A realist investigation of the impact of Healthy Start on the diets of low-income pregnant women in the UK

by

Heather Ohly

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STUDENT DECLARATION FORM

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Abstract

Healthy Start is the United Kingdom government's food voucher programme for low-income, pregnant women and young children. Eligible women receive vouchers worth £3.10 per week, which can be exchanged for fruit and vegetables, plain cow's milk or infant formula. There has been no robust evaluation of the impact of Healthy Start on nutritional outcomes since its introduction in 2006. Therefore, this study aimed to explore potential outcomes of the programme (including intended and unintended outcomes) and develop explanations for how and why these outcomes might occur.

A realist review was conducted in two iterative and overlapping stages: 1) developing theories or hypotheses about how the Healthy Start programme works, for who, in what circumstances and why; 2) testing those theories using relevant evidence from existing studies of Healthy Start and a similar food voucher programme in the United States. The review findings comprised three 'evidence-informed programme theories' about how low-income pregnant women use Healthy Start vouchers and why.

A qualitative study was undertaken to further refine and consolidate the programme theories derived from the realist review, and to develop new and emerging programme theories. Semi-structured interviews were conducted with 11 low-income women from North West England, who received Healthy Start vouchers during pregnancy. An innovative combination of realist interview techniques and vignettes was used to communicate and exchange theories with low-income women. A realist logic of analysis was applied to generate clear and transparent linkages between outcomes and explanations. Five 'evidence-based programme theories' were developed to explain why low-income pregnant women may experience one or more of the following outcomes from the Healthy Start programme: dietary improvements, shared benefits, financial assistance, stockpiling formula, misuse of vouchers.

These programme theories were integrated with existing behaviour change theories and an overarching theoretical model for Healthy Start was developed. This model illustrates the combination of context and resources needed to generate the intended outcome of dietary improvements for low-income pregnant women, and the mechanisms by which this outcome may be generated.

Table of contents

List of tables and figures

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Abbreviations

BA	Barrow-in-Furness
BL	Blackburn with Darwen
BMJ	British Medical Journal
CARES	Centre for Advancement in Realist Evaluation and Synthesis
CEDAR	Centre for Diet and Activity Research
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CLAHRC	Collaboration for Leadership in Applied Health Research and Care
C	Context
CMOc	Context – Mechanism – Outcome configuration
COMA	Committee on Medical Aspects of Food and Nutrition Policy
COM-B	Capability – Opportunity – Motivation – Behaviour
DEFRA	Department for Environment, Food and Rural Affairs
DH	Department of Health
DWP	Department for Work and Pensions
EBT	Electronic Benefits Transfer
EMBASE	Excerpta Medica Database
ETHOS	E-Theses Online Service
FFQ	Food Frequency Questionnaire
FV	Fruit and vegetables
GP	General Practitioner
HO	Heather Ohly

M	Mechanism
MEDLINE	Medical Literature Analysis and Retrieval System Online
NDNS	National Diet and Nutrition Survey
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
O	Outcome
PCT	Primary Care Trust
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RAMESES	Realist and Meta-narrative Evidence Syntheses: Evolving Standards
RCT	Randomised Controlled Trial
RNI	Reference Nutrient Intake
STEMH	Science, Technology, Engineering, Medicine and Health
UHT	Ultra-High Temperature (processing of milk)
UK	United Kingdom
UNICEF	United Nations Children's Fund
US	United States (of America)
WFS	Welfare Food Scheme
WIC	Special Supplemental Nutrition Program for Women, Infants and Children
WHO	World Health Organisation

Glossary of realist terminology

Context – the pre-existing conditions into which a programme is introduced.

Demi-regularity – a semi-predictable outcome pattern reflecting variations in human behaviour.

Generative causation – the potential for social programmes to generate change by activating causal powers within individuals.

Mechanism – the reasoning and reactions of individuals in response to the resources offered by the programme.

Middle-range theory – a theory that is specific enough to explain the phenomenon of interest, and yet general enough to be useful across a range of programmes or contexts.

Outcome – the observable effects of the programme, including intended and unintended effects.

Programme theory – a theory of change for a specific social programme, which explains (in part) how the programme generates change and what conditions are required for this change to occur.

Realist review (or realist synthesis) – a review designed to develop and test programme theories using existing empirical evidence.

Realist evaluation – a theory-driven approach to evaluation, which aims to understand the inner workings of social programmes by developing and testing programme theories using empirical evidence.

Retroduction – an iterative approach to realist theory development, which involves creative thinking about underlying causes and generative mechanisms.

INTRODUCTION AND OVERVIEW OF STUDY

1.1 Introduction

This study investigates a programme (or intervention) called Healthy Start, which aims to improve maternal and child nutrition. This chapter begins with an overview of why maternal and child nutrition is important, and what is known about the short and long term effects of (poor) nutrition during pregnancy and early childhood. The next section examines nutrition inequalities in the UK and the need for targeted support for low-income women and children. This PhD studentship was funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care North West Coast (NIHR CLAHRC NWC). Its goal is to produce high quality research to reduce health inequalities and improve population health. Healthy Start was chosen as the subject of investigation because it is the only nutrition intervention in the UK that targets low-income women and children. Therefore, it has potential to reduce nutrition and health inequalities, but little is known about the impact of the programme. The remainder of the chapter outlines the scope of the study and the structure of the thesis.

1.2 The importance of maternal and child nutrition

Good nutrition in early life is essential for optimal growth and cognitive development, and has implications for health, educational attainment, economic productivity and socioeconomic development (Branca, Piwoz, Schultink, & Sullivan, 2015; Hansen, 2015). Malnutrition is a condition that may be caused by undernutrition (insufficient energy, protein or micronutrients) or overnutrition (usually refers to overweight and obesity). It affects countries at all stages of development. The 2013 Lancet Series on Maternal and Child Nutrition called for continued investment to reduce the 'double burden of malnutrition', or the coexistence of undernutrition, overweight and obesity (The Lancet, 2013). The 2016 Global Nutrition Report emphasised the importance of adequate nutrition in the first 1000 days of life, from conception to the child's second birthday – a critical period for linear growth and brain development (International Food Policy Research Institute, 2016).

A large body of evidence exists on the importance of nutrition during pregnancy for optimal growth and cognitive development. An adequate supply of energy is required for a healthy pregnancy – too much or too little may be harmful. A recent systematic review and meta-analysis, including data from more than one million pregnant women, found

that excess gestational weight gain was associated with increased risk of 'large-for-gestational-age' and macrosomia (birth weight greater than 4000 grams), whereas insufficient gestational weight gain was associated with increased risk of 'small-for-gestational-age' (Goldstein et al., 2017). Protein-energy malnutrition may result in intrauterine growth retardation and impaired brain development in the cortex and hippocampus (Georgieff, 2007). Micronutrients are essential for in utero growth and brain development – in particular, iron, iodine, zinc, folate, vitamin A and vitamin D (Moran & Lowe, 2017). Deficiencies in these micronutrients are associated with adverse pregnancy outcomes, some of which are irreversible, such as neural tube defects associated with folate deficiency.

The effects of maternal nutrition extend throughout the life course and may determine morbidity and mortality. The 'foetal origins of adult disease' hypothesis was developed by an epidemiologist, Barker, who noticed strong correlations and geographical patterns between infant mortality rates (1921-25) and death rates from ischaemic heart disease (1968-78) in England and Wales (Barker & Osmond, 1986). Other causes of death, such as chronic bronchitis and stomach cancer, showed similar associations with infant mortality. In most cases, death rates had declined as living standards improved during the 20th century. However, death rates from ischaemic heart disease had increased over time and, paradoxically, were highest in areas of socioeconomic deprivation. Infant mortality rates and incidence of low birth weight were also highest in areas of socioeconomic deprivation. Barker suggested that nutritional deprivation in pregnancy may cause metabolic adaptations as the foetus anticipates conditions of scarcity. If babies are then exposed to a plentiful food supply, these adaptations increase the risk of developing ischaemic heart disease in later life. He referred to this as 'long term programming' in early life (Barker, 1990).

This theory has since been supported by evidence from epidemiological and clinical studies, and more recently 'epigenetics' – the study of how early life environmental factors can modify gene expression (Dunford & Sangster, 2017; Gluckman, Hanson, & Pinal, 2005; Jang & Serra, 2013). This field has emerged since the completion of the Human Genome Project in 2003. It became clear that information stored in the DNA sequence did not completely explain variations in human development, physiology and disease (Jang & Serra, 2013). The DNA sequence cannot be altered, but gene activity or expression can be modified by non-genetic factors. Therefore, one genotype may result in a range of phenotypes. The responsiveness of genes to environmental factors is known

as ‘developmental plasticity’ and maternal nutrition is known to be an important factor during critical periods of development. Epigenetic studies have shown that early life nutrition may contribute to the development of diseases such as obesity, diabetes, hypertension and cancer in later life (Bishop & Ferguson, 2015; Jang & Serra, 2013).

Infancy is another crucial opportunity for nutrition, and the superiority of breastfeeding over other infant feeding practices is well established. Exclusive breastfeeding for the first six months of life is a global public health recommendation (WHO & UNICEF, 2003). The evidence to support exclusive breastfeeding is unequivocal. It is associated with a range of short and long term benefits for mothers (including more rapid weight loss after birth, improved birth spacing, reduced risk of breast cancer and ovarian cancer) and for infants (including protection against infections, increased intelligence, reduced risk of obesity and type 2 diabetes) (Horta & Victora, 2013; Kramer & Kakuma, 2012; Victora et al., 2016). Breastfeeding also enhances maternal well-being, attachment and the emotional bond between mother and baby (UNICEF UK, 2013). Not breastfeeding is associated with a range of adverse health outcomes for mothers (including retained gestational weight gain, increased risk of breast cancer, ovarian cancer and type 2 diabetes) and for infants (including increased risk of infections, childhood obesity and type 2 diabetes) (Stuebe, 2009). In terms of economic benefits, breastfeeding has been described as “the single most effective intervention a country can make in any sector for any reason!” (Hansen, 2015, p.386). An economic modelling study in the UK found that supporting mothers to continue to breastfeed exclusively for the first four months of life could save at least £11 million per year by reducing the incidence of childhood illnesses (Pokhrel et al., 2014).

1.3 Nutrition inequalities in the UK

Poor diet and nutrition are associated with socio-economic deprivation in the UK. Data from four national surveys are presented below, which demonstrate income gradients across a range of nutrition outcomes, including energy intakes, purchase and consumption of fruit and vegetables (key indicators of healthy diet) and breastfeeding rates. Maternal and infant outcomes are presented where possible. The survey findings are limited by self-reported data, but they have the advantage of large sample sizes.

The ‘Food and You’ consumer survey is conducted by the Food Standards Agency. The most recent results are from the 2016 survey (n=3,118) (Bates, Roberts, Lepps, & Porter, 2017). It assessed household food security, defined as “having access at all times to

enough food that is both sufficiently varied and culturally appropriate to sustain an active and healthy life" (p. 26). In this survey, 8% of households were food insecure (low or very low food security). Women were more likely to live in food insecure households than men (10% and 6% respectively). A third (34%) of respondents in the lowest income quartile said they often or sometimes worried about running out of food before they had money to buy more, compared with 7% in the highest quartile.

The National Diet and Nutrition Survey (NDNS) is conducted by Public Health England and the Food Standards Agency. For four consecutive years (2008/09 – 2011/12), the survey compared food consumption and energy and nutrient intakes by income quintiles (Bates et al., 2014). The combined results from this period (n=6,828) showed that women aged 19-64 years with lower household incomes (quintiles 1-3) had significantly lower energy and nutrient intakes than women with the highest household incomes (quintile 5) (Table 1). Low-income women also consumed less fruit and vegetables compared to those on higher incomes, and were less likely to achieve the recommended five portions a day (Table 1). The most recent surveys (2012/13 – 2013/14) did not include comparisons by income, so it is unclear how these nutritional inequalities may have changed since 2012 (Bates et al., 2016). NDNS does not include children under 18 months of age.

Table 1. Selected data from NDNS (2008/09 – 2011/12) showing average daily energy and nutrient intakes and average daily consumption of fruit and vegetables for women aged 19-64 by income quintile (Bates et al., 2014).

Income quintile	1 Lowest	2	3	4	5 Highest
Energy intake (kcal/day)	1576*	1578*	1569*	1629	1687
Iron intake (mg/day)	8.7*	9.1*	9.5*	10.1	10.4
Calcium intake (md/day)	686*	711*	709*	753	767
Folate intake (µg/day)	210*	218*	232	234	242
Total fruit (g/day)	70*	78*	98*	119	135
Total vegetables (g/day)	163*	152*	187	200	207
Total fruit and vegetables excluding juice (g/day)	232*	230*	285*	319	342
5-a-day (portions/day)	3.5*	3.4*	4.0*	4.6	4.9

*statistically significant difference compared to the highest quintile.

The Living Costs and Food Survey is conducted by the Department for Environment, Food and Rural Affairs (DEFRA) and it includes a section on Family Food. The most recent results are from the 2015 survey (n=4,918) (Department for Environment, Food and Rural Affairs, 2017). Households were divided into income deciles, which revealed an income gradient for fruit and vegetables. The average number of portions of fruit and vegetables purchased (per person per day) was 3.3 in decile 1, 3.1 in decile 2, and 3.9 for all households. Total energy intake was similar between income deciles; other food and nutrient intakes were not compared.

The Infant Feeding Survey was conducted by the National Health Service (NHS), but it was recently discontinued. The most recent results are from the 2010 survey (n=15,724) (McAndrew et al., 2012). Breastfeeding rates were compared with a range of variables including maternal age, ethnicity, socioeconomic classification (occupation) and level of education. In this summary, associations with level of deprivation are used to illustrate income-related inequalities. The survey found that incidence of breastfeeding decreased as level of deprivation increased; 73% of mothers in the most deprived quintile initiated breastfeeding, compared to 89% in the least deprived quintile. Likewise, prevalence of breastfeeding was inversely associated with level of deprivation at all ages of the baby. At two weeks, 56% of mothers in the most deprived quintile were breastfeeding, compared to 75% of mothers in the least deprived areas. By six months, the gap was narrower: 31% in the most deprived areas and 40% in the least deprived areas. Similar associations were observed for prevalence of exclusive breastfeeding from birth to four months. At birth, 60% of mothers in the most deprived areas breastfed exclusively, compared to 77% in the least deprived areas. By four months, the gap was narrower: 10% in the most deprived areas and 16% in the least deprived areas.

These data consistently suggest that nutrition inequalities exist in the UK. Despite being one of the richest countries in the world, the poorest families in the UK do not have adequate nutrition. As maternal and infant nutrition are known to influence other health outcomes (as evidenced in section 1.2), nutrition interventions targeting low-income women and infants should be high priority. It is necessary to find effective ways to improve health outcomes for the poorest in society, otherwise health inequalities will persist (Marmot, 2017). Healthy Start is the only nutrition intervention in the UK that specifically targets low-income women and young children. The next section explains how this study of Healthy Start contributes original knowledge about how to improve maternal and child nutrition and reduce nutrition inequalities.

1.4 Scope of this study

Healthy Start is the UK's food voucher programme for low-income pregnant women and young children. It aims to improve maternal and child nutrition, and reduce health inequalities, by providing support to low-income families (Greenwood, 2017). It was introduced in 2006, but the impact of the programme on nutritional outcomes remains understudied. The overall aim of this study was to explore potential outcomes of the Healthy Start programme (including intended and unintended outcomes) and develop explanations for how and why these outcomes might occur.

The realist approach to evaluation assumes that any programme is likely to work better for some beneficiaries than for others. Therefore, this study does not consider 'low-income families' as one homogenous group; instead it examines the influence of individual circumstances and context on the effectiveness of the programme. The findings offer in-depth insights into the conditions that may be necessary for dietary behaviour change to occur and ways to maximise programme benefits for low-income families.

This study was conducted in two phases: a realist review and a qualitative study. The overall objectives were to develop and test theories or hypotheses about how the Healthy Start programme works, for who, in what circumstances and why. Specific objectives and research questions evolved as the study progressed and, therefore, they are stated in subsequent chapters. The next section outlines the structure of the thesis chapter by chapter.

1.5 Structure of thesis

This is the first of seven chapters in the thesis. Chapter 2 introduces the Healthy Start programme including programme details (aims, eligibility, benefits), some background about how the programme was developed, and a critical review of previous studies of Healthy Start since 2006. It presents the rationale for conducting this study. Chapter 3 introduces realism as a philosophical and methodological approach to scientific inquiry. It explains why realist evaluation was chosen as the methodology for this study and describes some key methodological concepts: programme theories, context, mechanisms and outcomes. It presents my personal perspective and motivations as the researcher and considerations relating to ontology and epistemology. Chapters 4 and 5 present the realist review, which was conducted in two iterative and overlapping stages: developing programme theories (chapter 4) and testing programme theories (chapter 5). Chapter 4

explains how the scope and aims of the review were gradually narrowed down to focus on how low-income pregnant women use Healthy Start vouchers. Chapter 5 describes how existing empirical evidence was used to test programme theories, resulting in three 'evidence-informed' programme theories. Chapter 6 presents the qualitative study, which was conducted in North West England. The purpose of this study was to continue to develop, refine and consolidate the programme theories from the realist review, and to explore alternative outcomes and explanations. Five evidence-based programme theories are presented, which provide in-depth, plausible explanations for five possible outcomes (intended and unintended). Chapter 7 draws together the overall findings of this study and highlights the original contribution to knowledge. It extends that contribution by integrating the programme theories with existing behaviour change theories and developing an overarching theoretical model for Healthy Start. Finally, it considers implications for policy and practice and recommendations for further research.

1.6 Chapter summary

This chapter has presented the broader context for this study and why it is important. It has outlined the scope of the study and the structure of the thesis. The next chapter provides a more detailed introduction to the Healthy Start programme and rationale for this study.

2.0 THE HEALTHY START PROGRAMME

2.1 Introduction

After taking a broader view on maternal and child nutrition in chapter 1, this chapter focuses on the UK government's Healthy Start programme – the programme under study in this PhD. It begins by introducing the programme, its aims, what it provides and to whom. The next section explains how and why the Healthy Start programme was developed, to replace the pre-existing Welfare Food Scheme in 2006. It compares the evidence-based recommendations and the reforms that were implemented. This is followed by a summary of a policy analysis, which helps to explain how politics may have influenced the development of Healthy Start. The longest section of this chapter is dedicated to a critical review of previous studies of Healthy Start, which summarises the aims, methods, findings, strengths, limitations and recommendations of all published studies between 2006 (when Healthy Start was implemented) and 2017 (when this PhD was submitted). The chapter ends by highlighting gaps in the current evidence base and the rationale for this study. It emphasises how this study contributes original knowledge about the Healthy Start programme.

2.2 Programme details: aims, eligibility, benefits, support

Healthy Start is the United Kingdom (UK) government's food voucher programme for low-income, pregnant women and young children. The Department of Health (DH) has overall responsibility for the management and delivery of Healthy Start, with support from other government departments and the National Health Service (NHS). DH has broadly described the 'aims' (without using this term) of the programme:

> "Healthy Start offers a basic nutritional safety net to specified groups of pregnant women and young children…[it] also encourages women and families to make positive nutritional choices affecting their longer term health." (Department of Health, 2010, p. 4)

The aims of the programme were more clearly interpreted and articulated by the authors of a previous evaluation of Healthy Start (further details about this evaluation in 2.5.2) (McFadden et al., 2013):

1. To provide a nutritional safety net;
2. To improve the diets of pregnant women, breastfeeding mothers and children;

3. To promote breastfeeding, healthy eating and early access to health professionals in pregnancy.

Women are eligible to apply for Healthy Start if they are at least 10 weeks pregnant or have a child under four years old AND (as a household) receive one or more of the following benefits (National Health Service, 2017):

- Income support, or
- Income-based Jobseeker's Allowance, or
- Income-related Employment and Support Allowance, or
- Child Tax Credit *(with a family income of £16,190 or less per year)*
- Universal Credit *(with a family take home pay of £408 or less per month)*

Universal Credit has been a qualifying benefit for Healthy Start since 1st November 2016 (National Health Service, 2017). It was introduced in 2013 to replace six other means-tested benefits, with the aim of simplifying the social security system (Welfare Reform Act, 2017). The income threshold for Healthy Start is now lower than it was under Child Tax Credit (£408 per month equates to £4896 per year) and it is possible this will influence eligibility in the future as more families move onto Universal Credit.

Pregnant women under 18 years are eligible for the whole of their pregnancy and after the baby is born, regardless of their income or benefits status. When they turn 18, they only continue to receive the vouchers if they meet the above criteria.

Data obtained from the Healthy Start Issuing Unit (DH) in March 2017 indicated that 455,164 households (and 545,163 individual beneficiaries) were eligible to apply for Healthy Start, of which 294,060 households (and 362,922 individual beneficiaries) were receiving vouchers. Therefore, the take-up rate was 65% of households (and 67% of individual beneficiaries).

Healthy Start food vouchers can be spent on any combination (one or more) of the following type of foods (National Health Service, 2017):

- Plain cow's milk – whole, semi-skimmed or skimmed (pasteurised, sterilised, long life or UHT);
- Plain fresh or frozen fruit and vegetables (with no added ingredients) – whole or chopped, packaged or loose;

- Infant formula milk that says on the packet it can be used from birth (i.e. not follow-on formula) and is based on cow's milk.

The weekly voucher values are: one voucher per week during pregnancy (£3.10); two vouchers per week for each baby under one year (£6.20) and one voucher per week for each child aged 1-4 years (£3.10). These voucher values have not increased since 2009, even though food prices increased sharply during the economic crash in 2008, and food price inflation remained higher than overall inflation until 2014 (Department for Environment, Food and Rural Affairs, 2017). Hence, the value of Healthy Start vouchers has not kept up with the rising cost of food. This problem was highlighted in a previous evaluation of Healthy Start, which warned that the 'nutritional safety net' could be eroded (McFadden et al., 2013).

Vouchers are posted to the home address every four weeks and must be used within four weeks (expiry dates are printed on the vouchers). Retailers must be registered with Healthy Start to accept the vouchers (and later claim back the value). Most large supermarkets and some smaller retailers will accept the vouchers. The full value of a voucher must be used in one transaction and retailers are not allowed to give change if the full value is not used on permitted items.

In addition to food vouchers, eligible families receive separate vouchers (every eight weeks) for free vitamins (National Health Service, 2017). The beneficiary categories for free vitamins are slightly different to food vouchers and they are sent to: pregnant women, women with a child under 1 months, and children aged six months to four years. Table 2 shows the content of women's vitamin tablets and children's vitamin drops provided by Healthy Start. Local distribution systems vary and women are advised to check on the Healthy Start website or ask their midwife or health visitor about local distribution points (National Health Service, 2017). In 2011/12, the uptake of Healthy Start vitamins was below 10% in most areas (Jessiman, Cameron, Wiggins, & Lucas, 2013; McFadden et al., 2015). Reasons for low uptake of vitamins included poor access and distribution, lack of promotion by health professionals, and lack of awareness and motivation among parents. A subsequent report by the National Institute for Health and Care Excellence included a cost effectiveness review and an economic modelling exercise. It concluded that it would be cost effective to offer Healthy Start vitamins to all women who are planning a pregnancy, women less than 10 weeks pregnant, infants aged 0-6 months, and children aged 4-5 years (National Institute for Health and Care Excellence, 2015a). From

1st April 2017, free vitamins became available to all pregnant women in Scotland. It is not yet known (at the time of submission in September 2017) whether Healthy Start vitamins will be 'universalised' across the rest of the UK.

Table 2. Content of Healthy Start vitamins compared to UK recommendations

Women's vitamin tablets	Content	% RNI
Folic acid	400 micrograms	>100%
Vitamin C	70 milligrams	>100%
Vitamin D	10 micrograms	100%
Children's vitamin drops	Content	% RNI*
Vitamin A	233 micrograms	67%
Vitamin C	20 milligrams	80%
Vitamin D	7.5 micrograms	75%

RNI = Reference Nutrient Intake (British Nutrition Foundation, 2016); *for children the RNI for 7-9 months has been used for comparison (or safe intake for vitamin D)

Health professionals have an important role in supporting Healthy Start. Application forms must be countersigned by a registered health professional, usually a midwife or health visitor, who is required to confirm the expected date of delivery (for pregnant women) or the date of birth of the child/children (for mothers) (National Health Service, 2017). The health professional is not required to confirm the applicant's eligibility for Healthy Start; this is confirmed by the Department for Work and Pensions (DWP). The requirement to have application forms countersigned is intended to encourage low-income women to attend health services and create opportunities for health professionals to provide information and advice on healthy eating, breastfeeding and vitamins.

The National Institute for Health and Care Excellence (NICE) quality standard for improving maternal and child nutrition clearly states that health professionals should: "ensure that they give information to pregnant women and the parents and carers of children under 4 years who may be eligible about the Healthy Start scheme, and provide them with support to apply, such as giving them a signed application form" (National Institute for Health and Care Excellence, 2015b, p. 21). It is unclear how they should determine who may be eligible and whether this should be discussed with all pregnant women. Health professionals should also: "ensure that they explain to parents and carers receiving Healthy Start food vouchers how they can use them to increase the amount of

fruit and vegetables in their family's diet" (p. 32). This second statement implies that Healthy Start aims to improve the diets of low-income families, and the role of health professionals is to facilitate that outcome.

Healthy Start Alliance is a group of organisations and individuals working together to support, promote, protect and advocate for Healthy Start (Healthy Start Alliance, 2017). It was set up in 2014 to demonstrate that there is widespread support for Healthy Start among non-governmental organisations, professional bodies and experts. It is a registered charity managed by the First Steps Nutrition Trust. Healthy Start Alliance values the Healthy Start programme as both a public health initiative and a welfare benefit. It provides the public with up-to-date information about Healthy Start, including examples of good practice and practical ways to support eligible families.

2.3 Historical policy development

Healthy Start was introduced to replace the Welfare Food Scheme in November 2006. The Welfare Food Scheme was established in 1940 to maintain adequate nutrition for pregnant women and young children during wartime food shortages. After the war, it evolved into a basic 'nutritional safety net' for the 'most needy' low-income families (Department of Health, 2010). The scheme provided weekly milk tokens that could be exchanged for cow's milk or infant formula, as well as free vitamin supplements (see Table 3).

Reform of the Welfare Food Scheme was initiated after the 'Independent inquiry into inequalities in health report' drew attention to income as one of the major determinants of health inequalities (Acheson, 1998). The report called for government policies to improve the health and nutrition of women of childbearing age and their children – emphasising the elimination of food poverty – and policies to promote breastfeeding (Acheson, 1998). DH subsequently asked the Committee on Medical Aspects of Food and Nutrition Policy (COMA) to conduct the 'Scientific review of the Welfare Food Scheme' (Committee on Medical Aspects of Food and Nutrition Policy, 2002). The review highlighted that the Welfare Food Scheme did not support sufficient diet diversity to address the nutritional needs of low-income women and children, and was effectively a disincentive to breastfeed because women could exchange their tokens for greater quantities of infant formula than cow's milk (see Table 3). Since research evidence has increasingly shown the benefits of breastfeeding and the importance of nutrition during

pregnancy, the Welfare Food Scheme was at odds with public health recommendations (Healthy Start Alliance, 2017).

Specific recommendations in the review included (Committee on Medical Aspects of Food and Nutrition Policy, 2002):

- A wider choice of foods should be offered to address dietary inequalities more effectively;
- Pregnant women of all ages should have equitable access to welfare foods;
- An incentive for mothers to breastfeed should be considered;
- Liquid cow's milk should not be provided for infants under 12 months of age;
- At 6 months of age the allowance of infant formula should halve in favour of supporting complementary foods;
- An equal volume of infant formula should be offered as an alternative to cow's milk until the child is at least 18 months old.
- Extending the provision of free vitamins should be considered (e.g. to children from ethnic minority groups).

DH produced a consultation document outlining proposals for the new Healthy Start scheme, which would differ from the Welfare Food Scheme in three main ways: a broader range of foods including fruits and vegetables (to address nutritional needs); vouchers with a fixed monetary value rather than tokens (to allow greater flexibility); involvement of health professionals in the application process (to create an opportunity to provide advice and guidance on nutrition including breastfeeding) (Department of Health, 2002). DH received over 500 written responses in addition to feedback from focus groups and consultation events. There was wide support for many of the proposed changes, but concerns were raised about the potential effect on the dairy industry (such as doorstep delivery services) and the implications for health professionals in terms of workloads and training needs (Department of Health, 2003). Following the consultation period, a response document outlined refinements to the original proposals (Department of Health, 2004) and final decisions about Healthy Start were made during a series of government debates.

Table 3 summarises the key differences between the Welfare Food Scheme and Healthy Start. In relation to the recommendations from the COMA review, Healthy Start offered a wider choice of foods than the Welfare Food Scheme (with the addition of fruits and

vegetables). It provided equal support to pregnant women of all ages (with the inclusion of all pregnant teenagers). It was purported that Healthy Start would remove the disincentive to breastfeed by equalising the benefits for breastfeeding and non-breastfeeding women (Department of Health, 2004). It created an opportunity to encourage healthy eating and breastfeeding through engagement with health professionals, who were required to sign the application form. However, Healthy Start did not provide a clear incentive to breastfeed. The recommendations to restrict provision of cow's milk for infants under 12 months and to support complementary foods at 6 months were not implemented. The provision of free vitamins was not extended and remained means-tested.

Table 3. Differences between the Welfare Food Scheme and Healthy Start

	Welfare Food Scheme (1940 – 2006)	**Healthy Start (2006 – present)**
Beneficiaries	Pregnant women and children under 5 years	Pregnant women and children under 4 years
Eligibility criteria	Means-tested benefit	Means-tested benefit All pregnant teenagers
Qualifying foods	Weekly tokens to exchange for cow's milk (7 pints) or infant formula (900 grams)	Weekly vouchers to exchange for fruits and vegetables, plain cow's milk or infant formula
Vitamin supplements	Free vitamins	Free vitamins (different formulation)
Application process	Apply via benefits office	Apply via health professional (opportunity to access good quality information and advice)

Sources: (Dyson et al., 2007; National Health Service, 2017)

2.4 Summary of a policy analysis

Machell analysed the policy formation process of Healthy Start during her doctoral research at City University London, using the 'multiple streams approach' to consider what factors influenced its development (Machell, 2015). This approach was developed

by Kingdon, who suggested that policy change happens when three independent streams converge to create a window of opportunity: problem, policy and politics (Kingdon, 2003). In theory, the following events must occur before any major policy change happens: public attention turns towards a policy problem (problem); a solution to that problem is proposed or becomes available (policy); policymakers have the opportunity – and crucially the motivation – to turn it into policy (politics). However, Kingdon recognised that the reality of policy development is often chaotic and these events may not occur in a linear sequence (Kingdon, 2003).

The policy problem was defined as threefold: the outdated Welfare Food Scheme, the growing evidence base for optimum nutrition during pregnancy, and the increasing awareness of health inequalities in the UK (Machell, 2015). These problems have been described in more detail above (2.3) and in chapter 1. They were brought into focus by the 'Independent inquiry into inequalities in health report' (Acheson, 1998) and the 'Scientific review of the Welfare Food Scheme' (Committee on Medical Aspects of Food and Nutrition Policy, 2002), also described above (2.3). The government was under pressure to implement policies that would improve maternal and child health and reduce health inequalities.

In terms of the wider political climate (politics stream) in the early 2000s, Machell identified several themes relating to the development of Healthy Start. The New Labour government was pursuing other public health and inequalities agendas (such as Early Years/Sure Start) and it made political sense to review and reform the Welfare Food Scheme. The government was also promoting an approach to policymaking based on good practice in four key stages: 1) understanding the problem, 2) developing solutions, 3) putting the solutions into practice, 4) evaluating success and making necessary adjustments. This approach emphasised the importance of stakeholder consultations and using evidence to inform change. This combination of factors meant that policymakers were motivated to reform the Welfare Food Scheme and introduce Healthy Start in its place. However, there were some inconsistencies between the proposed changes and the problems they were intended to address, i.e. nutritional needs and health inequalities (Machell, 2015). The budget was set to remain the same as the Welfare Food Scheme, but the policy documents did not elaborate on how this budget would be used to deliver a more complex intervention that would support low-income women to eat well during pregnancy and to breastfeed. Furthermore, the proposal document referred to a range of cross-cutting agendas that Healthy Start would help to address, such as the future of

farming and child poverty (Department of Health, 2002). These agendas were beyond the scope of the evidence and Machell compared this to Kingdon's assertion that policy is often driven by the politics and not the problem (Kingdon, 2003; Machell, 2015).

The proposed policy solution was Healthy Start, and Machell considered the relative influence of 'visible' and 'hidden' actors during the development of Healthy Start. For example, there was an imbalance in the consultation exercise undertaken by DH, with less than 5% of responses obtained from parents (potential beneficiaries), 17% from the dairy industry and over 50% from health authorities and professionals. Therefore, concerns about the impact of Healthy Start on the dairy industry and health professionals (visible actors) were thought to be more influential than the perspectives of potential beneficiaries and other stakeholders such as the fruit and vegetable industry (hidden actors) (Machell, 2015).

When the three streams (problem, policy and politics) converged, there was a short window of opportunity during which Healthy Start was approved in Parliament (2005) and then implemented (2006). Despite the government's rhetoric around evaluation and evidence-based policy, there was no pilot study prior to the implementation of Healthy Start. The first phase of implementation was evaluated (Hills, 2006) and this study is described in more detail below (see 2.5). It was a 'rapid evaluation' and Machell noted that beneficiaries were underrepresented in this study (17/112 interviews) as in the consultation exercise (Machell, 2015). The national roll-out was not structured to allow for robust evaluation design and this was later summarised as "policy-related factors and timing-limited options for evaluation from the start" (Dyson et al., 2007, p. 14).

Machell concluded that political pressures and budget constraints took precedent over public health objectives during the development of Healthy Start. The politics stream dominated the policy formation process and overshadowed the problem.

> "…although it addressed the problem of the Welfare Food Scheme not being efficient, it has not reformed the policy in a way that will enable outcomes to be measured effectively or for the complexity of food poverty and nutrition insecurity to be fully realized." (Machell, 2015, p. 31).

2.5 Critical review of previous studies of Healthy Start

This section reviews previous research and evaluations of Healthy Start, with critical reflections on the strengths and limitations of each study. The review is chronological to give some sense of the evolution of knowledge and evidence about Healthy Start. It is important to emphasise that there has been no robust evaluation of the impact of Healthy Start on nutritional outcomes. Therefore, it is unclear if the programme has improved the diets of low-income women and children, as suggested in terms of encouraging them to make 'positive nutritional choices' (Department of Health, 2010) and increase the amount of fruit and vegetables in their diets (National Institute for Health and Care Excellence, 2015b). The most in-depth findings are from two independent and concurrent evaluations of Healthy Start (see 2.5.2) (Lucas et al., 2013; McFadden et al., 2013).

2.5.1 Studies conducted around the time of implementation (2006-07)

The first study of Healthy Start was a 'rapid evaluation' of the first phase of implementation in Devon and Cornwall (Hills, 2006). It was commissioned by DH and conducted by the Tavistock Institute (a social science research agency) in partnership with Symbia (management consultants). It evaluated the 'early impact' of Healthy Start on beneficiaries, health professionals, retailers and contractors. Mixed methods were used: postal and telephone surveys (n=70) and in-depth interviews (n=133) with a range of stakeholders in rural, urban and inner city areas. The authors acknowledged that the absence of a local coordinator in Devon and Cornwall made it difficult to understand the local context and contact stakeholders. The lack of ethnic diversity in the study sample (and the region) meant the findings were not generalizable to other areas of the UK.

In general, the voucher system seemed to be working well and the transition from the Welfare Food Scheme to Healthy Start had been clearly communicated (Hills, 2006). Over half the beneficiaries surveyed reported buying more fruit and vegetables since receiving the vouchers. However, the evaluation highlighted some challenges with the first phase of implementation: inadequate knowledge about the scheme among health professionals and support workers; lack of management support and leadership; confusion among retailers about the need to register to accept the vouchers; confusion among potential beneficiaries about eligibility. It made several recommendations for the national roll-out of Healthy Start, including the need for better links with parallel services and initiatives (such as the 5-a-day campaign) to maximise the opportunities to reinforce

healthy eating messages. It also recommended that a national evaluation should be developed for the national roll-out of the programme.

