • Raising awareness*	"so, obviously you're aware of the one you apps, right [yeah] and the NHS apps library so I think there's also erm, a lot more research, ongoing at the moment in terms of how to better, sort of funnel people towards evidence-based apps and not really rely on commercial app stores" (P12) "I think short-term is raising awareness of the issue of obesity… It brought the topic of childhood obesity to the, to the forefront of the national conversation. So that's very short-term obviously the longer-term is policy change, the short-term is kicking off that conversation." (P5)
Objective 2: Describe the pathways by which dietary apps may impact on dietary intake and childhood obesity prevention		
Behaviour change techniques	• Impact of behaviour change techniques	"So, you kinda expect, ideally, overtime people would stop using it, but what you're trying to capture is that they've stopped using it because they've changed their behaviour,

	• Behaviour change technique analysis • Exposure to behaviour change techniques • Discontinued app use due to behaviour change*	not that they've stopped using it because they got bored with it" (P3) "And I mean what you want to do is, not only find out how many BCTs there are, but whether the extent of which what's present agrees with what has been shown to be effective." (P10)
Factors impacting app uptake	• Consequences of ill health • Health and appearance consequences • Obesity cause as motivation • Inapplicability of app to self • Commercial influences • User characteristics • App credibility • App maintenance impacts uptake	"… if you don't believe your weight to be an issue, you don't believe your child's weight to be an issue, you see all these great campaigns, you know that there's this app out there but that, that's not a problem for us [yeah] so why would I need to engage with that [mhm]…" (P11) "big players like Google and Apple, they've carefully designed their algorithms and carefully designed their, erm, portals to make sure it focuses on the things that they care about" (P12)
Factors impacting app effectiveness-usefulness	• App publicity on user engagement • App qualities impacting on engagement • Reasons for discontinued app use	"if you just look at the average user, or the median user, is gonna have disengaged within the first week [mhm] but then there's always a bunch of power users who are still using the app 1 year later… so I think that probably says more about those individuals rather than the intervention itself" (P12)

	• App use duration • App uptake • App engagement*	"I suppose some of that affect is gonna be if the people that download the app are already the kind of people that health conscious, your effectiveness might be limited because you're already kind of, the person, you know, bit more aware of it and perhaps those that are less aware maybe less likely to download" (P8)
Direct impact of app on psychological and behavioural factors	• Dietary changes* • Unintended consequences* • Food purchasing* • Habit formation* • Sugar consumption* • Behaviour change* • Impact of intervention on confidence in consuming healthy food* • Weight and Nutrition knowledge* • Maintenance of intervention effects**	"So, it is the purchases that's important, because one of the things you going to want to do is find out why if, if it has no impact which is my overwhelming expectation, we're going to want to find out at what point it's failing to work (yeah). So, is it not working because nobody uses it or, is it not working because they use it but it doesn't change what they buy. Or is it not working because they use it, they do buy different food, but they don't change the eating habits. So, the slightly healthier food goes in the bin and they just have to go back and buy additional, traditional foods." (P10) "you want to be able to say if they've stopped are they still, have the behaviour still changed or does stopping indicate that they have started buying chocolate? And so it, to move on to the childhood outcomes adolescent you need confidence in that it actually changed a habit, it actually maintained a change." (P3)
Health outcomes	• Health problems**	"So sort of, based on what is known in the literature of sort of, again, I suppose it's that proximal, distal kind of [mhm], the immediate

	• Dental problems** • Quality of life**	health behaviour change thing that you're expecting the intervention to have an effect on, whether that's the amount of sugar consumed, say, and then you say, OK, well, if we hope the amount of sugar that they've consumed has changed, the reason we care about that is because that will then impact on, whether it's their weight or their, I don't know, like cholesterol, but you know like other health related things [mhm] and then further down the line in 20 years, does that mean that there's going to be less people going to hospital [yeah] related to osteoarthritis [yep].” (P2) “We added to ours dental problems, cos it’s a health outcome that’s very relevant in childhood. Connections very strong so there’s evidence.” (P2) “Yes, absolutely. So, that’s why I would put, that’s why I’ve put child and parent, well quality of life in general, I’ve said generic as well as condition specific in essential because if the things making everybody in the household miserable, there’s absolutely no way it’s gonna be having any positive behavioural affect in the long-term.” (P6)
Impacts of app on the whole family	• Family unit • Parent to child behaviour change • Shared intervention	“it’s very unlikely that you’re going to get successful weight loss in a child, without the whole family changing their dietary behaviours” (P10)

	• Healthiness of home environment	"I think the age group is quite important as well because obviously from the reading I did is it 4 to 11 year olds that you're looking at (yeah), 4 year olds aren't gonna be using an app, it will be based on the carers using the app and then applying the information from the app to the household which can be an "n" of more than one child. So, obviously it can directly affect the family, the children, you know, it has wide reaching kind of implications I guess." (P3)
Wider/indirect app benefits	• Physical activity* • Policy change** • Product reformulation** • Product sales • Generational effect** • Wider app benefits** • Inequalities**	"I think short-term is raising awareness of the issue of obesity… the longer-term is policy change, the short-term is kicking off that conversation." (P5) "An alternative that we mentioned earlier was looking at the receipts of shopping, like key shopping cos they might swap snacks, for example, but at the start be like more high sugar snacks, towards the end and I guess that could be more attributed more towards using the app if there's a change within those three months compared to the sales" (P1)
Contextual factors impacting app effectiveness	• Biological factors • Social network • Stress consequences • Cooking skills • Affordability impacts on diet • Inconsistent health messages	"Stress' impact on decision-making is, is, is quite profound so, and particularly with this because it's impulse control, it's also about taking in novel information. If you're high stress, you're less likely to change your habits." (P5) "the whole problem about a lot of this work is that it emphasises individual responsibility

		and negates social responsibility, or socio political responsibility." (P10)

Objective 4: Describe the current resource pathways as a result of dietary apps (Development perspective; user perspective; healthcare perspective; societal perspective)

Stages of app development and maintenance	• App promotion • App ownership • App maintenance requirements • User-centred design	"Yeah, so you know that if you want to, if you want any digital health intervention to be used you need to have a very strong sense of what the user requirements are and then has to be co-designed with the end-user" (P10) "Something that I think a lot of people don't consider when developing an app, they think about the costs in the short-term so develop the app… But they haven't costed for what it will, you know, if there's an IOS software update or Google, you know, android update, that can have knock-on effects on the app." (P11)
App-related costs	• App maintenance costs • App development costs • App costs in comparison to other services • Opportunity costs • Marketing costs	"Well, one of the problems with health economic analyses of digital health interventions is that nobody's quite sure of the costs are. Because, should you be including the cost of the app development or not? On the whole, I've argued that you shouldn't because it's a sunk cost and if you think of it like Pharma, the Pharma companies recoup their develop, research and development costs through the sale price of the product… But, it's important not to see apps as cost, as, as having zero cost, because effective development is quite costly." (P10)

		"I suppose on app cost, so we have the discovery which is doing research on to what you should build, then you have dev which is actually building. So, you typically have one agency to do the discovery that would be basically understanding user needs and user stories and then you build the app to fit those needs. So, there's discovery, then you have dev, development, then you have user testing and then you'll have maintenance, you know, discovery, sorry development and user testing are obviously intertwined, well hopefully" (P5)
User costs	• Cognitive cost • Food costs • Compensation • Food wastage • Happiness • Indirect costs	"There was, we talked about like a cognitive cost, like it's potentially if you're gonna get this app out every time you're going to buy a snack or whatever." (P4) "But, potentially there's an environmental cost around food wastage, especially if you, so if you swap for something that the child then doesn't want to eat, you've got more waste." (P6)
Societal costs	• Productivity costs • Food sector costs • Societal costs • Under resourced app consequences	"There was, we had a quick chat around parental productivity… if it increases awareness and you go to the dentist more often, then parents might have to take time off work and things like that." (P4) "And maybe there's an impact, a cost to certain producers that make high sugar content

		food that over time they have less profit, which may lead to more marketing…" (P4)
Impact of app on health and healthcare utilisation	• Patient empowerment • Public health service demand • Importance of clinical outcomes • Weight and BMI* • Child healthcare resource use* • Quality of life** • Health outcomes** • Healthcare resource use** • Healthcare costs**	"Is there, just thinking of others, is there something, I think it's probably bit of a long shot actually, but is there something around increasing demand for services? Because if, if I think it is probably unlikely from an app, but if you're making parents more aware of their child's weight and their child's diet, could it lead to increase demand for support from public health services?" (P4) "So, can I just put something across, if thinking about clinical effectiveness, if weight and height isn't measured, if, if an app changes behaviour but there is no clinical data to demonstrate that it, it moves people from unhealthy weight to healthy weight. How well received will that be and take, in terms of clinicians promoting it, take-up, you know, where's the data to support the fact that this is app is doing something beyond behaviour change?" (P6)
Objective 5: Explore key factors to consider within an economic evaluation of a dietary digital intervention		
Considerations for economic evaluation	• Health economic evaluation perspective • Cost-effectiveness comparison • Limitations in guidance	"I would've, probably also say that any sort of promotional stuff could be offset [mhm] so that could be something that if, you know, if you could massively increase uptake by only a little bit of promotional [yeah] activity, maybe that, you know, should be [mhm] there as well." (P12)

	• Factors to include in economic model • Factors to model forward from • Importance of economic models • Economic evaluation of DHI • Factors not to include in economic model • Economic modelling of weight outcomes	“So, the, it would be really good to have child quality of life, it’s just I don’t, I don’t think, I don’t think you need it to say that the app works to impact on BMI. It depends what you’re trying to say what the app does.” (P4)
Consideration by population group of interest	• Intervention effects by subgroups • Target population	“I think you don't want to be looking at subgroups where your intervention's just been developed for the general popula-, you know [mhm] anybody… or done usability testing with people across sort of, that spectrum…” (P11) “4 year olds aren’t gonna be using an app, it will be based on the carers using the app and then applying the information from the app to the household which can be an “n” of more than one child. So, obviously it can directly affect the family, the children, you know, it has wide reaching kind of implications I guess.” (P3)