In 2006, DH funded a scoping study to advise on "approaches to monitoring and evaluation of longer-term health and social outcomes of the Healthy Start scheme, including establishment of baseline data" (Dyson et al., 2007, p. 6). The study was conducted jointly by the Mother and Infant Research Unit, University of York and the Institute of Child Health, University College London. The authors clearly stated that the most robust evaluation design would include an equivalent comparison group, and ideally a phased roll-out to compare different geographical areas. However, this was ruled out due to time limitations because the national roll-out was happening around the same time as the scoping study commenced. Therefore, the report presented four options for national monitoring and evaluation. Option 2 was recommended as the most robust and feasible way to provide good quality data to assess the effects of Healthy Start:

> "National monitoring and evaluation of comprehensive range of outcomes of effectiveness, coverage and impact of programme. Purposive national cross-sectional surveys or cohort study of recipients within planned nationally representative sentinel sites for outcomes of effectiveness: dietary intake, supplement intake; potentially nutrient intake; infant feeding including weaning and introduction of cow's milk, purchasing data; process outcomes: impact of programme on recipients; and explanatory variables." (Dyson et al., 2007, p. 9).

The report outlined how such an evaluation could be undertaken, advocating a prospective and longitudinal design. It highlighted several issues pertinent to evaluations of complex interventions: the difficulties of conducting research with vulnerable groups (such as low-income families), the confounding effects of other health initiatives, and the possibility of unintended consequences (Dyson et al., 2007). Option 2 was not implemented. However, some of the other options presented in the report were implemented (in part), including the adaption of existing national surveys (see Infant Feeding Survey below), and local or regional studies to describe impact of programme on core outcomes of dietary and nutrient intake (see Sheffield 'before and after' study below).

The Sheffield 'before and after' study was conducted during the transition from the Welfare Food Scheme to Healthy Start (Ford, Mouratidou, Wademan, & Fraser, 2009). It compared the food and nutrient intakes of pregnant and post-partum women who were beneficiaries or eligible for the Welfare Food Scheme (phase 1; 2005-06; n=176) and

women who were beneficiaries or eligible for Healthy Start (phase 2; 2007; n=160). It found that women in phase 2 reported significantly higher intakes of total energy, iron, calcium, folate and vitamin C, and significantly more portions of fruits and vegetables per day compared to women in phase 1 (Ford et al., 2009). This cross-sectional study was not able to draw any conclusions about causation since there were no baseline data or control groups. Some of the participants were not receiving the benefits, despite being eligible, and it is unclear why these women were included. This study provided a timely comparison of the diets of two groups of women exposed to two different interventions. However, it did not demonstrate the impact of either intervention on women's diets.

A follow-up study examined whether the differences observed at 4 weeks postpartum (n=142) were sustained at 8 weeks postpartum (n=86) and 12 weeks postpartum (n=86) (Mouratidou, Ford, Wademan, & Fraser, 2010). Women in phase 2 (beneficiaries or eligible for Healthy Start) reported higher intakes of energy and selected nutrients (protein, total fat, carbohydrate, fibre, calcium, iron, zinc, total folate and vitamin C) at all three time points compared to women in phase 1 (beneficiaries or eligible for the Welfare Food Scheme). In both phases, there was little change in women's energy and nutrient intakes from 4 weeks to 8 weeks to 12 weeks postpartum. Only 55 women provided data at all three time points, so the analyses were unbalanced. Both Sheffield studies used food frequency questionnaires to assess women's diets and the authors acknowledged the potential inaccuracy of this method (Ford et al., 2009; Mouratidou et al., 2010).

2.5.2 Studies conducted several years after implementation (2010-15)

The Infant Feeding Survey was conducted every five years between 1975 and 2010, before it was discontinued by the government. The last survey in 2010 was the only one conducted after Healthy Start was introduced in 2006. It included five questions about Healthy Start to "measure levels of awareness of and registration on the Healthy Start scheme and understand how Healthy Start vouchers are being used" (McAndrew et al., 2012, p. 13). The main strength of this survey was its large sample size. An unclustered sample of 30,760 births was selected from all births registered between August and October 2010. To ensure a robust sample size in each country, all births in Wales and Northern Ireland were included and a random sample from England and Scotland. The most deprived quintile from each country was oversampled. Over half (51%) of the mothers in the sample responded to the survey (n=15,724). The response rate was lower

among younger mothers and areas of higher deprivation, but this was corrected for statistically (McAndrew et al., 2012). The survey was conducted in three stages when the babies were 4-10 weeks old (n=15,724), 4-6 months old (n=12,565) and 8-10 months old (n=10,768).

At stage 1, mothers were provided with a description of Healthy Start, including the eligibility criteria, and asked if they considered themselves eligible. Less than a quarter (24%) of the mothers considered themselves eligible for Healthy Start. This was not validated against actual eligibility due to confidentiality. Of the mothers who considered themselves eligible for Healthy Start (n=3443), 58% were already registered with the programme. The highest levels of registration were reported by mothers aged under 20 (70%), mothers who had never worked (74%) and mothers of second or third babies (68%). Of the mothers who considered themselves eligible for Healthy Start but were not registered (n=1535), 59% were not aware of Healthy Start before the survey. Mothers who were registered or aware of Healthy Start (n=2506) were asked how they found out about the programme; they could select more than one source of awareness. The most common sources of awareness were midwives (51%), health visitors (29%), partners, friends or relatives (24%), the local benefit office or Jobcentre Plus (23%).

At stage 1, 84% of mothers who were registered with Healthy Start said they had used the vouchers. Of the mothers who had not used any vouchers (n=306), 68% said they had not received any vouchers or were waiting for a response from Healthy Start. At stage 1, mothers who said they had used the vouchers (n=1602) had used them to buy infant formula (68%), fresh fruit (52%), fresh vegetables (47%) and cow's milk (43%). As the babies got older, more mothers started to use the vouchers for fruit and vegetables. At stage 3, mothers who said they had used the vouchers (n=918) had used them to buy infant formula (70%), fresh fruit (57%), fresh vegetables (55%) and cow's milk (40%).

The Infant Feeding Survey also assessed prevalence of breastfeeding at various ages up to nine months. It was consistently lower for mothers who were registered with Healthy Start (n=1120) than for all mothers (n=10,768). For example, prevalence at birth was 60% for mothers who were registered (compared to 81% for all mothers); prevalence at six weeks was 32% (compared to 55%); prevalence at six months was 18% (compared to 34%). The authors acknowledged that these differences may be due to demographic patterns of breastfeeding (McAndrew et al., 2012).

In 2011, DH commissioned an independent market research agency to conduct a small qualitative study of retailers in England (n=72), including retailers who were registered to accept Healthy Start vouchers and retailers who were not registered (the numbers of each were unclear) (Department of Health, 2012). The aims of the study were to explore retailer views on and understanding of Healthy Start, and to understand more about voucher misuse (i.e. vouchers being used to pay for items not permitted by Healthy Start) and what could be done to prevent it. The published report was very brief and methods were poorly reported. Findings were not substantiated by direct quotations from retailers, as would be expected in a qualitative study.

Retailers' attitudes towards Healthy Start were generally positive; they understood how the system should work and appreciated the benefits for families and themselves (Department of Health, 2012). They reported that misuse of vouchers was rare and most customers wanted to spend their vouchers on permitted items. Checkout staff said it was easy to see what had been bought and visually verify (or 'guestimate') the approximate value of permitted items. However, some retailers recalled customers who had tried to spend their vouchers on alternative (non-permitted) items. There was some uncertainty about whether items such as 'seasoned' frozen vegetables, UHT milk and follow-on formula were permitted. Staff admitted that they sometimes used 'common sense' when they were unsure, and therefore may have allowed alternative items to be purchased. They also used 'discretion' and allowed vouchers to be spent on items like soya milk (e.g. for lactose intolerant children) because they felt this was logical and preferred to avoid conflict with parents. Some smaller retailers held vouchers for families (as permitted) and this made it easier for families to spend the full value across more than one visit, since retailers are not permitted to give change for partially spent vouchers. The main recommendation was to improve the availability and awareness of resources for retailers, to clarify the range of permitted items and support the checkout process and customer service (Department of Health, 2012).

DH also funded two independent and concurrent evaluations of Healthy Start in 2011. It is unclear why two evaluations were commissioned simultaneously, but they reinforced some of the same findings and recommendations (Healthy Start Alliance, 2017). Neither included an assessment of the impact of Healthy Start on nutritional outcomes using validated dietary assessment methods.

The first was a qualitative study conducted by the School for Policy Studies, University of Bristol and the Social Science Research Unit, Institute of Education (Jessiman et al., 2013; Lucas et al., 2013). Its aim was to understand the views and experiences of key stakeholders, including the perceived value and impact of Healthy Start and ways it could be improved. Interviews were conducted with parents (n=107, including 14 pregnant women), frontline professionals (n=65), small and independent retailers (n=20) in 13 Primary Care Trusts (PCTs) in England. The sampling strategy was designed to capture a diverse range of experiences of Healthy Start. Parents were mostly mothers, but two interviews were conducted with fathers and four with fathers also present. The sample included parents who were receiving Healthy Start vouchers (n=70), parents who were eligible but had failed to apply (n=11), parents who had applied but not received the vouchers (n=8) and previous users (n=18). The results are summarised here (as in the main report) for three groups of stakeholders.

Frontline professionals: Local management of Healthy Start varied between the 13 PCTs. Effective management tended to involve senior leadership, a multidisciplinary steering group (e.g. midwives, health visitors and children's centre staff) and a Healthy Start Coordinator (or 'champion'). The uptake of Healthy Start vitamins was below 10% in all research sites and two main barriers (reported by professionals and parents) were lack of access and awareness (Jessiman et al., 2013). In some areas, promotion and distribution of vitamins had become the focus of attention and the wider public health opportunities associated with food vouchers had been neglected. Frontline professionals requested more training and data on Healthy Start, to enable them to direct support towards eligible families. Midwives and health visitors generally had good knowledge of the programme and its aims, which they understood as "educating beneficiaries about healthy diet and nutrition, and providing a financial and nutritional 'safety net' to ensure that families on very low incomes could afford nutritious food" (Lucas et al., 2013, p. 34). They regularly promoted Healthy Start and countersigned application forms. However, they were concerned about understaffing, workload and the amount of information they were required to discuss with families. Therefore, the links between using Healthy Start vouchers to achieve a healthy diet may not always be made clear (Lucas et al., 2013). Health professionals were also concerned that some eligible (and vulnerable) families may be missing out due to confusion about eligibility, fluctuating income, chaotic lives, poor literacy, or lack of engagement with health services.

Parents (and pregnant women): Most parents felt they were well supported by health professionals to apply for Healthy Start; only a minority found the application process inconvenient or frustrating. However, some parents found the process for reporting the birth of babies (necessary to receive the additional vouchers) unclear or problematic. Parents valued the contribution of Healthy Start vouchers to their weekly budget. Parents who formula fed their babies tended to use the vouchers to offset the cost of formula – but they did not cover the whole cost. Around a third of parents reported buying more fruits and vegetables (amount and variety) than they would without the vouchers. Some parents considered fruits and vegetables to be 'non-essential' items, which might 'fall off the list' without the vouchers (Lucas et al., 2013, p. 50). Conversely, some parents said the vouchers made no difference to their food choices because they preferred to save the additional money or because they did not think they needed to improve their diets. Most parents used their vouchers in supermarkets due to convenience, lower prices, greater range of foods, and a sense of anonymity. However, some parents used them in smaller shops due to limited transport or because they perceived greater flexibility, i.e. they could use the vouchers to buy alternative items (in some cases non-food items). Parents had experienced different levels of vigilance in terms of how shops checked what they had bought using the vouchers. Sometimes this caused embarrassment when parents were asked to separate Healthy Start items. Parents did not always manage to spend the full voucher value and they resented when they lost the remaining value (as the rules state that no change should be given). Parents suggested various ways to improve Healthy Start, such as increasing the voucher value and expanding the range of items available (e.g. non-dairy milk, yoghurt, baby food and bread). The diet and nutrition advice parents had received from health professionals was inconsistent. They did not recall information about Healthy Start vouchers being linked to diet and nutrition advice, but some had made the connection themselves. Teenage mothers in this study (n=8) were more likely to refer to parents or partners as sources of information and advice and, in some cases, other family members did the shopping and prepared the meals.

Small and independent retailers: Retailers generally found the Healthy Start process straightforward, including registration, submission of vouchers and reimbursement. They reported that vouchers were often used to buy cow's milk, and they thought this was because infant formula and fruits and vegetables were more expensive in smaller shops than supermarkets. They felt that being part of Healthy Start was a service to the community. Some retailers were unsure what Healthy Start vouchers could be used for –

bread, eggs and baby food were among the items mentioned. Some retailers admitted 'bending the rules' by allowing families to use the vouchers for alternative items. This tended to be when they perceived a benefit to the children. Some retailers also reported (but did not name) other shops that allowed families to use the vouchers for items such as cigarettes. The study authors speculated that reporting the fraudulent behaviour of other shops may have been a way to frame their own behaviour as 'morally correct' (Lucas et al., 2013). It was unclear how frequently the misuse of vouchers occurred. Retailers requested marketing materials to increase visibility of the scheme, and suggested that a list of registered retailers should be sent out with the vouchers.

Some of the key recommendations from this study included:

- Improvements in the distribution and promotion of Healthy Start vitamins;
- Better promotion of the potential health benefits of Healthy Start;
- Integration of Healthy Start within other activities and services;
- Better use of existing data to assist local planning and management.

The second evaluation funded by DH in 2011 was a mixed methods study conducted by the Department of Health Sciences, University of York and the Health Economics Research Group, Brunel University (McFadden et al., 2013; McFadden et al., 2014; McFadden et al., 2015). The evaluation report included two literature reviews on food support programmes (contextual factors and impact), a systematic review of economic literature on voucher-based supplementary feeding schemes, and an assessment of the feasibility of using national databases to assess the impact of Healthy Start vouchers on consumer demand for products (McFadden et al., 2013). This critical review focused on the empirical study – an evaluation of the views and experiences of practitioners and women in relation to Healthy Start. Its aim was to provide a 'real-life view' of the operation of Healthy Start and evidence to inform programme improvements. The views and experiences of practitioners were assessed using focus groups and a national electronic consultation (n=669). The views and experiences of low-income women were assessed using participatory workshops, focus groups and telephone interviews (n=113). The sample included women who were receiving Healthy Start vouchers, women who had received vouchers within the last year, women who had recently applied and were not yet receiving vouchers, women who had applied and been refused, and women who

thought they might be eligible if they applied (number in each group not stated). The qualitative fieldwork was conducted in Yorkshire and the Humber and London. A strength of this study was purposive sampling to represent low-income women from a range of cultural backgrounds and vulnerable groups, including teenagers and women who did not speak English. The findings are summarised (as they were in two journal articles) under three main themes.

Accessibility of Healthy Start: Some low-income women and practitioners (including health visitors, midwives and public health specialists) felt that Healthy Start eligibility criteria were confusing, especially for teenage women and families with variable incomes. The online consultation with practitioners highlighted the importance of providing information about Healthy Start to women who might otherwise be unaware of their eligibility. However, some women said they had not been informed by their midwife or health visitor, for example women who did not speak English. Practitioners had a lot of information to communicate during antenatal appointments and they were conscious of overloading women with information. Some practitioners targeted women who they thought were likely to be eligible and they acknowledged that some eligible women may have been missed due to incorrect assumptions. The application process was described as 'cumbersome' especially for women with poor literacy or not fluent in English. Practitioners tried to support women through the application process, but did not always have sufficient time. There were often delays of several weeks before women started receiving the vouchers. Many women felt that Healthy Start should be extended to low-paid working families (i.e. by raising the income threshold) and to the child's fifth birthday.

Using food vouchers: Most women in this study said that Healthy Start vouchers made a difference to their shopping and eating habits by increasing the quality and variety of fruits and vegetables. Many women said they bought similar amounts of milk, fruits and vegetables, but the vouchers helped them to manage better financially. The vouchers also acted as a reminder to eat well, and to establish good habits for themselves and their children. Several pregnant teenagers said the vouchers provided resources for food they would not otherwise have been able to afford. Practitioners and women were concerned about rising food costs and some thought the voucher value should be increased. In general, women who breastfed spent the vouchers on fruits, vegetables or cow's milk, whereas women who formula fed their babies spent the vouchers on formula – but they did not cover the whole cost. There were differing opinions among practitioners about

whether Healthy Start should support women who formula feed, and whether it was an incentive to formula feed. Many women said it had not influenced their infant feeding decisions. However, some women said it made the decision to formula feed seem more acceptable, or they had switched from breast to formula sooner than they would have without the vouchers. Most women used the vouchers at supermarkets for convenience and price reasons, but supermarkets were less accessible for rural families. It was not always possible to use the vouchers in smaller shops (if they were not registered with the scheme). Some women felt judged or stigmatised when they used the vouchers in supermarkets. Practitioners and women suggested the vouchers should be valid for online shopping. It was unclear which shops were registered and women were reluctant to ask staff because it identified them as poor. Practitioners suggested that women should be given a list of local registered retailers, and Healthy Start should be made more visible in stores using promotional materials.

Low uptake of Healthy Start vitamins: Practitioners were concerned about the low uptake of Healthy Start vitamins (less than 10%) and the consequences for health outcomes. The main barriers were supply chain and distribution issues, such as limited times and venues for families to collect the vitamins. Most women were unaware that they were entitled to free vitamins or where to get them from. Most practitioners agreed that all pregnant women and young children should receive free vitamins, and thought this would be more cost effective than the current system. It would also enable women to receive vitamins earlier in pregnancy, which is known to be important for folic acid supplementation in particular (McFadden et al., 2015). Practitioners suggested that vitamins should be more widely available from midwives, health visitors, children's centres, pharmacies and GPs. These changes would free up more time to promote the Healthy Start vouchers.

Some of the key recommendations from this study included:

- Communication strategy to increase awareness of Healthy Start;
- Streamline the application process and provide more support for women;
- Increase the voucher value in line with rising food prices
- Training on Healthy Start for health and social care practitioners who work with pregnant women and low-income families;

- Free vitamin supplements for all pregnant women, postnatal and breastfeeding women and children up to their fifth birthday.

These two DH-funded evaluations provided a comprehensive picture of how Healthy Start was operating five years after it was introduced (Lucas et al., 2013; McFadden et al., 2013). Neither of the studies were designed to assess the impact of the programme. The perceived outcomes and benefits were similar in both studies and women reported using the vouchers in a variety of ways: to buy more healthy foods (greater amount, quality or variety), to save money and manage better financially, or to offset the cost of infant formula. The reasons why women used the vouchers in different ways were not fully explored. Similar barriers and challenges emerged from both studies: low uptake of Healthy Start vitamins; confusion around eligibility; problems with the application process; inconsistent or inadequate support for low-income families; concerns about stigmatisation. The two evaluations recommended ways to improve access, awareness and integration of the programme and optimise the benefits for low-income families. DH did not formally respond to the recommendations and it was unclear to what extent they were considered or implemented.

2.5.3 Recent and ongoing studies of Healthy Start

A study by the Institute for Fiscal Studies compared spending behaviour before and after the introduction of Healthy Start (Griffiths, von Hinke Kessler Scholder, & Smith, 2015). It was a secondary analysis of grocery purchasing data collected from 266 low-income households in the UK between 2004 and 2008, by market research firm Kantar. A 'triple differences' approach was used to compare: 1) spending behaviour before and after the introduction of Healthy Start; 2) households predicted to be 'eligible' and 'ineligible' for Healthy Start; 3) households defined as 'distorted' (those who would otherwise spend less than the value of the voucher on milk, fruits and vegetables) and 'infra-marginal' (those who never spent less than the value of the voucher on milk, fruits and vegetables). This showed that 'eligible' households increased spending on fruits and vegetables by 15.5% (equivalent to two thirds of a portion per household per day). However, the effects were heterogeneous. The 'distorted' households (arguably those with the greatest need to change their behaviour) increased spending on fruits and vegetables by 23.2%, whereas the 'infra-marginal' households used the Healthy Start vouchers as a cash benefit and did not increase spending on fruits and vegetables ($p<0.001$). Since the 'infra-marginal' households made up 40% of (predicted) Healthy Start recipients, this was considered a

"sizeable deadweight cost for targeted benefits designed to change dietary choices" (Griffiths et al., 2015, p. 1). The authors concluded that their findings corresponded with standard economic predictions of the effects of targeted benefits, and that further work was needed to understand the behavioural mechanisms influencing dietary choices (Griffiths et al., 2015).

This economic effectiveness study suggests that families with the lowest prior spending on fruits and vegetables may experience the greatest nutritional benefits from receiving Healthy Start vouchers. It also suggests that some families may use the vouchers to subsidise the cost of items they would have bought even without the vouchers – in other words for financial assistance rather than nutritional benefits. However, the study had several limitations. Purchases were recorded by participants in the home using a handheld scanner, which was more difficult for loose items like fruits and vegetables. Possible sources of bias included selection bias and reporting error. The dataset did not include household income or benefits received, so eligibility for Healthy Start was predicted based on the number of hours worked and the presence/age of children in the household. Various 'robustness checks' were built into the analyses to account for these limitations, such as excluding months where no loose fruits and vegetables were recorded.

A recent study in Lothian, Scotland reported on efforts to increase the uptake of Healthy Start vouchers using the Model for Improvement (Mackenzie & Dougall, 2016). This model (or tool) is designed to accelerate improvement, using the Plan-Do-Study-Act cycle to test changes in real work settings and determine if they were improvements (Institute for Healthcare Improvement, 2017). The Early Years Collaborative project considered various areas for improvement in the Healthy Start application process and tested small changes that might streamline the process. The testing started with one midwife and one pregnant woman, and was gradually scaled up. Over the study period, voucher receipt in Lothian increased by 13.3% (313 to 355 women) compared to an 8.4% decline for the rest of Scotland (Mackenzie & Dougall, 2016). This improvement was attributed to understanding the application process, sharing data, and employing welfare rights advisers to support low-income pregnant women and families.

An ongoing evaluation of Healthy Start was funded by the National Institute for Health Research (NIHR) and is being conducted by the University of Glasgow. The study aims to evaluate the extent to which Healthy Start improves the nutrition of pregnant women and the health outcomes of their infants (National Institute for Health Research, 2015). It

has three components: secondary analysis of data from two existing surveys; a cost effectiveness analysis; a qualitative study to explore factors affecting the uptake of Healthy Start and how the vouchers are used. The study design is described as a 'natural experiment' with three comparison groups: recipients of Healthy Start (group 1), eligible non-recipients (group 2), and women who are just outside the eligibility criteria for Healthy Start (group 3). The primary outcomes are vitamin use in pregnancy (maternal outcome) and breastfeeding initiation and duration (infant outcome). Secondary outcomes include child growth, child morbidity, child feeding and maternal health. This evaluation was due to be completed in May 2017, but no findings were available at the time of submission in September 2017.

In 2016, DH commenced an internal project called Healthy Start Discovery, which has been reported through a series of blog posts (Department of Health, 2016a; Department of Health, 2016b; Department of Health, 2016c). This project is ongoing and the completion date is unclear. It aims to explore the potential of digital technology to improve the Healthy Start user experience and the cost-effectiveness of the programme. The first phase included 'user research' but the methods were not clearly reported. Interviews were conducted with 19 mothers (across a range of locations and demographics) and 11 health professionals (including midwives and health visitors) (Department of Health, 2016b). The findings were 'triangulated' with previous studies of Healthy Start and data from the DH Healthy Start Issuing Unit, but no precise details about this analysis were published (Department of Health, 2016b). The findings reiterated some of the problems identified in previous studies, such as declining take-up (from 80% in 2009 to 72% in October 2016), overreliance on health professionals to promote and support the programme, delays in the application process, loss of voucher value (when vouchers expire or no change is given). Healthy Start users expressed some interest in digital options like online shopping and the ability to spend smaller amounts. However, they also expressed some concerns such as limited credit on mobile phones and lack of confidence with digital technology. The next phase of the project will test a range of digital solutions, including 'auto-enrolment', online application form, online accounts, online shopping, social media campaigns, and signposting users to relevant services and information (Department of Health, 2016a). It is unclear how long this phase will last, but the findings will be used to decide whether to launch a new digitalised voucher programme.

2.6 Research gaps and rationale for this study

Several common themes emerged from the review of previous studies of Healthy Start. The uptake of Healthy Start vitamins is very low across the UK due to problems with access, distribution and awareness (Jessiman et al., 2013; Lucas et al., 2013; McFadden et al., 2013; McFadden et al., 2015). Provision of free vitamins for women and children is currently under review (at the time of submission in September 2017) and, therefore, Healthy Start vitamins will not be the focus of this study. Barriers and challenges relating to the operation of the Healthy Start voucher scheme included lack of awareness, confusion about eligibility, difficulties with the application process, inconsistent support from health professionals, and potential for vouchers to be used incorrectly (Department of Health, 2012; Hills, 2006; Lucas et al., 2013; McAndrew et al., 2012; McFadden et al., 2013). Previous studies made recommendations to address these issues, and the recent investment by DH in the Healthy Start Discovery project indicates that potential digital solutions may be developed in the coming years.

An omission from the evidence base is a national evaluation of the impact of Healthy Start on nutritional outcomes. This was recommended in the scoping review funded by DH (Dyson et al., 2007), but was not part of the brief for two evaluations funded by DH (Lucas et al., 2013; McFadden et al., 2013). It has been suggested that an evaluation strategy was neglected at the time of implementation due to other political priorities (Machell, 2015). It remains unclear what impact the Healthy Start programme may have on the nutritional outcomes of low-income pregnant women and young children, and whether it achieves its aim to encourage positive nutritional choices (Department of Health, 2010).

Several studies have investigated the perceived benefits of Healthy Start (Lucas et al., 2013; McAndrew et al., 2012; McFadden et al., 2013) and estimated its effects on household spending behaviour (Griffiths et al., 2015). Their collective findings suggest that some women use Healthy Start vouchers to buy more healthy foods (cow's milk, fruits and vegetables) than they would otherwise be able to afford, whereas some women use them to subsidise the cost of healthy foods or infant formula, and some women use (or rather misuse) them to buy alternative items. However, these studies did not elucidate the reasons why women may have experienced these different outcomes, or the extent to which they may have overlapped. This is another area where further research is needed. It is important to understand how individual women may respond to being given food

vouchers, and consider contextual factors that may influence this. This kind of in-depth knowledge is essential to maximise programme benefits for low-income families.

Therefore, in response to these priorities, this PhD study sought to explore how low-income women use Healthy Start vouchers and why. The following chapters explain in greater detail how this research question was identified. They describe how a realist approach was used to achieve the depth of knowledge that was missing from previous studies of Healthy Start. This approach was used to investigate complex relationships between contextual factors, causal mechanisms and potential outcomes (including intended and unintended outcomes) of the Healthy Start programme.

This study provides an original and timely contribution to the evidence base: plausible and evidence-based explanations for why the Healthy Start programme is likely to work better for some beneficiaries than for others. The findings of this study could be used to inform the design of future evaluations (sampling strategy and outcome measures), and to inform programme development. The findings are specific to the Healthy Start programme, but they also offer insights at a more abstract and theoretical level, some of which may be relevant and transferable to similar programmes.

2.7 Chapter summary

This chapter has introduced the Healthy Start programme: its aims, eligibility, benefits received and how the programme is supported. It provided relevant background information, including what came before Healthy Start (the Welfare Food Scheme), what prompted the reforms (and the extent to which they were evidence-based) and political influences on the policy formation process. It provided a comprehensive review of what is already known about Healthy Start programme, from previous and ongoing research studies, and what remains to be discovered. It highlighted research gaps and the rationale for this realist study of Healthy Start. The purpose of this chapter was to inform decisions about methodology, study design and research questions. The next chapter introduces realism as a way of thinking and an approach to scientific inquiry. It explains why realist evaluation methodology was chosen for this study.

3.0 METHODOLOGY

3.1 Introduction

This chapter presents the philosophical and methodological approaches that have been adopted and used in this study. It begins with an overview of the philosophy of critical realism, which provides a lens through which science can seek explanations for things that happen in the real world. This philosophy led to the development of other realist perspectives, including realist evaluation, which uses a combination of evidence and theory to understand the inner workings of social programmes. Realist evaluation (a term used broadly to encompass realist synthesis and realist evaluation) is the chosen methodology for this PhD study. This chapter describes some key concepts in realist evaluation: programme theories, context, mechanisms and outcomes. The rationale for choosing this methodology is justified in relation to what is already known about Healthy Start and what more needs to be known – the original contribution to knowledge that realism can offer. My personal perspective and motivations as the researcher are acknowledged in terms of how it influenced the choice of realist evaluation, and in relation to ontology and epistemology. The chapter concludes by outlining how realist evaluation was applied in two phases: a realist review and a qualitative study using realist interviews. The research methods are reserved for subsequent chapters.

3.2 Critical realism: the philosophy

Critical realism is a philosophy of science – a way of conceptualising what science can tell us about the real world. It originated from the work of Bhaskar, the late British philosopher, who questioned what the world must be like for science to be possible (Bhaskar, 1975; Bhaskar, 1998; Bhaskar, 2016). He differentiated two dimensions of knowledge: ‘intransitive’ objects of knowledge that exist independent of human thought (i.e. regardless of whether or what we know about them) and ‘transitive’ objects of knowledge that exist only in human thought. Objects of knowledge could be things, processes, events or phenomena. The differentiation between intransitive and transitive dimensions implies that we can never know all there is to know. Bhaskar (2016) referred to science as a social process (transitive dimension), through which we study a world and objects within it that exist and act independent of science (intransitive dimension). It is also a process in motion and only captures one moment in time. Critical realism considers all scientific knowledge to be partial, fallible and liable to change over time.

Furthermore, Bhaskar considered the nature of reality and how science should seek to understand reality. He presented a model of 'stratified reality' (Figure 1) with three overlapping domains: that which we experience (the 'empirical' domain); the patterns of events and phenomena that occur, which we may or may not experience (the 'actual' domain); the underlying mechanisms that generate those events and phenomena (the 'real' domain) (Bhaskar, 1998). He argued that science should not be reduced or limited to deriving knowledge only from what can be observed or experienced (empirical/actual domains). Rather it should seek to produce explanations by developing theories about 'generative mechanisms' and subjecting those theories to empirical scrutiny (Archer, Bhaskar, Collier, Lawson, & Norrie, 1998). The term 'retroduction' is used by critical realists to describe/advocate "the imaginative activity in science by which the scientist thinks up causes or, as we shall say, generative mechanisms which, if they were real, would explain the phenomenon in question." (Bhaskar, 2016, p. 3).

Figure 1. Stratified reality (Bhaskar, 1998)

	Domain of Real	Domain of Actual	Domain of Empirical
Mechanisms	X		
Events	X	X	
Experiences	X	X	X

Generative mechanisms were succinctly described as "nothing other than a way of acting of a thing." (Bhaskar, 1998, p. 38). In the social sciences, mechanisms are the causal powers that explain social phenomena and these may reside within people or structures. Sociologists described the interdependent relationship between 'structure' (rules and resources e.g. traditions, social norms, moral codes) and 'agency' (human actions) to explain the process of social change (Giddens, 1984). Critical realists later suggested that society pre-exists individuals, therefore social structures may influence (enable or constrain) people's actions, and in turn people's actions may reproduce or transform the social structures that already exist (Archer, 1998). They argued that, by looking at the sequence of change over time, it would be easier to identify mechanisms of action. As well as being influenced by social structures, people's actions (or agency) are determined by their beliefs, desires, values and concerns. An internal process of 'reflexive deliberation' occurs, which may be conscious or unconscious, and critical realism regards this deliberation or reasoning as the causal mechanism that triggers a particular course of action (Bhaskar, 2016).

Critical realism views society (or social reality) as an open system, which implies that social sciences cannot be investigated using closed experiments (Archer et al., 1998; Bhaskar, 2016). This means that realist theories will be explanatory, not predictive, but they can still identify mechanisms at work in specific contexts. Social phenomena may involve multiple layers of mechanisms, and the relationships between them are likely to be complex and change/evolve over time. Bhaskar described mechanisms as tendencies, which may be exercised or unexercised, actualised or unactualised, with or without human awareness or perception (Archer et al., 1998). In other words, causal powers are dormant within people and structures – they may remain dormant or come into effect, depending on the surrounding conditions.

In summary, critical realism offers a philosophical approach to understanding the world and makes several recommendations for science:

- Acknowledge that scientific knowledge is always partial and fallible;
- Search for explanations beyond what is observable and measurable;
- Create theories or hypotheses about what the generative mechanisms might be (imagine the possibilities) and then subject them to empirical scrutiny;
- Anticipate complex explanations for social phenomena.

Going forward to explore specific research questions requires a methodology. From the foundations of critical realism, several forms of scientific realism have emerged. The chosen methodology for this study is realist evaluation.

3.3 Realist evaluation: the methodology

Realist evaluation is a methodological orientation – a way of operationalising scientific inquiry. It provides a pragmatic way to apply realist principles and philosophy to real world research questions. Realist evaluation was developed by British social scientists, Pawson and Tilley. During the last twenty years, this approach has been applied across many disciplines and an expert group has developed quality standards and training materials (RAMESES, 2016). The realist research community continues to support the development and evolution of the methodology.

Realist evaluation is a theory-driven approach to evaluation; it aims to understand the inner workings of social programmes by scrutinising their underlying theories, hypotheses and assumptions (Pawson & Tilley, 1997). It provides an alternative to

positivist evaluation designs, like randomised controlled trials (RCTs), which attribute the effects of an intervention to the 'treatment' and do not contribute to understanding how and why the effects come about. In public health nutrition, an RCT might indicate that an intervention or programme caused dietary change, but it would not reveal the reasons why people were persuaded to modify their eating behaviours (mechanisms), or whether the same changes would occur if people's circumstances were different.

Realist evaluation centres around developing 'programme theories' and testing them using empirical evidence. Programme theories are like theories of change for a specific programme: "the rationale or assumptions about mechanisms that link a programme's processes and inputs to outcomes – both intended and unintended, as well as specifying the conditions (or context) necessary for effectiveness" (Davidoff, Dixon-Woods, Leviton, & Michie, 2015, p. 3). In realist programme theories, the emphasis is on generative causation: the potential for social programmes to generate change by activating causal powers within individuals and understanding the conditions that are required for this activation to occur (Pawson & Tilley, 1997). The next section (3.4) describes the function and components of realist programme theories in more detail.

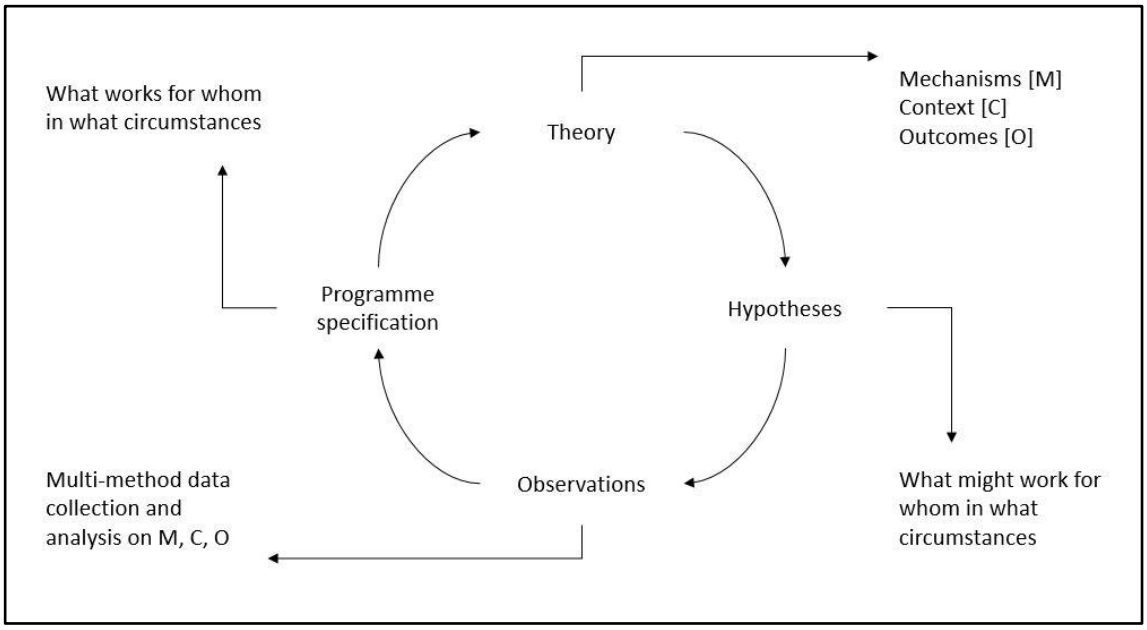
In an ideal world, policy makers and programme designers would develop and clearly communicate programme theories at the time of implementation. Unfortunately, this is often not the case, and so realist researchers and evaluators must develop programme theories retrospectively. As described in chapter 2, the aims and intended outcomes of Healthy Start were not clearly stated at the time of implementation. It appears to have been assumed by policy makers that Healthy Start would deliver improved outcomes compared to the Welfare Food Scheme. However, it was unclear what the intended outcomes were and how, precisely, the programme would affect change. Since 2006, there has been no communication or publication of any programme theories, theoretical models or frameworks to explain how the Healthy Start programme works.

Advocates of theory-driven evaluation suggest that existing theoretical knowledge may be used to enhance our understandings of both social programmes and wider social phenomena (Chen & Rossi, 1983). In realist evaluation, the unit of analysis is the programme theory (rather than the programme) and this can be considered at different levels of abstraction. 'Middle-range theories' may be used (or adapted or modified) to help explain what is happening at the programme level. This term refers to "theories intermediate to the minor working hypotheses evolved in abundance during the day-by-

day routine of research, and the all-inclusive speculations comprising a master conceptual scheme" (Merton, 1968). Therefore, middle-range theories should be specific enough to explain the phenomenon of interest, and yet general enough to be useful across a range of programmes or contexts (Pawson & Tilley, 1997; Westhorp, 2013). Pawson (2000) described this process as "abstracting away from the concrete instances to a generic conceptual framework" (p. 290).

Pawson (2013) also introduced the concept of 'reusable conceptual platforms' meaning that different programmes may use similar strategies, and operate through similar generative mechanisms, to encourage behaviour change. While the aim of this study is to understand more about the Healthy Start programme, there may be much to learn from similar food voucher programmes (and the wider literature on behaviour change and incentives) about what it takes for them to succeed. Realist evaluation encourages us to build on what is already known. This principle of cumulative knowledge and iterative theory development relates back to critical realism. Our understanding of how social programmes work (our 'transitive' knowledge) will always remain partial and fallible, since programmes and the conditions in which they operate change in space and time. An evaluation provides only a snapshot in time and should be part of an ongoing evaluation cycle, within which programme theories are continually developed and refined (Figure 2) (Pawson & Tilley, 1997).

Figure 2. The realist evaluation cycle (Pawson & Tilley, 1997, p. 85)



Finally, realist evaluation may be considered 'complexity-consistent' because social programmes are viewed as systems embedded within larger social systems, and their effects may be contingent on interactions and relationships between different levels of systems (Westhorp, 2013). Consequently, social programmes are unlikely to be equally successful in all circumstances (Pawson, 2006). There is increasing recognition of the need for complex systems approaches to public health research and evaluation, which take account of real world circumstances and non-linear models of causation (Rutter et al., 2017). Realist evaluation embraces the complexity and variability within social programmes. It seeks to explain the range of potential emergent effects, including long-term changes and unintended consequences (Pawson, 2013).

3.4 Key concepts in realist evaluation

3.4.1 Programme theories and CMO configurations

The function of realist programme theory is: "to describe and explain (some of) how and why, in the 'real world', a programme 'works', for whom, to what extent and in which contexts" (Wong et al., 2016). This statement reflects the logic of realist explanation: outcomes (O) are caused by mechanisms (M), and mechanisms may (or may not) be 'triggered' in certain contexts (C) (Pawson, 2006). It has become customary, but not essential, to construct realist programme theories as CMO configurations (CMOc).

$$C + M \rightarrow O \text{ (Pawson \& Tilley, 1997)}$$

Programme theories are likely to comprise multiple CMOc, which may be sequential and/or represent alternative explanations. A programme may go through several stages of implementation, involving different stakeholders and a range of beneficiaries who may respond in different ways. Realist researchers and evaluators are encouraged to examine every 'link in the chain' (each one a theory) and consider the cumulative effect of the entire sequence of theories (Pawson, 2006). The goal is to understand what mechanisms may be triggered by the programme, what social and cultural conditions are necessary for those mechanisms to be triggered, and how those mechanisms change the status quo (Pawson & Tilley, 1997).

CMOc may be used as an 'aide memoire' or 'heuristic' to facilitate the development of realist programme theories, and clearly articulate the causal linkages between context, mechanisms and outcomes (Wong, 2017). They provide clear and testable hypotheses, which can be modified and refined throughout the course of an evaluation. However, sometimes it may not be immediately obvious which category (C, M or O) some aspect of the explanation fits into, and realist experts have cautioned against spending too much time trying to do this (Wong, 2015). It is more important to think creatively about explanations for outcomes, especially in the early stages of theory development.

3.4.2 Context

Context may be defined as the pre-existing conditions into which a programme is introduced (Pawson & Tilley, 1997). This broad definition includes a vast array of social and cultural factors. Context is more than just the geographical location or setting into which the programme is introduced; it is "the prior set of social rules, norms, values and interrelationships gathered in these places which sets limits on the efficacy of program mechanisms" (Pawson & Tilley, 1997, p. 70). Context has some similarities with the notion of social 'structure' because it exists before the programme is introduced; it influences which mechanisms are triggered or activated by the programme; it may be reproduced (maintained) or transformed (altered) by the programme. However, there is also 'agency' within context because it can include 'conditions' within people, such as established behaviours and decision-making processes. In realist evaluation, it is not necessary to separate structure and agency – but to recognise what existed before the programme (context) and what happened because of the programme (mechanisms).

The success of any social programme depends upon certain aspects of context, which determine the extent to which its causal potential is realised – they enable or constrain

mechanisms. Therefore, it is important to identify which aspects of context are important and for which subgroups of stakeholders. A social programme may be implemented across different geographical areas, socio-economic groups, ethnic groups and/or age groups. These subgroups, and the individuals within them, have their own unique social contexts and are likely to interact with the programme in different ways. Likewise, programme managers and staff operate within their own social contexts, which may influence how they implement and support the programme. Pawson (2006) described four layers of context surrounding a programme: individual, interpersonal, institutional and infra-structural.

Individual context refers to the capacities of stakeholders – anyone involved in the programme, such as participants, beneficiaries, professionals or commissioners. For women who become beneficiaries of the Healthy Start programme, individual aspects of context could include their values, beliefs, experiences and circumstances relating to food, healthy eating and health in general. These factors may influence how women decide to use the vouchers and the significance they attach to them.

Interpersonal context refers to the interactions and relationships between stakeholders. An example might be the interaction between low-income pregnant women and health professionals (such as midwives or health visitors). The level of trust, mutual respect and understanding between low-income women and midwives could influence the take up of Healthy Start.

Institutional context refers to the organisation setting, such as its ethos and culture. This could include the quality of information and training provided to health professionals about the Healthy Start programme, and whether their workload allows them sufficient time to communicate the importance of healthy eating and how Healthy Start vouchers can be used to achieve health benefits.

Infrastructural context refers to wider aspects of the social systems in which the programme is embedded. The impact of Healthy Start may be influenced by other healthy eating initiatives, public health policy, changes to welfare benefits, and the cost of food. For example, since Universal Credit became a qualifying benefit on 1st November 2016 (with a lower income threshold than previous benefits), there may be fewer women and families who are eligible for Healthy Start.

Previous studies of Healthy Start (as reviewed in chapter 2) identified some aspects of context that were thought to influence the success of the Healthy Start programme. They were described as 'stakeholder views' (such as whether women valued healthy eating) or 'barriers' (such as lack of time during antenatal appointments). It was not clear how or why these contextual factors might influence outcomes. Therefore, this realist study sought to examine these and other aspects of context, specifically how they enable and constrain outcomes by activating mechanisms.

3.4.3 Mechanisms

Mechanisms may be defined as the reasoning and reactions of individuals in response to the resources offered by the programme (Pawson, 2006). The essence of realist logic is that programmes do not generate change – people do. In other words, programmes introduce and encourage ideas and opportunities, but the desired change does not occur until people respond to those ideas and opportunities, or make use of the programme resources. Realist evaluation's conceptualisation of mechanisms relates to causal forces within people. There may be different ways that different individuals could respond to any programme, which may be context-dependent. Realist researchers and evaluators must consider alternatives and possibilities, rather than assuming one causal pathway will be the same for everyone.

Mechanisms may be considered the crux of realist programme theory: does the programme activate the necessary mechanisms, in the existing context, to generate the desired outcomes for the target beneficiaries? If not, then it may be necessary to modify the context or the programme (or both) to achieve the desired outcomes.

The 'reasoning and reactions' definition does not limit mechanisms to logical thought processes and decision making. Mechanisms also include emotions, values, feelings, motivations and subconscious thought – anything that happens inside the mind of the individual concerned. This quote helps to conceptualise mechanisms by explaining two ways in which programmes may influence reasoning:

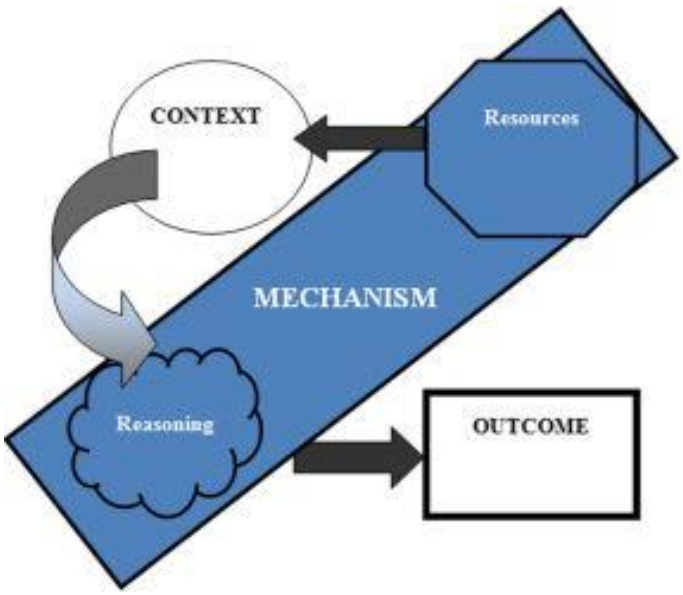
> "…programmes may work by enabling existing reasoning ("I'd like to do this but I can't because I don't have the resources to do so – this programme provides the resources to do so") or by changing reasoning ("I have a new understanding of the value or importance of 'x' so now I will do 'y'")." (Westhorp, 2014, p. 6).

The activation of mechanisms was originally compared to the lighting of gunpowder (Pawson & Tilley, 1997). If a spark is introduced to gunpowder, the chemical reaction is the mechanism that causes an explosion – but this only happens if the context is right. The gunpowder must be dry and compact, with sufficient oxygen etc. This analogy was used to illustrate how outcomes are generated by mechanisms, which are dependent on context. However, this analogy can sometimes seem too dramatic and instantaneous.

More recently, the activation of mechanisms has been likened to a dimmer switch, suggesting that human volition and reasoning operates along a continuum, and mechanisms may be activated to varying degrees, depending on context (Dalkin, Greenhalgh, Jones, Cunningham, & Lhussier, 2015). The same authors developed an alternative model for CMOc (Figure 3) because they were concerned that mechanisms might be conflated with programme strategy (Dalkin et al., 2015). They disaggregated the 'resources' and 'reasoning' within mechanisms to help clarify that programme resources are introduced into a context, which leads to a change in reasoning:

$$M(\text{resources}) + C \rightarrow M(\text{reasoning}) = O$$

Figure 3. A CMOc framework showing the relationship between context, mechanism (comprising resources and reasoning) and outcome; reproduced with permission from the study authors (Dalkin et al., 2015)



This alternative model helps to visualise the chronological sequence within the CMOc and thereby distinguish context from mechanisms. More important than how we choose to illustrate CMOc, is the way we conceptualise mechanisms as cognitive processes in

the minds of the people who interact with the programme. This takes us back into the 'real' domain of critical realism, where we are searching for underlying explanations beyond what is observable and measurable.

Previous studies of Healthy Start (as reviewed in chapter 2) identified some ways that stakeholders responded to the programme, such as women who valued the contribution of the vouchers and retailers who admitted 'bending the rules' for their customers. However, these studies did not fully explore the 'inner reasoning' of stakeholders and potential relationships with context and outcomes. For example, why did some women value the contribution of vouchers; what did they perceive this contribution to be; how did that influence how they decided to use the vouchers; why did other women value the vouchers less or in other ways? This realist study sought to elucidate (some of) the generative mechanisms that may determine the potential outcomes of the Healthy Start programme, and the context required to activate these causal processes.

3.4.4 Outcomes

Outcomes are the observable effects of the programme. Realists anticipate that social programmes will produce semi-predictable outcome patterns, or variations in human behaviour, which are sometimes described as 'demi-regularities' (Lawson, 1997). Final outcomes may be the most obvious, especially if they are articulated in the aims of the programme, but often there will be intermediate outcomes as well. This may lead to sequences of CMOc, whereby the outcome from one CMOc becomes (or transforms) the context for the next. Social programmes usually work better for some people than others, so outcome patterns are likely to reflect a range of experiences and effects – positive and negative, intended and unintended. Since policy documents and programme aims tend to specify only the intended outcomes, it is essential to theorise about outcomes that may not have been anticipated during programme development. There may be many possible reasons why an individual may be diverted from the intended outcomes of the programme. Unintended outcomes or 'unintended consequences' may be negative, but there may also be positive outcomes that were unanticipated.

As well as multiple outcomes, there may be multiple causal pathways leading to one outcome – this is known as 'equifinality' (Byrne & Ragin, 2009). Different individuals may experience the same outcome, but for different reasons. This is partly why some realists recommend starting with an outcome of interest and working backwards to identify the possible mechanisms and contexts (Westhorp, 2013; Wong, 2015).

As highlighted in chapter 2, there has been no robust evaluation of the impact of the Healthy Start programme on nutritional outcomes; previous studies were limited to perceived and self-reported outcomes. However, they highlighted a range of possible outcomes, including intended and unintended outcomes, which are worthy of further investigation to understand how and why they might occur. This realist study sought to explore potential outcomes of the Healthy Start programme (not limited to nutritional outcomes) and develop plausible, evidence-based explanations for how and why they outcomes might occur – for who, in what circumstances and why.

3.5 Research perspective, ontology and epistemology

It is important to be clear and transparent about how one's research perspective and chosen methodology are situated in relation to wider considerations of ontology and epistemology. This underpins subsequent decisions about methods and interpretation of findings. The following paragraph explains my personal perspective and motivations as the researcher *(in a reflexive style)* and the reasons why realist evaluation methodology was chosen for this study. This is followed by considerations relating to ontology and epistemology.

> *As a public health nutrition researcher, I have always been passionate about improving nutrition outcomes for low-income women and children. I became interested in Healthy Start because I wanted to know more about the impact of the programme on nutrition outcomes. I was frustrated by the lack of robust evaluation since 2006, but I knew that I would not have sufficient time or resources to conduct a nationally representative, longitudinal study within my PhD. I was sceptical about the potential impact of Healthy Start on the diets of beneficiaries. I suspected that some of the alternative outcomes identified in previous studies (such as using the vouchers to free up money for other things) might apply to many families living on low incomes and in challenging social circumstances. The realist perspective is grounded in assumptions of complexity and generative causation. Realist evaluation offers an opportunity to investigate a range of potential outcomes (including intended and unintended outcomes) and develop in-depth explanations for how and why different outcomes might occur for different individuals. This approach to evaluation appealed to me because it would strengthen the evidence base for Healthy Start and facilitate evidence-*

based recommendations. I was also attracted to the personal challenge of embracing a new methodology in my PhD.

Ontology is a branch of philosophy concerned with the form and nature of reality and, therefore, what can be known about it (Guba & Lincoln, 1994). In its broadest sense, realism is the ontological notion that reality exists independent of the human mind (Crotty, 1998). That is not to say that humans do not influence the world around them or vice versa, but there is a reality separate from human thought. Critical realists consider ontological objectivity to be necessary for science to investigate generative causation (Bhaskar, 2016). Likewise, realist evaluation strives for 'ontological depth' by searching for mechanisms and explanations beyond what is observable and measurable (Pawson & Tilley, 1997). For example, to study the underlying reasons why low-income women use Healthy Start vouchers in certain ways, we must acknowledge that women may not be fully aware of their own reasoning and reactions (mechanisms). There are conscious and unconscious cognitive processes happening inside their minds, about which we will never know the whole truth (and are likely to change over time) but we strive to develop a deeper understanding through science.

Epistemology concerns theory of knowledge, or how we know what we know (Crotty, 1998). While some ontological beliefs set limits on how knowledge can be acquired, realism is less constrained. A belief in objective (or independent) reality does not mean we must only value objective knowledge. Bhaskar (1998) said it was important to detach the ontological conclusion from the epistemic investigation, to avoid committing the 'epistemic fallacy' whereby statements about being are reduced to statements about knowledge. Realist evaluation rejects traditional boundaries between scientific paradigms and "steers a path between empiricist and constructivist accounts of scientific explanation" (Pawson, 2006, p. 17). Therefore, while empiricism regards scientific knowledge as a product of sensory experience, and constructivism regards it as a human construct, realism (and realist evaluation) adopts a more neutral position.

It has much in common with the post-positivist perspective, which pursues objective knowledge, but also recognises the role and influence of human conjecture in the research process. Post-positivism questioned the certainty and absoluteness of positivism. In the post-positivist era, Popper suggested that science should seek to falsify or disprove hypotheses, because they could never be proven beyond all doubt. This concurs with the realist principle that scientific knowledge is always partial and fallible.

> "The demand for scientific objectivity makes it inevitable that every scientific statement must remain tentative for ever." (Popper, 1959, p. 280).

Realism also values human interpretations of the world, which can reveal the unseen causal forces or mechanisms within people. There is some compatibility with the constructivist perspective, which values meanings that are constructed by individuals when they interact with the world (Crotty, 1998). However, realism is more compatible with the interpretivist perspective, which is that meanings are constructed as individuals interpret the reality that exists (Porter, 2017). In other words, reality constrains the interpretations that are possible to make of it (Westhorp, 2014). Furthermore, Pawson and Tilley rejected the constructivist view that all social situations are unique and research findings cannot be generalised between contexts.

> "Social initiatives are [thus] begged, stolen and borrowed the world over, and the notion that this process is devoid of learning beggars belief." (Pawson & Tilley, 1997, p. 22)

The open-minded epistemological position of realist evaluation means that it is not committed to any one data collection strategy. In fact, it prides itself on being pluralist (Pawson & Tilley, 1997). Research methods are chosen based on which elements of the programme theory are to be tested. Pawson (2013) suggested that data on outcomes should be quantitative, data on mechanisms should be qualitative, and data on context should be comparative and sometimes historical. This approach makes sense when studying public health nutrition interventions or programmes, such as Healthy Start. Quantitative data are needed to assess the overall impact on dietary outcomes (food and nutrient intakes) and make subgroup comparisons. Qualitative data illuminate how and why the programme works (for some people better than others) and how it could be improved. However, this is only one recommended approach and realist evaluation may be adapted to the scope and limitations of any project. Any method (or combination of methods) are acceptable if they are used consistently with the realist ontological and epistemological assumptions outlined above.

3.6 Application of realist evaluation in this study

This study was conducted in two phases over three years:

1. Realist review (see chapters 4 and 5)

2. Qualitative study using realist interviews (see chapter 6)

The overall aim of this study was to explore potential outcomes of the Healthy Start programme (including intended and unintended outcomes) and develop explanations for how and why these outcomes might occur. Both phases were designed to contribute original knowledge about the Healthy Start programme based on realist questions: what works, for who, in what circumstances and why (Pawson & Tilley, 1997). Since Healthy Start was introduced in 2006 (8 years before the start of this PhD), and several previous research studies and evaluations had been published, it was logical to start by conducting a realist review – also known as realist synthesis. The purpose of realist synthesis is to "articulate underlying programme theories and then to interrogate the existing evidence to find out whether and where these theories are pertinent and productive" (Pawson, 2006, p. 74). Therefore, the objectives of the realist review were to develop programme theories about Healthy Start, and to test some of those theories using existing evidence. Information from a variety of sources was used to develop 'candidate theories' about how Healthy Start works, for who, in what circumstances and why. These candidate theories represented initial, untested ideas and hypotheses. After a process of prioritisation, to narrow down the scope of the review, some of the candidate theories were tested using existing evidence from studies of Healthy Start and a similar food subsidy programme in the United States. The findings of the realist review consist of three 'evidence-informed programme theories'.

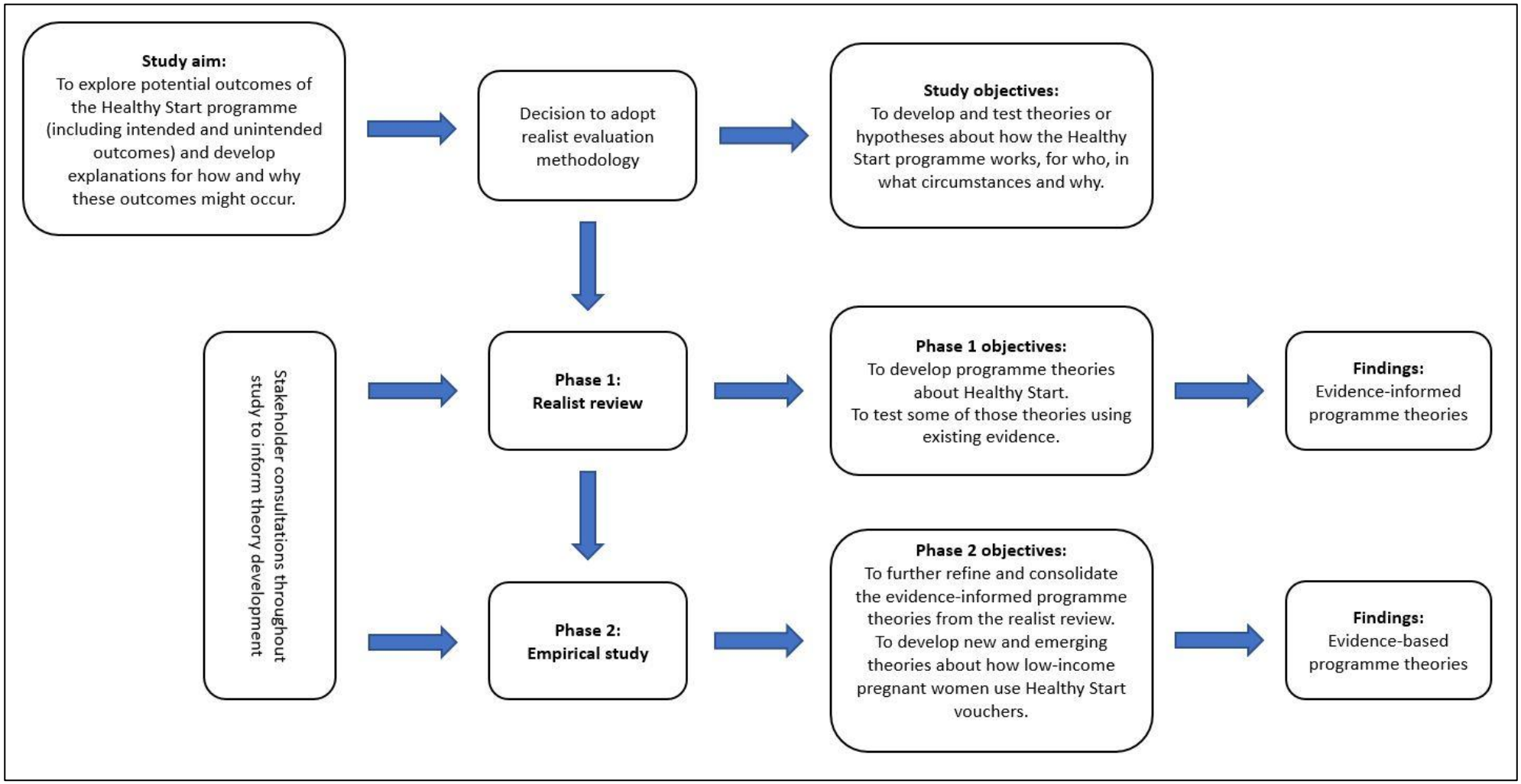
The empirical phase of this study had two objectives: to further refine and consolidate the evidence-informed programme theories from the realist review, and to develop new and emerging theories about how low-income pregnant women use Healthy Start vouchers. Qualitative methods were used to explore the views and experiences of low-income pregnant women in North West England. It was important to focus on programme beneficiaries as the key informants, to achieve a greater depth of knowledge about mechanisms – the inner reasoning and reactions of low-income pregnant women in response to Healthy Start vouchers – and relationships with context and outcomes. This depth of knowledge was missing from previous studies of Healthy Start (as identified in chapter 2). Realist interview techniques were used to 'exchange theories' between the interviewer and the interviewee. Vignettes were used to encourage women to share their own ideas and experiences. This innovative combination of methods was effective in generating in-depth explanatory data, which were used to develop five evidence-based programme theories. The findings will be useful for policy makers, advocates, service

managers and health professionals working to promote and enhance the Healthy Start programme.

Figure 4 illustrates the structure of this study. It shows how the overall study aim influenced the decision to adopt realist evaluation methodology, and how the study objectives evolved during phases 1 and 2, as programme theories were gradually and iteratively developed, tested and refined. It also shows how stakeholder consultations informed theory development throughout the study. This process will be described in more detail in chapters 4 and 6.

A realist logic of analysis was consistently applied throughout both phases of this study. Programme theories and CMOc were developed gradually and iteratively. The emphasis was on searching for evidence to support and refute the proposed causal linkages between context, mechanisms and outcomes. As recommended by other realist researchers, the analytical process started with outcomes and worked backwards to develop explanations (Punton, Vogel, & Lloyd, 2016; Wong, 2015). The precise coding and analysis methods evolved from phase 1 to phase 2, and this study offers insights into the flexibility and practical applications of realist evaluation. The importance of creative theorising and reflexivity is emphasised throughout.

Figure 4. Structure of the study originating from aims and developing into phase 1 and 2 with specific objectives.



3.7 Chapter summary

This chapter has introduced and justified realist evaluation as the chosen methodology for this study. It emerged from the philosophy of critical realism, which encourages science to search for explanations beyond what is observable and measurable – at the level of generative mechanisms. Realist evaluation provides a pragmatic approach to studying complex social programmes, by developing and testing programme theories constructed as context – mechanism – outcome configurations (or CMOc). It aims to explore what works, for who, in what circumstances and why (Pawson & Tilley, 1997). This chapter defined and explained the key concepts in realist evaluation, which assumes that programme outcomes are caused by mechanisms, which will only be activated in certain 'enabling' contexts. It provided the rationale and justification for using realist evaluation to study Healthy Start and highlighted ways in which this would contribute original knowledge. My personal perspective and motivations as the researcher were situated alongside considerations relating to ontology and epistemology. Finally, this chapter outlined the structure of the study and summarised how realist evaluation was applied. Chapters 4, 5 and 6 present the methods and findings of this realist study.

4.0 REALIST REVIEW: DEVELOPING PROGRAMME THEORIES

4.1 Introduction

This realist review was the first phase of work completed during this PhD study. It was recently published in BMJ Open (Ohly, Crossland, Dykes, Lowe, & Hall-Moran, 2017) (Appendix A). The review was conducted in two iterative and overlapping stages: developing programme theories (chapter 4) and testing programme theories (chapter 5). These stages are presented in two separate chapters of this thesis for clarity. This chapter describes the creative process of theory development. It includes reflexive sections *(written in first-person tense and in italics),* which capture my thoughts about the theory development process and the rationale for decisions made. The scope and focus of the review were determined during this stage. Specific review questions were identified as the review progressed. This contrasts with traditional systematic reviews, in which review questions, search terms, inclusion criteria and outcomes of interest are clearly defined at the outset. This chapter starts with an overview of the realist review process, and then describes in detail the methods used to develop 'candidate theories' (initial, untested theories) in this study. It includes reflections on support and advice received during the review and how that influenced theory development. Decisions were made to focus on how low-income pregnant women use Healthy Start vouchers – the period after women have received the vouchers, when the outcomes for women are determined. This chapter presents two main outcome strands and candidate theories that were taken forward into the testing stage.

4.2 Overview of review process

Pawson (2006) suggested six practical steps for conducting a realist review: identifying the review question, searching for primary studies, quality appraisal, extracting the data, synthesising the data and disseminating the findings. At first glance, these steps appear very similar to a traditional systematic review, but the realist review process is much more flexible and creative. Pawson stressed that these steps were oversimplified and over-prescriptive; the actual process should happen iteratively based on the judgements of the reviewer/s.

> *I found this flexibility challenging and bewildering as a novice realist reviewer. I wanted a clear process to follow but soon realised that it was not going to be so straightforward. Having previously conducted two previous systematic reviews*

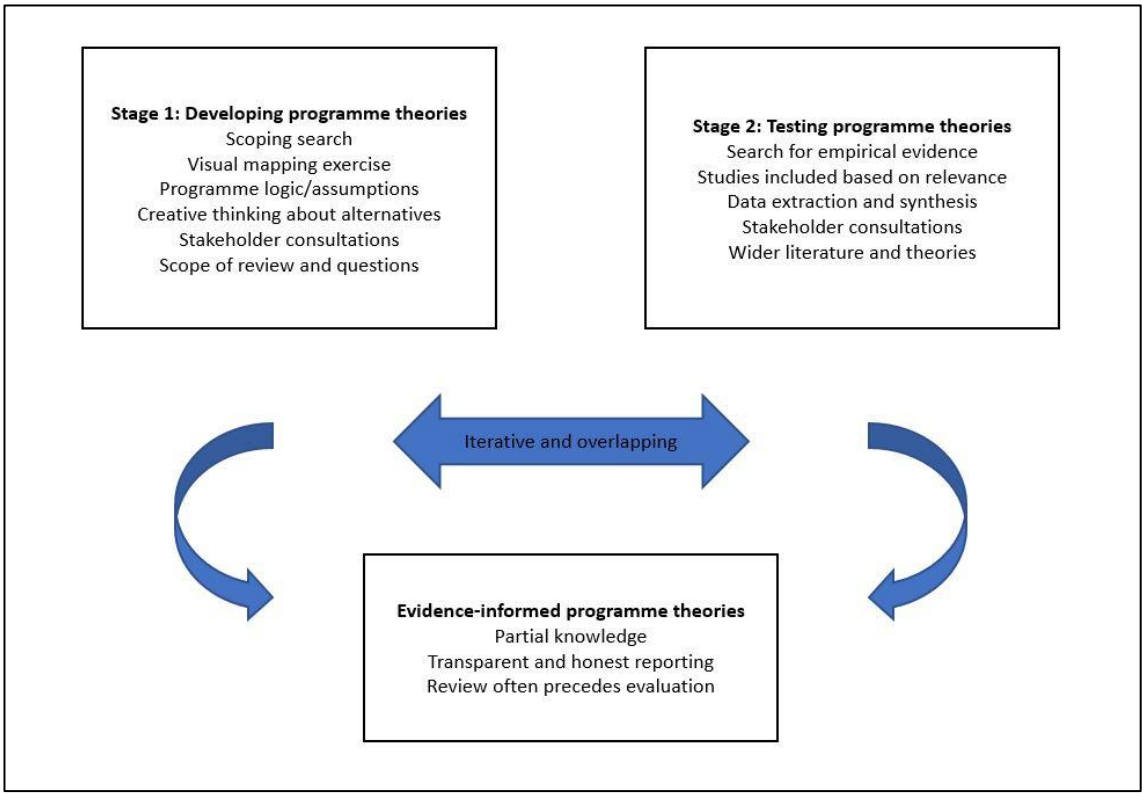
was helpful and I reflected on (compared/referred to) that process often during the conduct and reporting of the realist review. This helped me to maintain consistency, clarity and transparency. Fortunately, there was a great deal of support available from the realist research community (see section 4.6) and I learned as I went along. I would say that Pawson's first step – identifying the review question – is oversimplified and understated because it encompasses the whole of the theory development stage as described in this chapter. This took most of the first year of my PhD, before I was ready to move onto theory testing.

Realists consider all interventions and programmes as theories, "based on hypotheses (and assumptions) about how they will work and what effects they will have" (Pawson, 2006). As highlighted in chapters 2 and 3, very little published information exists about the hypotheses and assumptions of policy makers when Healthy Start was designed and implemented. The programme aims were vague and brief in policy documentation: to provide "a nutritional safety net" and encourage "women and families to make positive nutritional choices affecting their longer term health" (Department of Health, 2010, p. 4). This lack of information meant that it was necessary to develop more specific programme theories retrospectively during this review. The purpose of the review was to explore how Healthy Start works, for who, in what circumstances and why – standard questions in realist methodology (Pawson & Tilley, 1997). It was also important to consider potential reasons why Healthy Start might not work so well for some women i.e. alternative or unintended outcomes.

It has been over a decade since Healthy Start was introduced, and a variety of sources of information about the programme exist. Therefore, it was possible to develop 'candidate theories' about the programme. These candidate theories represented initial, untested ideas and hypotheses, which would eventually be tested and modified to become 'evidence-informed programme theories' (see chapter 5). In this review, candidate theories were developed using the 'bottom up' approach, as described by Shearn and Allmark in the Realist Research Seminar Series, Sheffield Hallam University, 2016. This contrasts with the 'top down' approach, which starts with a conceptual framework of abstract theories and may be more useful for programmes that are less well-defined (such as programmes that are in the earlier stages of development or implementation) or programmes that are highly complex and 'messy' (Shearn et al., 2017). The 'bottom up' approach was considered more appropriate for this review of Healthy Start, which is well established.

Theory development in realist reviews has been described as 'the swamp' (Pawson, Greenhalgh, Harvey, & Walshe, 2004) because it can be time consuming and confusing, throwing up countless possibilities and alternatives, which must be prioritised to make the review manageable and useful. It is generally accepted that theory development is likely to continue until at least halfway through the review period (Pawson, 2006). These expert opinions reflect the experience during this review and justify the decision to dedicate an entire chapter to theory development. Figure 5 illustrates how this realist review was conducted in two iterative and overlapping stages, with due emphasis on theory development in stage 1.

Figure 5. Summary of the realist review process used in this review.



4.3 Scoping search and visual mapping exercise

The first task was to find information about the Healthy Start programme, from which to identify review questions and develop candidate theories. I already had some familiarity with the Healthy Start literature, but it was important to check for new and additional sources of information (including academic and grey literature). A scoping search was conducted in January 2015 using the search terms ‘Healthy Start’ and ‘UK’ (there is an infant mortality reduction programme called Healthy Start in the United States) in PubMed, Scopus and Google. Reference lists of all documents identified were checked for additional sources. This scoping search identified 25 sources of information about Healthy Start including eight journal publications, six research reports, nine policy documents (or government reports) and two websites (Table 4).