Outcomes of Objective 3: Priority outcomes for evaluation of a dietary digital intervention are integrated within the table through the use of asterisks:
*Short-term factors to capture from a dietary app
**Long-term factors we want to capture from a dietary app

***Key priority outcomes

Appendix 11: PPI Discussion Schedule and Outcomes

Topic	Questions	Responses
Participation interest	• Given the tasks involved (and the time involved in completing them), would a parent be willing to participate? • How much would participants be willing to do within the tasks outlined? • Are there any ideas on acceptable ways to prevent drop out?	• Parents need to know the limit for child sugar cube consumption. • There is confusion around what your child should and should not have – a lot of mixed messages. • Schools are trying to be more proactively healthy and may welcome information and advice. • Usually you will find that those who are interested in healthy diets will be more keen to participate. Those who are not will likely have a lot of missing or inaccurate data. • In order to draw participants in you need to play on parents' concerns, e.g. "are you concerned about your child's sugar consumption? Would you like to participate in a study that…"
Incentives	• What incentives might best engage parents? • Would financial incentives be seen as something attractive? • In what way should they be received? • How much should I offer to parents that would make the best	• Considering this is an intervention focused on healthy eating behaviours, the reward should be pro-health. • Giving shopping vouchers is very common; it can be spent carelessly without much thought or spent on unhealthy foods and snacks. • Consider giving a reward to both the parent and the child so that participation is seen as attractive to both.

	difference in their participation?	• "Experience" vouchers are seen as attractive to parents – it can count as a fun day out for the child for something that they may not usually be able to afford, and it promotes physical activity, e.g. trampolining, ice skating, bowling. • Potentially offer them a choice between different experiences.
Height and weight measurements	• If someone told you, you'd have to make a visit to the university with your child to get height and weight measurements done, would this affect you participating in the study? • Would you be accepting of someone to visit you at home to take these measurements (including evenings and weekends)?	• Schools are usually keen to get involved in initiatives revolving obesity prevention; they may be on board to take measurements on your behalf (this suggestion was later dismissed due to ethics implications and matters of confidentiality). • Self-reported height and weight measurement outcomes should not be considered as parents have a tendency to either not know their child's height and weight or likely underestimate this. • Giving the option of both home visit and university visit is more attractive than having only one option.
Survey questions	• I have a subset of potential survey questions that I may use in my final survey, and I wanted to get your opinion on these questions, specifically whether you thought:	• Respondents found all questions suitable to ask. • Not all questions were deemed easy to understand. PPI provided suggestions for how questions should be worded to ease comprehension. • Parents' knowledge should be tested through some open ended questions, e.g.

	• Is this question easy to understand? • Is this question suitable to ask? • Is it appropriate to ask for someone's household income?	rather than "do you know what the daily recommended sugar intake for children is?" (yes/no), should ask, "What is the daily recommended sugar intake for children?" (open ended response with "don't know" option). • Household income is a standard question in surveys. People will answer it if you make it multiple choice with suggested pay bands.

Appendix 12: Participant Information Sheet

1. Research Project Title:

What do parents think about dietary online programmes?

2. Invitation paragraph

You are being invited to take part in a research project. Before you decide whether or not to participate, it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part.

3. What is the project's purpose?

There are now many tools available online and on the mobile app market that can help people with their family's diet. The aim of this study is to gather information on what parents think about different dietary tracking tools, gain insight into their acceptability and feedback on user experience over a three-month period.

4. Why have I been chosen?

We are asking parents of children aged 4-11 years to take part in this study. As we want to get a better understanding of parental attitudes towards dietary digital tools, we will be recruiting around 150 parents from all over Yorkshire and the Humber.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to complete an online consent form) but you can still withdraw at any time without any negative consequences. If you wish to withdraw from the research, please contact Ms. Sundus Mahdi (smahdi1@sheffield.ac.uk), or there will be an option to do so on the surveys that you are sent. Please note that whilst you can withdraw from any on-going or future participation and data collection over the three-month study period, it will not be possible to get rid of any data that has already been collected from you after July 2020. Once the study comes to an end, your data will be anonymised (all personal and identifiable information about you is removed) and placed in a large dataset along with other participants. If you choose to withdraw from the study or decide to no longer complete the surveys that are sent to you, you may be sent an email from us asking for reasons why. You do not have to reply to this email or give a reason if you do not want to. Collecting information on why people decide to no longer participate in our research will help us improve it in the future.

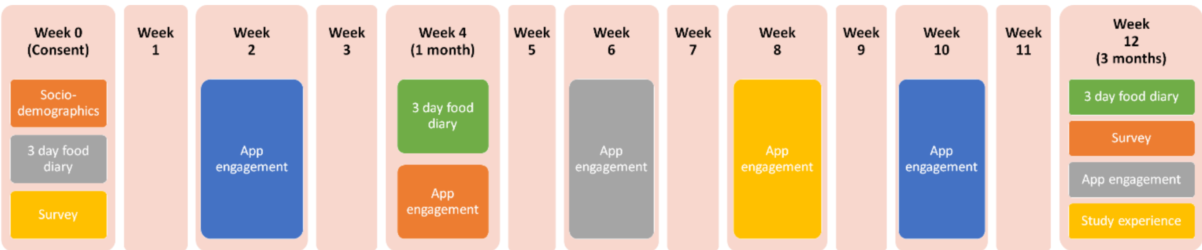
6. What will happen to me if I take part? What do I have to do?

Should you decide to participate in this research, we will ask you to complete tasks over a three-month period. Before agreeing to take part, you will be asked some questions to check that you are eligible to participate in this research. If you are eligible and you have agreed to take part, you will be taken to a page where you will be asked questions about yourself and your child such as questions on height, weight, ethnicity, education and income. You will then be asked for your email address and contact number so that we can send you study material.

Once you have provided us with your email address and contact number, we will contact you within 48 hours and ask you to complete a 3-day food diary and a survey throughout the next week. Food diaries will be completed on a website called MyFood24. You will be sent a special link to this with further instructions on how to complete the food diary. A food diary requires you to write everything your child ate and drank on a specific day. We will ask you to complete a food diary on two weekdays and one weekend day of your choosing, but these must all be within the same week (within a 7-day period). After completion, you will be notified of your food diary submission, and will be reminded of your next task. After completing the food diaries, you will then be asked to complete a survey. Most survey questions will give you a selection of answers to choose from and will ask you questions around the topics of food and nutrition, quality of life and use of healthcare services. There may be some open-ended questions where you will be asked to write your response. There are no right or wrong answers. We are interested in knowing what you think about the questions being asked. A food diary takes approximately 20 minutes to complete, and the survey takes approximately 15-20 minutes to complete, but this can vary.

Some participants will be randomly selected to download and use some dietary mobile apps when making food choices for their child. This is a requirement for continued participation. The apps have been designed to provide dietary advice. We are interested in getting your opinion about these apps. You will be contacted every two weeks throughout the 3-month study period to answer additional questions on your use of the apps as well as your feedback and experience of using them. For this reason, it is essential that all participants have access to a smartphone and mobile data. If you are not asked to download and use a mobile app, you are still expected to complete food diaries and survey material when requested.

One-month and 3-months into the study, all participants will be asked to complete an online 3-day food diary again. There will also be survey questions for you to complete. Some of them will be familiar, and some will be different to what you have already answered. You will also be asked to provide your feedback on the use of Myfood24 and completing food diaries in general. Please see the figure below for a timeline of activities.



All communication will be made through e-mail and text message. You will be sent the links to the food diaries and surveys by email and will be asked to start completing these within a week of receiving them. You will need to follow the unique links sent to you to complete food diaries and/or surveys. For this reason, it is important that you check your emails regularly, including your junk folder.

After you have completed the 3-month study period, you will be asked for your home address. Your home address is needed so we can send you a thank you reward. All participants will be rewarded with at least a £30 gift voucher and will be entered into a prize draw for every food diary submitted, for a chance to win a Virgin Experience Days gift card worth £150.

Am I able to take part?

In order to be eligible to participate, you must be:

- A parent of primary school child, aged 4-11 years old
- Living in Yorkshire and the Humber
- Own a smartphone (e.g. iPhone or Android phone)
- Have enough data storage (at least 100mb) on your smartphone to download required mobile apps
- Have access to the internet on a smartphone when outside the home
- Have access to the internet inside and outside the home
- Available to participate in the study and complete a number of food diaries and short surveys over a three month period
- Willing to complete survey questions throughout the duration of the study when prompted.
- An active grocery shopper for the household *or* involved in decisions over children's food.
- Grocery shopping is dominantly undertaken in a grocery store` and not online.

Please be aware that if you have more than one child between the ages of 4-11 years, you only have to collect data from one child.

7. What are the possible disadvantages and risks of taking part?

It is very unlikely that the study will cause you any distress as all study tasks will be carried out online, in your own comfort. You may find that the survey questions may be tiring to complete, however we have tried to keep these as short as possible. If you do experience any distress during the study, please contact the lead researcher, Ms Sundus Mahdi (smahdi1@sheffield.ac.uk). If any distress continues after taking part in the study please contact your GP or visit the NHS Wellness pages: https://www.nhs.uk/conditions/stress-anxiety-depression/improve-mental-wellbeing/

8. What are the possible benefits of taking part?

As a thank you for your 3-month participation, all individuals participating in this research will be rewarded with a £30 multi-use gift voucher. Those who have randomly been selected to download and use some mobile apps will receive an additional £5 gift voucher for their time. All participants will also be entered into a prize draw for a chance to win a Virgin Experience Days gift card worth £150, which provides you with a selection of adventures to choose from to suit you and your family's needs. Should you decide you no longer wish to participate in this study, you may be asked to complete a short online form, anonymously, providing reasons for your withdrawal. As a thank you for your time, you will be entered into a prize draw for a chance to win a £25 Love2Shop voucher.