Table 4. Sources of information about Healthy Start identified from the scoping search (in order of publication/website last accessed)

Type of document	**Full reference**
Policy document	Department of Health. (2002) Healthy Start: Proposals for reform of the Welfare Food Scheme. London: Department of Health.
Policy document	Department of Health. (2003) Healthy Start: The results of the consultation exercise. London: Department of Health.
Policy document	Department of Health. (2004) Healthy Start: Government response to consultation exercise. London: Department of Health.
Policy document	Department of Health. (2006) Healthy Start: Qualitative research to evaluate communication materials among potential beneficiaries. London: Department of Health.
Research report	Hills, D. (2006) Healthy Start: Rapid evaluation of early impact on beneficiaries, health professionals, retailers and contractors. London: Tavistock Institute/Symbia.
Research report	Dyson, L., Renfrew, M. J., Jenkins, R., Thomas, J., McCormick, F., Pearce, A., & Law, C. (2007) Approaches to evaluating Healthy Start – a scoping review. Mother and Infant Research Unit, University of York.
Policy document	Department of Health. (2008) The Healthy Start Scheme and Welfare Food (amendment) Regulations 2008. London: Department of Health.
Journal publication	Ford, F. A., Mouratidou, T., Wademan, S. E., & Fraser, R. B. (2009) Effect of the introduction of Healthy Start on dietary behaviour during and after pregnancy: Early results from the before and after Sheffield study. British Journal of Nutrition, 101(12), 1828-1836.
Policy document	Department of Health. (2010) Healthy Start: Equality impact assessment. London: Department of Health.

Type of document	Full reference
Journal publication	Mouratidou, T., Ford, F. A., Wademan, S. E., & Fraser, R. B. (2010) Are the benefits of the 'Healthy Start' food support scheme sustained at three months postpartum? Results from the Sheffield 'before and after' study. Maternal and Child Nutrition, 6(4), 347-357.
Policy document	Department of Health. (2012) Healthy Start: Retailer research summary. London: Department of Health.
Policy document	Department of Health. (2012) Healthy Start: New statutory arrangements for Healthy Start vitamins. London: Department of Health.
Research report	McAndrew, F., Thompson, J., Fellows, L., Large, A., Speed, M., & Renfrew, M. J. (2012) Infant Feeding Survey 2010. Health and Social Care Information Centre.
Journal publication	Moonan, M., Hanratty, B., & Whitehead, M. (2012) Which is more effective, a universal or targeted approach, to implementing the national Healthy Start programme? A mixed methods study. Journal of Epidemiology and Community Health, 66(Suppl 1), A44-A45.
Journal publication	Lucas-Herald, A., Grosset, K., Robertson, M., & Ahmed, S. F. (2012) The GP's role in improving the uptake of Healthy Start vitamins. British Journal of General Practice, 62(601), 407.
Policy document	Department of Health. (2012/13) Delivering a Healthy Start for pregnant women, new mums, babies and young children. London: Department of Health.
Journal publication	Jessiman, T., Cameron, A., Wiggins, M., & Lucas, P. J. (2013) A qualitative study of uptake of free vitamins in England. Archives of Disease in Childhood, 98(8), 587-591.

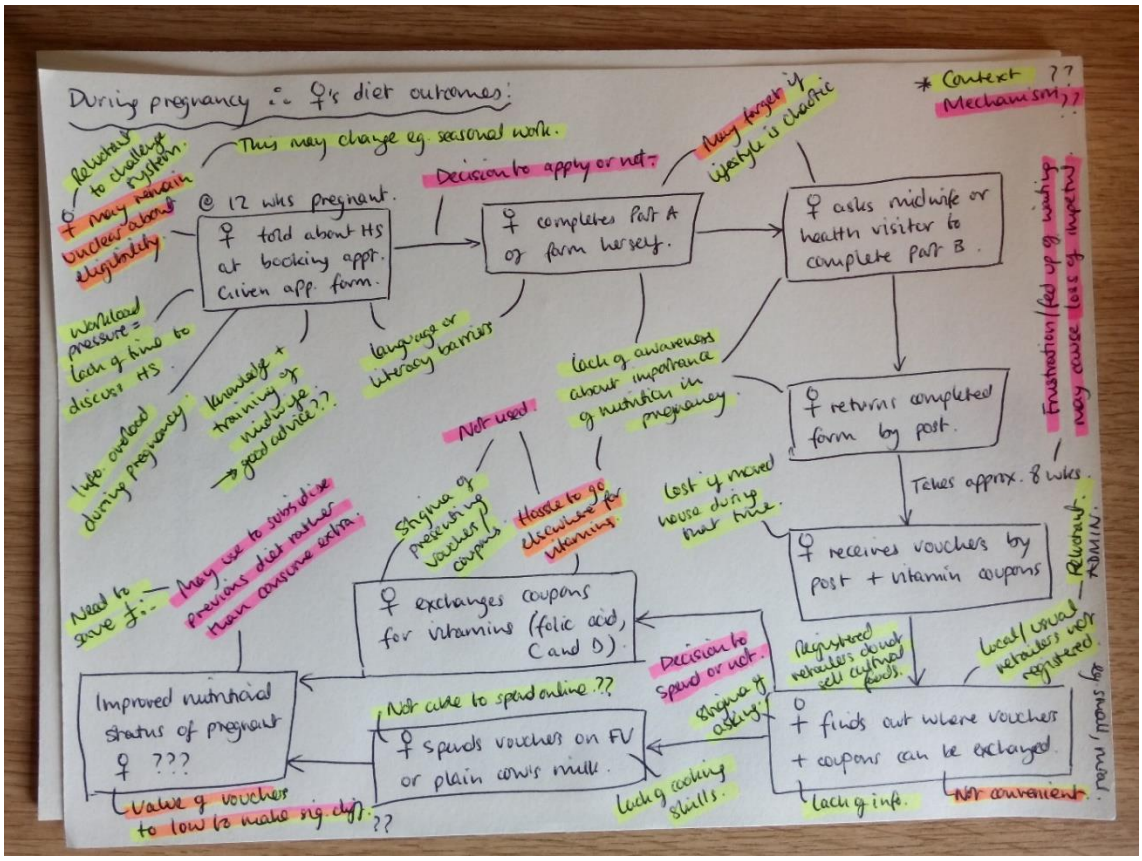
Type of document	Full reference
Research report	Lucas, P. J., Jessiman, T., Cameron, A., Wiggins, M., Hollingworth, K., & Austerberry, C. (2013) Healthy Start vouchers study: The views and experiences of parents, professionals and small retailers in England. School for Policy Studies, University of Bristol.
Research report	McFadden, A., Fox-Rushby, J., Green, J. M., Williams, V., Pokhrel, S., McLeish, J.,…Renfrew, M. J. (2013) Healthy Start: Understanding the use of vouchers and vitamins. College of Medicine, Dentistry and Nursing, University of Dundee.
Journal publication	McFadden, A., Green, J. M., Williams, V., McLeish, J., McCormick, F., Fox-Rushby, J., & Renfrew, M. J. (2014) Can food vouchers improve nutrition and reduce health inequalities in low-income mothers and young children: A multi-method evaluation of the experiences of beneficiaries and practitioners of the Healthy Start programme in England? BMC Public Health, 14(1), 1-24.
Research report	Griffiths, R., von Hinke Kessler Scholder, S., & Smith, S. (2015) Getting a healthy start: The effectiveness of targeted benefits for improving dietary choices. London: Institute of Fiscal Studies.
Journal publication	Machell, G. (2015) Considering influences on the policy formation of Healthy Start: A government-funded nutrition support program for low-income women and children in the UK. Journal of Policy Practice, 14(1), 14-34.
Journal publication	McFadden, A., Green, J. M., McLeish, J., McCormick, F., Williams, V., & Renfrew, M. J. (2015) Healthy start vitamins – a missed opportunity: Findings of a multimethod study. BMJ Open, 5(1) doi:10.1136/bmjopen-2014-006917
Website	Healthy Start Alliance. (2017) Healthy Start Alliance. Retrieved from: http://www.healthystartalliance.org/
Website	National Health Service. (2017) Healthy Start. Retrieved from: https://www.healthystart.nhs.uk/

After reading the information from the scoping search several times over, a visual mapping exercise was conducted by hand drawing a 'mind map' of the Healthy Start programme (see Figure 6). This involved identifying the 'steps along the programme pathway' from the beneficiary perspective, such as how potential beneficiaries become involved, what processes they go through, who else is involved, what resources they receive and what the intended outcomes are. Pawson (2006) described how 'mapping the terrain' can help the reviewer "to establish which programme theories seem important; to get a feel for the circumstances in which they tend to get tried; to gather hunches on implementation difficulties; to tease out ways in which the programme might misfire, and so on" (p. 80). The resulting diagram of Healthy Start included the following steps, which started to resemble assumptions (or theories) about how the programme was intended to work:

- Woman attends antenatal appointment
- Health professional provides information and advice on healthy eating
- Health professional signposts woman to information about Healthy Start
- Woman checks eligibility criteria and completes application form
- Woman asks health professional to complete and sign form
- Woman returns form by post
- Woman receives Healthy Start vouchers and vitamin coupons by post
- Woman finds out where she can use the vouchers/coupons
- Woman decides how to use the vouchers/coupons

After mapping out the general pathway of the programme, I used the information from the scoping search and her own knowledge about Healthy Start to annotate the diagram with any factors that seemed to be important (both internal and external to the programme). This included some of the barriers and facilitators identified in previous studies of Healthy Start (as reviewed in chapter 2). Different coloured pens were used to highlight possible aspects of context (yellow) and mechanisms (pink) along the programme pathway (Figure 6).

Figure 6. Mind map of the Healthy Start pathway



The next stage was to decide which area of the programme pathway to focus on during this realist review. Pawson (2006) emphasised the importance of prioritising review questions and suggested this can be done based on the reviewer's prior interests, burning issues or areas of dispute within the programme, and the time available. As described in the following reflexive section, these decisions reflected my personal interests, the research gaps identified (in section 2.6) and possible changes to Healthy Start that were being considered in early 2015.

> *I enjoyed the process of 'mapping the terrain' (as described by Pawson) and it helped me to identify which areas of Healthy Start I was most interested in exploring. As a public health nutrition researcher, I was keen to find out more about the potential nutritional benefits of the programme for low-income women and children. I felt that it was particularly important to explore the outcomes for low-income pregnant women as the first beneficiaries of Healthy Start and the primary decision makers (for themselves and their children). If pregnant women experience nutritional benefits from the programme, it is logical to anticipate that their children may also experience nutritional benefits. Previous studies focused*

less on this 'end of the pathway' compared to issues around the application process and eligibility criteria. A previous evaluation reported very low take-up of Healthy Start vitamins and recommended universal provision of free vitamins to all pregnant women (Jessiman et al., 2013). A report from the National Institute for Health and Care Excellence was anticipated later in 2015 (National Institute for Health and Care Excellence, 2015a). Therefore, in the light of possible changes to the vitamin component of the programme, I decided to focus on the food voucher component. I started to experiment with ideas about context, mechanisms and outcomes at this stage, but it was early in my realist training and I was still getting to grips with these methodological concepts.

4.4 Theorising outcomes and explanations

The mapping exercise generated some early (and rough) ideas about how low-income pregnant women might use Healthy Start food vouchers. These included positive outcomes (assumed to be intended) and some negative or alternative outcomes (assumed to be unintended). Next it was important to start developing some realist explanations. Candidate theories must include explanations as well as outcomes, which together offer testable hypotheses about how the programme works. In this review, early explanations were derived partly from the information identified in the scoping search and partly through creative thinking. The realist concept of 'retroduction' was introduced in the previous chapter (section 3.2) as an 'imaginative activity' in which scientists think about how and why outcomes, events and phenomena might occur (Bhaskar, 2016). This creativity was essential to achieve 'ontological depth' and explanations at the level of generative mechanisms. An explanatory compendium for complex programmes was also used to guide this stage of theory development (Pawson, 2006, p. 80). Its questions can be applied to any programme to stimulate the researcher to think about possible explanations and variations (Table 5).

Table 5. How Pawson's explanatory compendium was used to develop candidate theories about the Healthy Start programme

Questions selected	**Examples relating to Healthy Start**
Programme theories – how is the programme supposed to work?	How is the Healthy Start programme (voucher component only) supposed to work? What assumptions were made by policy makers?
Reasoning and reactions of stakeholders – are there differences in the understanding of the programme theory?	How do low-income pregnant women respond to the vouchers? How do health professionals support eligible women to apply for and use Healthy Start vouchers?
Integrity of the implementation chain – is the programme theory applied consistently and cumulatively?	Are there variations in how Healthy Start is implemented around the UK? Do midwives and other health professionals provide adequate and consistent support? Do different retailers process the vouchers in different ways?
Contextual influences – does the programme theory fare better with particular individuals, interpersonal relations, institutions and infrastructures?	Is there enough support for women with poor English language skills? How do partners and other family members influence how women use the vouchers? How do existing beliefs, values, knowledge and behaviours influence how women use the vouchers?
Multiple, unintended, long-term effects – is the theory self-affirming or self-defeating or self-neutralising?	Do the vouchers encourage and enable women to improve their diets during pregnancy? Do women use the vouchers to increase their consumption of healthy foods, or to reduce the shopping bill? What does this depend on?

I attempted to structure my candidate theories as CMO configurations (CMOc), but this became frustrating and at times I felt like I was going around in circles trying to figure out what was context and what were mechanisms. However, this was all part of the learning process and I was gradually building explanatory hypotheses about how the programme works (or may not work so well), for who, in what circumstances and why. It was comforting to discover, later, that my candidate theories could have been less structured but still explanatory (Wong, 2015) and it is common to find CMOc challenging in the early stages of theory development. I think my haste to construct CMOc reflects my enthusiasm to 'get stuck in' to realist methodology, and my desire to use some sort of analytical framework or structure (based on previous experience). Fortunately, the creative process of theory building became easier with time.

I was working on my candidate theories shortly after an alternative CMOc framework was published, which separated the 'resources' and 'reasoning' within mechanisms (Dalkin et al., 2015). There was a lot of interest in this new approach and I decided to try it out. It definitely helped me to focus on mechanisms as 'the reasoning and reactions of individuals'. However, I was a little unclear what should be classed as 'resources provided by the programme' as opposed to pre-existing aspects of context. I decided to include support from health professionals as 'resources' at this stage. However, it could also be considered as context because this support is provided within routine antenatal services (usually by midwives or health visitors). This distinction is explored further in subsequent chapters.

Tables 6A and 6B show early versions of the candidate theories (dated 14th May 2015), including hypotheses or assumptions about what the programme is 'supposed to do' (leading to assumed intended outcomes) and alternative hypotheses (leading to assumed unintended outcomes), under two distinct headings:

1. Candidate theories about how low-income pregnant women are encouraged and supported to apply for Healthy Start vouchers (i.e. before receiving the vouchers) (Table 6A);
2. Candidate theories about how low-income pregnant women use Healthy Start vouchers (i.e. after receiving the vouchers) (Table 6B).

Table 6A. Candidate theories about how low-income pregnant women are encouraged and supported to apply for Healthy Start vouchers (i.e. before receiving the vouchers) (14th May 2015)

Programme assumptions and 'supposed to do' hypotheses (intended outcomes)			
Context	**Resources**	**Mechanisms**	**Outcomes**
Pregnant women engage with health services and attend screening clinics during the first trimester.	Health professionals provide information about the importance of nutrition in pregnancy, assess eligibility for Healthy Start and support eligible women to complete the application process.	Pregnant women are motivated by the potential health benefits for themselves and their baby and, with the support from health professionals, they feel confident to apply.	Eligible women receive the Healthy Start vouchers they are entitled to.
Potential barriers/pitfalls and alternative hypotheses (unintended outcomes)			
Context	**Resources**	**Mechanisms**	**Outcomes**
Health professionals have busy jobs and multiple priorities when dealing with pregnant women.	Health professionals may not receive adequate information and training on Healthy Start, or may be too busy during short appointments to discuss it.	Women may not understand what they are entitled to and how to apply. If they are confused, they may lack the confidence to ask questions.	Eligible women may not complete the application process successfully.
Women may have chaotic lifestyles, competing priorities and/or poor organisational skills. They also receive lots of information during pregnancy.	Health professionals can only provide a limited amount of support and ultimately it is the woman's responsibility to apply.	Women may feel overloaded with information. They may forget to complete the application form, or lose interest or prioritise other things in order to cope with life.	Eligible women may not complete the application process successfully.

Table 6A continued.

Context	**Resources**	**Mechanisms**	**Outcomes**
Women may have poor literacy or English language skills.	Lack of information available in other languages.	Women may be unaware of Healthy Start or unable to complete the application process themselves.	Eligible women may not complete the application process successfully.
Household incomes may fluctuate with seasonal labour, zero hours contracts etc.	The eligibility criteria are complex and some women may move in and out of eligibility.	Women may find this frustrating or confusing and decide not to persist with the scheme.	Eligible women may not receive the Healthy Start vouchers they are entitled to.

Table 6B. Candidate theories about how low-income pregnant women use Healthy Start vouchers (i.e. after receiving the vouchers) (14th May 2015)

Programme assumptions and 'supposed to do' hypotheses (intended outcomes)			
Context	**Resources**	**Mechanisms**	**Outcomes**
Low income women typically have limited money to spend on food. They may prioritise energy-dense foods over nutrient-rich foods. They do not like to waste perishable food such as FV.	Eligible women receive the Healthy Start vouchers they are entitled to (weekly by post). Health professionals provide information about the importance of nutrition in pregnancy.	Women feel grateful for the financial support and are motivated by the potential health benefits. The vouchers act as a visible reminder and a financial incentive to eat well.	Pregnant women use the vouchers to increase their consumption of FV and plain cow's milk during pregnancy. They may also be tempted to experiment with different varieties of FV.
Pregnant teenagers living with their parents may not have full control over the household shopping budget.	Healthy Start vouchers are sent to the eligible teenager rather than the head of the household.	This gives them some independence to make their own food choices.	Pregnant teenagers use the vouchers to increase their consumption of FV and plain cow's milk during pregnancy.
Potential barriers/pitfalls and alternative hypotheses (unintended outcomes)			
Context	**Resources**	**Mechanisms**	**Outcomes**
Women may have well-established food shopping routines determined by prices, transport, convenience, work patterns, culturally acceptable foods etc.	Their local/usual/preferred shops may not be registered to accept Healthy Start vouchers (e.g. small shops or market stalls).	Women may be reluctant to ask them to register due to fears about stigmatisation or lack of confidence. They may be reluctant to change their shopping routines in order to spend the vouchers.	Women may not spend the vouchers even after they have received them.
Health professionals have busy jobs and multiple priorities when dealing with pregnant women.	Health professionals may not receive adequate information and training on Healthy Start, or may be too busy during short appointments to discuss it.	Women may not understand the benefits of eating FV and the importance of nutrition in pregnancy. They may perceive FV as unnecessary.	Women may use the vouchers to subsidise their existing diet rather than to increase their consumption of FV and plain cow's milk.

Table 6B continued.

Context	**Resources**	**Mechanisms**	**Outcomes**
Financial conditions including austerity, cuts to benefits, rising food prices, unemployment etc. Women may struggle to afford the foods they would like to eat.	The value of Healthy Start vouchers has not increased to keep pace with these financial conditions.	Women may prioritise financial concerns (saving money) over nutrition and health benefits, even if they do understand the importance of nutrition in pregnancy.	Women may use the vouchers to reduce their shopping bill (and subsidise their existing diet) rather than to increase their consumption of FV and plain cow's milk.
Healthy Start was preceded by the Welfare Food Scheme and some women still perceive the vouchers as milk tokens.	In some communities, the differences between the Welfare Food Scheme and Healthy Start have not been effectively communicated.	These perceptions may influence women's decisions about how to spend their vouchers.	Women may spend the vouchers on plain cow's milk but not FV.
Women may not have the skills, confidence or cooking facilities to prepare healthy meals containing vegetables.	Women may not be engaged with local activities and services to teach them cooking skills.	These practical issues may influence women's decisions about how to spend their vouchers.	Women may spend the vouchers on plain cow's milk or fruit but not vegetables.

FV = fruit and vegetables

4.5 Consultations with study advisory group

Realist reviewers often engage with expert and stakeholder groups (including patients, service users, practitioners, managers and policy makers) to help to develop candidate theories and refine the focus of the review (Coles, Cheyne, & Daniel, 2015; Greenhalgh et al., 2014; Hardwick, Pearson, Byng, & Anderson, 2013; Williams et al., 2016). Ethical approval was obtained in May 2015 from the University of Central Lancashire Science, Technology, Engineering, Medicine and Health Ethics Committee (reference STEMH 329) to begin consultations with the study advisory group. This group included six midwives, two academics and two public health practitioners, who were invited to join the group because they had direct experience and involvement with the Healthy Start programme. Permission letters were obtained from two NHS Trusts to consult the six midwives and these discussions took place on NHS sites.

First, the academics and public health practitioners were consulted. This was an expert group of stakeholders with in-depth knowledge of the Healthy Start programme: both academics were authors of previous studies of Healthy Start (Machell, 2015; McFadden et al., 2013); one practitioner was the founder of the Healthy Start Alliance advocacy network (Healthy Start Alliance, 2017); the other practitioner was involved with promoting the uptake of Healthy Start in Scotland. These people were located around the UK so this consultation was conducted by email. A consultation document was prepared, which summarised the purpose of the realist review and some of the key concepts in realist methodology (Appendix B). It requested their feedback and opinions, which they returned by email. It was mostly about the nuances of how the programme worked and some of the challenges they were aware of from their own research or practice. For example, one of the academics highlighted several potential barriers, which had already been reported in previous evaluations of Healthy Start (Lucas et al., 2013; McFadden et al., 2013):

- Screening is often the focus of antenatal care visits and there may not be time for discussions about Healthy Start;
- Women must wait until their next antenatal appointment for a health professional to sign the completed application form and this may lead to unnecessary delays;
- A lack of information about Healthy Start in languages other than English;
- Healthy Start vouchers cannot be used for online shopping;

- Pregnant women may choose to 'stockpile' infant formula rather than spend the vouchers on herself.

The next phase of consultation was with the midwives, which was important because "practitioner wisdom…is a prime source of programme theory" (Pawson, 2013, p. 122). For this review, it was logical to consult midwives, who are responsible for supporting low-income pregnant women to apply for Healthy Start vouchers and supporting all pregnant women to eat well. In June 2015, an informal discussion group was held with four midwives at Royal Preston Hospital. The group discussed the candidate theories about Healthy Start and provided verbal feedback, which was digitally recorded. The midwives said it was a high priority to signpost low-income women to Healthy Start and to discuss healthy eating with them. However, they felt that Healthy Start was less visible than it used to be (with fewer promotional materials available) and some women were not aware of the programme when they arrived at their first antenatal appointment. They did not think that many women would find the application process difficult because the form was very simple. They had heard stories about shopkeepers who would 'take a cut' of the voucher value (i.e. exchange the vouchers for less than £3.10 worth of items) or exchange the vouchers for non-target items. They thought that some women would be likely to share the foods purchased with the vouchers with other family members, especially children. They agreed that some women may use the vouchers to deduct money from the shopping bill, rather than increase their consumption of target foods. Finally, the midwives emphasised the importance of nutrition education during pregnancy, beyond what they could deliver in short appointments, so that women would know how to use their vouchers to eat well during pregnancy.

> *I decided at this point to prioritise candidate theories about how low-income pregnant women use Healthy Start vouchers. This decision reflected my personal interests – the potential of Healthy Start to improve the dietary outcomes of low-income women. The reasoning and reactions of women in response to receiving the vouchers (mechanisms) had not been explored in previous studies of Healthy Start. I was becoming increasingly interested in how variations in context might influence which mechanisms were activated, and how those mechanisms might alter women's behaviour. There was also another consideration – recent changes to the UK welfare system and the introduction of Universal Credit (Welfare Reform Act, 2017). One of the public health practitioners in the study advisory group had informed me that this was likely to change the eligibility criteria for*

Healthy Start. In June 2015, the potential effects of this were unclear and I decided it would be unwise to focus on candidate theories about programme administration and the application process, because such theories could become out-of-date or obsolete. However, there was no indication that the Healthy Start programme was under threat, so I was confident to proceed with my review and focus on how low-income pregnant women use the vouchers.

Table 7 shows the candidate theories produced after the decision was made to focus on how low-income pregnant women use Healthy Start vouchers (dated 18th June 2015). It highlights concepts from the Behaviour Change Wheel in bold letters (Michie, van Stralen, & West, 2011). The following reflexive section explains how this theory helped to shape the development of the candidate theories. It will be revisited in more depth in chapter 7 as a 'middle-range' theory (see section 7.3).

Around this time, I was reading about the Behaviour Change Wheel, which identified three conditions that may influence behaviour change: capability, opportunity and motivation (the COM-B system). I started to think about my candidate theories in a similar way. Healthy Start might provide the 'capability' (through support from health professionals) and the 'opportunity' to eat healthy foods (vouchers), which could make women feel 'motivated' to eat well during pregnancy, leading to increased consumption of healthy foods. Alternatively, I had identified a variety of scenarios and reasons why this idealistic outcome may not occur, such as inadequate support from health professionals, lack of control over household resources, problems using vouchers in smaller shops, inconsistent verification of what vouchers are exchanged for, concerns about stigmatisation etc. I remember putting a lot of effort into assigning the labels of context, resources and mechanisms, but I was still finding this difficult. Therefore, this version reads more like a list of contributing factors than explanatory, linked CMOc.

Table 7. Candidate theories about how low-income pregnant women use Healthy Start vouchers (18th June 2015)

Context	Resources	Mechanisms	Outcomes
Low income families more likely to have poor diets and limited resources to spend on food (wider socio-economic determinants).	Healthy Start vouchers worth £3.10 per week give women extra income to spend on FV or cow's milk during pregnancy. OPPORTUNITY (FINANCIAL)	Women are motivated to eat well during pregnancy to achieve health benefits for themselves and their baby. MOTIVATION (HEALTH) OR Women are motivated to eat well during pregnancy and they also want the whole family to eat well. MOTIVATION (HEALTH) May need combination of opportunity + capability to produce motivation.	Vouchers are spent on FV or cow's milk and women increase their consumption of these foods during pregnancy. OR Vouchers are spent on FV or cow's milk and these items are shared with older children and other family members. INTENDED OUTCOME
Women may have shopping routines determined by food prices, transport, convenience, work patterns etc.	Many retailers are registered to accept Healthy Start vouchers and most women should be able to use them in their local or usual shops. OPPORTUNITY (CONVENIENCE)		
Adjacent campaigns like 5-a-day and change4life inform women about the need to consume more FV.	Health professionals provide information and advice on nutrition and healthy diet during routine antenatal appointments. CAPABILITY (EDUCATION)		
Alternatively: Chaotic lives or poor organisational skills. Women may experience information overload. Lack of cooking skills and/or facilities. Lack of engagement with local services to teach cooking skills.	Alternatively: Smaller shops may not be registered to accept vouchers. Inconsistent rules about how vouchers can be used (e.g. taking a cut, only one at a time). Vouchers cannot be used for online shopping. Lack of training on Healthy Start…	Alternatively: Lack of motivation to eat well during pregnancy. Lack of control over household resources. Lack of independence to make decisions (e.g. living with extended family). Fears about stigmatisation.	Alternatively: No increase in consumption of target foods. Stockpiling infant formula during pregnancy. UNINTENDED OUTCOME

Table 7. continued.

Context	**Resources**	**Mechanisms**	**Outcomes**
	Lack of time during appointments. Focus on antenatal screening. Women delay attending antenatal care visits; may receive nutrition advice later in pregnancy. Healthy Start less visible than it used to be. Women and health professionals' misperceptions about milk tokens.		
Current political and economic climate of austerity, cuts to benefits, rising food prices, unemployment etc. means that household budgets are stretched even further.	The value of Healthy Start vouchers has not increased to keep pace with the economic challenges faced by low income families (£3.10 since 2009).	Women are motivated to reduce their shopping bill or prioritise spending on other items. They perceive certain items as being better value for money. MOTIVATION (FINANCIAL)	Vouchers contribute to weekly food shop and provide financial assistance, but with no overall increase in consumption of FV or cow's milk. UNINTENDED OUTCOME
	Other factors: *Nobody checks what they have got at the check-out or can use vouchers at self-check-out.* *Shopkeepers may allow women to spend vouchers on other items (foods/other).*	*Other factors:* *Liberate funds for other things.*	

FV = fruit and vegetables

In July 2015, the second informal discussion group was held with two midwives at Furness General Hospital, Barrow-in-Furness. They provided feedback on the latest version of the candidate theories (Table 7), and agreed with the rationale for focusing on how low-income pregnant women use Healthy Start vouchers. They highlighted under 18s, who are eligible for Healthy Start regardless of household income, and suggested various aspects of context (circumstances) that might influence how they use the vouchers: living with their parents, fears about pregnancy, apathy, lack of awareness about the importance of eating well during pregnancy, perceived lack of convenience etc. The group discussed women's motivations for using the vouchers, which they felt would depend on the perceived value of healthy foods. They said that some women prefer to swap their vouchers with friends for cash (usually less than the voucher value). They felt that access to shops might be problematic for some women in this semi-rural area of Cumbria. They said that some women felt stigmatised using the vouchers in smaller shops, compared to the anonymity of larger supermarkets. This discussion group confirmed the relevance of the candidate theories developed thus far (Table 7). This discussion group, and the support received from realist networks around the same time (see 4.6), helped to finalise which candidate theories would be tested.

At the end of this consultation stage, the following review questions were confirmed:

1. How do low-income pregnant women use Healthy Start vouchers?
2. What are the intended and unintended outcomes of the programme?
3. What are the underlying mechanisms and how do variations in context influence (enable or constrain) these mechanisms

4.6 Support from realist networks

This chapter would not be complete without acknowledging the tremendous support I received when conducting this realist review, especially during the theory development stage, when I was still trying to understand what realist methodology was all about. I engaged with three realist support networks during the early stages of my realist review. I wrote a guest blog on The Realist Hive encouraging other novice realist researchers to engage with these and similar networks (Appendix C) (University of Exeter, 2016).

The RAMESES Project (Realist and Meta-narrative Evidence Syntheses: Evolving Standards) has produced various documents to assist realist reviewers, including training materials, publication standards and quality standards, which were extremely helpful

during this review (RAMESES, 2014; Wong, Westhorp, Pawson, & Greenhalgh, 2013; Wong, Greenhalgh, Westhorp, Buckingham, & Pawson, 2013). Equally helpful was the RAMESES email list, where anyone can post a question about any aspect of realist philosophy or methodology or ask advice about their own projects. The responses tend to be generous and considered, often leading to several days of discussion and debate. At first I found the emails confusing because some of them are fairly high level. As I progressed through my own realist journey, I was able to follow the threads more and more confidently. I found this very reassuring, especially when I could see that other people around the world were experiencing similar challenges to me.

The Centre for Advancement in Realist Evaluation and Synthesis (CARES) at the University of Liverpool organises regular events to support realist researchers. I attended two events in 2015: a two-day workshop in March and a three-day summer school in June. As well as interactive taught sessions, these events offer one-to-one consultations with realist experts. At the summer school, I shared my candidate theories (dated 18th June 2015) in two separate consultations with Justin Jagosh and Geoff Wong. They agreed with my rationale for the scope and focus of the review. Geoff emphasised the importance of identifying the causal links between context, mechanisms and outcomes; 'free floating' context must be avoided (i.e. unclear relationship with mechanisms) and the review cannot include all aspects of context. They suggested that I could present my candidate theories in two 'strands' leading to two possible outcomes: women who use vouchers to increase consumption of healthy foods (dietary improvements) and women who use vouchers to reduce food expenditure (financial assistance). This would help me to 'work backwards' to develop explanations for these outcomes (Wong, 2015). At the end of the summer school, having had some time to reflect on this advice, I explained to Justin Jagosh that my candidate theories seemed much clearer, but I was struggling to fit them into CMOc. I wanted to move on to start exploring the evidence from primary studies, which I hoped would help to clarify the CMOc. Justin thought that was an excellent idea and reassured me that I should not get too 'bogged down' with detailed explanations and CMOc this early in the review. This advice really helped me to move forward into the testing stage.

The third source of support was from a smaller, informal, peer support network. At the CARES workshop in March 2015, I met two other researchers who were learning how to use realist methodology for the first time (one PhD student and one senior researcher). We decided to stay in touch and share our realist journeys through monthly Skype chats.

This has been phenomenally useful for me, and I think they would both say the same. We have given each other constructive feedback on our programme theories and CMOc, discussed the strengths and limitations of realist methodology, continued some of the debates that arose on the RAMESES forum, and provided encouragement.

4.7 Candidate theories to be tested

Two main outcome strands emerged during the theory development stage:

1. Women who use vouchers to increase consumption of target foods (intended outcome: dietary improvements)
2. Women who use vouchers to reduce food expenditure (unintended outcome: financial assistance)

The first strand was based on policy documentation, which stated the aims of Healthy Start to provide a "basic nutritional safety net" and encourage "women and families to make positive nutritional choices affecting their longer term health" (Department of Health, 2010, p. 4). Therein lies an implicit assumption that low-income pregnant women will use the vouchers to purchase target foods in greater quantities than they did before. This may be thought of as an 'active' response to the programme i.e. women use the vouchers to improve their diets during pregnancy.

The second strand was based on the findings of three previous studies of Healthy Start, which suggested that some women may use the vouchers to subsidise the cost of healthy foods or infant formula (Griffiths et al., 2015; Lucas et al., 2013; McFadden et al., 2013). This outcome may be thought of as a 'passive' response to the programme i.e. women use the vouchers to subsidise their existing behaviours. For the purposes of this review, strand 1 was assumed to be the intended outcome of the Healthy Start programme and strand 2 was assumed to be an unintended outcome.

The candidate theories taken forward to the testing stage were those in Table 7 (dated 18th June 2015). There was still some uncertainty about what constituted context, resources, mechanisms and outcomes and these labels were used tentatively. However, the theory development stage identified a variety of factors that may be important in explaining how low-income women use Healthy Start vouchers. These factors and the causal linkages between them were tested and refined in the next stage of the review.

4.8 Chapter summary

This chapter has described the theory development stage of the realist review. Candidate theories (initial, untested theories) about Healthy Start were identified and prioritised using a combination of methods: information derived from academic and grey literature on Healthy Start, an intervention mapping exercise, existing knowledge, creative and retroductive thinking, consultations with stakeholders (in person and by email) and discussions among the review team. These methods were used to narrow down the scope and focus of the review – leading to more specific realist review questions. The decision was made to explore how low-income pregnant women use Healthy Start vouchers. This reflected my personal interests, the research gaps identified (in chapter 2), and system changes that were thought likely to influence certain aspects of the programme in the months during which the review would be completed. Two main outcome strands were identified (intended/unintended outcomes) and a variety of possible explanations were developed. Advice from realist experts confirmed that the candidate theories were good enough to move onto the testing stage of the review. The next chapter describes the second stage of the review, in which candidate theories were tested using existing empirical evidence.

5.0 REALIST REVIEW: TESTING PROGRAMME THEORIES

5.1 Introduction

This chapter presents the second stage of the realist review: testing candidate theories using existing empirical evidence. As described in chapter 4, the two stages of realist reviews tend to be iterative and overlapping – a gradual process of developing, testing and refining programme theories. The 'testing' stage is important because this is the stage at which the reviewer's ideas and hypotheses (or candidate theories) are subjected to scientific scrutiny, and substantiated, refuted or modified. This chapter starts with an explanation about the scope of evidence used to test candidate theories about Healthy Start. The realist review methods are described in similar stages to a traditional systematic review: search strategy, inclusion criteria, study selection, data extraction, quality appraisal, analysis and synthesis. They are described as such for clarity, but the realist synthesis approach offered greater flexibility and, in practice, these stages overlapped. The criteria for study selection and quality appraisal evolved as the review progressed; they were not specified at the start as would be typical in traditional systematic reviews. The included studies were read and re-read many times, as data extraction informed theory development and vice versa. The iterative nature of realist synthesis has been described in other reviews (Camprubí et al., 2016; Jagosh et al., 2012; Lhussier, Carr, & Forster, 2015) and sets this method apart from other approaches to evidence synthesis. Quality standards for realist synthesis were used to guide the review process and ensure transparent reporting (RAMESES, 2014). The results present three 'evidence-informed' programme theories about how low-income pregnant women use Healthy Start vouchers. These theories offer plausible and tentative explanations for why low-income pregnant women might receive the same Healthy Start vouchers and yet experience different outcomes, due to variations in context and mechanisms. The findings were utilised to inform the empirical phase of this PhD.