9. Will my responses in this project be kept confidential?

Please note that any information you enter will be stored and processed using services provided by Qualtrics. These services have been the subject of independent assessment to ensure compliance with applicable data security standards. Further information can be found on the Qualtrics website (https://www.qualtrics.com/security-statement/).

Myfood24 is a third-party website and is separate to the University of Sheffield. They may use your aggregated and anonymised food diary data for their administrative purposes as well as any ongoing development and improvement of myfood24. No personal data identifying you shall be kept. Further information can be found on the myfood24 website (*https://cdn2.hubspot.net/hubfs/4571479/myfood24_June2019%20Theme/PDF/da_ltd_privacy_notice_7.0.pdf*).

During the trial the research team will have access to identifying information (e.g. email address). This will only be used for contact purposes and will not be linked with any responses to the study questionnaires. This information will be destroyed as soon as you complete the study. You will not be identifiable in any reports or publications unless you have given your explicit consent for this. If you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included. Any information provided to us by you which may risk your anonymity (email address, contact number and home address) will be deleted after study completion.

10. What is the legal basis for processing my personal data?

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

As we will be collecting some data that is defined in the legislation as more sensitive (information about ethnic origin), we also need to let you know that we are applying the following condition in law: that the use of your data is 'necessary for scientific or historical research purposes.

11. What will happen to the data collected, and the results of the research project?

Due to the nature of this research it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will ask for your explicit consent for your data to be shared in this way. In all cases, data will be anonymised after the research study comes to an end. This means that no one will know that the data came from you, or that you have taken part in this research. Once this research is complete and you have received your thank you vouchers, we will destroy any identifiable personal data that you have shared with us. We hope to present the findings of this research at conferences within a year of data collection and write up the results for publication within 3 years. If you are interested in receiving a copy of any published work that comes out of this study, please let the lead researcher know. Research data collected will be stored for at least 10 years after publication in ORDA (Online Research Data). This is a facility for storing University of Sheffield research data.

12. Who is organising and funding the research?

School of Health and Related Research, University of Sheffield, through a Wellcome Trust PhD studentship.

13. Who is the Data Controller?

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

14. Who has ethically reviewed the project?

This project has been ethically approved via the University of Sheffield's Ethics Review Procedure, as administered by the School of Health and Related Research.

15. What if something goes wrong and I wish to complain about the research?

We hope that you have a positive experience when participating in this research. However, if for whatever reason you wish to complain about any unpleasant experiences or any of the research procedures, please do not hesitate to contact the supervisors of this research (Dr Nicola Buckland, n.buckland@sheffield.ac.uk or Prof Jim Chilcott, j.b.chilcott@sheffield.ac.uk).

Should you feel that your complaint has not been handled to your satisfaction, you can contact the Head of Department (Prof John Brazier; j.e.brazier@sheffield.ac.uk), who will then escalate your complaint through the appropriate channels.

If your complaint relates to how your personal data has been handled, you can raise a complaint to the University of Sheffield's Data Protection Officer, Anne Cutler (dataprotection@sheffield.ac.uk). If you are not satisfied with how your complaint has been handled, you may then escalate the matter to the Information Commission Office (https://ico.org.uk/make-a-complaint/). Further information on the University's Privacy Notice can be found here: https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

16. Contact for further information

Lead researcher: Ms Sundus Mahdi; email: smahdi1@sheffield.ac.uk; office number: 0114 2226389; mobile number: 07426789290.

Supervisors: Dr Nicola Buckland, email: n.buckland@sheffield.ac.uk, office number: 0114 2226508;
Prof Jim Chilcott, email: j.b.chilcott@sheffield.ac.uk, office number: 0114 2220689

Finally …

Upon consenting to participate in this study, the researcher will email you your own personal copy of this information sheet and consent form.

Appendix 13: Intervention Exposure

Please read the following text to the end, have your mobile ready and follow the instructions presented.

SUGAR!

Kids are having 2 times more sugar than they should!

Be sugar smart!

Kids are getting half their sugar intake from unhealthy snacks and sugary drinks. It's time for some food smart choices!

Kids are getting a LOT of their sugar from...

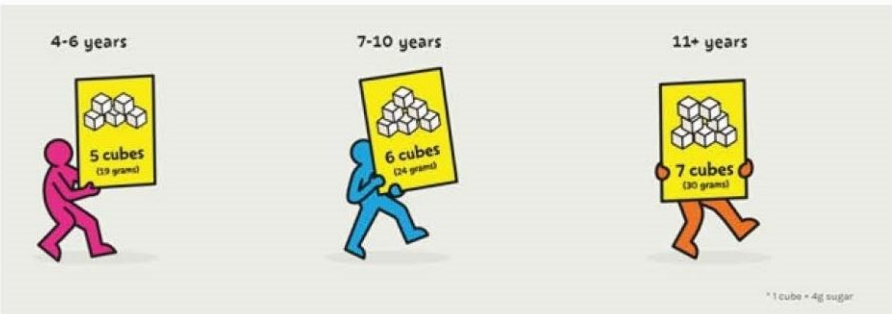
How sugar affects our kids

Too much sugar is bad for children's health as it can lead to the build-up of harmful fat on the inside that we can't see. This fat can cause weight gain and serious diseases like type 2 diabetes, which people are getting younger than ever before, and heart disease and some cancers.

How much is too much?

When we talk about added sugar, we mean sugar that has been added to food and drink to sweeten it. It could be added by the food manufacturer, by a cook or chef, or by you at home. It doesn't just mean the sugar you add to your tea – it also includes honey, syrups, fruit juice and nectars.

The maximum daily amounts of added sugar are:



You have a task!

How can I cut down on my child's sugar intake?

Get the FREE Food Scanner app!

To continue with this study, please go on your mobile app market/store and search for "Change4Life Food Scanner".

Install the app.

Scan barcodes using the app to find out what's inside popular food and drink.

The Food Scanner app will show you the amount of sugar cubes, saturated fat, salt and calories inside popular food and drink.

The app has other great features too. You'll find loads of simple hints and tips to help you make healthier choices

The Food Scanner app will also show you traffic light coloured labels. Choose more greens and ambers, and fewer reds.

Be a sugar smart shopper!

At the supermarket, look out for sugar-free and lower-sugar versions of your family favourites.

Use the Food Scanner app to help you make healthier choices!

Make a swap when you next shop!

Make sure you check your emails regularly for questions on your progress.

Get scanning!

Appendix 14: Food Scanner App Survey Questions

Question	Answers
BASELINE – *ALL PARTICIPANTS*	
Psychological predictors: Attitudes*	
How important is it for you that your family eat a healthy diet? ‡	Extremely important/ Very important/ Moderately important/ Slightly important/ Not at all important
Please rate how much you agree with the following statements: 1. Having too much sugar leads to disease (West et al., 2017) 2. When buying food, snacks or drinks for my child, it is important to pay attention to the amount of sugar it contains (Chien et al., 2018) 3. For my child to be healthy, I need to be careful how much *saturated fat* my child eats‡ 4. For my child to be healthy, I need to be careful how much *sugar* my child eats‡ 5. For my child to be healthy, I need to be careful how many *calories* my child eats‡	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree
Psychological predictors: Perception of eating habits	

How healthy do you think your child's diet is? (Neal et al., 2017)	Very unhealthy/ Somewhat unhealthy/ Normal/ Somewhat healthy/ Very healthy
How much do you agree with the following statement: "I should improve my child's eating habits" (Kakinami et al., 2016)	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree
Psychological predictors: Perceived Behavioural Control*	
How much control do you have over your child's sugar consumption? (Povey et al., 2000)	Almost total control/ A lot of control/ Moderate control/ A little bit of control/ No control at all
Psychological predictors: Perceived weight status	
How would you describe your child's weight status? ‡	Underweight/ Healthy weight/ Overweight/ Obese
COM-B MODEL	
Psychological predictors: Physical capability	
The Government's recommended daily guidelines for child sugar intake is: 4-6 years: 19 grams 7-10 years: 24 grams 11+ years: 30 grams *for reference, a standard 330ml can of coca cola contains 35g sugar	

How often, if at all, do you keep track of how much sugar your child eats or drinks each day?* (Stevely et al., 2018)	Always/ Most of the time/ About half the time/ Sometimes/ Never
Psychological predictors: Psychological capability	
“Too much sugar intake for my child increases their risk of obesity”* (Chien et al., 2018)	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree
“Nutritional labels are hard to understand” † (Méjean et al. (2013)	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree/ I did not know there was a nutritional food label
How easy or difficult do you find it to limit your child's sugar intake to the amounts recommended in the above guidelines?* (Stevely et al., 2018)	Extremely easy/ Somewhat easy/ Neither easy nor difficult/ Somewhat difficult/ Extremely difficult/ I don’t know how much sugar my child consumes
How much do you think you know about making healthy food choices? †‡	A great deal/ A lot/ A moderate amount/ A little/ None at all

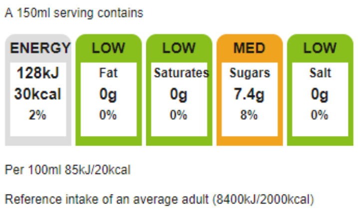
Psychological predictors: Capability (knowledge)

What do you think is the daily-recommended sugar intake for your child's age, in grams?* (Stevely et al., 2018)

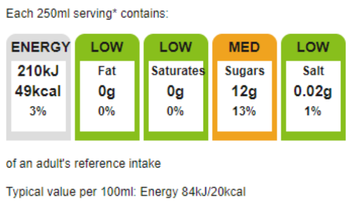
Open ended response
Not sure

These are nutritional labels taken from real drinks. Which of these two options has less sugar? Please consider all information provided. ‡

Option A/ Option B/ Not sure



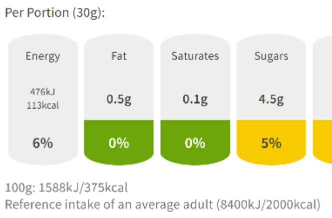
OPTION A



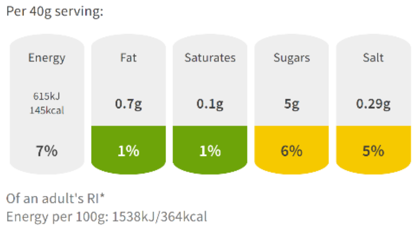
OPTION B

These are nutritional labels taken from real cereals. If you want to have 100g of this cereal, which of these two options has less sugar? Please consider all information provided. ‡

Option A/ Option B/ The same/ Not sure



OPTION A



OPTION B

This is a nutritional label taken from a popular chocolate bar available in most supermarkets. Approximately how many sugar cubes do you think are in this chocolate bar based on the information provided? ‡

Options from 1-10

Not sure

Nutritional Values

Typical values	/ 100g	/ 23g (%*)
Energy	2072kJ	477kJ (6%)
	495kcal	114kcal (6%)
Fat	23.9g	5.5g (8%)
of which saturates	13.9g	3.2g (16%)
Carbohydrate	64.6g	14.9g (6%)
of which sugars	48.8g	11.2g (12%)
Protein	4.5g	1.0g (2%)
Salt	0.44g	0.10g (2%)
*Reference intake of an average adult (8 400 kJ/2 000 kcal)		

Psychological predictors: Social opportunity (Stevely et al., 2018)

How easy or difficult do you think your lifestyle makes it for you to limit your child's sugar intake to the above guidelines, a day?*	Extremely easy/ Somewhat easy/ Neither easy nor difficult/ Somewhat difficult/ Extremely difficult

Psychological predictors: Automatic motivation (Stevely et al., 2018)

How concerned, if at all, are you about your child consuming more sugar than what is recommended?*	Extremely/ Very/ Moderately/ Slightly/ Not at all
To what extent do you <u>want to keep</u> your child's sugar consumption within recommended guidelines?*	Extremely/ Very/ Moderately/ Slightly/ Not at all

Psychological predictors: Reflective motivation	
To what extent do you intend to keep your child's sugar consumption within recommended guidelines?* (Stevely et al., 2018)	Definitely yes/ Probably yes/ Might or might not/ Probably not/ Definitely not
To what extent are you actively trying to reduce your child's sugar intake?* (Stevely et al., 2018)	Always/ Most of the time/ Sometimes/ Rarely/ Never
Food labels, also called nutrition labels, show how much sugar, saturated fat and salt are inside what we are buying. Food labels can be found on most food and drink, usually on the front of the pack.	
Do you look at food labels when buying food? ‡	Always/ Most of the time/ About half the time/ Sometimes/ Never/ I did not know there was a nutritional food label
Does nutritional information on food labels affect your shopping choices? (Kakinami et al. (2016)	Always/ Most of the time/ About half the time/ Sometimes/ Never
Child Health Utility 9D instrument* (Stevens, 2012)	
These questions ask about how your child is today. For each question, read all the choices and decide which one is most like your child today. Only tick one box for each question.	

Worried	My child doesn't feel worried today/ My child feels a little bit worried today/ My child feels a bit worried today My child feels quite worried today/ My child feels very worried today
Sad	My child doesn't feel sad today/ My child feels a little bit sad today/ My child feels a bit sad today/ My child feels quite sad today/ My child feels very sad today
Pain	My child doesn't have any pain today/ My child has a little bit of pain today/ My child has a bit of pain today/ My child has quite a lot of pain today/ My child has a lot of pain today
Tired	My child doesn't feel tired today/ My child feels a little bit tired today/ My child feels a bit tired today/ My child feels quite tired today/ My child feels very tired today

Annoyed	My child doesn't feel annoyed today/ My child feels a little bit annoyed today/ My child feels a bit annoyed today/ My child feels quite annoyed today/ My child feels very annoyed today
School work/homework (such as reading, writing, doing lessons)	My child has no problems with their schoolwork/homework today/ My child has a few problems with their schoolwork/homework today/ My child has some problems with their schoolwork/homework today/ My child has many problems with their schoolwork/homework today/ My child can't do the schoolwork/homework today
Sleep	Last night my child had no problems sleeping/ Last night my child had a few problems sleeping/ Last night my child had some problems sleeping/ Last night my child had many problems sleeping/ Last night my child couldn't sleep at all

Daily routine (things like eating, having a bath/shower, getting dressed)	My child has no problems with their daily routine today/ My child has a few problems with their daily routine today/ My child has some problems with their daily routine today/ My child has many problems with their daily routine today/ My child can't do their daily routine today
Able to join in activities (things like playing out with their friends, doing sports, joining in things)	My child can join in with any activities today/ My child can join in with most activities today/ My child can join in with some activities today/ My child can join in with a few activities today/ My child can join in with no activities today
Healthcare service use* (Cottrell et al., 2018)	
Please complete the following questions about your child's health.	
Has your child used any of the following services in the last 3 months?	
GP (family doctor)	Yes/No
Practice or district nurse	Yes/No
Hospital inpatient stay (staying in hospital overnight)	Yes/No
Hospital outpatient clinic(doctor visits, scans, other health professional)	Yes/No

Hospital accident and emergency department	Yes/No
Non-routine dentist or dental care	Yes/No
Questions repeated for each of the services above:	
What are the total number of times your child used this service?	Open-ended question
What was the total length of time spent per contact (minutes)	Open-ended question
Were you with your child during the visit?	Yes/No
School absenteeism/Workplace productivity* (Powell et al., 2013, Beecham and Knapp, 2001)	
How many full days (or half days) has your child been absent from school because of health problems (e.g. attending hospital or seeing the family doctor) in the last 3 months?	Open-ended question
How many days have you been absent from work in the last 3 months?	Response options: 0-93
Of these, how many are due to your child's health?	Response options: 0-93
Physical activity (Carroll et al., 2017)	
Moderate intensity physical activity causes people to get warmer, breathe harder and their hearts to beat faster.	
In a typical week how many days does your child do any physical activity or exercise of at least moderate intensity, such as brisk walking, bicycling at a regular pace, and swimming at a regular pace?	Daily/ 4-6 times a week/ 2-3 times a week/ Once a week/ Never

On the week days that your child does any physical activity or exercise of at least moderate intensity how long do they do these activities?	_____ hours/ _____minutes
On the weekend days that your child does any physical activity or exercise of at least moderate intensity how long do they do these activities?	_____ hours/ _____minutes

Previous dietary app use‡

Please indicate which of the following apps you have previously used.	MyFitnessPal Nootric Change4Life Food Scanner Lifesum Change4Life Smart Recipes FoodSwitch UK Change4Life Sugar Smart Other, please specify: None

FORTNIGHTLY APP ENGAGEMENT – *APP USERS ONLY* ‡

On how many days in the last 2 weeks did you use the app to help make food choices for your child?	______ days (choices from 0-14)

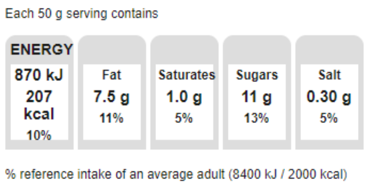
On the days that you used the app, on average how much time (in minutes) did you spend using it? _______ minutes

When using the Food Scanner app, how many items did you scan in the last 2 weeks? You can find a list of the last 20 items scanned through the app. _______

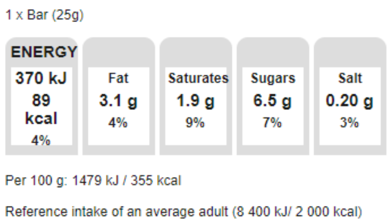
3-MONTH FOLLOW UP – *ALL PARTICIPANTS (in addition to all questions at baseline marked with *)*

Psychological predictors: COM-B model – Capability (knowledge) ‡

These are nutritional labels taken from real breakfast bars. Which of these two options contains less sugar? Please consider all information provided. Option A/ Option B/ The same/ Not sure



OPTION A



OPTION B

This is a nutritional label taken from a popular chocolate flavoured drink available in most supermarkets. Approximately how many sugar cubes do you think are in this chocolate drink based on the information provided?

Options ranging from 1-10
Not sure

Nutritional Values

Typical values	/400ml
Energy	940kJ
	223kcal
Fat	7.5g
of which saturates	5.1g
Carbohydrate	26.6g
of which sugars	24.3g
Protein	11.7g
Salt	0.99g
**Reference intake of an average adult (8400kJ/2000kcal)	

These are nutrition labels taken from real cereals. If you want to have 100g of this cereal, which of these two options has less sugar? Please consider all information provided?