5.2 Scope of evidence used

Previous studies and evaluations of Healthy Start were critically reviewed in chapter 2. There has been no national evaluation (or robust smaller evaluation) of the impact of Healthy Start on nutritional outcomes since the programme was introduced in 2006. A variety of perceived outcomes were identified in previous studies, but they did not investigate possible reasons why some low-income women might experience intended

outcomes (such as using the vouchers to buy and consume more healthy foods) while other low-income women might experience alternative or unintended outcomes (such as using the vouchers to deduct money from the shopping bill). Therefore, it was clear that additional sources of evidence would be required to explore the research questions identified in chapter 4:

1. How do low-income pregnant women use Healthy Start vouchers?
2. What are the intended and unintended outcomes of the programme?
3. What are the underlying mechanisms and how do variations in context influence (enable or constrain) these mechanisms

In realist synthesis, when evidence from the programme under study is insufficient, it is often necessary to draw upon "collective wisdom" from similar programmes (Pawson, 2006, p. 11). This may be enlightening because similar programmes may operate through similar mechanisms. However, it is important to be aware of differences in programme resources and context and critically assess which mechanisms may be transferable between programmes.

The most obvious source of potentially relevant evidence was the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) in the United States (US). WIC is the only other national 'nutrition assistance' programme that specifically targets low-income women, infants and children. It was introduced in 1974 and has supported low-income families across all 50 States for over 40 years. Its goals are to promote and support breastfeeding and to safeguard the health of low-income women, infants and children (National Academies of Sciences, Engineering and Medicine, 2017). In 2016, WIC supported 8 million women, infants and children through 47,000 authorised retailers (source: National WIC Association, First Steps Nutrition Trust Conference, April 2016). WIC has four components: a nutritious food package; mandatory nutrition education; breastfeeding promotion and support; referrals to health and social services. The WIC food package was revised in 2009 to reflect current US dietary guidance (Institute of Medicine of the National Academies, 2005). These revisions included the introduction of 'cash value vouchers' for fruits and vegetables, which can be used to purchase a wide variety of fresh, canned, dried or frozen fruits and vegetables. The previous food package only included an allowance for vitamin C rich juice. Further revisions were recommended in 2017 to enhance the nutritional quality of the food package, but these are much smaller

changes than in 2009 and will not be reflected in any published studies included in this review (National Academies of Sciences, Engineering and Medicine, 2017).

Figure 7 illustrates the assumed intervention model of the WIC programme, which suggests that the combination of knowledge and financial support will encourage low-income families to purchase and consume healthy food. This is not a realist programme theory because it does not specify the mechanisms (reasoning and reactions of individuals) activated by this combination of knowledge and financial support, which are thought to generate behaviour change. However, the assumed outcome in this model is similar to the intended outcome of the Healthy Start programme, as identified in chapter 4: women who use vouchers to increase consumption of healthy foods (dietary improvements).

Figure 7. WIC intervention model assumption (presented at the First Steps Nutrition Trust Conference, April 2016; reproduced with permission from the National WIC Association)

Therefore, it seemed logical to include studies of WIC in this realist review to explore: if the programme works as the above model suggests; what mechanisms may be activated by the combination of knowledge and financial support; what aspects of context may be necessary for the programme to work; whether it is more successful for some participants than others; to what extent the evidence from WIC studies might be generalisable to Healthy Start. For pragmatic reasons, the scope of evidence used was limited to studies of Healthy Start and WIC. A review team with more time or resources might have expanded the scope of evidence used, for example to include other types of voucher programmes and/or other low-income groups.

The main similarities and differences between the Healthy Start and WIC programmes are summarised in Table 8. WIC appears to be more comprehensive in its approach to improving dietary behaviours. It supports a broader range of foods and each category of food has a separate allowance (‘maximum monthly allowance’ by weight or ‘cash value

vouchers' for fruits and vegetables) so that women and children can access the full range of recommended nutrients. There is also a separate allowance for infant formula, and breastfeeding women receive a more attractive food package with greater quantities of healthy foods – a clear incentive to breastfeed. WIC provides mandatory nutrition education, delivered in dedicated WIC clinics by trained WIC Nutritionists. It is well integrated with other health, welfare and social services. There may be much to learn from WIC in terms of what works, for who, in what circumstances and why.

Table 8. Comparison of programme characteristics of Healthy Start and the Special Supplemental Nutrition Program for Women, Infants and Children (WIC)

Programme characteristics	**Healthy Start (UK)**	**WIC (US)**
Beneficiaries	Women 10+ weeks pregnant and children under the age of 4 years	Pregnant and postpartum women and children under the age of 5 years
Eligibility criteria	Annual family income of £16,190 or less; income-related benefits; all pregnant women under 18 years	Income eligibility guidelines based on household size and income (at or below 185% of the US Poverty Income Guideline) plus an assessment of nutritional risk
Type and value of food subsidy	Food vouchers (£3.10 per week) to be spent of any combination of foods listed below	Cash value vouchers for fruits and vegetables ($10 per month); monthly checks or Electronic Benefits Transfer (EBT) for other categories of food in prescribed amounts
Foods available	Fruits and vegetables, plain cow's milk, infant formula	Fruits and vegetables, milk, cheese, eggs, whole grain cereals, whole wheat bread, juice (single strength), fish (canned), legumes (dry or canned) and/or peanut butter
Position on infant formula	Same voucher as food and women must choose; no difference in voucher value for women who breastfeed	Separate allowance for infant formula; enhanced food package for fully breastfeeding women
Rules for using vouchers	Any registered retailer; women can use more than one voucher at a time as long as within use-by date; no change given	Any registered retailer; EBT system will be introduced in all states by 2020; most states still (in 2016) using checks in combination with cash value vouchers
Nutrition education and resources	Standard antenatal support from midwives and other health professionals; healthy eating advice available on website (links to start4life)	Nutrition education and counselling (based on individual needs) provided by WIC nutritionists; mandatory component but delivery and content varies state to state; range of resources provided through WIC Works website
Additional support	Vitamin supplements	Screening and referrals to other health, welfare and social services (e.g. immunisations); breastfeeding promotion and support

5.3 Methods

5.3.1 Search strategy

Separate searches were conducted for Healthy Start and WIC:

Healthy Start – Studies were identified through the manual, purposive scoping search described in chapter 4 (4.3). Pawson (2006) described how primary studies identified during the theory development stage may also be used as evidence in the testing stage. Electronic database searches were considered unnecessary due to the paucity of empirical studies and the reviewer's familiarity with the literature on Healthy Start.

WIC – A broad search strategy was devised in collaboration with an Information Specialist in the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North West Coast. This strategy was adapted and run in six electronic databases in September 2015: MEDLINE, EMBASE, CINAHL, Open Grey, ETHOS and PubMed. Table 9 shows the search terms used in MEDLINE. No date or language restrictions were used. Reference lists of all included studies, two systematic reviews (Black et al., 2012; Schultz, Byker Shanks, & Houghtaling, 2015) and an online list of WIC studies (United States Department of Agriculture: Food and Nutrition Service, 2015) were checked for any additional studies that met the inclusion criteria.

Table 9. Search strategy used in MEDLINE to identify WIC studies

#	Search terms	Results
1	WIC.tw.	1008
2	(nutrition or food or voucher or "nutrition program").tw.	377002
3	1 and 2	599
4	(Special* adj4 Supplement* adj4 Nutrit* adj4 Program* adj4 Women* adj4 Infant* adj4 Child*).tw.	415
5	3 or 4	688

5.3.2 Inclusion criteria

Primary or empirical studies (of any study design) were included if they contributed relevant evidence or insights about how low-income women use food vouchers from the Healthy Start (UK) or WIC (US) programmes. Assessment of 'relevance' is essential in

realist synthesis, to ensure that all included studies contribute to theory development, refinement and testing (Pawson, 2006; RAMESES, 2014). In this realist review, the interpretation of 'relevance' was deliberately broad to ensure that the reviewers remained open to new ideas from a variety of sources of evidence. A bespoke system was used to maintain a consistent and transparent approach. Table 10 shows the questions used to assess relevance during the selection process (5.3.3). These questions were developed by the lead reviewer (Heather Ohly), agreed with the review team (PhD supervisors) and finalised towards the end of the theory development stage, to ensure they reflected the candidate theories to be tested. Studies that scored 5/8 or more (based on the total number of yes answers) were included.

Table 10. Questions used to assess the relevance of primary studies

#	Question:
1	Do the research questions or study aims refer to Healthy Start or WIC?
2	Does the study focus on the food voucher (cash value vouchers or food package for WIC) component of the programme?
3	Does the study focus on beneficiaries rather than eligibility status?
4	Does the sample include pregnant women?
5	If the sample does not include pregnant women, could some of the findings be generalisable to pregnant women?
6	Does the study report women's food or nutrient intakes (measured or perceived)?
7	Does the study provide any insights about how food vouchers are used?
8	Does the study provide any insights about which women may benefit most/least and why?

Possible answers: yes, no or unclear (scored 1 for every yes)

5.3.3 Selection process

Results from the WIC database searches were uploaded into RefWorks (web version; ProQuest; Michigan, US) and screened using titles and abstracts. Studies that appeared to meet the inclusion criteria were obtained as full text articles. Studies for which insufficient information was available to determine relevance were also obtained as full text articles. The full text screening process was fully documented, including the assessment of relevance and reasons for exclusions (Appendix D). The same criteria were

applied to studies of Healthy Start. Study selection was completed by the lead reviewer (Heather Ohly) and double-checked by a second reviewer (Victoria Hall Moran). Any disagreements were resolved by discussion.

5.3.4 Data extraction

Data extraction was purposive – only data that were considered useful to programme theory development (guided by the review questions) were extracted. Quantitative data on women's nutritional outcomes were extracted using bespoke tables in Microsoft Word 2013 (version 15.0.4815.1001; Microsoft Corporation). Other non-relevant data were not extracted. Qualitative data, textual descriptions of findings, and author interpretations were extracted using MAXQDA 11 (version 11; VERBI Software GmbH; Berlin). A coding system was created with three main headings: context, mechanisms and outcomes. Subheadings were added deductively (based on candidate theories) and inductively (as new themes emerged from the data). Data extraction was completed by the lead reviewer (Heather Ohly) and a sample was double-checked by a second reviewer (Nicola Crossland). Using MAXQDA enhanced the transparency of the review process because each coded item of data could be viewed within the original paper (imported into the software as pdf) as well as being collated under the headings and subheadings. Similar benefits were documented in a blog post by realist researchers who used NVivo software to "keep an audit trail of theory development" (Dalkin, Forster, Hodgson, Lhussier, & Carr, 2015). The evolution of this coding system to track data linkages and develop explanatory CMO configurations (CMOc) is described in 5.3.6. Data extraction, quality appraisal, analysis and synthesis happened concurrently.

5.3.5 Quality Appraisal

Studies were not formally appraised at the data extraction stage, as would be the case in traditional systematic reviews. Instead, an assessment of 'rigour' was used to judge the credibility and trustworthiness of the evidence as it was integrated into the analysis and synthesis (Pawson, 2006; RAMESES, 2014). This assessment was not scored because weaker studies were still included, but it meant that methodological limitations were acknowledged and study findings were not over-interpreted or over-generalised. The goal was to 'safeguard inferences' or 'nuggets of information' from studies that were 'good enough' to contribute to the synthesis, rather than to 'remove bias procedurally' as a systematic review would do (Pawson, 2006, p. 90). Table 11 shows the questions used to

assess rigour in this review. These questions were developed by the lead researcher (Heather Ohly) and agreed with the review team (PhD supervisors). Quality appraisal criteria developed by other researchers were modified and simplified for this review (Wallace, Croucher, Quilgars, & Baldwin, 2004). The assessment of rigour was fully documented, including reasons for any studies not considered rigorous (Appendix E). Quality appraisal was completed by the lead reviewer (Heather Ohly) and double-checked by second reviewers (Nicola Lowe and Victoria Hall Moran).

Table 11. Questions used to assess the rigour of primary studies

#	Question:
1	Are the study methods clearly reported (including study design, recruitment, data collection and analysis)?
2	Are the study methods appropriate to answer the research questions?
3	Are the sample characteristics reported to enable judgements about generalisability?
4	Are the study findings and conclusions supported by raw data?
5	Are the study limitations acknowledged and clearly reported?

Possible answers: yes, no, partial or unclear

5.3.6 Analysis and synthesis

This process involved gradual and iterative theory development, whereby evidence from primary studies was used to modify, refine and substantiate programme theories about how low-income pregnant women use Healthy Start vouchers, in what circumstances, and why. Theories were constructed as explanatory CMOc, usually by starting with the outcome and working backwards to determine "what caused it (the mechanism) and under what contexts was the mechanism triggered" (Wong, 2015, p. 2). This process has also been described as the "reconstruction of meaning from the previously disaggregated pieces of evidence" (Lhussier et al., 2015, p. 3). The focus of the analysis was searching for evidence to support and refute the proposed causal linkages between context, mechanisms and outcomes. A combination of evidence synthesis and realist analysis techniques was used:

1. Narrative synthesis of quantitative data on women's nutritional outcomes; meta-analysis was not appropriate due to heterogeneity of study designs and data collection methods (and was beyond the scope of this review).

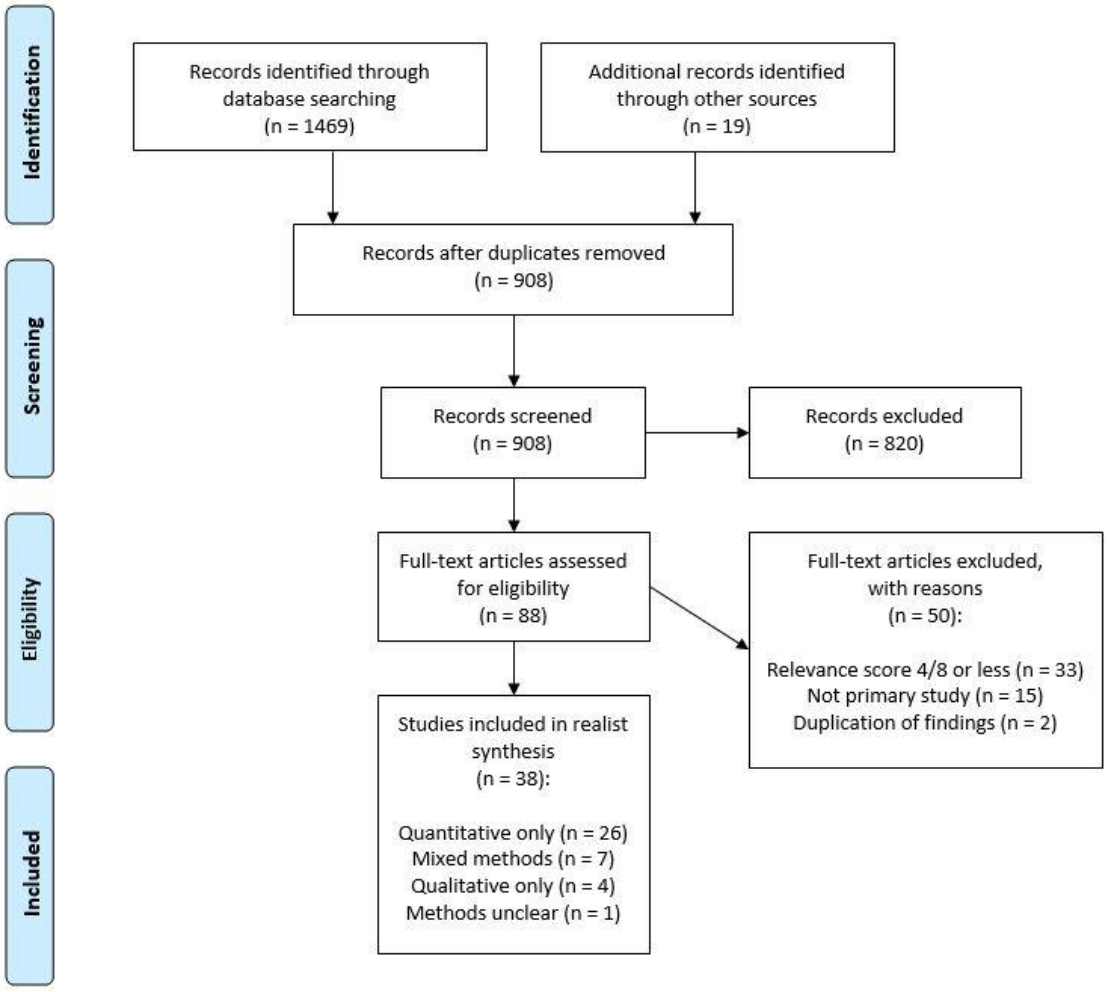
2. Thematic synthesis of qualitative data, by creating codes and themes (already described in 5.3.4) and then 'going beyond' the interpretations of the original studies to generate new understandings or hypotheses (Thomas & Harden, 2008). The original codes were re-examined and new codes were created for any items of data that provided insights into potential explanations and linkages within the emerging CMOc (e.g. C→M, M→O, C→M→O).
3. Creative theorising or 'retroduction' in collaboration with the review team (PhD supervisors) and the study advisory group. This involved in-depth reflection and discussions (throughout the review) about the underlying causes of outcome patterns, at the level of generative mechanisms and explanatory context. The data from included studies did not always provide such in-depth insights and explanations. Where individual extracts of data only supported part of the CMOc, it was necessary to make logical inferences about the complete causal pathways and explanations (Ford, Wong, Jones, & Steel, 2016).

5.4 Results

5.4.1 Search results and study characteristics

A total of 908 records were identified through the two separate searches. After screening titles and abstracts, 88 records were obtained in full text format. Fifty full text articles were excluded based on the assessment of relevance (n=33) or because they were not primary studies (n=15) or the findings were duplicated (n=2). Therefore, 38 primary studies were included in this review: four UK studies on Healthy Start and 34 US studies on WIC. The study selection process is shown in Figure 8. The following sections (5.4.2 to 5.4.6) describe in detail how evidence from the included studies was used to test the candidate theories from chapter 4.

Figure 8. PRISMA flow diagram (Ohly et al., 2017)



5.4.2 Working backwards from outcomes to explanations

Two main outcome strands emerged during the theory development stage and these were further substantiated using evidence from primary studies:

1. Women who use vouchers to increase consumption of target foods (intended outcome: dietary improvements)
2. Women who use vouchers to reduce food expenditure (unintended outcome: financial assistance)

In relation to outcome strand 1, 25 of the included studies reported women's nutritional outcomes: three Healthy Start studies and 22 WIC studies. The three Healthy Start studies reported perceived outcomes only. In all three studies, some women said they bought or consumed more healthy foods (greater amount, quality or variety) after receiving Healthy Start vouchers (Hills, 2006; Lucas et al., 2013; McFadden et al., 2013). These studies

were reviewed in more detail in chapter 2. None of the Healthy Start studies measured women's nutritional outcomes using dietary assessment or nutritional biomarkers. Therefore, it was important to consider how the evidence on women's nutritional outcomes from WIC studies could be used to make inferences about the potential impact of the Healthy Start programme and further support outcome strand 1.

The 22 WIC studies were published between 1981 and 2015, with 17 studies conducted before the 2009 revisions to the WIC food package (which included the introduction of cash value vouchers for fruits and vegetables) and five studies conducted after the 2009 revisions. Although there were fewer similarities with Healthy Start before the 2009 revisions, it was important to be aware of the observed effects of WIC before and after the revisions were implemented.

Four out of 17 WIC studies conducted before the 2009 revisions provided support for outcome strand 1. These four studies found significant dietary improvements associated with WIC for most of the nutritional outcomes assessed. A before/after study of pregnant women in North Carolina (n=378; mostly Black) found that energy and nutrient intakes increased after receiving WIC ($p<0.009$), although some nutrient intakes remained below the Recommended Daily Amounts (Farrior & Ruwe, 1987). A large experimental study of pregnant women (n=3472; mixed ethnicity) found that four out of five target nutrient intakes increased in the WIC group compared to the control group: protein ($p<0.01$), iron, calcium and vitamin C (all $p<0.001$) and this was mostly attributable to WIC foods (Rush et al., 1988). The other two (linked) studies piloted cash value vouchers for fruits and vegetables before they were introduced in 2009 (Herman, Harrison, & Jenks, 2006; Herman, Harrison, Afifi, & Jenks, 2008). Postpartum women in Los Angeles (n=602; 89% Hispanic) reported using the vouchers to purchase a wide variety of fruits and vegetables (Herman et al., 2006). The same women reported consuming more fruits and vegetables after receiving the vouchers for six months ($p<0.001$ compared to baseline) and this increase was sustained six months after they stopped receiving the vouchers (Herman et al., 2008). However, the vouchers provided in these pilot studies were worth $10 per week, compared to $10 per month when they were introduced nationally in 2009. The other 13 studies conducted before the 2009 revisions showed mixed effects on women's nutritional outcomes, or found that women who received WIC had inadequate diets.

Five WIC studies conducted after the 2009 revisions showed mixed effects on women's nutritional outcomes. Two studies were limited by poor study design and their findings are not presented. The other three studies used dietary assessment methods to compare women's nutritional outcomes before and after the 2009 revisions. A longitudinal study of African American and Hispanic women in Chicago (n=273) found some significant dietary improvements six months after the 2009 revisions (Odoms-Young et al., 2014). Hispanic mothers (n=143) reported consuming more fruit, more reduced fat milk, less whole milk, less fruit juice (food intakes) and less saturated fat (nutrient intake) (all $p<0.05$); other dietary changes such as vegetables were not statistically significant. African American mothers (n=130) reported consuming less whole milk ($p=0.02$) but no other dietary changes were statistically significant (Odoms-Young et al., 2014). Most of these women (n=222) were also assessed 18 months after the revisions (Kong et al., 2014). Hispanic mothers reported consuming less fruit juice ($p<0.05$) and both groups reported consuming less whole milk ($p<0.05$) compared to baseline; no other dietary improvements were sustained at 18 months. A cross-sectional study comparing two random samples of WIC participants in California (both 80% Hispanic) found that women assessed six months after the changes (n=2996) reported consuming significantly more whole grains, reduced-fat milk and vegetables, and less whole milk, compared to women assessed before the changes (n=3004) (all $p<0.001$) (Whaley, Ritchie, Spector, & Gomez, 2012).

In relation to outcome strand 2, seven of the included studies reported outcomes related to women's food expenditure: two Healthy Start studies and five WIC studies. These studies provided support for outcome strand 2 (financial assistance). The two Healthy Start studies reported perceived outcomes only. In one study, some women said the vouchers "freed up money to do other things" and "helped them to manage better financially" (McFadden et al., 2013, p. 59). In the other study, some parents (mostly mothers) said the vouchers made no difference to their food choices because they preferred to save the additional money (Lucas et al., 2013).

Four WIC studies reported findings from analyses of electronic sales data from WIC retailers (one large supermarket chain) in New England between 2009 and 2010 (Andreyeva & Luedicke, 2013; Andreyeva, Luedicke, Tripp, & Henderson, 2013; Andreyeva, Luedicke, Henderson, & Schwartz, 2014; Andreyeva & Luedicke, 2015). They compared purchasing patterns in 2137 WIC households before and after the 2009 revisions to the WIC food package. The findings for different food groups were reported

in separate papers. Overall, household purchasing patterns shifted towards items provided in the WIC package after the 2009 revisions. Fruits and vegetables, reduced-fat milk, brown rice, whole grain cereals and bread replaced less nutritious options. For example, the amount of fruits and vegetables purchased (kg/month) increased by 28.6% and 17.5% respectively between 2009 and 2010 ($p<0.001$) (Andreyeva & Luedicke, 2015). However, this was partly accounted for by 'substitution effects' whereby women substituted the method of payment i.e. vouchers were used to pay for fruits and vegetables that would previously have been paid for using non-WIC funds. Substitution effects were relatively small (as a % of the amount purchased in 2009); the largest effect was observed for canned vegetables (13%). The electronic sales data used in this study were collected from one supermarket chain and did not represent the overall diets and purchasing patterns of the households included. Sample characteristics such as ethnicity were not available. Finally, a mixed-methods study of Hispanic and African–American pregnant women (n=313) found that two-thirds of women reported using WIC vouchers to reduce food expenditure.33 The money they saved was used to purchase items for the unborn baby, other foods and for bills and emergencies.

These findings suggest that the WIC food package (including cash value vouchers for fruits and vegetables) leads to dietary improvements for some, but not all women. This may be because some women use the package/vouchers to reduce expenditure on foods they would previously have bought using cash or other funds. This is referred to as 'financial assistance' in outcome strand 2. The WIC studies described above were not representative of ethnic groups in the UK, and the samples included mothers as well as pregnant women. The dietary assessment studies were limited by convenience samples and self-reported outcomes. Furthermore, the differences between the two programmes (such as broader range of foods and mandatory nutrition education in WIC) mean the findings from WIC studies are not generalisable to women receiving Healthy Start vouchers. However, these studies provide much needed insights about the potential impact of Healthy Start, and alternative ways in which the programme might influence the behaviours of low-income women. It is important to emphasise that the two outcome strands (dietary improvements and financial assistance) are not mutually exclusive. It is possible that some women might experience both outcomes at different times, or both outcomes at the same time.

5.4.3 Evidence-informed programme theories

The purpose of this chapter is to describe how 'candidate theories' (initial, untested theories) were tested using existing empirical evidence and gradually transformed (i.e. substantiated, refuted or modified) into 'evidence-informed' programme theories. The previous section described how two main outcome strands were substantiated using (mostly quantitative) data from studies of Healthy Start and WIC. The following three sections describe how data were used to develop and substantiate explanations for these outcomes. Three 'evidence-informed' programme theories are presented. These were the explanations (developed from candidate theories in chapter 4) that were best supported by the studies included in this review. They offer plausible and tentative explanations for why low-income pregnant women might receive the same Healthy Start vouchers (£3.10 per week) and yet experience different outcomes, due to variations in context and mechanisms. The programme theories are constructed as CMOc and illustrated using quotations from included studies.

Figure 9 (p. 109) shows the key aspects of context, mechanisms and outcomes identified and the proposed causal pathways linking them together. Table 12 (p. 110) shows how each included study contributed to the evidence-informed programme theories. Individual primary studies rarely provided in-depth explanatory data that could be used to substantiate complete CMOc, and it was necessary to 'piece together' the evidence from within and between studies.

5.4.4 Programme theory 1: Prioritisation of resources

Women living on low incomes must constantly prioritise how they spend their money. Food vouchers may be considered as one part of the household resources and decisions must be made about how best to use the vouchers. This theory proposes that a key aspect of individual level context is the 'relative value' of healthy eating (compared to other things women value), which can lead women to prioritise resources in different ways. Context is not static and women's values may change over time. Therefore, it is logical to infer that some women may fluctuate between the two contrasting CMOc described below. This theory is an example of how a mechanism (in this case 'prioritisation of resources') may be modified by context. In the first CMOc it generates the intended outcome of dietary improvements, whereas in the second it generates the unintended outcome of financial assistance.

Women who value healthy eating and aspire to eat well during pregnancy [context] are more likely to perceive Healthy Start vouchers as an opportunity to achieve health benefits for themselves and their unborn baby [mechanism]. The vouchers alleviate the financial barrier associated with healthy eating and make healthy foods seem more affordable [mechanism]. Therefore, women who value healthy eating are more likely to prioritise healthy eating [mechanism] and use Healthy Start vouchers to increase consumption of target foods – fruits and vegetables or cow's milk [outcome]. This CMOc (leading to intended outcome) was developed and substantiated using data from two studies (Lucas et al., 2013; Treiman et al., 1996).

Questionnaire interviews with WIC participants including pregnant women and mothers (n=207) found that 'eating healthy food when you are pregnant' was valued by twice as many women (81%) as 'eating healthy food when you are not pregnant' (41%), and far fewer women were concerned about 'not spending too much money on food' (18%) (Treiman et al., 1996). This data suggests that some low-income women valued healthy eating highly despite low income, and that it was more important than economising on food. WIC provides mandatory nutrition education, delivered in dedicated WIC clinics by trained WIC Nutritionists (although the delivery and content varies between states) and this is likely to increase women's awareness of the importance of healthy eating during pregnancy. The findings of this study cannot be generalised to all low-income pregnant women (such as those who do not participate in WIC), but it highlights the potential importance of women's values around healthy eating in pregnancy in terms of how they might prioritise their spending.

The following quote illustrates how the additional resources from Healthy Start made healthy foods seem more affordable and enabled this mother to buy more vegetables. Prioritisation is implicit within the quote, since she admitted to making different choices than she would have without the vouchers.

> "I have them at Asda when I do my shop, and I think how many vouchers I've got and I buy the veg that I have the vouchers for. I suppose if I didn't have the vouchers, I would just pick out the little things. I don't think if I didn't have the vouchers I'd buy half as much, no." Mother, UK (Lucas et al., 2013, p. 50).

Alternatively, some women may value healthy eating less than other things they want or need to spend money on, which are considered more important or urgent [context]. They

are more likely to perceive Healthy Start vouchers as an opportunity to save money, which may be redirected and prioritised in other ways [mechanism]. These women are more likely to use Healthy Start vouchers to deduct money from the shopping bill, with no increase in consumption of target foods [outcome]. This CMOc (leading to unintended outcome) was developed and substantiated using data from three studies (Herman, Harrison, Afifi, & Jenks, 2004; Lucas et al., 2013; McFadden et al., 2013).

The following quote illustrates how the additional resources from Healthy Start were used to save money for other things. This mother clearly stated that the extra £3.10 was not used to buy milk, or fruits and vegetables. To her, the perceived value was financial and the vouchers helped her to manage financially.

> "£3.10 a week when you're working doesn't feel like much but when you're not working and are on benefits it does make a difference, it's £3.10 a week you have of your money to spend on other things aside from milk, fruit and veg." Mother, UK (Lucas et al., 2013, p. 52)

This quote, from a midwife, describes how low-income pregnant women may be aware of the need to eat well, but other things may be considered more important and difficult decisions must be made about how to prioritise resources.

> "Women are often in a dilemma about whether they should or shouldn't eat healthy foods because something else is needed more. Their own health and maybe the health of their younger children are on the back burner because something else is more pressing." Midwife, UK (Lucas et al., 2013, p. 35).

A survey of pregnant women who received WIC (n=313; 69% Hispanic) found that two thirds of women reported using WIC to reduce food expenditure (Herman et al., 2004). When women were asked what the money they saved was used for, responses included items for the baby (such as clothes, diapers and medicines), other food items (such as fruits and vegetables, which were not included in the WIC food package at the time), clothes and other items needed by older children, childcare, eating out, transport, paying bills, and saving the money for emergencies. This highlights the range of things that low-income women may consider when budgeting, which may reduce the relative value of healthy eating.

Both CMOc are examples of how evidence from different studies was pieced together to make inferences about possible explanations. Individual extracts of data did not support the complete CMOc, but together they were used to infer plausible linkages and suggest tentative explanations for the outcomes (intended and unintended).

Further evidence is required to understand how low-income pregnant women in the UK could be better supported to prioritise healthy eating and use Healthy Start vouchers to improve their diets during pregnancy.

5.4.5 Programme theory 2: Bending the rules

The Healthy Start voucher system relies on retailers to verify that the items on the checkout include permitted items (fruits and vegetables, plain cow's milk or infant formula) matching or exceeding the value of the vouchers presented. This must be done visually because the barcodes on the vouchers are not electronically matched to specific items on the till system. There is a reminder printed on each voucher about which foods may be purchased, along with a warning about prosecution, but this theory suggests that some customers and retailers may disregard this information.

Retailers who are registered to accept Healthy Start vouchers have some discretion over how vigilantly they check what vouchers are spent on [context]. Women may put pressure on retailers to 'bend the rules' or make exceptions [mechanism]. Some retailers may decide to 'turn a blind eye' because they feel duty bound to help families in whatever ways they can [mechanism] or because they prefer to avoid conflict [mechanisms]. This enables women to exchange the vouchers for alternative food or non-food items [outcomes]. This CMOc (leading to unintended outcome) was developed and substantiated using data from five studies (Andreyeva, Middleton, Long, Luedicke, & Schwartz, 2011; Department of Health, 2012; Gittelsohn et al., 2012; Hills, 2006; Lucas et al., 2013).

The following quote was from a shopkeeper who felt he was acting in the best interests of his customers, who he said were struggling on low incomes. He appeared to be aware that he was breaking the rules on how Healthy Start vouchers should be used, but he felt morally obliged to allow them to buy gas and electricity. In this example, women used the vouchers to reduce general household expenditure rather than food expenditure. This would also be classed as 'financial assistance' (outcome strand 2) and an unintended outcome of the programme.

> "But you have to realise that I get people coming in here, they are buying £1 pound of electricity every day. £1. That must run out after an hour. How do they live? And in the winter, it really does get very cold and they come in and ask me if they can use the voucher for electricity. What can I do? I can't see them living in the flat with young children, with no heating, it's so cold. So I do let them do that. They come in and show me their empty wallet and I have to believe them and I do sell gas and electricity for the voucher. You can report that back. I don't care, what can I do?" Retailer, UK (Lucas et al., 2013, p. 69)

This quote from a WIC retailer suggests that customers may get angry if they are not permitted to buy what they want to buy with their vouchers. This kind of situation may lead to conflict and retailers may lose customers if they choose to enforce the rules.

> "[Customers] get angry when WIC rules are enforced, and will go to another store to get their products if you do not make illegal transactions'." Retailer, US (Andreyeva et al., 2011, p. 1028)

The flexibility of the Healthy Start voucher system enables retailers to 'bend the rules' (especially small, independent retailers) because there is no audit trail. It is unclear from previous studies how frequently this occurs. Further evidence is needed to understand why this might happen and how it could be prevented.

5.4.6 Programme theory 3: Lack of empowerment

Pregnant women are the intended beneficiaries of Healthy Start, but some women may not be empowered to make decisions about how to use the vouchers themselves. The vouchers are posted to women at their home address, but there is no name printed on the actual vouchers and no identification is required at the checkout, so there is nothing to stop other people from using them. This theory does not specify what the vouchers are used for (the outcome may be considered interim). Regardless of what the vouchers are used for, and who benefits (nutritionally or financially), this would surely be considered an unintended outcome of the programme.

Women may not be empowered to make decisions about household resources or food shopping, such as pregnant teenagers who live with their parents [context], or women who live in large, multi-generational households [context]. Women who are not empowered are more likely to hand over their Healthy Start vouchers to other family

members [mechanism] who then decide how they are used [outcome]. This CMOc (leading to unintended outcome) was developed and substantiated using data from three studies (Lucas et al., 2013; Reyes, Klotz, & Herring, 2013; Treiman et al., 1996).

An evaluation of Healthy Start found that some teenage mothers relied on their parents for food shopping and preparation (Lucas et al., 2013). This practitioner explained that some of the young women she worked with did not know how to cook, which increased the reliance on their parents. This implies lack of empowerment, but this context was not directly linked to handing over the Healthy Start vouchers.

> "We have a lot of young parents who are very much under the influence of their parents and changing that cycle can be really difficult...Some of the young parents as well just don't know how to cook. Well they know what they should be giving but it's about 'how do I cook that?'." Early years practitioner, UK (Lucas et al., 2013, p. 34).

The evidence to support this mechanism came from a small qualitative study of African American women (n=21), many of whom lived in large, multi-generational households (Reyes et al., 2013). Some of these women reported handing over WIC benefits to their mothers, older sisters or grandmothers, who controlled food choices (including shopping, cooking and provision of healthy options) for the entire household. For example:

> "She (mom) makes most of the decisions. We get the same thing every time we go shopping." African-American mother living in multi-generational household, US (Reyes et al., 2013, p. 5)

Further evidence is required to understand which groups of women in the UK may not be empowered to make decisions about how to use Healthy Start vouchers. This should include pregnant teenagers, since all pregnant women under 18 years are eligible for Healthy Start, regardless of their income or benefits status.