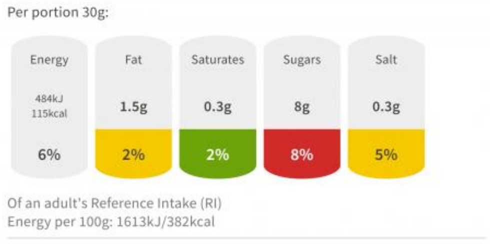
Option A/ Option B/ The Same/ Not sure

Per portion (45g):

Energy	Fat	Saturates	Sugars	Salt
846kJ 201kcal	6.8g	1.4g	12g	0.43g
10%	10%	7%	13%	7%

100g: 1879kJ/447kcal
Reference intake of an average adult (8400kJ/2000kcal)

OPTION A



OPTION B

Psychological predictors: COM-B model – Social opportunity

If you wanted advice or information on how to cut down on your child's sugar consumption, do you know where to go? (Stevely et al., 2018)

Definitely yes/ Probably yes/ Might or might not/ Probably not/ Definitely not

COVID-19 and impact on diet

To what extent do you feel that the lifestyle changes imposed by the Government in relation to the Coronavirus has affected the following:

A great deal/ A lot/ A moderate amount/ A little/ Not at all

Your child's diet

Your ability to make healthier food choices for your child

Your food purchasing behaviour

The types of food you bought

Your participation in this study

"The lifestyle changes imposed by the Government in relation to the Coronavirus led my child to…"

… eat more sugar than they did before … eat more snacks than they did before … eat more fruit and vegetables than they did before … eat more home cooked meals than they did before … be more physically active than they were before	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree
To what extent do you feel that the lifestyle changes imposed by the Government in relation to the Coronavirus (COVID-19) has affected the following, in comparison to before the lockdown: Since the COVID-19 lockdown, I carry out online grocery shopping… Since the COVID-19 lockdown, my children eat take out food… Since the COVID-19 lockdown, I have been purchasing sugary foods or treats/snacks… Since the COVID-19 lockdown, I have been spending on food…	A lot less/ Slightly less/ The same/ Slightly more/ A lot more
Has the Coronavirus outbreak, or any other events, affected your responses or engagement in the trial? If yes, please detail.	Yes/No
External confounders‡	
Has the introduction of the sugar tax led you to buy different drinks for the household?	Always/ Most of the time/ About half the time/ Sometimes/ Never/ Do not know

Has the introduction of the sugar tax reduced your child's sugar intake?	Always/ Most of the time/ About half the time/ Sometimes/ Never/ Do not know
Please indicate how much you agree with this statement: "Existing public health campaigns and messages have helped me improve my child's diet"	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree/ I am not aware of any public health campaigns or messages
How familiar are you with Change4Life?	Extremely familiar/ Very familiar/ Moderately familiar/ Slightly familiar/ Not familiar at all
Do you currently use Change4Life resources?	Always/ Most of the time/ About half the time/ Sometimes/ Never
Are there any other factors that may have had an influence over your child's sugar consumption in the last 3 months? If yes, please specify.	Yes, please specify…. No
Study acceptability and feasibility (Reale et al., 2018)	
To what extent was this study easy to complete?	Extremely easy/ Somewhat easy/ Neither easy nor difficult/ Somewhat difficult/ Extremely difficult

To what extent was participating in this study time consuming/demanding?	A great deal/ A lot/ A moderate amount/ A little/ None at all
Did you find that receiving reminders to complete food diaries and surveys helpful?	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree
Were you able to complete all requested study tasks?	Completed all the tasks/ Completed the majority of the tasks/ Completed a fair amount of the tasks/ Completed very few of the tasks
What prevented you from completing all study tasks?	Open-ended response
Was there anything we could have done to keep you more engaged in completing food diaries and surveys throughout this study? Please explain.	Open-ended response
Food diary acceptability (Buckland et al., 2019)	
How has the food diary affected your child's eating or what you have recorded generally over the past 3 months? I did not report everything my child ate I changed what my child actually ate to make it easier to record	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree

It had no effect on what my child ate	
It was easy to use	
I found it too much work	
Sustainability	
If this study was extended to a 12-month follow-up, would you be willing to continue for 9 more months?	Definitely yes/ Probably yes/ Might or might not/ Probably not/ Definitely not
Do you have any other comments you would like to make about the study?	Open-ended response
3-MONTH FOLLOW UP – ***APP USERS ONLY***	
Psychological predictors: COM-B model – Physical capability	
Think about the nutrition app that you have used in the past 3 months. "Using the app has increased my ability to reduce the number of high sugar snacks that my child eats" (West et al., 2017)	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree
"The Food Scanner app has helped me make healthier food choices for my child" ‡	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree

Psychological predictors: COM-B model – Psychological capability	
How much do you think you know about making healthy food choices after using the Food Scanner app? (Méjean et al., 2013)	A great deal/ A lot/ A moderate amount/ A little/ None at all
With the Food Scanner App, I find nutritional labels hard to understand (Méjean et al., 2013)	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree
App engagement‡ (Méjean et al., 2013)	
Have you noticed any changes or updates in the Food Scanner app, in the past 3 months?	Yes/No
Has the latest Food Scanner app update improved your engagement with the app?	A great deal, a lot, a moderate amount, a little, none at all
App likeability (West et al., 2017)	
The app was helpful The app was easy to use I enjoyed using the app I liked the app I would recommend the app to others	Strongly agree/ Somewhat agree/ Neither agree nor disagree/ Somewhat disagree/ Strongly disagree
App usefulness (Neal et al., 2017)	
Did you use the Food Scanner app at least once throughout this study?	Yes/No

How useful did you find the sugar cube images shown in the app?	Extremely useful/ Very useful/ Moderately useful/ Slightly useful/ Not at all useful
How easy to understand were the sugar cube images shown in the app?	Extremely easy/ Somewhat easy/ Neither easy nor difficult/ Somewhat difficult/ Extremely difficult
How useful would it be to have those sugar cube images printed on food packages, as part of the nutritional label?	Extremely useful/ Very useful/ Moderately useful/ Slightly useful/ Not at all useful
How often did the Food Scanner app help you choose to buy different foods or drinks?	Always/ Most of the time/ About half the time/ Sometimes/ Never
App consequences‡	
Using the food scanner app has led me to spend _____ on groceries	A lot more/ Slightly more/ The same/ Slightly less/ A lot less
App feedback – open ended questions (Lieffers et al., 2018)	
What did you like about the app?	
What did you dislike about the app?	

How can the app be improved to make it more attractive to use (e.g. app features)?	
How can the app be improved to help you use it more often?	
How can the app be improved to help support healthier eating behaviours?	
Did anything prevent you from using the app? Please detail.	
COVID-19 and impact on diet‡	
To what extent do you feel that the lifestyle changes imposed by the Government in relating to the Coronavirus has affected the following:	A great deal/ A lot/ A moderate amount/ A little/ Not at all
Your ability to scan barcodes using the Food Scanner app	
Did the Food Scanner app support you at this time in making healthier food choices?	

*Questions asked at both baseline and follow-up
† Questions asked at both baseline and follow-up for controls only
‡ Question produced by the researcher for the purposes of this study

Appendix 15: Best Practice Guidelines for Dietary Assessment in Health Research

Stage 1. Define what you want to measure in terms of dietary intake.

1	What? – Characteristics of the main dietary component of interest	
1.1	Clearly define what needs to be measured	Nutrient intake over the whole day, at several time points: total energy intake (kcal), sugar (g), salt (g), saturated fat (g) this includes the reporting of both frequently and infrequently consumed foods, snacks, beverages and meals.
1.2	Determine how the dietary data will be analysed and presented	Total daily intakes rather than specific meal time consumptions or snacks only.
2	Who? Considerations around the characteristics of study participants	
2.1	Define the target sample in terms of characteristics	**Age**: 4-11 year olds; measured via parent proxy. Parents may be busy in between work and looking after their child, so low participant burden is necessary if participant retention is to be upheld. **Ethnicity**: All welcome – acknowledge that individuals from different ethnic groups may have different diets. A measurement method that is based on what is available in UK supermarkets is required. **BMI**: As this study is focused on prevention, all individuals are invited to participate. **SES**: will be targeting those from both middle/high and low SES groups. Research suggests that those from lower SES groups are more likely to underreport their dietary intake (Poslusna et al., 2009).
2.2	Identify other issues that could affect the choice of dietary assessment tool (DAT)	Dietary recall may be a time consuming process, therefore a method is required whereby minimal participant time and burden will be imposed, as this may lead to incomplete data, missing day or possibly drop outs.

		Inability to understand tasks or what is expected from the participant may also hinder completion (unless it is interviewer led then this may prevent any misunderstandings of task requirements). Technological literacy will be required if dietary data will be collected through online methods (considering additional survey materials will be administered online, it is reasonable to require all tasks to be administered through the same medium).
2.3	Consider the study sample size required in related to the level of variation of your dietary component of interest and study power	There is a need to capture dietary intake over a number of days of the week in order to capture within-individual differences in dietary intake. This will enable a more precise mean estimate that is reflective of an individual's diet. A large sample size is also necessary in order to establish a small effect size for the nature of the intervention. Due to the large sample size requirements, this will result in an exhaustive amount of data. A tool that minimises researcher burden with regards to translating and quantifying food intake into energy (kcal) and nutrient intake (g).
3	When? – Time frame consideration	
3.1	Are you interested in 'actual'/short-term (up to one week) or 'usual'/long-term intake (months/years)	For the purposes of the research aims, only a snapshot into dietary intake is required at baseline, 1 month follow up and 3 month follow up. This is to see if there have been any intervention effects on dietary intake.
3.2	Will data collection in your study be retrospective or prospective?	Prospective; individuals will be required to recall their current dietary intake rather than provide a historical account.
Stage 2. Investigate the different types of DATs and their suitability for your research question		
4	Consider and appraise the different DAT types	
4.1	In relation to your research question, consider the	**Food diaries**

suitability, strengths and weaknesses of different DAT types	<u>Description</u>: prospective; detailed data on all food and drink consumed <u>Strengths</u>: provides food and nutrient data that will be suitable for statistical analysis; less cognitive constraints due to 'immediate' recall; can account for non-typical foods and seasonal variations in diet; multiple food diaries to get better estimate of usual intake. <u>Weaknesses</u>: can be time consuming; lower completion if deemed too exhaustive; researcher burden due to manual coding of diary data; relies on individuals' ability to estimate portion sizes; prone to forgetfulness of complementary foods unless prompted. <u>Suitability</u>: captures desired level of data however concerns around participant and researcher burden, especially under time constraints. **24 hour recalls** <u>Description</u>: retrospective; all foods and drink consumed in the last 24 hours recalled; to be administered by an interviewer. <u>Strengths</u>: detailed data on food and nutrient intake; literacy issues minimised due to interviewer-led; moderate participant burden; multiple 24 hour recalls can increase accuracy of intake estimates. <u>Weaknesses</u>: Single 24 hour recall can't account for within-subject dietary variations; high researcher burden especially around manual coding; relies on participant's ability to estimate portion sizes. <u>Suitability</u>: low participant but high researcher burden – may not be suitable considering there is one researcher and a large sample size. Researcher would need to undertake training to be suitable for administering interviews. High researcher burden also for coding.

	Food Frequency Questionnaires Description: retrospective; frequency of particular foods over specified period of time; can be completed independently and online. Strengths: good way to quantify quantities of foods consumed; low researcher and participant burden; useful in large population studies; length can be varied so has potential to estimate usual dietary intake or intake of small number of specific items. Weaknesses: Not suitable for cross-cultural comparisons; short FFQs not reliable for measuring total dietary and nutrient intake; requires good participant memory; restricted to items specifically listed on the questionnaire; requires specialist software to convert frequencies to nutrients. Suitability: low participant and researcher burden, however does not capture data in the detail required. **Emerging technologies** Description: dietary data collected through use of software, to include sensory devices or web or app based versions of traditional DATs (e.g. myfood24®; INTAKE24) Strengths: collects real time data; more accurate portion size estimates whether through taking a picture or being presented with pictures of various portion sizes; low/moderate participant burden; lower researcher burden for large sample online recalls; lower researcher burden for coding. Myfood24® has nutritional data on over 207,000 products in supermarkets; INTAKE24 has access to a database of more than 2500 foods. Weaknesses: validation data may not yet be available; similar measurement error to other DAT methods;

		internet access required; technology-based skills required; costly for researcher. Suitability: addresses potential weaknesses found in food diary collection methods, such as low researcher burden pertaining to coding (e.g. myfood24® does this on behalf of the individual). Although costly, this is not a barrier for a research project with funding.
4.2	Think about participant burden	Literacy: study participants will need to be able to read and comprehend the English language. It is assumed that if a parent provided consent, then they were able to read and understand the online information sheet and consent form. Internet access: as the intervention will be carried out online, using online-tools of data collection is the most logistical method. For this purpose, it would be part of the eligibility criteria to participate in the study. However, this could lead to a participant bias and may lead to the lack of representation for those that do not have the means to obtain internet access. Participant burden: food diaries can be burdensome to complete, however some methods may lead to easier and quicker completion than others. It is also expected that with practice, completion of diary data will become less time consuming. On their website, INTAKE24 suggest a 20 minute average completion time; in a seminar provided by the founder of myfood24®, it was suggested that approximate completion time was on average 20 minutes to begin with, and goes down to 13 minutes per diary with practice. Both online tools provide portion size estimates, hence lower participant burden in having to weigh food. Technologically-savvy: some new technologies may require a tutorial or instructions to guide their use.

		Myfood24® and INTAKE24 provide this to users before they commence.
4.3	Identify the availability of resources	Manual coding of diaries will not be possible, as the researcher neither has the time capacity to undertake this nor do they have the expertise or experience, which could potentially lead to measurement errors. For this reason, it is an integral part of the decision that the tool used has an integrated feature whereby nutrient data is summarised on behalf of the researcher and is ready to be used for analysis purposes.
Stage 3. Evaluate existing tools to select the most appropriate DAT		
5	Research and evaluate available tools of interest	
5.1	Read any available published validation studies	Myfood24®: Validation study undertaken by Wark et al. (2018) to compare myfood24® with biomarkers and standard interviews. Total sugars was compared with predictive biomarkers and energy intake was compared with energy expenditure measured via accelerometry and calorimetry. In comparison to biomarkers, myfood24® and interviewer-based 24 hour recalls had weakened outcomes. Similar results were obtained for the two self-reported measures. Indicates that myfood24® is no worse than more classical dietary assessment methods. Another validation study compared myfood24® to an interviewer led multiple pass recall. No significant difference in total energy intake between the two methods; lower reported energy intake in myfood24® (Albar et al., 2016). INTAKE24: Validation study comparing against interviewer-led multiple pass 24-hour recall amongst 11-24 year olds (Bradley et al., 2016). Comparable results between the two methods, whereby INTAKE24

		had slightly lower total energy intake (1% difference; non-significant)
6	If, based on the validation studies, none of the existing DATs is entirely or wholly suitable, consider the need to modify or update an existing DAT, or create a new DAT and evaluate it	
6.1	Decide whether an existing tool can be improved.	There are two tools that are suitable to address my research aims: myfood24® and INTAKE24.
Stage 4. Think through the implementation of your chosen DATs		
7	Consider issues relating to the chosen DAT and the measurement of your dietary component of interest	
7.1	Obtain information regarding DAT logistics	Myfood24®: payment of £500 per annual access plus £1 for every food diary entry. An order can be placed and an invoice issued. Once payment is received, access is granted through username and password. INTAKE24: free to use.
7.2	Check that the chosen DAT has the most appropriate food/nutrient database and software	Myfood24®: has the largest food/nutrient database of over 207,000 foods. INTAKE24: Has access to database of more than 2500 foods.
7.3	Check the requirements for dietary data collection	For the most part, both myfood24® and INTAKE24 allow you to write a food item, and a list of suggested items appear for accurate selection. A recipe builder component is also available in both these systems to allow respondents to write in the ingredients of meals they may have prepared at home. Ingredients are then used to calculate macro and micro nutrients. It is common that cooked foods may lose vitamins and minerals, therefore the accuracy of micronutrient reporting may be lacking, however these are not outcomes of interest.
7.4	Consider collecting additional related data	There are opportunities to add in additional questions, such as whether intake is typical of a normal day. As

		we are not looking at micronutrients, we will not be asking about supplement use.
8	Prepare an implementation plan to reduce potential biases when using your chosen DAT	
8.1	Consider potential sampling/selection bias and track non-participation/dropout/withdrawal at different stages	Both myfood24® and INTAKE24 can track participant reporting, and reminders can be sent. An incentive will be provided to participants upon study completion, which may help minimise drop out. Recruitment will be undertaken via multiple mediums, including schools, university mailing lists, community centres and online platforms. There will be an increased effort to recruit individuals from areas of lower SES.
8.2	Minimise interviewer bias	This will not be interviewer led.
8.3	Minimise respondent biases	Both myfood24® and INTAKE24 allow you to track participants, so you can see who does and does not complete questionnaires. In myfood24®, reminder emails can be sent to participants to nudge them to complete the food diary.
8.4	Quantify misreporting	Misreporting of dietary intake is common in dietary assessments (Poslusna et al., 2009). There are also statistical techniques that can be adopted such as the Goldberg equation, which can help identify under reporters (Black, 2000), or through the use of stratification methods (Tooze et al., 2016). Either way, the importance of accurate reporting will be stressed and participants will be encouraged to report as accurately as they are able to.

Appendix 16: Open-Ended Survey Questions, Themes and Supporting Statements.

Theme	Quote
Food Scanner app feedback	
App usefulness	“Easy to use and understand broke down nutritional labels into comprehensible information allowing informed and healthy decisions.”
	“The app assumes that you don't know much about child nutrition in the first place. As a parent I regularly meal plan and write a shopping list I don't just wander round the supermarket scanning random items. The app also assumes you have ample time to wander round when in reality I like to spend the least amount of time shopping.”
	“Not sure. Once you know the content of a product you don’t need to scan it again. It was very useful at first but once we’d made changes we didn’t need it as much.”
	“I think it is aimed at parents who only buy ready made food for their children. It is not helpful for parents who cook from scratch. It also assumes that you know very little about basic nutrition. For example I know a can of Coke is unhealthy and contains several cubes of sugar, I don't need an app to tell me. I wouldn't bother to scan several to see which had the least amount of sugar, I just wouldn't buy it in the first place. I didn't use the app after a while as it didn't give me any further information.”

	“It only concentrated on sugar and not on other things like carbs or fibre which could be more useful. I looked at the recipes they had and all it did was reinforce that I am already feeding my child a balanced diet. I tend to buy the same sorts of things each week as my child is a fussy eater and I want to make sure he has a balanced diet. Sometimes I struggle to get him to eat. Using the app wouldn't make a difference to this.”
	“Helpful for making decisions on what to buy.”
	“I don't feel like I buy enough 'snack foods' for the app to be that useful for me.”
	“Very helpful to be able to scan items and check how healthy they are.”
	“I didn't feel that personally it gave a massive amount more information than current labelling.”
	“Too time consuming, just as easy to look at a label.”
	“Don’t feel that I need to use it, as I instead check nutritional labels.”
	“Once you’ve scanned an item you know that info so you don’t need to use it again.”
	“I just tend to look at packaging directly.”
	“I am not bothered to use it. I do not feel that I need it.”
Better product recognition	“Better range of goods recognised.”
	“Maybe search for an item rather than having to scan.”

	"Include more items." "Limited products available to be scanned." "Not everything scanned easily." "It didn't always recognise the items I scanned. I shop at aldi and a lot of the products weren't on there. It only seemed to recognise branded products. Once you scanned an item it wasn't very easy to find your way round the app to things such as recipes." "It didn't recognise a lot of the products I wanted to buy." "It doesn't recognise all products. We bought treats from the local corner shop and they weren't recognised. Some specialist foods for gluten free diet (for my other child) weren't picked up either." "Didn't always find food." "Easier scanning." "To be able to recognise more items."
Information provision and monitoring	"I liked the link to the change to life website for the NHS recipes." "It didn't recognise some items and would sometimes scam multipacks of crisps for example and five values based on the whole pack rather than individual packs."