Figure 9. Summary of evidence-informed programme theories about how low-income pregnant women use Healthy Start vouchers

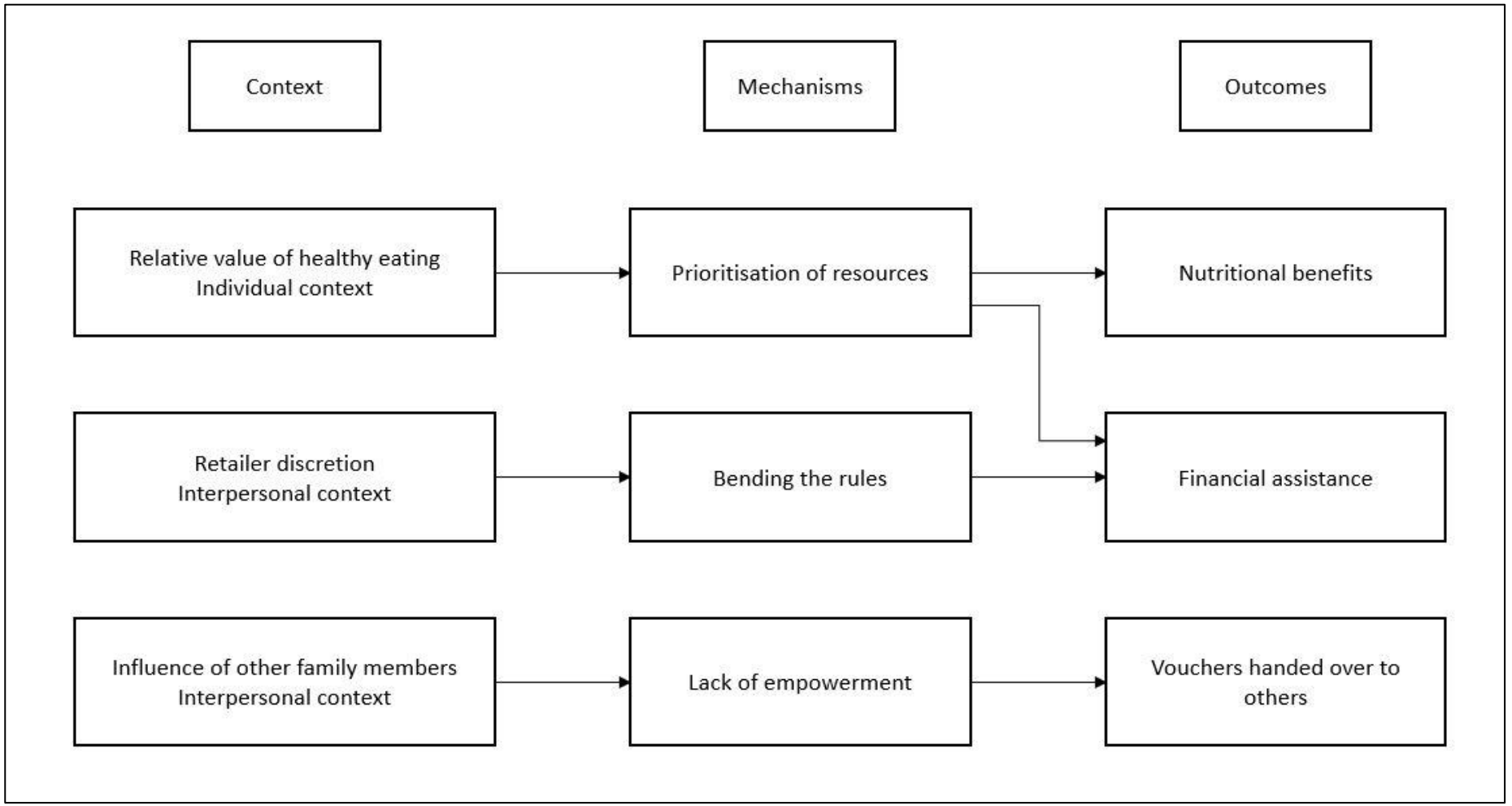


Table 12. Summary of included studies (n=38) and how they contributed to theory testing.

Full reference	**Intervention (country)**	**Study design and data collection methods**	**Contribution to data extraction (C/M/O) and synthesis (programme theories 1-3)**					
			C	**M**	**O**	**1**	**2**	**3**
Department of Health. (2012). *Healthy Start: Retailer research summary.* London: Department of Health.	Healthy Start (UK)	Methods unclear	✓	✓			✓	
Hills, D. (2006). *Healthy Start: Rapid evaluation of early impact on beneficiaries, health professionals, retailers and contractors.* London: Tavistock Institute/Symbia.	Healthy Start (UK)	Rapid evaluation; quantitative surveys and qualitative feedback		✓	✓		✓	
Lucas, P.J., Jessiman, T., Cameron, A., Wiggins, M., Hollingworth, K., & Austerberry, C. (2013). *Healthy Start Vouchers Study: The Views and Experiences of Parents, Professionals and Small Retailers in England.* School for Policy Studies, University of Bristol.	Healthy Start (UK)	Qualitative study; in-depth interviews	✓	✓	✓	✓	✓	✓
McFadden, A., Fox-Rushby, J., Green, J. M., Williams, V., Pokhrel, S., McLeish, J., . . . Renfrew, M. J. (2013). *Healthy Start: Understanding the use of vouchers and vitamins.* Dundee: University of Dundee, 2013.	Healthy Start (UK)	Focus groups; online consultations; workshops and telephone interviews	✓	✓	✓	✓		
Andreyeva, T., Middleton, A. E., Long, M. W., Luedicke, J., & Schwartz, M. B. (2011). Food retailer practices, attitudes and beliefs about the supply of healthy foods. *Public Health Nutr*ition,14:1024-31.	WIC (US)	Before/after study; structured interviews to assess perceived customer demand for healthy foods (mostly quantitative)		✓	✓		✓	

Full reference	Intervention (country)	Study design and data collection methods	Contribution to data extraction (C/M/O) and synthesis (programme theories 1-3)					
			C	M	O	1	2	3
Andreyeva, T., Luedicke, J., Henderson, K.E., & Tripp, A.S. (2012). Grocery store beverage choices by participants in federal food assistance and nutrition programs. *American Journal of Preventive Medicine*, 43, 411-8.	WIC (US)	Cross-sectional study; electronic sales data from WIC retailers			✓			
Andreyeva, T., Luedicke, J., Tripp, A. S., & Henderson, K. E. (2013). Effects of reduced juice allowances in food packages for the women, infants, and children program. *Pediatrics, 131*, 919-927.	WIC (US)	Before/after study; electronic sales data from WIC retailers			✓			
Andreyeva, T., & Luedicke, J. (2013). Federal food package revisions: effects on purchases of whole-grain products. *American Journal of Preventive Medicine, 45*, 422-429.	WIC (US)	Before/after study; electronic sales data from WIC retailers			✓			
Andreyeva, T., Luedicke, J., Henderson, K. E., & Schwartz, M. B. (2014). The positive effects of the revised milk and cheese allowances in the special supplemental nutrition program for women, infants, and children. *Journal of the Academy of Nutrition & Dietetics, 114*, 622-630.	WIC (US)	Before/after study; electronic sales data from WIC retailers			✓			
Andreyeva, T., & Luedicke, J. (2015). Incentivizing fruit and vegetable purchases among participants in the special supplemental nutrition program for women, infants, and children. *Public Health Nutrition, 18*, 33-41.	WIC (US)	Before/after study; electronic sales data from WIC retailers			✓			
Ayala, G.X., Laska, M.N., Zenk, S.N., Tester, J., Rose, D., Odoms-Young, A., … Andreyeva, T. (2012). Stocking characteristics and perceived increases in sales among small food store managers/owners associated with the introduction of new food products approved by the Special Supplemental Nutrition Program for Women, Infants, and Children. *Public Health Nutrition*, 15, 1771-9.	WIC (US)	Cross-sectional study; in-depth interviews to assess perceived changes in sales of WIC foods (quantitative data from closed questions)			✓			

Full reference	Intervention (country)	Study design and data collection methods	Contribution to data extraction (C/M/O) and synthesis (programme theories 1-3)					
			C	M	O	1	2	3
Bailey, L.B., O'Farrell-Ray, B., Mahan, C.S., Dimperio, R.D.D. (1983). Vitamin B6, iron and folacin status of pregnant women. *Nutrition Research*, 3, 783-93.	WIC (US)	Cross-sectional study; dietary assessment using 24 hour recalls; blood tests for nutrient status			✓			
Bertmann, F.M., Barroso, C., Ohri-Vachaspati, P., Hampl, J.S., Sell, K., & Wharton, C.M. (2014). Women, infants, and children cash value voucher (CVV) use in Arizona: a qualitative exploration of barriers and strategies related to fruit and vegetable purchases. *Journal of Nutrition Education & Behavior*, 46, S53-8.	WIC (US)	Qualitative study; focus groups to explore attitudes and behaviours related to FV voucher use	✓		✓			
Black, M.M., Hurley, K.M., Oberlander, S.E., Hager, E.R., McGill, A.E., White, N.T., & Quigg, A.M. (2009). Participants' comments on changes in the revised special supplemental nutrition program for women, infants, and children food packages: the Maryland food preference study. *Journal of the American Dietetic Association*, 109, 116-23.	WIC (US)	Cross-sectional study; questionnaire to assess current and anticipated consumption; focus groups to explore reactions to proposed changes to WIC package			✓			
Chen D.Y. & Gazmararian, J.A. (2014). Impact of personal preference and motivation on fruit and vegetable consumption of WIC-participating mothers and children in Atlanta, GA. *Journal of Nutrition Education & Behavior*, 46, 62-7.	WIC (US)	Cross-sectional study; questionnaire to assess FV consumption			✓			

Full reference	Intervention (country)	Study design and data collection methods	Contribution to data extraction (C/M/O) and synthesis (programme theories 1-3)					
			C	M	O	1	2	3
Endres, J., Dunning, S., Poon, S.W., Welch, P., & Duncan, H. (1987). Older pregnant women and adolescents: nutrition data after enrollment in WIC. *Journal of the American Dietetic Association,* 87, 1011.	WIC (US)	Cross-sectional study; dietary assessment using 24 hour recalls			✓			
Endres, J.M., Sawicki, M., & Casper, J.A. (1981). Dietary assessment of pregnant women in a supplemental food program. *Journal of the American Dietetic Association,* 79, 121-6.	WIC (US)	Cross-sectional study; dietary assessment using 24 hour recalls			✓			
Ettienne-Gittens, R., McKyer, E.L., Odum, M., Diep, C.S., Li, Y., Girimaji, A., & Murano, P.S. (2013). Rural versus Urban Texas WIC participants' fruit and vegetable consumption. *American Journal of Health Behavior,* 37, 130-40.	WIC (US)	Cross-sectional study; questionnaire to assess FV consumption and variety			✓			
Farrior, E.S., & Ruwe, C.H. (1987). Women, infants and children program. Prenatal participation and dietary intakes. *Nutrition Research,* 7, 451-549.	WIC (US)	Before/after study; dietary assessment using 24 hour recalls			✓			
Gittelsohn, J., Laska, M.N., Andreyeva, T., Foster, G., Rose, D., Tester, J., …Ayala, G.X. (2012). Small retailer perspectives of the 2009 women, infants and children program food package changes. *American Journal of Health Behavior,* 36, 655-65.	WIC (US)	Qualitative study; in-depth interviews with small store owners and managers	✓	✓	✓		✓	

Full reference	Intervention (country)	Study design and data collection methods	Contribution to data extraction (C/M/O) and synthesis (programme theories 1-3)					
			C	M	O	1	2	3
Herman, D.R., Harrison, G.G., Afifi, A.A., & Jenks, E. (2004). The Effect of the WIC Program on Food Security Status of Pregnant, First-Time Participants. *Family Economics & Nutrition Review*, 16, 21.	WIC (US)	Longitudinal study; US Food Security Survey Module; qualitative interviews on use of WIC food package as income transfer (presented as quantitative data)			✓	✓		
Herman, D.R., Harrison, G.G., & Jenks, E. (2006). Choices made by low-income women provided with an economic supplement for fresh fruit and vegetable purchase. *Journal of the American Dietetic Association*, 106, 740-4.	WIC (US)	Cross-sectional study; data from retailers on FV purchases			✓			
Herman, D.R., Harrison, G.G., Afifi, A.A., & Jenks, E. (2008). Effect of a targeted subsidy on intake of fruits and vegetables among low-income women in the Special Supplemental Nutrition Program for Women, Infants, and Children, *American Journal of Public Health*, 98, 98-105.	WIC (US)	Longitudinal study; dietary assessment using 24 hour recalls			✓			
Horswill, L.J., & Yap, C. (1999). Consumption of foods from the WIC food packages of Chinese prenatal patients on the US west coast. *Journal of the American Dietetic Association*, 99, 1549-53.	WIC (US)	Cross-sectional study; dietary assessment using FFQ	✓		✓			
Kong, A., Odoms-Young, A., Schiffer, L.A., Berbaum, M.L., Porter, S.J., Blumstein, L., Fitzgibbon, M.L. (2013). Racial/ethnic differences in dietary intake among WIC families prior to food package revisions. *Journal of Nutrition Education & Behavior*, 45, 39-46.	WIC (US)	Cross-sectional study; dietary assessment using 24 hour recalls	✓		✓			

Full reference	Intervention (country)	Study design and data collection methods	Contribution to data extraction (C/M/O) and synthesis (programme theories 1-3)					
			C	M	O	1	2	3
Kong, A., Odoms-Young, A., Schiffer, L.A., Kim, Y., Berbaum, M.L., Porter, S.J., … Fitzgibbon, M.L. (2014). The 18-month impact of special supplemental nutrition program for women, infants, and children food package revisions on diets of recipient families, *American Journal of Preventive Medicine*, 46, 543-51.	WIC (US)	Longitudinal study; dietary assessment using 24 hour recalls (baseline data from Kong et al. 2013)	✓		✓			
Meiqari, L., Torre, L., & Gazmararian, J.A. (2015). Exploring the Impact of the New WIC Food Package on Low-Fat Milk Consumption Among WIC Recipients: A Pilot Study. *Journal of Health Care for the Poor & Underserved*, 26, 712-25.	WIC (US)	Before/after study; questionnaire to assess primary consumption of low-fat milk (yes/no)			✓			
Nestor, B., McKenzie, J., Hasan, N., AbuSabha, R., Achterberg, C., (2001). Client satisfaction with the nutrition education component of the California WIC program, *Journal of Nutrition Education*, 33, 83-94.	WIC (US)	Cross-sectional study; client satisfaction survey; focus groups to assess client experiences and satisfaction	✓	✓	✓			
Odoms-Young, A., Kong, A., Schiffer, L. A., Porter, S. J., Blumstein, L., Bess, S., . . . Fitzgibbon, M. L. (2014). Evaluating the initial impact of the revised special supplemental nutrition program for women, infants, and children (WIC) food packages on dietary intake and home food availability in African American and Hispanic families. *Public Health Nutrition, 17*, 83-93.	WIC (US)	Longitudinal study; dietary assessment using 24 hour recalls (baseline data from Kong et al. 2013) and questionnaire to assess home food availability			✓			

Full reference	Intervention (country)	Study design and data collection methods	Contribution to data extraction (C/M/O) and synthesis (programme theories 1-3)					
			C	M	O	1	2	3
Pehrsson, P.R., Moser-Veillon, P.B., Sims, L.S., Suitor, C.W., & Russek-Cohen, E. (2001). Postpartum iron status in nonlactating participants and nonparticipants in the Special Supplemental Nutrition Program for Women, Infants, and Children. *American Journal of Clinical Nutrition*, 73, 86-92.	WIC (US)	Longitudinal study; iron status using FFQ and blood tests			✓			
Reyes, N.R., Klotz, A.A., & Herring, S.J. (2013). A qualitative study of motivators and barriers to healthy eating in pregnancy for low-income, overweight, African-American mothers. *Journal of the Academy of Nutrition & Dietetics*, 113, 1175-81.	WIC (US)	Qualitative study; semi-structured interviews to explore motivators and barriers to healthy eating	✓	✓	✓			✓
Rush, D., Sloan, N.L., Leighton, J., Alvir, J.M., Horvitz, D.G., Seaver, W.B., … Holt, M. (1988). The National WIC Evaluation: evaluation of the Special Supplemental Food Program for Women, Infants, and Children. V. Longitudinal study of pregnant women. *American Journal of Clinical Nutrition*, 48, 439-83.	WIC (US)	Before/after study; food expenditure assessed by recall (and diary)			✓			
Rush, D., Kurzon, M.R., Seaver, W.B., Shanklin, D.S. (1988). The National WIC Evaluation: evaluation of the Special Supplemental Food Program for Women, Infants, and Children. VII. Study of food expenditures. *American Journal of Clinical Nutrition*, 48, 512-9.	WIC (US)	Longitudinal study; dietary assessment using 24 hour recalls			✓			
Swensen, A.R., Harnack, L.J., Ross, J.A. (2001). Nutritional assessment of pregnant women enrolled in the Special Supplemental Program for Women, Infants, and Children (WIC). *Journal of the American Dietetic Association*, 101, 903-8.	WIC (US)	Cross-sectional study; dietary assessment using FFQ; blood tests for iron status			✓			

Full reference	Intervention (country)	Study design and data collection methods	Contribution to data extraction (C/M/O) and synthesis (programme theories 1-3)					
			C	M	O	1	2	3
Treiman, K., Freimuth, V., Damron, D., Well, A.L., Anliker, J., Havas, S., Langenberg, P. (1996). Attitudes and behaviors related to fruits and vegetables among low-income women in the WIC program. *Journal of Nutrition Education*, 28, 149-56.	WIC (US)	Qualitative study; focus groups to explore attitudes and behaviours related to FV; central location intercept interviews (questionnaires)	✓	✓	✓	✓		✓
Watts, V., Rockett, H., Baer, H., Leppert, J., Colditz, G. (2007). Assessing diet quality in a population of low-income pregnant women: a comparison between Native Americans and Whites. *Maternal & Child Health Journal*, 11, 127-36.	WIC (US)	Cross-sectional study; FFQ to assess diet quality			✓			
Whaley, S.E., Ritchie, L.D., Spector, P., Gomez, J. (2012). Revised WIC food package improves diets of WIC families. *Journal of Nutrition Education & Behavior*, 44, 204-9.	WIC (US)	Cross-sectional study; questionnaire to assess usual dietary habits and changes compared to 6 months earlier			✓			
Wunderlich, S.M., Hongu, N.K., Courter, A., Bendixen, C.A. (1996). Nutrient intake and nutritional status of low-income pregnant women. *Topics in Clinical Nutrition*, 12, 66-74.	WIC (US)	Cross-sectional study; dietary assessment using 24 hour recalls			✓			

WIC = Special Supplemental Program for Women, Infants, and Children; FV = fruits and vegetables; FFQ = Food Frequency Questionnaire;

C = context; M = mechanisms; O = outcomes; Programme theories: 1. Prioritisation of resources; 2. Bending the rules; 3. Lack of empowerment

5.5 Discussion

5.5.1 Integration of evidence and theory

This realist review aimed to contribute original insights and hypotheses, to enhance our understanding of the following questions, by analysing and synthesising evidence from primary studies of Healthy Start and WIC:

1. How do low-income pregnant women use Healthy Start vouchers?
2. What are the intended and unintended outcomes of the programme?
3. What are the underlying mechanisms and how do variations in context influence (enable or constrain) these mechanisms?

This review does not answer these questions comprehensively or definitively. It offers evidence-informed programme theories, which may be considered emerging hypotheses worthy of further investigation. It identified aspects of context and causal mechanisms that are likely to be important in determining outcome patterns for low-income pregnant women. In a recent webinar, the Director of CARES described how realist programme theories and CMOc are usually 'evidence/theory configurations' because theory is used to 'fill in the gaps' in evidence (Jagosh, 2017). Likewise, in this realist review, insights from the wider literature and theories were used to enhance the explanations in the evidence-informed programme theories.

Programme theory 1 is about how women prioritise household resources and, within that reasoning process, decide how to use Healthy Start vouchers. The 'relative value' of healthy eating (compared to other things women value) was identified as an important aspect of context. This theory relates to the economics of decision-making. If women value healthy eating and want to do everything they can to give their baby the best possible start in life, these beliefs and motivations will influence the decision-making process when it comes to using the vouchers. However, other factors will also influence the decision-making process and women must consider whether additional healthy foods are what they need the most.

Frick (2009) considered the everyday economic analyses that take place at family level in relation to infant and young child feeding, whereby mothers and other family members must decide how to allocate financial resources, weighing up food choices and nutrition against a range of other considerations. He described how societal and individual values

influence these trade-offs between nutrition and other priorities. Decisions about how to use Healthy Start vouchers are subject to similar trade-offs through the mechanism of prioritisation.

Attree (2005) found that low-income women 'strategically adjust' to poverty by prioritising or 'juggling' what they spend money on. Food may be ranked below other basic needs such as rent and household bills, with more flexibility to cut back on healthy items like fruits and vegetables. Similar 'competing values' were observed in relation to women's infant feeding decisions and behaviours, whereby immediate needs and concerns (such as pain, anxiety, lack of sleep) may outweigh the longer-term health benefits associated with breastfeeding (Hoddinott, Craig, Britten, & McInnes, 2012).

In relation to Healthy Start vouchers, some low-income pregnant women may be diverted away from the aspirational outcome of dietary improvements because other things are considered more important or urgent. Therefore, Healthy Start may be seen as a way to manage financially by reducing food expenditure. The programme provides additional resources to (ideally) enable low-income pregnant women to improve their diets, but only women who highly value healthy eating (and associated health benefits for mother and child) are likely to use the vouchers in this intended way.

Programme theory 2 is about retailers who misuse the Healthy Start programme by allowing women to exchange vouchers for alternative items. It is presented under the context of retailer discretion, which highlights weaknesses in the system, but this theory also relates to the context of women who value other things above healthy eating (as in theory 1), who would be more likely to put pressure on retailers to 'bend the rules' or make exceptions. The evidence suggests that some retailers may bend the rules because they feel they are acting in the best interests of the customer. In the wider literature, this is similar to the 'responsible subversion' identified among health professionals who admitted to bending or breaking the rules for what they perceived to be patient benefits (Furber & Thomson, 2006; Hutchinson, 1990). Hutchinson's theory defines four phases of responsible subversion: evaluating, predicting, rule bending and covering. The first three phases can be identified in the quote used to illustrate theory 2 (5.4.5), but this retailer does not attempt to cover up his deviant behaviour, presumably because he believes his motives are good. However, there may be other (unscrupulous) reasons why retailers bend the rules and previous evaluations reported women's claims that some

retailers exchanged Heathy Start vouchers for cigarettes and alcohol (Lucas et al., 2013; McFadden et al., 2013).

Programme theory 3 is about women who may not be empowered to decide how to use Healthy Start vouchers. Their choices may be heavily influenced (or constrained) by significant others, such as partners, mothers or other relatives, who may take charge of food shopping and allocation of household resources. Similar issues around women's rights and lack of empowerment have been identified in relation to decisions about infant feeding: women may be surrounded by networks of people who participate in decision making, so they may be unable to exercise their 'right to choose' despite knowing what the options are and possessing their own opinions (Blystad et al., 2010). This may be particularly the case in communities where there are high levels of interdependence within the extended family network.

Healthy Start is dependent on individual agency to achieve dietary improvements, in contrast with other types of nutrition interventions that can be said to be less dependent on individual agency (such as food fortification). These evidence-informed programme theories illustrate how aspects of context may enable or constrain women's agency. A recent paper by the Centre for Diet and Activity Research (CEDAR) considered the role of individual agency in public health interventions, concluding that 'low agency' interventions are more likely to be effective and equitable by reducing the need for individual decisions (Adams, Mytton, White, & Monsivais, 2016). Food vouchers for free fruits and vegetables were positioned in the middle of a continuum of 'the degree of agency required to benefit from the intervention'. This review highlights some ways in which the level of agency required could be reduced in the Healthy Start programme, such as by 'tightening up' the system for verifying who uses the vouchers and what they are exchanged for. Therefore, it contributes to ongoing debates about how public health interventions should be designed to maximize outcome effectiveness.

5.5.2 Strengths and limitations

This was the first study to use a realist, theory-driven approach to investigate how low-income pregnant women use Healthy Start vouchers, in what circumstances, and why. The inclusion of relevant studies from a similar programme in the US (WIC) provided insights and explanations beyond what was available from the Healthy Start literature. The review identified two main outcomes strands and produced plausible explanations

for how and why low-income pregnant women might experience one or both of these outcomes, depending on variations in context, which are thought to activate different mechanisms. They provide in-depth and useful insights into the workings of the Healthy Start programme, which has been under-evaluated since it was introduced in 2006.

It was necessary to limit the scope of this realist review due to time and resource limitations within the PhD. Therefore, the study focused on women's outcomes and the food voucher component of the Healthy Start programme. The aspects of context explored were individual (women's values and perceptions) and interpersonal (interactions with retailers and other family members). There was insufficient evidence to link these aspects of context with women's sociodemographic and cultural characteristics, such as which groups of women may be most or least likely to value healthy eating. Some of the candidate theories identified during the theory development stage (chapter 4) were not substantiated by the evidence included in this review. Further evidence from the UK is required to explore some of these theories, such as the role of health professionals in supporting women to eat well during pregnancy. This may be another aspect of context with potential to influence the relative value of healthy eating (programme theory 1) and women's empowerment (programme theory 3).

Evidence from 34 WIC studies was judged to be 'relevant' to test programme theories about Healthy Start, but was not generalisable to the UK context due to population and programme differences. The limitations of individual primary studies were described in the narrative synthesis and the 'evidence-informed' programme theories. Future realist reviews on Healthy Start could include a wider range of evidence, such as other types of voucher programmes and/or other low-income groups.

Furthermore, individual primary studies did not have the same explanatory focus as this realist review and consequently some of the CMOc were substantiated by fragments of evidence that were 'pieced together' from more than one study. This is a common limitation in realist reviews, hence they are often used as the starting point for realist evaluations. The following chapters describe the empirical phase of this PhD, which was used as an opportunity to gather evidence specific to Healthy Start and continue to develop and test programme theories.

5.5.3 Further reflections on the review process

One of the main challenges I encountered during this realist review was that the process of theory development and testing did not always feel very scientific. Such feelings are common among novice realist researchers, not helped by the paucity of high quality examples in the literature and insufficient training materials (Wong, 2017). This was my first experience of using realist methodology and it was a steep learning curve. I was fortunate to be well supported by my supervisors and realist networks (as acknowledged in section 4.6). The quality and credibility of this realist review was validated by its publication in an international, peer-reviewed journal (Ohly et al., 2017). However, I would not necessarily approach it in the same way if I started again. This statement reflects the fact that I am more experienced now, but also the flexibility and subjectivity of the realist approach.

Despite adopting a systematic approach to theory testing (5.3), the process involved a series of decisions and judgements, such as where to search for evidence, how to assess relevance and rigour, and what could logically be inferred from the data. Another reviewer might have made different decisions, as might I with the benefit of hindsight. For example, I could have restricted the WIC studies to those published after the 2009 revisions, when the cash value vouchers for fruits and vegetables were introduced. However, I wanted to see how the evidence base had evolved (outcomes) and did not want to exclude potential sources of evidence on context and mechanisms. Realist synthesis does not claim to be reproducible (like a traditional systematic review aims to be) and guidance emphasises the importance of honest and transparent reporting, so that readers can make their own judgements about whether the programme theories are coherent, trustworthy and plausible (Pawson, 2006; Wong et al., 2013). I have tried to be transparent in my reporting of this review.

When I look back on how my theories evolved throughout the review, it seems obvious now that I tried to structure my explanations as CMOc too early in the process. Now that I am more experienced, I would advise others to hold back from putting labels on their early explanations and candidate theories. It is more important to focus on uncovering and clearly articulating the possible explanations for outcomes of interest. For me, the causal pathways and linkages between context, mechanisms and outcomes became clearer once I started to interrogate the evidence and scrutinise the candidate theories. At the same time, it became clearer that I could only go so far with the existing evidence

from primary studies, and that my theories would remain tentative even at the end of the review. I am comfortable with that position, because I understand that my findings are an important first step towards a realist understanding of how Healthy Start works, for who, in what circumstances and why.

5.6 Chapter summary

This chapter describes how candidate theories about how low-income pregnant women use Healthy Start vouchers were tested using existing evidence from 38 primary studies of Healthy Start (n=4) and a similar programme in the US called WIC (n=34). Bespoke criteria were used to assess the relevance and rigour of each study. Data was extracted and synthesised to modify, refine and substantiate programme theories – gradually and iteratively. Limitations of the primary studies were acknowledged and care was taken not to overgeneralise their findings. This realist review suggests that some women use Healthy Start vouchers to increase consumption of healthy foods (intended outcome: dietary improvements) and some women use them to reduce food expenditure and save money for other things (unintended outcome: financial assistance). These two outcome strands are not mutually exclusive – some women may experience both outcomes at different times, or both outcomes at the same time. Three evidence-informed programme theories offer plausible and tentative explanations for how and why these outcomes may occur. They are realist programme theories because they identify aspects of context (and generative mechanisms) that may be important in determining outcomes: the 'relative value' of healthy eating (prioritisation of resources); retailer discretion (bending the rules); the influence of other family members (lack of empowerment). This was the first time that any study has articulated realist programme theories about how the Healthy Start programme works. Further research is required to understand which women are likely to experience these outcomes and how they can be better supported to use Healthy Start vouchers to improve their diets during pregnancy. The next chapter of this thesis presents an empirical research study in which these programme theories were further scrutinised and refined, and other programme theories were developed.

6.0 QUALITATIVE STUDY

6.1 Introduction

Realist evaluation is a broad term used to encompass realist synthesis and evaluation. The two often go hand in hand, as programme theories produced in a realist review may be further explored and refined using empirical methods. Chapters 4 and 5 described how 'candidate theories' about Healthy Start were developed and tested using relevant evidence from existing studies. The realist review findings were limited by the available evidence, especially in relation to in-depth explanations about how low-income women use Healthy Start vouchers and why. Therefore, it was logical to continue the iterative process of programme theory refinement in the empirical phase of the PhD. Low-income pregnant women were the key informants in this study. The study advisory group also continued to provide valuable input to consolidate the evidence-based programme theories. Realist approaches to data collection, coding and analysis were consistently applied throughout the study. Qualitative methods were used to obtain in-depth explanatory data on context, mechanisms and outcomes. The results section presents five evidence-based programme theories about how low-income pregnant women use Healthy Start vouchers and why. These realist theories explain why some women may experience the intended outcome of the programme, while others may be diverted towards alternative or unintended outcomes.

6.2 Methods

6.2.1 Study design and objectives

A qualitative study to explore the views, perceptions, perspectives and experiences of low-income pregnant women in relation to using Healthy Start vouchers. A realist approach was used to generate in-depth insights and explanations about how Healthy Start works, for who, in what circumstances and why (Pawson & Tilley, 1997). The evidence-informed programme theories from the realist review were used as the starting point for this study. However, the purpose was not merely to confirm and consolidate existing knowledge, but also to explore alternative outcomes and explanations. The objectives of this study were:

1. To further refine and consolidate the evidence-informed programme theories from the realist review;

2. To develop new and emerging theories about how low-income pregnant women use Healthy Start vouchers.

6.2.2 Population and sample

This study was conducted in three local authority areas in North West England: Barrow-in-Furness, Blackburn with Darwen, and Preston. All three local authority areas have high claim rates for out-of-work benefits compared to the average for Great Britain (Table 13). This indicated they would have higher than average levels of eligibility for Healthy Start, but no data were available to verify this. Barrow-in-Furness is predominantly White British, in part explained by its geographical isolation at the southwest tip of the Furness peninsula. Blackburn with Darwen and Preston have higher than average ethnic diversity; in both areas, the largest non-White ethnic groups are Indian and Pakistani (Office for National Statistics, 2017). It was anticipated that these three areas would enable a diverse sample of women to be recruited into the study. This was important to capture a range of different contexts in which low-income pregnant women interact with the Healthy Start programme.

Table 13. Characteristics of study areas compared to Great Britain average

	Year	Great Britain	Barrow-in-Furness	Blackburn with Darwen	Preston
Population	2015	63,258,400	67,500	146,800	141,300
Out-of-work benefits	2017	2.0%	2.8%	2.8%	2.3%
White (ethnicity)	2011	86.7%	98.3%	69.0%	80.1%

Data source: (Office for National Statistics, 2017)

Women were eligible to participate in this study if they were pregnant and receiving Healthy Start vouchers, or if they had been pregnant within the previous six months (referred to as 'recently pregnant') and received Healthy Start vouchers during that pregnancy. They were required to speak good enough English to be interviewed without a translator due to budget limitations (note: no women were excluded on this basis).

In qualitative research, it is generally accepted as good practice to conduct 20-30 interviews, the goal being to achieve theoretical saturation (Mason, 2010). However, this depends on the research question and, in some qualitative studies, smaller or larger

samples may be required. In realist evaluation, the concept of saturation defers to relevance and rigour, whereby 'fragments' or 'nuggets' of data may be used to confirm or refute theories or hypotheses (Emmel, 2013; Pawson, 2013). Practical considerations, such as the feasibility of data collection, are also factored into study design (Manzano, 2016). Therefore, in this study, the aim was to conduct 15-20 interviews with low-income women who were using Healthy Start vouchers. It was considered impractical to aim for a larger sample size as only one year of the PhD remained after the realist review was complete and approvals were in place to commence the empirical study. The sample size was adjusted as the study progressed (see 6.4.4).

6.2.3 Recruitment strategy

A combination of strategies was used to identify and recruit women into this study between September 2016 and May 2017. The main strategy was face-to-face recruitment in Sure Start children's centres. Managers were consulted about which children's centres were in the most deprived areas and had the best attendance. All pregnant women have the option to access midwifery services in children's centres. This includes the first trimester appointment (known as 'booking') and subsequent follow-up appointments (known as 'antenatal'). Low-income pregnant women should be informed about Healthy Start at the booking appointment and then it can take several weeks to proceed through the application process. Therefore, antenatal clinics were considered the best opportunity to approach women about this study. Drop-in sessions were also attended, such as breastfeeding support groups, mother and baby groups, and a parenting class for pregnant teenagers in Barrow-in-Furness. Women were asked if they were receiving (or had recently received) Healthy Start vouchers. This was done individually and subtly to avoid awkwardness or embarrassment. If they said yes, women were asked whether they would be willing to participate in an interview about their experiences of using Healthy Start vouchers. A £10 LovetoShop voucher was offered as a token of appreciation after the interview, along with a healthy recipe book provided by First Steps Nutrition Trust. Women were asked if they knew anyone else who might be willing to participate.

The option of recruiting women through hospital maternity care services was considered. However, many pregnant women only attend hospital for routine ultrasound scans at 8-14 weeks (the 'dating scan') and 18-20 weeks (the 'anomaly scan') because other services are available in community settings. It was considered more appropriate to focus on children's centres where women may attend multiple antenatal appointments between 25

and 42 weeks depending on their individual needs. The study advisory group advised that eligible women who apply for Healthy Start towards the end of the first trimester would normally start receiving the vouchers by around 20 weeks. It was important for this research study to recruit women who had been using the vouchers for at least a few weeks. Therefore, the timing of the later antenatal appointments was more suited to this study.

In addition to the face-to-face approach, which was very time-intensive, posters and flyers (Appendix F) were placed around the children's centres and staff were asked to share them with any women who they thought might be eligible. Heather Ohly (HO)'s name and mobile phone number were printed on the posters and flyers. Similar posters were distributed around the University of Central Lancashire campus.

Social media was used to reach a wider audience in similar geographical areas: Barrow-in-Furness, Blackburn and Preston. A Facebook page called 'Healthy Start Study' was created and recruitment posts (Appendix G) were repeated between December 2016 and May 2017. Some adverts were 'boosted' (to the value of £8 per advert) so that they targeted women aged 16-40 years and reached a greater audience (sometimes over 2000 views). The posts were regularly shared with a variety of relevant Facebook pages, including children's centres (e.g. Preston Children's Centres), community pages (e.g. Blackburn Life), breastfeeding and parenting support groups (e.g. Birth in East Lancashire, Mumsnet Preston, Barrow Breastfeeding Support) and local radio stations (e.g. Lakeland Radio). The University of Central Lancashire promoted the study using Twitter.

Women who were eligible to participate and expressed an interest were given a detailed information sheet to read (Appendix H) and asked if they had any questions. If they agreed to participate, the interview was arranged at a convenient time and location for them. Participants were asked to sign a consent form immediately before the interview (Appendix I). Nobody who agreed to participate was excluded from the study.

Ethical approval for this study was obtained in June 2016 from the University of Central Lancashire Science, Technology, Engineering, Medicine and Health Ethics Committee (reference STEMH 486). Three amendments were subsequently approved relating to the use of incentives (September 2016), social media (November 2016) and recruitment on campus (April 2017) as the recruitment strategy evolved throughout the data collection period. Permission letters were obtained in July 2016 from the relevant local authorities:

Cumbria County Council, Blackburn with Darwen Borough Council, and Lancashire County Council.

6.2.4 Data collection methods

An innovative combination of interview techniques was used to explore women's views, perceptions, perspectives and experiences of using Healthy Start vouchers during pregnancy and, where applicable, since having their babies. Firstly, the interviews were semi-structured. An interview topic guide was used for consistency and transparency (Appendix J). This started with some general questions about age, stage of pregnancy, number of children and when they started receiving the vouchers. It continued with open questions about what the vouchers tended to be used for and what influenced those decisions. The questions and prompts became more in-depth as the interviews progressed. Women were encouraged to explain how they responded to receiving the vouchers and why they used them in certain ways. For example: What made you decide to use the vouchers in that way? Could you tell me more about why you did that? The topic guide was referred to throughout the interview, but was not necessarily used in the same order or in full. It was regularly reviewed and adjusted, so that each interview built on the knowledge gained from previous interviews.

Secondly, the interviews were realist. There is no definitive or standard way to conduct realist interviews, but a recent article provided clear guidance on realist study design and realist interview techniques (Manzano, 2016). It proposed three stages of realist interviews: theory gleaning interviews, theory refinement interviews and theory consolidation interviews (Manzano, 2016). In this study, evidence-informed programme theories had already been 'gleaned' (or rather, developed and tested) during the realist review. Therefore, the qualitative study was designed to further refine and consolidate programme theories. The emphasis was firmly on understanding the relationships between context, mechanisms and outcomes. The interviews were informed and underpinned by realist assumptions relating to generative causation: volition, change and conditionality (Manzano, 2016).

Realist interviews have been described as a two-way exchange of theories or 'teacher-learner cycle', in which the interviewer explains what they think might be happening within the programme and the participant offers their views in return (Pawson & Tilley, 1997). This differs from traditional interview methods, in which the interviewer adopts a

more neutral standpoint (Fielding & Thomas, 2001). Realist interviews are designed to test specific programme theories. Therefore, the interviewer must direct the conversation towards those theories and try to elicit the participant's reasoning processes (Manzano, 2016). Realist interviewers are encouraged to communicate their own ideas, while remaining open and responsive to new or different ideas that might emerge. Therefore, the roles of 'teacher' and 'learner' are interchangeable between the interviewer and the interviewee (Manzano, 2016).

It was essential to conduct the interviews in a relaxed and informal way, without using realist terminology or presenting complex ideas. A third technique was used to do this – vignettes. This technique allowed programme theories to be presented as 'scenarios' or 'things other people have said'. Previous qualitative studies have found that vignettes can help participants to reveal things about themselves by focusing the attention on an unknown third person (Gourlay et al., 2014). It was anticipated that this tool would facilitate interviews with low-income women in three ways: by directing the conversation towards the programme theories; by making women feel confident to share their own (similar or contrasting) experiences; by generating relevant explanatory data at the level of context and mechanisms.

The vignettes were fictional quotations, printed on laminated cards, which represented CMO configurations (CMOc) developed during the realist review. This included some CMOc that were not substantiated in the review, but were considered worthy of further investigation. Draft vignettes were shared with the study advisory group, who agreed that they would help to encourage low-income women to talk about their own experiences by 'validating' a range of values and perspectives. Additional feedback from the study advisory group and realist peers (note: 4.6 explains how peer support was obtained) included recommendations to remove superfluous details from the vignettes (to avoid obscuring CMOc) and to remove personal characteristics such as age from the vignettes (to avoid stereotyping). Seven vignettes were prepared with associated questions/prompts (Appendix K). This example relates to programme theory 1 from the realist review: prioritisation of resources (5.4.4):

> "I don't buy more of the healthy foods than I did before. The main thing for me is saving money – I never say no to discounts because money is always so tight. The vouchers really help."

In some interviews, all seven vignettes were presented and the participant was prompted to discuss any that were similar (or different) to her own experiences. In other interviews, the participant was directed towards certain vignettes in response to the preceding conversation. The interview style was consistent with realist assumptions about heterogeneity and conditionality: different individuals may experience the same programme in different ways; mechanisms may be enabled or constrained by context. Therefore, the interview questions evolved as the interviewer's knowledge was altered by each answer (Manzano, 2016).

Three pilot interviews were conducted with young women (teenagers) attending a parenting class in Barrow-in-Furness. The purpose of the pilot interviews was to make sure that women responded well to the vignettes and the wording was clear, and for the interviewer to practice the realist interview style. Those women were not invited to participate in another interview. Women recruited during the main fieldwork period were initially invited to participate in one interview. However, later in the study, some participants were invited (by text message) to participate in a second interview. This was decided after the original interviews had been analysed and theory development had progressed, because HO felt that further insights could be gained from some of the same participants.

6.2.5 Coding and analysis

Interviews were digitally recorded and securely stored, as specified in the application for ethical approval. The digital recordings were transcribed verbatim by the Research Support Team in the Faculty of Health and Wellbeing, University of Central Lancashire. Participant names and contact details were held confidentially by HO only. The quality and accuracy of transcription was checked by HO. Coding and analysis were completed by HO and approximately 10% was double-checked by Victoria Hall Moran (PhD supervisor). While coding and analysis were distinct tasks in this study, the analysis was also an ongoing and iterative process of internal thought, reflection and dialogue with others, as ideas and theories were gradually assimilated. Processing the data helped to formalise these ideas and theories, by attributing evidence and assessing which theories had the most salience within the study sample. The realist logic of analysis was consistent with the realist review and with the realist evaluation principle of generative causation: outcomes (O) are caused by mechanisms (M), and mechanisms may (or may not) be 'triggered' in certain contexts (C) (Pawson, 2006). The analysis process always started

with an outcome and worked backwards to determine "what caused it (the mechanism) and under what contexts was the mechanism triggered" (Wong, 2015, p. 2).

However, the coding and analysis method used in this study differed from the realist review (see 5.3.6). The following method was described in a practice paper (Punton et al., 2016) and then presented at the CARES pre-conference workshop in October 2016. During the workshop, Punton encouraged other realist researchers to adapt and use this approach. A bespoke Microsoft Excel database was used to extract data and assign codes relating to context (C), mechanisms (M) and outcomes (O). Each interview transcript was carefully read (at least twice) and annotated with initial thoughts and interpretations. The next task was to identify outcomes relating to how women used their Healthy Start vouchers. An outcome was only coded if there was some degree of explanation within the transcript – how and why did it come about? A separate row was used for each unique outcome, and the adjacent cells in that row were used to enter notes and direct quotations relating to the explanation (context and/or mechanism). Sometimes not all cells were completed, if the participant only provided evidence relating to C/O or M/O (Punton et al., 2016). The database was completed iteratively such that explanations were entered tentatively at first (e.g. entire quotes pasted into cells) and specific codes relating to context and mechanisms were assigned later.

At the analysis stage, rows were filtered so that evidence coded under each outcome could be compared between interviews. This allowed patterns and variations in the explanatory data (context and mechanisms) to be observed. The main advantage of this approach was that proposed linkages between C, M and O were recorded transparently. It was not always possible to find evidence of complete CMOc within one quote, so linkages were inferred by drawing together evidence from across an interview transcript (things the participant said at different times during the same interview). Sometimes, inferences based on one transcript were more clearly evidenced within another transcript – if HO saw an opportunity during the later interview to further explore insights from the earlier interview. This approach reinforced the importance of researcher interpretation and iterative theory development in realist inquiry (Pawson, 2006).

6.2.6 Stakeholder consultations

As well as the interviews with programme beneficiaries, it was important to represent the perspectives of other stakeholders with broader experiences of the programme.

Practitioners often have ideas and knowledge about what works because they have witnessed the successes and failures of the programme (Manzano, 2016; Pawson, 2013). This had already proven to be the case in earlier consultations with the study advisory group during the realist review. Therefore, a stakeholder consultation meeting was held with the study advisory group in early June 2017. Several members of the original group had moved on by this stage (e.g. changed jobs), but five key informants remained: two midwives, two academics (both experts in health inequalities and maternal and child nutrition) and one public health professional. All five stakeholders have strong interests or roles in implementing, promoting, advocating and researching Healthy Start.

The purpose of the meeting was to gain feedback on theories and CMOc that had emerged from the interviews with low-income women. It was like a six-way exchange of theories; a continuation of the 'teacher-learner cycle' (Pawson & Tilley, 1997). It was anticipated that this group would be familiar enough with realist methodology (through involvement with this study since 2014) to clearly articulate ideas about context and mechanisms, which would enhance and enrich the data obtained from low-income women. Crucially, these ideas and insights would be informed by their experience of working with Healthy Start beneficiaries across the UK for many years. This was the last opportunity to consolidate and refine the evidence-based programme theories. However, it was important to remain open to new and alternative explanations even at this stage of the study.

A document was shared by email two weeks in advance of the meeting, which included interim CMOc and illustrative quotes. A subsequent email reminded the group about key realist concepts such as programme theory, context, mechanisms and outcomes. They had also read the realist review publication (Ohly et al., 2017). At the start of the meeting, HO provided an overview of the study aims and objectives, the purpose of the meeting and how their feedback would be used. The group responded by sharing their insights and experiences. The stakeholders asked questions about the study findings, which generated further in-depth discussion and mutual understanding.

6.3 Results

6.3.1 Sample characteristics

A total of 11 women participated in this study: seven from Barrow-in-Furness and four from Blackburn with Darwen. No women were recruited from Preston – the reasons for this are explained in the limitations section of the discussion (6.4.4). Table 14 shows the characteristics of the study participants, each of whom were allocated a unique code (BL1, BL2 etc.) and pseudonym so that data could be treated anonymously. One of the pilot interviews contained relevant data that were included in the analysis (BA1). Five women were pregnant at the time of interview and six women had been pregnant (and received vouchers) within the previous six months. Two women were experiencing their first pregnancy and the other nine women had older children as well; eight of them received vouchers for at least one child under 4 years in addition to the vouchers for herself. Seven women were aged 18-25 years, including two teenagers. Six women were single parents. All 11 women were White British. Six out of 11 women were invited to participate in a second interview, but only three women accepted.

Table 14. Characteristics of 11 study participants

Participant code	**BA1**	**BA2**	**BA3**	**BA4**	**BA5**	**BA6**	**BA7**	**BL1**	**BL2**	**BL3**	**BL4**
Pseudonym for this study	Nicky	Lucy	Jane	Katie	Anna	Emma	Sophie	Mia	Emily	Zoe	Claire
Barrow-in-Furness	✓	✓	✓	✓	✓	✓	✓				
Blackburn with Darwen								✓	✓	✓	✓
Face-to face recruitment	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Facebook recruitment										✓	
Pregnant at time of interview	✓			✓				✓	✓	✓	
Pregnant within previous 6 months		✓	✓		✓	✓	✓				✓
First pregnancy	✓			✓							
Older children in family		✓	✓		✓	✓	✓	✓	✓	✓	✓
Aged 18-25 years	✓		✓	✓	✓	✓	✓		✓		
Aged 26-35 years		✓						✓		✓	✓
Single parent	✓	✓			✓	✓		✓	✓		
White British	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Second interview conducted		✓		✓			✓				

6.3.2 Continuation of theory development

The evidence-informed programme theories from the realist review (presented in chapter 5) provided the starting point for this qualitative study. The overarching themes from the realist review were the 'relative value of healthy eating' (context) and 'prioritisation of resources' (mechanism). The programme theories proposed that women's existing values, beliefs and motivations about healthy eating would influence whether they prioritised healthy foods. The evidence available in the review did not support theory development relating to wider contextual influences on the relative value of healthy eating, or which women were most or least likely to value healthy eating. Nor did it suggest more nuanced mechanisms relating to why women prioritise in certain ways.

This study aimed to further refine and consolidate the programme theories from the realist review, while remaining open to new and emerging theories about how low-income pregnant women use Healthy Start vouchers and why. Women reported a variety of intended and unintended outcomes, but this small qualitative study cannot draw any conclusions about the extent or prevalence of these outcomes. The realist approach to data collection, coding and analysis illuminated individual level mechanisms about women's reasoning i.e. how the vouchers influenced women's decision making processes, and which aspects of context may have enabled or constrained those processes.

The following sections present evidence-based theories relating to five different outcomes, or ways that low-income pregnant women reported using Healthy Start vouchers:

1. Dietary improvements
2. Shared benefits
3. Financial assistance
4. Stockpiling formula
5. Misuse of vouchers

Table 15 shows which interviews contributed data to support each programme theory. In each subsection, a narrative description of the programme theory is accompanied by a diagram showing the CMOc that contributed to the theory (Figures 10 to 14). A series of examples and quotes from the interviews illustrate how data were used to develop and refine the CMOc.

The CMOc abbreviation has been used for consistency throughout this thesis (since it was introduced as a key concept in realist evaluation in section 3.4.1). However, in this chapter, the configurations have four elements: context, resources, mechanisms, outcomes. This alternative CMOc framework (see Figure 3) was suggested by other realist researchers, who felt that the 'resources' and 'reasoning' within mechanisms should be disaggregated, to help clarify that programme resources are introduced into a context, which leads to a change in reasoning (Dalkin et al., 2015). In this chapter, programme resources refer to the Healthy Start vouchers and how they were perceived by women. Mechanisms refer to the reasoning and reactions of individuals in response to the vouchers (Pawson, 2006). The richness of the interview data made this distinction clearer than it was during the realist review.

Table 15. Summary of interviews that contributed data to support each programme theory

Participant code	**BA1**	**BA2**	**BA3**	**BA4**	**BA5**	**BA6**	**BA7**	**BL1**	**BL2**	**BL3**	**BL4**
Pseudonym for this study	Nicky	Lucy	Jane	Katie	Anna	Emma	Sophie	Mia	Emily	Zoe	Claire
Dietary improvements	✓	✓	✓	✓				✓		✓	✓
Shared benefits				✓		✓	✓		✓	✓	✓
Financial assistance		✓			✓		✓		✓	✓	
Stockpiling formula	✓		✓		✓		✓		✓		
Misuse of vouchers			✓			✓	✓	✓			

6.3.3 Programme theory 1 – dietary improvements

Some women reported that Healthy Start vouchers enabled them to improve their diets during pregnancy (Table 15). Throughout this study, this has been assumed to be the intended outcome of the programme for low-income pregnant women. This theory depends on context whereby women value healthy eating enough for the vouchers to encourage behaviour change. It builds on the 'prioritisation of resources' mechanism identified in the realist review (5.4.4). This has been refined into a more nuanced realist explanation about the inner reasoning that underpins prioritisation. In summary:

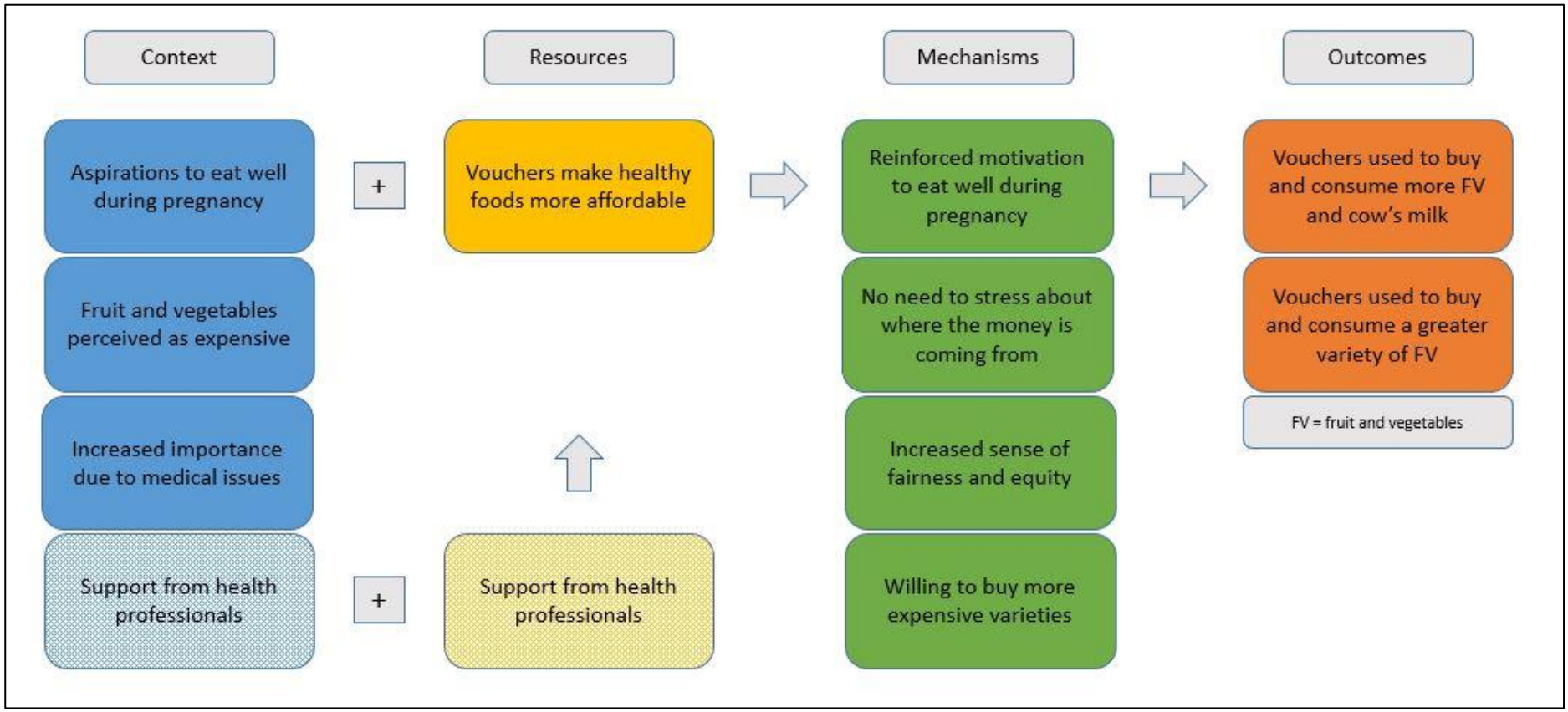
For women who valued healthy eating and aspired to eat well during pregnancy [context], the vouchers made healthy foods more affordable [resources], which reinforced their existing values, beliefs and motivations [mechanism] and alleviated concerns about the cost of healthy foods [mechanism]. This led them to buy and consume more fruit and vegetables and cow's milk, or a greater variety or fruit and vegetables during pregnancy [outcome].

Figure 10 shows the CMOc that contributed to this theory. The following examples illustrate how interview data were used to develop and refine the CMOc.

Mia admitted she ate 'rubbish' before she was pregnant [context] but she wanted to improve her diet so that her unborn daughter would benefit [context]. Healthy Start vouchers helped her to afford more healthy foods [resources] and reinforced her motivation to eat well during pregnancy [mechanism]. She used them to increase the amount of fruit and vegetables she bought and consumed [outcome].

> "...when I used to go shopping I didn't look at fresh foods or anything like that it didn't really appeal to me but then with the vouchers that actually pushed me forward to start eating healthy and buy more stuff…I think that is what it was because I was pregnant as well and obviously I wanted to have the benefits, my daughter to have a good start instead of eating rubbish." (Mia)

Figure 10. CMOc leading to dietary improvements (programme theory 1)



Paler boxes indicate aspects of context and resources not substantiated by interview data (see 6.4.2)

Katie (aged 19) was aware of the need to eat vegetables to be healthy [context]. She always tried to include vegetables with her evening meal, but it was difficult to find the money [context]. Healthy Start vouchers helped her to afford vegetables [resources] without having to worry about the money [mechanism]. She admitted to being a fussy eater [context] and she was concerned about food waste [mechanism], so she tended to use the vouchers to buy frozen vegetables [outcome].

> "I have always liked to have a bit of veg with my tea so it is not completely unhealthy. I just never had the money to buy the veg before, so now it helps a lot because I can buy it and I don't have to worry about it." (Katie)

> "We usually go for peas, carrots, sweetcorn just the usual because I am a fussy eater when it comes to veg…I don't really use a lot of veg, so if it is frozen I don't have to worry about it wasting." (Katie)

Jane described the challenges of eating well on a low income [context – not included in Figure 10 because it applies to all Healthy Start beneficiaries]. She did not enjoy healthy eating or cooking before she was pregnant and admitted that her diet was poor [context]. However, she suffered with persistent sickness during pregnancy and the baby was growing slowly [context]. Healthy eating became more important to her for the sake of the baby's development [context and mechanism]. The vouchers made healthy foods more affordable [resources] and she used them to buy extra fruit and vegetables [outcome].

> "If I didn't have the vouchers then no, I wouldn't have got extra fruit and veg it is the cost when you have only got, when you are on a low income and you go shopping and you have only got £20-30 to go shopping with and you have got most of your food, freeze food, fridge food, cupboard food and you have got to get fruit and that you don't have a lot of money left." (Jane)

> "I think when I became pregnant I became more healthy because before I fell pregnant I just ate whatever like crisps, sweets, junk so I just didn't like cooking. When I was pregnant, I was like I need to eat healthy now she has got to gain weight so I started eating healthy." (Jane)

Claire was aware of the importance of eating well during pregnancy [context], but also the higher cost of fruit and vegetables compared to less healthy foods [context]. The

vouchers made the higher cost items more affordable [resources] and took away some of the financial stress of being pregnant [mechanism]. She also felt a sense of fairness compared to other women [mechanism] because she could buy the fruit and vegetables she needed [outcome].

> "It gives people like it says, ease to be able to get the extras that they say you need rather than sit there and thing oh! my god I am pregnant I am not going to be able to afford. Let's be honest veg and fruit are higher than chocolate and sugary foods anyway. So for us to be able to go and buy the higher food, it wouldn't be fair if people like myself couldn't afford it without the Healthy Start vouchers." (Claire)

Zoe was suffering with severe heartburn during pregnancy [context] and she found milk and vegetables (especially soup) were the most palatable foods. Her motivation to eat well was driven by this rather than long term health benefits [context]. Convenience was also important because she was registered blind [context]. She perceived Healthy Start vouchers as 'extra money' for healthy foods [resources], which made her more willing to buy more expensive items [mechanism]. Therefore, the vouchers were used to buy extra milk and a greater variety of fruit and vegetables, including pre-prepared vegetables for soup [outcome].

> "For myself heartburn is really bad so I go through a lot of milk at the minute…I get through 8 pints of the skimmed milk that I like…I like to get the soup mixes as well. It is just basically ready prepared, it is all diced and chopped and mixed in for you already and then you just stick it in a pan with a veg stock cube and you can make soup with it, so that is quite good." (Zoe)

> "A lot of your pregnancy you have to eat what you can eat without either being sick or getting heartburn or just not fancying it. I think a lot of pregnancy you just have to listen to your body and eat what you can. You can try and eat healthy but it is better to eat at all than to eat nothing just because you don't fancy a tuna salad bagel." (Zoe)

> "I would probably stick to the cheaper fruit and vegetables. I probably wouldn't get the prepared soups if it wasn't for the sake of the extra money being there it might as well be spent." (Zoe)

These findings provide further support for 'relative value of healthy eating' as an important aspect of context, and more nuanced explanations about why some women value healthy eating. These women valued healthy eating and aspired to eat well during pregnancy for different reasons; in some cases, these values originated from before pregnancy and, in other cases, were amplified by medical complications or illness during pregnancy. The vouchers made healthy foods more affordable, which enabled women to make decisions based on their values, beliefs and motivations, without worrying about the financial implications. Therefore, it was inferred that Healthy Start reinforced the motivation to eat well during pregnancy.

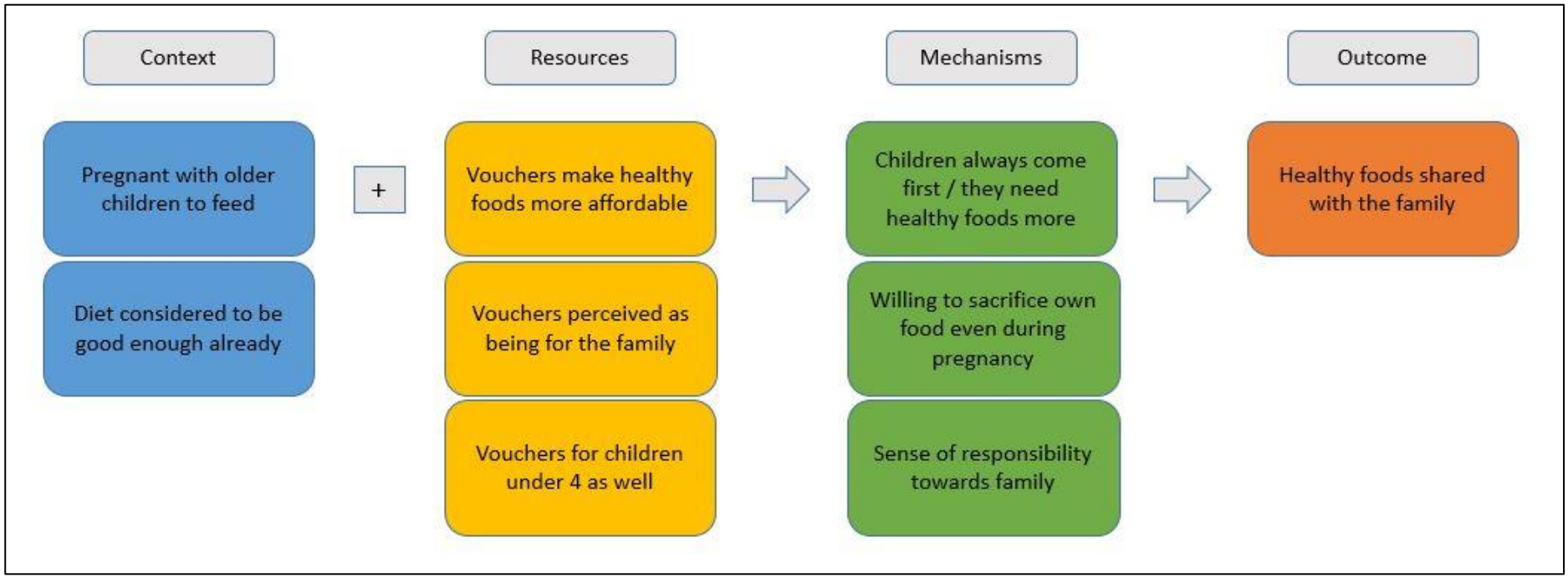
6.3.4 Programme theory 2 – shared benefits

Some women reported that Healthy Start vouchers enabled them to buy more healthy foods (intended outcome) but these foods were shared with other family members (Table 15). Most of these women had at least one child under 4 years and they were receiving vouchers for the children as well as for themselves. This theory builds on a 'candidate theory' that was developed during the realist review (4.5) but was not substantiated at the testing stage of the review. Again, this theory offers a more nuanced realist explanation about how women prioritise resources and decide how to use the vouchers. In summary:

For women with older children and other family members to feed [context], and women who received vouchers for children under 4 as well [context], the monthly bundle of vouchers was perceived as being for the family [resources]. Women felt a strong sense of responsibility towards their families [mechanism] and they were willing to make personal sacrifices so that their children could eat well [mechanism]. This led them to share the foods bought with the vouchers with children and other family members [outcome].

Figure 11 shows the CMOc that contributed to this theory. The following examples illustrate how interview data were used to develop and refine the CMOc.

Figure 11. CMOc leading to shared benefits (programme theory 2)



Emily was pregnant and a single mother of two children (2 and 4 years) [context]. She was receiving Healthy Start vouchers for herself and her 2-year-old, and used them as one bundle rather than separate vouchers for separate people [resources]. She was clear that her children always come first [mechanism] and she was willing to go hungry if they needed the food – even during pregnancy [mechanism]. She did not keep tabs on who ate what, and the household food (including food bought with the vouchers) was shared with her two children [outcome].

> "I don't put it in like, you have got £5 and you've got £5 we just put it all together in one big shop and we just help ourselves really if we want something you go and get it" (Emily)

> "As a mum you don't set it down if you think about it your kids come first so your kids get if they need it, if you have only got a limited amount of something there is not enough for everybody you are always going to give it to your children first. You would leave yourself hungry for your children." (Emily)

Emma was a single mother of three children (8 weeks, 3 and 7 years) [context]. She was receiving Healthy Start vouchers for the baby and the 3-year-old, and had received them for herself during the recent pregnancy [resources]. She considered her diet to be 'balanced' with plenty of fruit and vegetables, and she did not eat differently when she was pregnant [context]. Her two sons consumed more cow's milk, fruit and vegetables than her and enjoyed it more [context], so it was natural for her to prioritise their needs when she felt the voucher intended for herself was surplus to requirement [mechanism]. The combined vouchers enabled her to buy more healthy foods, including a greater variety of fruit and vegetables, most of which were consumed by the children [outcome].

> "I don't eat any different when I am pregnant because I eat a lot of fruit and veg, I have quite a balanced diet anyway. I don't really change it just because I am pregnant. The only difference I did was to take folic acid and vitamin D." (Emma)

> "Yes, when I was pregnant it went more towards…my older two boys. I would eat the fruit and veg and the milk as well but I put it more towards them with them being children. I thought they enjoy it more." (Emma)

> "I only put a tiny bit in [cups of tea] whereas the children are drinking milk…by itself or cereal so it went more towards them because they use more of the things that you can get with the Healthy Start voucher more than what I do." (Emma)

> "Yes, it makes us be able to choose more because if I didn't have the vouchers I would probably only pick one or two [fruit and vegetables] apart from the actual weekly shopping. I would probably only choose one or two as an extra but with the vouchers we can get more of a variety." (Emma)

Katie (aged 19) was pregnant for the first time [context], felt that her partner was just as important as her [mechanism], so the frozen vegetables bought with the vouchers were shared with him [outcome – see quote in 6.3.3].

> "They are addressed to me but when you have got a family they are more important, they come just as important as you as well…He needs to be fed as well it is not just me." (Katie)

These findings indicate that 'prioritisation' mechanisms may be influenced by older children and other family members. These women felt a strong sense of responsibility towards their families and wanted them to benefit from the additional healthy foods. They were willing to make sacrifices for their children, even during pregnancy. It could be inferred that other family members – those who were tangible and visible – took priority over the unborn baby when resources were limited. However, this study did not assess women's diets so the context of dietary adequacy or inadequacy was unclear.

6.3.5 Programme theory 3 – financial assistance

Some women reported that Healthy Start vouchers were used to deduct money from the shopping bill (Table 15). In other words, they used the vouchers to subsidise the cost of foods they would have bought even without the vouchers, rather than to improve their diets. The money saved was redirected to pay for other things. This theory is an alternative to theory 1, whereby context limits the 'relative value of healthy eating' and this influences how resources are prioritised. The mechanisms identified in this study relate to alleviation of stress and freeing up money without buying less than they did before. In summary:

For women who struggled to manage financially [context], Healthy Start vouchers were perceived as a contribution to the household budget [resources], which alleviated some

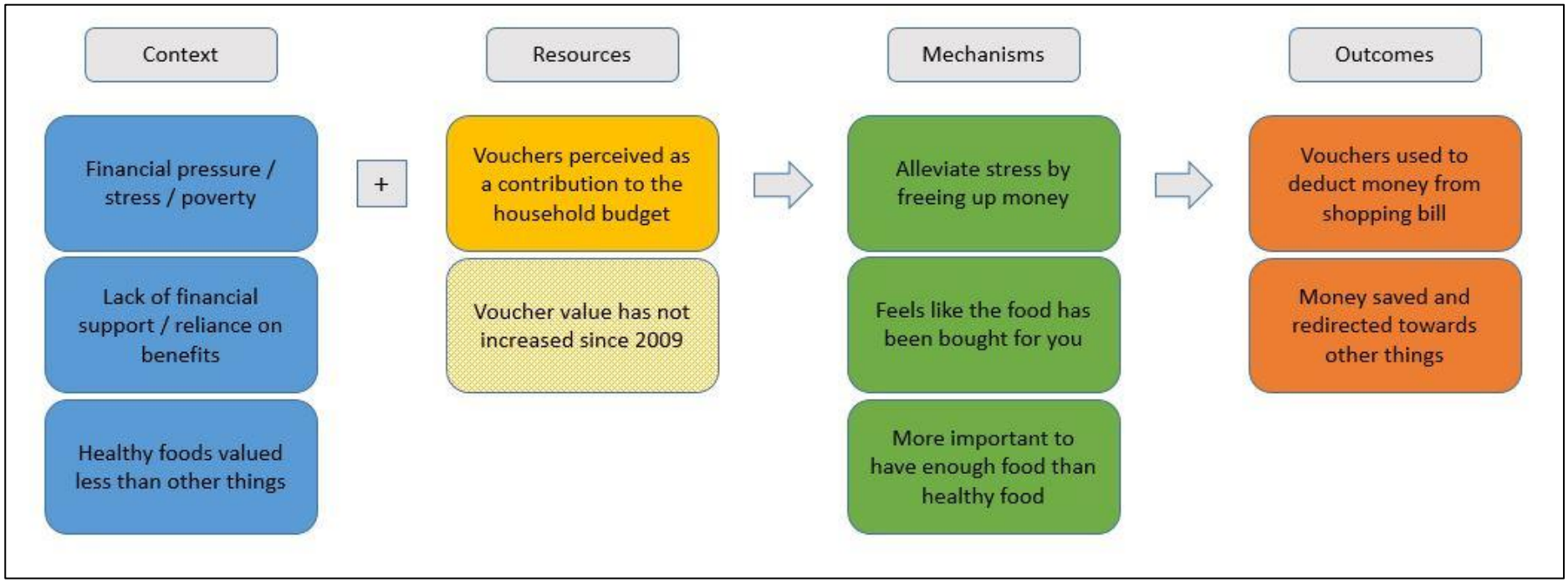
of the stress associated with providing for the family [mechanism]. The vouchers were used to deduct money from the shopping bill [outcome] and the money saved was redirected towards other things [outcome] that were considered more important [context].

Figure 12 shows the CMOc that contributed to this theory. The following examples illustrate how interview data were used to develop and refine the CMOc.

Emily described how the vouchers she received for herself and 2-year-old child covered the cost of fruit and vegetables [resources] so it felt like they had been bought for her [mechanism]. The money she would otherwise have spent on fruit and vegetables was used for other things for the family, which she referred to as 'essential' [outcome]. This suggests that these other things were considered more important than the opportunity to buy and consume more healthy foods during pregnancy [context].

> "They do because like I said at the beginning if I pay £10-£15 a fortnight on fruit and veg that is coming out of the vouchers it is not coming out of my money. It is like sounds cheap but it sounds like it has been bought for you. It saves you that money because if you think about it, that a month is £20-£30 a month being saved that can go towards kid's cloths, days out, just stuff like that, essential other stuff that you need as well." (Emily)

Figure 12. CMOc leading to financial assistance (programme theory 3)



Paler box indicates an aspect of programme resources identified by the study advisory group (see 6.4.1); not substantiated by interview data.