	“Have the amount per serving.”
	“Keep score.”
	“Don't use the app, make it attached to the food label.”
	“A chart to show positive changes to see progress.”
	“Sometimes it gave the sugar for the entire box rather than one serving.”
	“Examples of healthy treats advertised on it.”
	“The information per portion clearer.”
	“Have a menu on the front page. When you sxan an item it doesn't give much information straight away.”
	“Recipe ideas? Like alternatives for birthday party treats that have less sugar in?”
Presentation	“It was very easy to scan products and see their information. It was bright and interested my daughter too.”
	“Simple encouraging terms.”
	“Less colour clashes makes it hard to concentrate.”
	“Simpler colours”
	“Simple graphics.”

	“Colourful.”
	“Bit preachy.”
Rewards and incentives	“Incentives- money off vouchers, rewards system, make into a game to get children involved in making food choices.”
	“Possibly incentives for parents that otherwise may choose cheaper options like potential discount and money accumulators.”
	“Give free healthy food for using the app.”
	“Prize incentive in using it.”
	“Rewards system.”
Child involvement	“Engage children directly to integrate with daily life.”
	“Maybe a chart to log a child’s progress when they’ve made swaps.”
	“Maybe a bit more child friendly so they can be engaged with making healthy choices.”
	“Make it suitable for children to use.”
Personalisation	“Provide individual targets.”
	“Maybe link with social media.”

Convenience and practicality	"It was easy to use and handy to have on my mobile so when I was in a shop I could use it to decide which was a healthier choice of product." "Use less memory." "It consumes my phone memory." "Too time consuming." "Using the app to scan every time was time consuming." "It's difficult to get the app out in shops and start scanning everything before making a purchase." "I have to prepare food quickly so didn't have time." "Disinfecting phone." "Daily reminders to use it." "I often forgot about the app." "It was straightforward." "To a certain extent the current Covid-19 situation has reduced or food choices and we have spent more time thinking about our weekly food menus anyway so the last 6 weeks may not have been typical of what had been happening before or after."

	"That it was instant to use."
	"It was relatively easy to use."
	"That you could scan labels from your phone."
	"Annoying having your phone out all the time scanning."
	"During COVID-19 I don't really like getting my phone out in supermarkets, especially without disinfecting first."
	"Easy to use."
	"It was easy to use very user friendly."
	"My memory. I kept on forgetting about it."
Has the Coronavirus outbreak, or any other events, affected your responses or engagement in the trial?	
Are there any other factors that may have had an influence over your child's sugar consumption in the last 3 months?	
Lockdown demand causing time constraints	"Second survey was pandemic peak - we struggled to fit in the surveys also."
	"Working from home and childcare means I had a lot less time to complete the food diary than I usually would have."
	"Life became hectic going back to work and home-schooling so had difficulty completing all tasks."

Changes to diet	“Only in the first few weeks of lockdown when I couldn’t buy my usual groceries.”
	“Because at school her food intake would be very different.”
	“Eating more snacks, have less time.”
	“Eat out to help out.”
	“Emotional eating during lockdown, we found we were using good as a way of bringing the family together.”
Out of routine	“Out of routine and getting time to track things.”
	“My sister and mum use to help with childcare whilst I was working. School pick up's and feed my daughter tea. Use to give her treats etc biscuits, chocolate after school.”
	“More 'treat time' at home , including film nights etc.”
	“Being at home has increased snack consumption.”
	“Boredom at home leads to increased snacking.”
	“The contact with their father has been more during lockdown and now they don’t see him at all.”
Other	“Family ailments.”
	“Other children.”

	"Celebrations."
What prevented you from completing all study tasks?	
Forgetfulness	"I forgot to submit one diary."
	"Was finding the time and not forgetting."
Time	"Shift work."
	"Time. I missed the last set of tasks because of holiday."
	"Going away."
	"Time consuming with COVID as went back to work and shopping was a rush and didn't allow me extensive time to scan food and use the app or fill in diaries."
	"I am a busy NHS worker who has worked more over the previous few months due to the Covid pandemic."
Personal or family illness	"The last month to complete the study. I wasn't well and therefore the diary was added on Monday 17/08 but was intended for Sunday 16/08."
	"Father being ill and in hospital, took my focus away."
Was there anything we could have done to keep you more engaged in completing food diaries and surveys throughout this study?	
Food diary completion	"Being able to complete the food diaries retrospectively would have been helpful."

	“I could have done with receiving the food diary email on a Monday rather than mid week when half the week was already gone. The layout of the food diary was not very user friendly. I found it hard to use on my phone.”
myfood24® improvements	“Perhaps when a diary is partially completed but not yet submitted a reminder to ask you to submit would have been useful.”
	“More food choices on menu.”
	“My son has a plant-based diet and it was often very difficult to find the exact things that he eats. We also usually cook most from scratch and do not eat a lot of processed food, but it was sometimes impossible to find something like 'red onion', whereas the list with red onion in processed food was very long.”
	“The interface isn't brilliant on mobile phone, it would be easier of it we could complete the survey etc. from an interface designed for mobile phone use.”
	“Filling in the food diaries is quite time consuming and fiddly.. getting the right amounts etc. But not sure what the alternative is!”
	“The food diary does not include all food we had (in terms of brand, cooking methods, ingredients etc).”
	“Not all foods in database.”
	“Sometimes it was difficult to find the exact food/brand in the diary.”
	“Couldn't always find exact food brands.”

	"wasn't easy searching for foods sometimes if you spelt a word wrong it made it longer to fill in food diaries."
Task for the child	"Maybe have something for the child themselves to do."
Greater monetary incentive	"Give me more prize. It is the only motivation I have to complete this study."
	"I'd happily continue with the study subject to reward."
	"£30 seems a bit low in hindsight for the participation and time committed."
Transparency around study tasks and objectives	"I think explaining at the beginning how many surveys will need to be completed would be good. The person who recommended it said it would be quite short. However the subject was important and interesting so I didn't mind in the end."
	"Perhaps given more information about what you intend to do with the data? What are you wanting to test or prove?"
Positive feedback	"This study has reminded me of our daily diet and it was good opportunity to look back."
	"No there was not. I found the reminders extremely useful for when I forgot to do the food diaries."
	"Easy to find certain ingredients."
	"Enjoyed documenting with my child, good engagement with him."
	"I really appreciated the reminders."

	“Communication was good and helpful. Diaries and surveys made easy to complete and understand.”
	“No, was straight forward to follow.”
	“My child and I thoroughly enjoyed participating in this study.”
	“Interesting to see what my child does actually eat in a whole day.”
	“Thank you for allowing me to be part of your study, I wish you all the best with it.”
	“I think it’s very well organised.”
	“No i enjoyed doing it found it very interesting.”
	“All communication was excellent.”
	“No I have thoroughly enjoyed the food diary tasks.”
Study withdrawal – Do you have any advice or suggestions to help us keep participants more engaged in this study?	
Issues with using myfood24®	“Due to us following a vegan diet, I found the food diary difficult & time consuming. It would have been much easier if I had been able to just write in what food my son had eaten rather than having to find it on a non-existent list!”
	“I kept meticulous written record of what she ate, but it was hard to find matching foods/work out portions etc. If we could write down the food consumed and photo/scan it to you it would be good.”

	“The way to enter the food was too complicated, especially the home made recipes.” “An app that would make filling the food diary in easier, rather than a web link.”
Transparency	“Yeah be clear on what u need to them to do and how long for. also, if you promise vouchers or any of the sort then make sure u deliver on that promise.”

Appendix 17: A Within-Subjects Comparison (Mean ±SD) of Psychological Predictors of Behaviour Change Between Baseline and 3-Month Follow-up.

Measure	**Intervention (*n=29*)**			**Control (*n=35*)**		
	Baseline	3MFU	Mean difference (95% CI)	Baseline	3MFU	Mean difference (95% CI)
Attitudes						
How important is it for you that your family eat a healthy diet?	4.03 (±0.63)	4.00 (±0.71)	-0.03 (-0.22; 0.16)	4.17 (±0.62)	4.03 (±0.57)	-0.14 (-3.66; 0.80)
Having too much sugar leads to disease	4.28 (±0.75)	4.48 (±0.634)	0.21 (-0.07; 0.48)	4.43 (±0.61)	4.43 (±0.70)	0.000 (-0.20; 0.20)
When buying food, snacks or drinks for my child, it is important to pay attention to the amount of sugar it contains (attitudes)	4.21 (±0.77)	4.17 (±0.76)	-0.03 (-0.31; 0.24)	4.29 (±0.62)	4.37 (±0.55)	0.09 (-0.14; 0.31)
For my child to be healthy, I need to be careful how much saturated fat my child eats	4.03 (±0.68)	3.93 (±0.75)	-0.10 (-0.32; 0.11)	4.11 (±0.72)	4.17 (±0.79)	0.06 (-0.13; 0.24)

For my child to be healthy, I need to be careful how much sugar my child eats	4.55 (±0.51)	4.38 (±0.72)	-0.17 (-0.40; 0.06)	4.57 (±0.50)	4.57 (±0.56)	0.000 (-0.19; 0.19)
For my child to be healthy, I need to be careful how many calories my child eats	3.28 (±0.88)	3.10 (±1.11)	-0.17 (-0.58; 0.24)	3.26 (±1.05)	3.50 (±1.19)	0.24 (-0.06; 0.53)
Perceived behavioural control [a]						
How much control do you have over your child's sugar consumption?	3.89 (±0.74)	3.75 (±0.70)	-0.14 (-0.42; 0.13)	4.09 (±0.61)	3.91 (±0.74)	-0.17 (-0.48; 0.14)
COM-B measures: Physical capability [b]						
How often, if at all, do you keep track of how much sugar your child eats or drinks each day?	2.76 (±1.35)	2.86 (±0.99)	0.10 (-0.37; 0.57)	2.74 (±1.38)	3.00 (±1.18)	0.27 (-0.05; 0.58)
COM-B measures: Psychological capability						
How easy do you find it to limit your child's sugar intake to the amounts recommended in the above guidelines?	3.07 (±1.39)	3.10 (±1.54)	0.03 (-0.73; 0.80)	3.47 (±1.35)	3.24 (±1.30)	-0.24 (-0.79; 0.32)
"Too much sugar intake for my child increases their risk of obesity"	4.59 (±0.57)	4.66 (±0.48)	0.07 (-0.11; 0.24)	4.69 (±0.47)	4.63 (±0.55)	-0.06 (-0.26; 0.15)
COM-B measures: Automatic motivation						

How concerned, if at all, are you about your child consuming more sugar than what is recommended?	2.90 (±1.01)	2.97 (±1.02)	0.07 (-0.42; 0.56)	3.15 (±0.89)	3.03 (±0.94)	-0.12 (-0.53; 0.29)
To what extent do you want to keep your child's sugar consumption within recommended guidelines?	3.69 (±0.85)	3.79 (±1.01)	0.10 (-0.25; 0.46)	3.97 (±0.76)	3.94 (±0.69)	-0.03 (-0.21; 0.15)
COM-B measures: Reflective motivation						
To what extent do you intend to keep your child's sugar consumption within recommended guidelines?	4.07 (±0.70)	3.90 (±0.94)	-0.17 (-0.42; 0.08)	4.24 (±0.70)	4.18 (±0.72)	-0.06 (-0.27; 0.15)
To what extent are you actively trying to reduce your child's sugar intake?	3.41 (±0.83)	3.48 (±0.99)	0.07 (-0.27; 0.41)	3.59 (±0.74)	3.44 (±0.79)	-0.15 (-0.42; 0.13)
COM-B measures: Social opportunity						
How easy or difficult do you think your lifestyle makes it for you to limit your child's sugar intake to the above guidelines, a day?	2.90 (±0.98)	2.76 (±1.06)	-0.14 (-0.54; 0.27)	3.41 (±0.99)	3.47 (±0.90)	0.06 (-0.28; 0.40)

N.B. Outcomes are based on 5-point Likert scales: 1 = negative attitudes (e.g. not at all important; none at all; strongly disagree; never; definitely not); 5 = positive attitudes (e.g. extremely important; a great deal; strongly agree; always; definitely yes).
[a] intervention arm, n=28
[b] sample size of this measure onwards, control arm, n=34

Appendix 18: Impact of the COVID-19 Lockdown on Children's Diets

Measure	n	High agreeability (%)	Medium agreeability (%)	Low agreeability (%)
To what extent do you feel that the lifestyle changes imposed by the Government in relation to the Coronavirus has affected the following[a]:				
COVID has affected your child's diet	55	29	42	29
COVID has affected your ability to make healthier food choices for your child	46	20	46	35
COVID has affected your food purchasing behaviour	55	51	44	6
COVID has affected the types of food you bought	46	37	50	13
COVID has affected your participation in this study	55	31	36	33
COVID has affected your ability to scan barcodes using the Food Scanner app	19	32	42	26
Did the Food Scanner app support you at this time in	19	26	37	37

making healthier food choices?				
“The lifestyle changes imposed by the Government in relation to the Coronavirus led my child to…” [b]				
…eat more sugar than they did before	63	29	32	40
…eat more snacks than they did before	62	61	10	29
…eat more fruit and vegetables than they did before	62	44	39	18
…eat more home cooked meals than they did before	62	76	15	10
… be more physically active than they were before	62	40	24	36
To what extent do you feel that the lifestyle changes imposed by the Government in relation to the Coronavirus has affected the following, in comparison to before the lockdown [c]*:*				
Since the COVID-19 lockdown, I carry out online grocery shopping…	44	43	43	14
Since the COVID-19 lockdown, my children eat take out food…	46	9	33	59
Since the COVID-19 lockdown, I have been purchasing sugary foods or treats/snacks…	46	39	39	22

Since the COVID-19 lockdown, I have been spending on food…	46	72	17	11

N.B. Questions pertaining to the Food Scanner app were only presented to those within the intervention condition.
Lower sample sizes than total number of study completers (n=64) was due to the late introduction of these measures.
[a] Response options: a great deal, a lot, a moderate amount, a little, not at all.
[b] Response options: strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, strongly disagree.
[c] Response options: A lot more, slightly more, the same, slightly less, a lot less.

Appendix 19: Parent-Reported Child Health-Related Quality of Life Outcomes

CHU9D	Intervention (n=28)		Control (n=34)	
	Baseline	Follow up	Baseline	Follow up
Total CHU9D				
Mean (SD)	13.61 (3.52)	13.14 (4.36)	13 (3.38)	12.41 (3.38)
Median	13	11.5	12.5	12
Range	9-22	9-26	9-21	9-22
Worried				
Mean (SD)	1.71 (1.12)	1.32 (0.67)	1.65 (1.04)	1.44 (0.75)
Median	1	1	1	1
Range	1-5	1-3	1-5	1-4
Sad				
Mean (SD)	1.5 (0.79)	1.21 (0.57)	1.29 (0.72)	1.35 (0.73)
Median	1	1	1	1
Range	1-4	1-3	1-4	1-4
Pain				
Mean (SD)	1.14 (0.36)	1.07 (0.26)	1.09 (0.29)	1.09 (0.38)
Median	1	1	1	1
Range	1-2	1-2	1-2	1-3
Tired				
Mean (SD)	1.86 (0.93)	1.89 (0.83)	1.68 (0.88)	1.56 (0.75)

Median	2	2	1	1
Range	1-4	1-4	1-4	1-4
Annoyed				
Mean (SD)	1.75 (0.93)	1.71 (0.98)	1.65 (0.85)	1.59 (0.93)
Median	1.5	1	1	1
Range	1-4	1-4	1-4	1-4
School work				
Mean (SD)	1.61 (1.1)	1.57 (1.07)	1.32 (0.48)	1.41 (0.78)
Median	1	1	1	1
Range	1-5	1-5	1-2	1-5
Sleep				
Mean (SD)	1.57 (0.96)	1.46 (0.84)	1.38 (0.65)	1.32 (0.77)
Median	1	1	1	1
Range	1-4	1-4	1-3	1-4
Daily routine				
Mean (SD)	1.25 (0.65)	1.36 (0.68)	1.44 (0.61)	1.18 (0.39)
Median	1	1	1	1
Range	1-4	1-3	1-3	1-2
Joint activities				
Mean (SD)	1.21 (0.50)	1.54 (1.11)	1.5 (1.05)	1.47 (1.02)
Median	1	1	1	1
Range	1-3	1-5	1-5	1-4

Utilities

Mean (SD)	0.89 (0.08)	0.89 (0.10)	0.90 (0.08)	0.91 (0.08)
Median	0.88	0.92	0.9	0.93
Range	0.72 – 1	0.61 – 1	0.73 – 1	0.73 – 1

N.B. Based on complete case analysis of the Child Health Utility-9 Dimension instrument data.
Scores rated as 1=least severe; 5=most severe.
Possible range for total scores: 9 (least severe across all 9 dimensions)-45 (most severe across all 9 dimensions).

Appendix 20: Multiple Imputation Outcomes Totals and Means (SD)

Absenteeism and associated costs	**Intervention (n=55)**		**Control (n=59)**	
	Baseline	**Follow up**	**Baseline**	**Follow up**
Healthcare Resource costs (£)				
Total (95% CI)	3051.83 (828.07; 5275.58)	1145.09 (562.77; 1727.41)	2315.32 (1324.16; 3306.49)	1033.99 (510.86; 1557.11)
Mean (SD)	55.49 (149.56)	20.82 (39.16)	39.24 (64.46)	17.53 (34.02)
Child school absence				
Total (95% CI)	22.16 (8.17; 36.16)	7.86 (3.09; 12.64)	35.66 (19.60; 51.73)	0.51 (-0.29; 1.33)
Mean (SD)	0.40 (0.94)	0.14 (0.32)	0.60 (1.04)	0.01 (0.05)
Parent work absenteeism				
Total (95% CI)	29.74 (6.22; 53.26)	1.95 (-0.08; 3.98)	9.59 (2.79; 16.39)	-0.19 (-0.65; 0.26)†
Mean (SD)	0.54 (1.58)	0.04 (0.14)	0.16 (0.44)	-0.003 (0.03) †
Productivity costs (£)				

Total (95% CI)	3217.82 (673.32; 5762.31)	211.21 (-8.71; 431.14)	1037.90 (302.32; 1773.48)	-21.04 (-70.55; 28.47) †
Mean (SD)	-58.51 (171.35)	3.84 (14.79)	17.59 (47.84)	-0.36 (3.22) †

† Implausible figure; therefore, should be interpreted as zero.

Appendix 21: Multiple Imputation of Costs (£) and Consequences Related to Intervention and Control Conditions

Costs and consequences	Intervention (n=55)	Control (n=59)
Child healthcare costs (£)		
Mean difference (SD) between baseline and follow-up	-34.67 (148.86)	-21.72 (68.63)
95% CI	-74.91; 5.57	-39.60; -3.83
Quality Adjusted Life Years		
Mean difference (SD) between baseline and follow up	0.22 (0.01)	0.23 (0.01)
95% CI	0.22; 0.23	0.22; 0.23
School absenteeism		
Mean difference (SD) between baseline and follow-up	-0.26 (0.94)	-0.60 (1.04)
95% CI	-0.51; -0.01	-0.87; -0.32
Workplace productivity due to child's health (£)		
Mean difference (SD) between baseline and follow-up	-54.67 (167.49)	-17.95 (47.59)
95% CI	-99.95; -9.39	-30.35; -5.55

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