Sophie, who had three children (7 weeks, 3 and 6 years) said she worried about money all the time [context] and constantly had to prioritise what was needed the most [context and mechanism]. Healthy Start vouchers helped to alleviate the stress [mechanism] and she used them to cover the cost of fruit and vegetables that she would have bought anyway [outcome]. She felt that Healthy Start should include a wider range of 'essentials' like bread (she also mentioned yoghurts and baby wipes in similar statements). Although she referred to 'some people out there', this comment suggests that she considered these other items to be more important than fruit and vegetables [context].

> "All the time. All the time. Some weeks you've got to think about buying all your food but I always think she's growing, how am I going to buy next size of clothes if I'm buying her nappies and milk. I don't want to borrow money for clothes. You want to treat your kids all the time, but you've got to think about what you need first." (Sophie)

> "It just takes a little bit of worry off you." (Sophie)

> "That's how I have always seen it yes, rather than buy extra with the £3.10 I would just take that £3.10 off the fruit and veg that I would already be buying in that week." (Sophie)

> "Yes, that is what I say, it should be essentials voucher rather than fruit and veg. I know it is healthy but there are some people out there that don't get any food, never mind health food. It would be better if they had bread and milk in their cupboards than just fruit and veg." (Sophie)

In some interviews, relevant data emerged when women discussed their experiences of using vouchers since they had their baby (i.e. women who were recently pregnant). For example, Anna, a single mother of two children (5 months and 3 years), received no financial support from their father and was totally reliant on benefits [context]. She said she would struggle without the vouchers, which suggests they alleviated some of the financial pressure [mechanism]. The money she saved on food was used to pay the bills [outcome].

> "It is good because it helps people, like me…because with being on benefits and being on your own it does help. I don't get no help from their dad I don't get any money or anything like that so it is just literally my income support, child tax,

child benefit and then the Healthy Start vouchers that's all I get. So, it does help me out a lot." (Anna)

"I wouldn't be able to put as much on my gas and electric, I wouldn't be able to afford all my bills, like the TV licence, water rates, I would struggle a lot." (Anna)

These findings suggest that financial stress may reduce the relative value or importance of healthy eating, such that Healthy Start vouchers provide an opportunity to save or conserve money, rather than to achieve dietary improvements (as in 6.3.3). This theory highlights that prioritisation of resources is an aspect of context (i.e. a process that happens all the time) as well as a mechanism (i.e. a response to the vouchers). The vouchers influenced or modified women's prioritisation through alleviation of stress, and created a feeling that money had been released or freed up. This outcome has been assumed to be unintended throughout this study because women did not use the vouchers to improve their diets. However, the vouchers did provide a 'nutritional safety net' for these women because they freed up money without having to reduce the amount of healthy foods they bought.

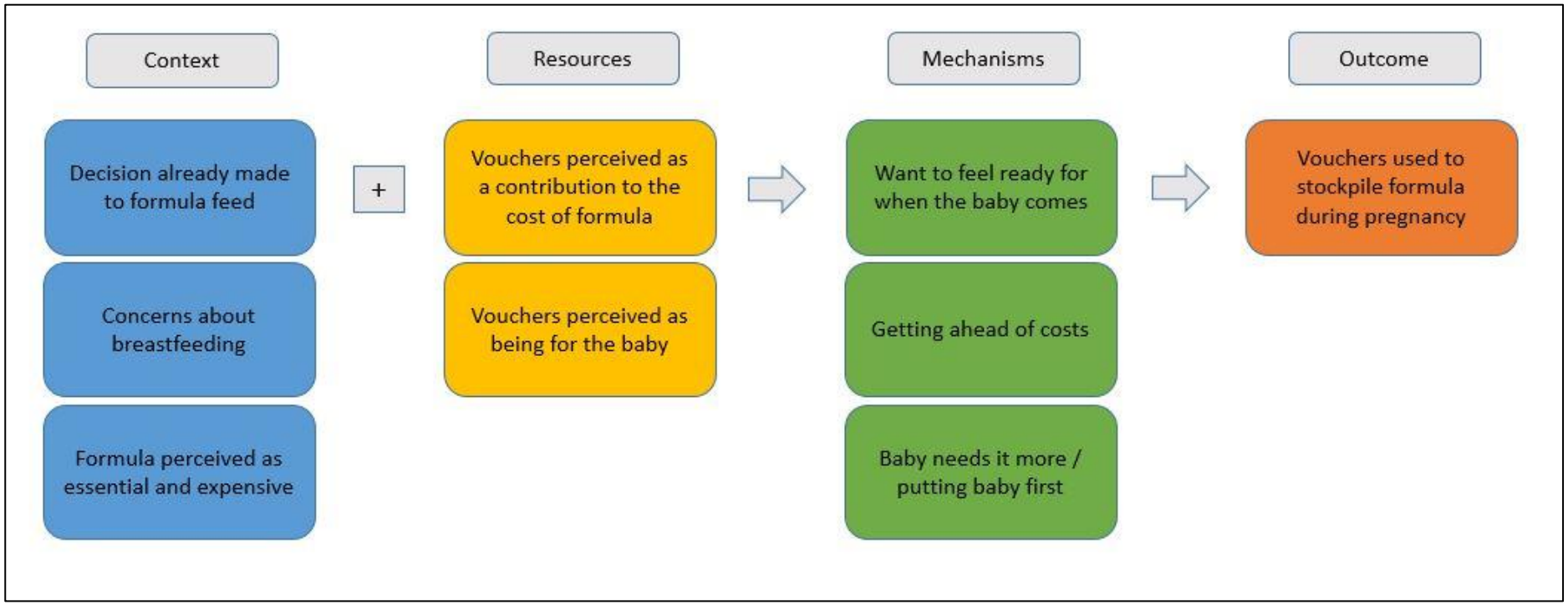
6.3.6 Programme theory 4 – stockpiling formula

Some women reported that Healthy Start vouchers were used to stock up on formula during pregnancy (Table 15). This outcome is within the legitimate use of the vouchers because the range of permitted foods is the same for pregnant women, babies and children under 4 (any combination of plain cow's milk, fruit and vegetables and infant formula). However, it is unlikely that policy makers anticipated this outcome, which displaces the potential health benefits for low-income pregnant women and children. In summary:

For women who had already decided to formula feed [context], Healthy Start vouchers were perceived as a contribution towards the cost of formula [resources], which they viewed as an essential and expensive item for the baby [context]. Women saw an opportunity to get ahead of costs [mechanism], so they felt ready and prepared for the baby's arrival [mechanism]. Therefore, the vouchers were used to stock up on formula [outcome] instead of for themselves during pregnancy.

Figure 13 shows the CMOc that contributed to this theory. The following examples illustrate how interview data were used to develop and refine the CMOc.

Figure 13. CMOc leading to stockpiling formula (programme theory 4)



Emily, who was 31 weeks pregnant, struggled to breastfeed her previous two babies and eventually switched to formula [context]. Rather than struggle again, she had decided to formula feed from the start with her third baby [context]. She decided to use some of her Healthy Start vouchers stock up on formula before the baby was born [outcome] because this would save her money after the baby was born [mechanism]. It also meant she would not need to worry about running out and therefore she felt more prepared [mechanism].

> "Well this is the first one that I have actually bought in advance because I didn't buy any in advance with the other two because I wanted to breast feed but they made it very difficult so I had to go out and buy it. So this time I didn't want to go through all the struggle again so I thought they were perfectly fine on formula and I was just going to go back on formula." (Emily)

> "Save money because I think they are about £9 something a tub so if you think about it if you round it up to a tenner you have got 5 tubs before the baby is even born you don't have to worry for all that time and you have saved yourself £50. So it does help it's there in advance then so you are not rushing about panicking that you have got no baby milk." (Emily)

Sophie, who was speaking about her recent pregnancy, had also decided to formula feed before the baby was born [context]. She felt uncomfortable and embarrassed about the idea of breastfeeding and wanting her partner to be able to contribute to feeding the baby [context]. Her view was that she did not need the vouchers (and by implication healthy foods) as much as the baby would need infant formula [mechanism]. She knew that the vouchers she would receive for the baby (worth £6.20/week) would not cover the cost of formula she would need [resources] and therefore she wanted to get ahead of those costs [mechanism]. If she invested the vouchers in the baby's food during pregnancy [outcome], she felt more prepared and less worried about affording it in the future [mechanism].

> "I am a bit embarrassed about breastfeeding I know it is not a bad thing but I could not imagine getting my boob out in front of my family and feeding my baby. It is more practical so my partner could feed as well, it is just how I have always personally felt. I am a bit embarrassed about things like that especially around family." (Sophie)

> "Because even two vouchers doesn't cover a tub of milk so I'd rather stock up while I don't need the vouchers as much, as to when she's born and then if I did have the vouchers when she was born then it was a case of I don't have enough vouchers to get the milk, I still have to put money towards it, so if I've got some tubs there ready it would be a while before I need it again and I can still be ahead of the milk if you know what I mean…If I'm more prepared, then I don't have to worry about money." (Sophie)

Anna had struggled to breastfeed her first baby, and was concerned about breastfeeding her second baby [context]. She wanted to be ready in case she needed formula [mechanism] and she did not want to have to worry about money when the baby was small [mechanism]. She decided to stock up on formula during pregnancy [outcome] and she was glad that she had because she did end up formula feeding the baby.

> "If I couldn't breastfeed I needed milk. With my oldest I tried to breastfeed and he wouldn't latch on. I thought if he will be the same I needed to be ready and I didn't have time to rush around just having a new born being a single mum, I wouldn't have time to run around trying to get money to get milk. I did breastfeed him for three weeks and then he lost quite a bit of weight so I lost my confidence in doing it so I did a bit of both and then I just did the formula." (Anna)

These finding suggest that Healthy Start vouchers presented an opportunity for some low-income pregnant women to save money and prepare for motherhood. However, by using the vouchers to stock up on formula during pregnancy, they missed out on the potential health benefits for themselves and the developing baby. There was no indication in this study that Healthy Start influenced women's decisions to formula feed. The quotes above illustrate some of the reasons why they had already made that decision.

6.3.7 Programme theory 5 – misuse of vouchers

Some women reported that Healthy Start vouchers were used to pay for alternative items, not permitted by the programme (Table 15). This would certainly be considered an unintended outcome of the programme. Most women said they had witnessed other people misusing the vouchers in this way; only one woman admitted doing so herself. This theory builds on the context of 'retailer discretion' identified in the realist review (5.4.5) and provides further insights from the perspectives of low-income women. As

only one study participant had experienced this outcome first-hand, the CMOc is tentatively presented as a 'possible' or 'potential' explanation. In summary:

For women who may be less concerned about healthy eating, or have different priorities and perspectives on health [context], there is potential to misuse Healthy Start vouchers because the system relies on visual verification of items at the checkout [resources]. Some local shops may be less strict than supermarkets [context] and this gives women the freedom to buy whatever they need the most for their family [mechanism]. They may justify or reconcile using the vouchers for alternative items because it helps them to provide a better standard of living for their children [mechanism]. The vouchers may be used for a range of food and non-food items [outcome].

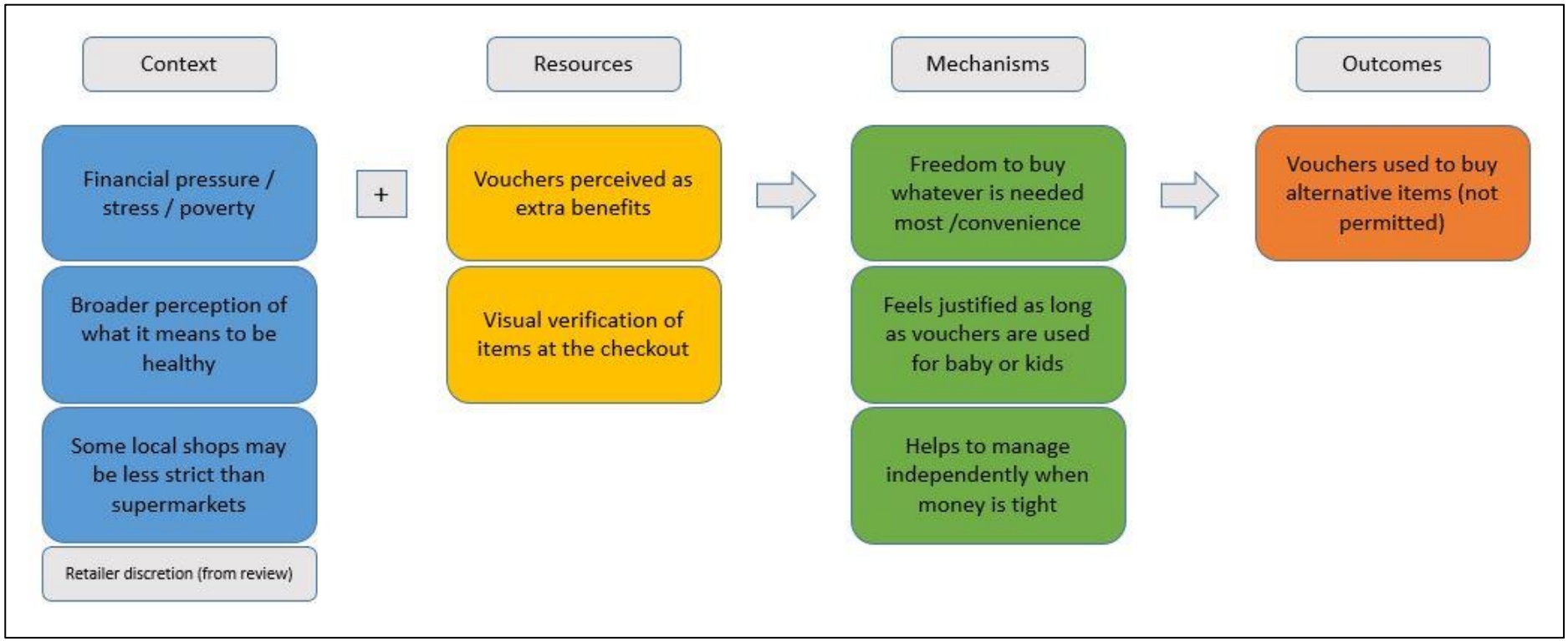
Figure 14 shows the CMOc that contributed to this theory. The following examples illustrate how interview data were used to develop and refine the CMOc.

Jane described how one of her local shops would encourage her to use Healthy Start vouchers for anything she needed, not just permitted items [context]. She did not want to do that, but she had seen another woman use her vouchers (in the same shop) to buy unhealthy snacks and drinks for her children [outcome].

> "Because I have seen a lady going in with milk vouchers and she would come out with sweets and bottles of little juice and crisp and everything for the kids and the baby was a little bit younger than (named child) she was in the pram and I was like where's the baby milk. I didn't want to say anything to her in case it would cause an argument so I just walked past and blanked her." (Jane)

> "Yes, I had seen her use the Healthy Start vouchers, but then when I went in I got milk with one of my vouchers and she was like do you need anything else I said no, she said you can use them for anything. It is not for that though it is for milk, baby's milk and then fruit and veg it says that on it." (Jane)

Figure 14. CMOc leading to misuse of vouchers (programme theory 5)



Sophie described how her local shop would allow her to use Healthy Start vouchers to buy anything for the family [context]. She used them for things like bread, cereals, toilet rolls, nappies and baby wipes [outcome] and she felt justified in doing this because they were all things the children needed [mechanism]. In terms of keeping her family 'healthy' the most important things were that the children were clean, clothed and had enough to eat – she was less concerned about providing fruit and vegetables [context]. She used the vouchers as extra money to achieve those standards [resources]. She appreciated the freedom to be able to make her own decisions about how to spend the vouchers [mechanism]. It helped her to manage towards the end of the month, without having to borrow money or miss bills payments [mechanism].

> "I asked a couple of times but they said you don't have to ask, as long as it's not for beer or magazines, you can spend it on what you want in the shop, because it was basically like a convenience shop, so it was just for what you needed, but obviously you couldn't spend it on the lottery." (Sophie)

> "I know there might be some people who would go and spend it on fags or alcohol because that's their addiction, but I reckon it's OK just spending it on your kids because as long as your kids are still eating they are healthy. Whether it be that they're not eating fruit and veg, if they're eating a meal it's more healthy than not eating at all. Even if you are using it for nappies and wipes, they are healthy by being clean and not soiled. I justified it because I wasn't spending it on anything that the kids wouldn't be using. You're only getting them because you've got the kids. You shouldn't be using them for anything else but providing for the child, whether it be something they need to feed them or clothe them. Just however you needed it, using it for that." (Sophie)

> "It was really handy for stopping me having to ask somebody to lend us money or taking money that's for a bill that I know is due out any time soon. The freedom to be able to go and buy those little things like toilet roll that you still need…just things like extra cereal if you've run out of that because what you use every month might be different the next month and you might run out of stuff that you might think you're not going to run out of…A big help towards the last week of the month." (Sophie)

These findings suggest that some shops are willing to use discretion and allow women to use Healthy Start vouchers for a wider range of items than the programme permits. Some

women may take advantage of this opportunity depending on their circumstances, beliefs and values. This demonstrates another way that women can use the vouchers to support the wider process of prioritisation that happens when they go shopping. However, the mechanisms outlined above were only supported by data from one participant (who was interviewed twice) and should be viewed as tentative. The data were not specific to her experience of using the vouchers during pregnancy (Sophie was not pregnant at the time of interview) but similar mechanisms may be transferable to some pregnant women.

6.4 Discussion

6.4.1 Summary and interpretation of main findings

In this study, five evidence-based programme theories were developed and refined using qualitative data from interviews with 11 low-income women. They provide in-depth realist explanations about how low-income women use Healthy Start vouchers and why. The study findings suggest that some women experienced the intended outcome of the programme by using the vouchers to improve their diets during pregnancy. However, some women were diverted towards alternative or unintended outcomes due to aspects of context. The realist evaluation approach demonstrated how women's individual circumstances, beliefs, values, views and perceptions (context) influenced their reasoning and reactions in response to the vouchers (mechanisms). Building on the theories identified in the realist review (chapters 4 and 5), this study showed in greater depth how low-income pregnant women made decisions and prioritised resources, and how Healthy Start vouchers influenced that process.

The following section explores outcome patterns and cross-cutting themes, informed by the analysis of interview data, researcher interpretation and insights from the study advisory group.

All 11 women reported more than one outcome (Table 15). The data suggest that women used the vouchers in different ways at different times, as changes in context altered the mechanisms activated. For example, Jane used the vouchers to improve her diet earlier in her pregnancy (theory 1) and to stock up on formula later in pregnancy (theory 4). It was not always clear from the interviews how women's outcome patterns changed over time (or overlapped), and this would be worthy of further investigation with a larger dataset.

In the stakeholder consultation meeting, members of the study advisory group said they had observed similar variations in how Healthy Start vouchers were used by low-income pregnant women. They suggested that many women started out with good intentions to use the vouchers to improve their diets (theory 1), but the reality was they were often used to save money (theory 3). They highlighted the 'stagnant' value of Healthy Start vouchers (£3.10 per week), which has not increased since 2009. In the wider context of austerity, they felt it was becoming increasingly difficult for low-income pregnant women to prioritise healthy eating, even with the vouchers. The study advisory group agreed that all five theories presented in this study were plausible, but they emphasised that the prevalence of these outcomes is unknown. They agreed that local and individual context were critical in determining how women would respond to the vouchers. They agreed that realist methodology had helped to identify more precisely how this works for some women in North West England.

In terms of cross-cutting themes, the women in this study described a range of views about what it means to be 'healthy' in pregnancy. While some women aspired to eat more fruit and vegetables, other women felt it was more important to eat enough food, foods they liked, or foods that made them feel good. Other aspects of context influenced the 'relative value of healthy eating', such as food prices, preferences, sickness, financial pressure, concerns about waste, and other family members. Ultimately, these aspects of context influenced how low-income pregnant women responded to Healthy Start vouchers – different mechanisms were activated and different outcomes were generated. However, there was no evidence that the Healthy Start programme influenced women's views about health. For women who already valued healthy eating and aspired to eat well during pregnancy, the vouchers reinforced their existing motivations and gave them extra resources to buy healthy foods.

The women in this study also expressed different ideas about what it means to be a 'good mother'. Some women were motivated to eat well during pregnancy because of the potential health benefits for themselves and the developing baby. However, other women were more focused on the immediate needs of older children. Women who shared the foods they bought with the vouchers felt they were putting their children's needs before their own. Similarly, women who used the vouchers to stock up on formula (during pregnancy) wanted to feel prepared for motherhood; this reflected desires to do the right thing for the baby as well as to save money. Finally, the woman who used her Healthy Start vouchers to buy alternative items was motivated to provide for her family as best

she could. She felt that if her children were clean, clothed and had enough to eat, they were healthy.

Therefore, while this study has provided in-depth explanations and insights about how low-income pregnant women use Healthy Start vouchers and why, it has also raised further questions about how women might be better supported to create more enabling context, so that vouchers are more likely to be used for the intended outcome of dietary improvements.

6.4.2 Programme theories not supported by this study

Three programme theories that were identified during the realist review (either as candidate theories or evidence-informed theories) were not further developed and refined in this qualitative study. However, they are considered worthy of further investigation.

1. Support from health professionals
2. Lack of empowerment
3. Stigmatisation

Firstly, in the theory development stage of the realist review (chapter 4), support from health professionals was considered as part of the programme resources. This candidate theory was derived from Healthy Start policy documents, which stated that health professionals would provide tailored information, advice and support to low-income families (Department of Health, 2004). More recent guidance on maternal and child nutrition stated that parents receiving Healthy Start vouchers should be offered "advice on how to use them to increase the amount of fruit and vegetables in their family's diet" (National Institute for Health and Care Excellence, 2015b). It was hypothesised that this kind of advice, provided alongside the vouchers, would motivate pregnant women to eat well and they would be more likely to use the vouchers to improve their diets (Table 6B). However, this candidate theory was not substantiated in the realist review. A previous evaluation of Healthy Start concluded, "We can find no examples of parents who recall information about the food vouchers provided by health professionals explicitly linked to health and nutrition advice" (Lucas et al., 2013, p. 62). Likewise, in this qualitative study, some women said they had received general advice (e.g. foods to avoid in pregnancy) or specific advice relating to medical issues (e.g. lactose intolerance), but they did not recall any discussions about the importance of nutrition in pregnancy or advice on how the vouchers could be used to support healthy eating.

> "Yes, kind of they didn't really. Obviously, I understood that the baby gets the nutrients from me but they didn't make it, how can I explain it, they really didn't say how important. I knew it was important but they didn't say how important it was if that makes sense." (Emma).

> "No, all they really did was sign the form for me and stamped it they didn't really explain it…Staying healthy it just said vouchers to help you get some things while you are pregnant, like fruit and veg. They didn't really explain." (Sophie)

This theory was discussed in the stakeholder consultation meeting with the study advisory group. They shared good practice from their areas, where midwives and health visitors consider supporting Healthy Start to be an important part of their role. However, they acknowledged that support varies depending on the needs of the woman and the judgement of the midwife. For example, if the woman has issues such as smoking, alcohol or drug abuse, then nutrition and healthy eating may not be discussed in antenatal appointments. This was described as a 'self-fulfilling prophecy' whereby women who showed an interest in nutrition and healthy eating might receive more support than women who did not. The study advisory group felt that support from health professionals could be considered as context (routine support for all women) and resources (targeted support for low-income families). It has been tentatively included in Figure 10 based on their feedback only.

Secondly, one of the evidence-informed programme theories presented in the realist review was about pregnant women who may not be empowered to make decisions about how to use their Healthy Start vouchers, and may instead hand them over to other family members (5.4.6). The evidence supporting this CMOc was limited to one study of African American women, who lived in multi-generational households and handed over WIC benefits (from the Special Supplemental Nutrition Program for Women, Infants and Children) to their mothers, older sisters or grandmothers (Reyes et al., 2013). A previous evaluation of Healthy Start found that young women (especially teenagers) may be "under the influence of their parents" (Lucas et al., 2013, p. 34), but this context was not linked to the mechanism of handing over vouchers. This theory was represented by one of the vignettes used in this qualitative study: "Mum does the shopping, so I give her the vouchers. I don't know what she spends them on." The sample included two pregnant teenagers but neither of them agreed with or responded to this vignette. Only one woman (aged 25) responded, but her experience was cooperative and she had chosen to use her

vouchers to contribute to the family shopping. This quote does not indicate lack of empowerment:

> "I did this when I was pregnant with my eldest son, I lived with my dad at the time so I was getting the Healthy Start vouchers and would just give them to my dad to go and get the shopping…he would say I am going to go shopping today and I would pass him a voucher and say you can put this towards the milk or the potatoes or anything he needs in that sense any fruit or veg or milk. I would just give it to him and he would go and get the shopping with it." (Emma)

Thirdly, in the theory development stage of the realist review (chapter 4), stigmatisation was considered as a possible reason why women may not use their Healthy Start vouchers. This candidate theory was informed by discussions with midwives from Barrow-in-Furness, who felt that stigmatisation might affect women who rely on smaller shops, which offer less anonymity compared to supermarkets. However, this candidate theory was not substantiated in the realist review. An evaluation of Healthy Start found that some women had experienced judgemental attitudes from staff and customers (McFadden et al., 2013), but this was not clearly linked to outcomes. In this qualitative study, two women expressed feelings of awkwardness or embarrassment in relation to using Healthy Start vouchers in supermarkets, but they both said this had not prevented them from using the vouchers. For example:

> "Yes, they accept them but they tend to, when you present them they are not very happy with you and then because they then have to type in the home number and they have got people moaning in the queue. You have to scan one side then the other side and every time they've tried they can't scan them. So it is a bit embarrassing bringing them out because you can see everyone in the queue, looking at you and then the checkout person is like 'oh not these again'…when they have got big queues that's when they make you feel awful…I keep using them but I dread getting them out, if that makes sense." (Lucy)

The midwives raised this again during the stakeholder consultation meeting with the study advisory group (June 2017). They said they knew of women in more affluent, rural areas of the South Lakes who did not use their vouchers due to fears about stigmatisation. They also knew of women who were eligible for the vouchers but had chosen not to apply for similar reasons. The study advisory group agreed that stigmatisation is likely to be very

context dependent, and further insights might have emerged from a larger, more diverse sample.

6.4.3 Strengths of this study

This qualitative study demonstrates the application of realist evaluation methods to explore the views, perceptions, perspectives and experiences of low-income pregnant women. It may be useful for other researchers or evaluators of social programmes targeting vulnerable or hard-to-reach groups. Programme theories from the realist review (Ohly et al., 2017) were further developed and refined, which provide plausible and in-depth explanations for five possible outcomes of the Healthy Start programme. These include intended and unintended outcomes. In the absence of any robust quantitative studies of Healthy Start, this study highlights the complexity of outcome patterns that should be anticipated and factored into the design of any future evaluations. It embraced the realist assumption that programmes do not work the same for everyone, and has shown the importance of local and individual context in determining who the programme works well for and who it could work better for. The decision to focus on programme beneficiaries has generated evidence and insights into mechanisms – individual reasoning processes in the minds of programme beneficiaries. These research findings will be useful for policy makers, advocates, service managers and health professionals working to promote and enhance the Healthy Start programme.

The combination of realist interviews and vignettes was an effective way to communicate programme theories to low-income women, and encouraged them to share their own ideas and experiences in return. While vignettes have been widely used in qualitative research, their application in realist studies has so far been limited. Two recent protocols for realist studies outlined plans to use vignettes in interviews with older people (Bunn et al., 2017) and focus groups with cancer patients (Tremblay et al., 2014). No completed realist evaluations or reviews using vignettes were found. Therefore, this study presents a novel approach to data collection, which could be used to engage any stakeholder group in realist interviews, and is particularly suited to low-income or vulnerable groups of programme beneficiaries.

This qualitative study may be judged against two sets of standards: quality standards for realist evaluation (RAMESES, 2017) and standards for assessing the trustworthiness of qualitative research (Lincoln & Guba, 1985; Seale, 1999). Firstly, it is closely aligned

with the quality standards for realist evaluation, which emphasise that studies should be underpinned by the realist principle of generative causation: "underlying causal processes (called 'mechanisms') operate (or not) in certain contexts to generate outcomes" (RAMESES, 2017, p. 3). They also emphasise the progressive refinement of programme theories and integration with substantive (or middle-range) theories. Adherence to these quality standards was reflected in previous sections of this chapter (including 6.2 and 6.3), and integration with middle-range theories is the focus of the discussion (chapter 7).

Secondly, this study may be considered credible (one aspect of trustworthiness in qualitative research) for the following reasons: prolonged engagement in data collection, coding and analysis (September 2016 to June 2017); double-checking of 10% of coding and analysis by the lead supervisor; regular discussions about methods and findings with supervisors throughout the study; openness to new theories (outcomes and explanations) throughout the study. Other aspects of trustworthiness include transferability (the extent to which findings are transferable to other contexts), dependability (the extent to which findings could be repeated with the same participants in the same context) and confirmability (the extent to which findings are determined by data collected from participants) (Lincoln & Guba, 1985; Seale, 1999). As described in chapter 3, realist programme theories are both programme-specific and context-specific, which implies they are not transferable to other contexts. However, the mechanisms within programme theories may be transferable between contexts (Pawson, 2013) and this is explored further in chapter 7. Efforts were made to maximise dependability and confirmability through clear and transparent reporting of study methods (section 6.2) and extensive use of quotations to support study findings, including linkages between context, mechanisms and outcomes (section 6.3).

6.4.4 Limitations of this study

The main limitation of this study was its small sample size of 11 women. Recruitment was challenging in all three local authority areas. The face-to-face approach was by far the most productive (10 out of 11 women) but this was also time intensive. The recruitment rate was around 5% of women approached, despite focusing on children's centres in the most deprived areas. Most women declined to participate because they were not eligible for Healthy Start. However, it is possible that some women may not have wanted to disclose their eligibility. In one area, two separate groups of new mothers were completely unaware of the programme, which may reflect problems with communication

at local and national levels. In two areas, local authority and children's centre staff were enthusiastic about the project and helped to distribute flyers, but no women were recruited by referral. In the other area, staff were less receptive and various barriers to recruitment were encountered.

Historically, national data on Healthy Start beneficiaries have not been publicly available. However, in March 2017, data were obtained by HO from the Department of Health (DH) Healthy Start Issuing Unit on the number of beneficiaries in each local authority. This showed that, in all three recruitment areas, less than 5% of beneficiaries were pregnant women and the majority were children aged over one year (Table 16). The accompanying email explained that DH does not receive data on pregnant women from the benefits system (other government departments) and, therefore, they cannot be invited to apply for Healthy Start. Hence the reliance on health professionals to signpost low-income pregnant women to the programme. This data confirmed why it had been so difficult to recruit women who were using (or had recently used) Healthy Start vouchers during pregnancy.

Table 16. Number of Healthy Start beneficiaries by group, January – February 2017.

Local authority	Total	Pregnant	Child <1	Child >1
Barrow-in-Furness	408	16	103	289
Blackburn-with-Darwen	1261	53	298	910
Preston	970	26	203	741

Data reproduced with permission from DH Healthy Start Issuing Unit

These challenges were discussed with the study advisory group, who explained that low-income women (and families) are less likely to be eligible for Healthy Start since the introduction of Universal Credit. As explained in chapter 2, this new benefit was introduced in 2013 to replace six other means-tested benefits, with the aim of simplifying the social security system (Welfare Reform Act, 2017). Universal Credit became a qualifying benefit for Healthy Start from 1st November 2016 (National Health Service, 2017). The income threshold for families receiving Universal Credit is £408 or less per month (equivalent to £4896 or less per year), compared to the previous income threshold of £16,190 or less per year. This suggests that many fewer families will now be eligible for Healthy Start, and raises wider questions about the purpose and impact of the programme.

With all of this in mind, 11 women may be considered a small but realistic sample for a qualitative study about how low-income pregnant women use Healthy Start vouchers. Data saturation was not reached, and additional programme theories may have emerged from a larger and more diverse sample. The representativeness of the sample is unclear because data on socio-demographic characteristics of beneficiaries were not available from DH. Therefore, the evidence-based programme theories presented above are unlikely to represent all low-income pregnant women who are beneficiaries of the Healthy Start programme. A larger study would be needed to explore the prevalence of outcome patterns and compare subgroups of women. Recommendations for further research are discussed in chapter 7.

6.5 Chapter summary

This chapter has provided a comprehensive account of the methods and findings of empirical research undertaken in this PhD. It described how an innovative combination of realist and qualitative methods was used to further develop, refine and consolidate programme theories about how low-income pregnant women use Healthy Start vouchers. The study focused on women's perspectives as programme beneficiaries, which revealed more nuanced programme theories compared to the realist review. Despite challenges with recruitment and a smaller sample than anticipated, the data provided in-depth, plausible explanations for five possible outcomes (intended and unintended). The evidence-based programme theories showed how low-income pregnant women made decisions and prioritised resources, and how Healthy Start vouchers influenced that process. This study confirmed that women may experience more than one outcome, as context is never static and different mechanisms may be activated by the programme in different circumstances. While the findings from this small qualitative study are not transferable to other contexts, some of the mechanisms identified may be transferable and this will be explored in the final chapter.

7.0 DISCUSSION AND FURTHER THEORY DEVELOPMENT

7.1 Introduction

This chapter draws together findings from the realist review and qualitative study. It starts by emphasising the original contribution to knowledge of this study so far – the development of evidence-based programme theories about Healthy Start using realist synthesis and realist evaluation methods. It extends the original contribution to knowledge by integrating the programme theories with three existing behaviour change theories, also known as 'middle-range' theories. The purpose of this integration is twofold: to strengthen the programme theories by using established concepts to explain the relationships between context, mechanisms and outcomes; to consider whether the generative mechanisms identified in the programme theories about Healthy Start may be transferable to other programmes. A theoretical model for Healthy Start presents the key findings of this study in terms of what works, for who, in what circumstances and why. This chapter considers implications of this study for policy makers and practitioners working to develop and support the Healthy Start programme. It makes tentative suggestions about who the programme works well for, and which women might need more support to achieve the intended outcome of dietary improvements. It concludes with some recommendations for further research.

7.2 Original contribution of this study

The Healthy Start programme has been studied and evaluated for over a decade since it was introduced in 2006. This PhD study has contributed to the ongoing cycle of evaluation and accumulation of knowledge. It is the first study of Healthy Start to use realist evaluation methodology to explore how the programme works, for who, in what circumstances and why (Pawson & Tilley, 1997). While previous studies and evaluations of Healthy Start identified perceived benefits, unintended consequences, barriers and challenges (see critical review in chapter 2), they did not achieve the same depth of understanding as this study in terms of generative causation. A realist analytical 'lens' was consistently and transparently applied throughout the realist review (chapters 4 and 5) and the qualitative study (chapter 6). Furthermore, the entire study was grounded in realist ontology: the notion that reality exists independent of the human mind (Crotty, 1998). Consequently, it has highlighted a range of possible programme outcomes and plausible, evidence-based explanations for how and why those outcomes may occur.

Theory has not been used in the development or evaluation of Healthy Start until this study. The programme was introduced in response to public health recommendations to improve maternal and child health. As discussed in chapter 2, political influences were also involved and the programme was not entirely evidence-based. It evolved from the Welfare Food Scheme, which had been in place since the 1940s. It appears to have been assumed by policy makers that Healthy Start would deliver improved outcomes compared to the Welfare Food Scheme. However, it was unclear what the intended outcomes were and how, precisely, the programme would affect change. There was no indication that programme development was informed by behaviour change theory. Similarly, none of the previous studies of Healthy Start were informed or underpinned by theoretical frameworks. The development of evidence-based programme theories in this study marks a turning point in how Healthy Start will be conceptualised. It highlights the complexity of relationships between contextual factors, causal mechanisms and outcomes (including intended and unintended outcomes).

The use of vignettes in combination with realist interview techniques, reported in chapter 6, was a novel approach to data collection. It was an effective way to communicate programme theories and encourage women to share their own experiences. This approach may be useful for other realist researchers working with low-income or vulnerable groups of programme beneficiaries. Vignettes have been used in previous qualitative studies to explore a range of sensitive topics, such as drug abuse in prisons (Hughes, 1998), women's infant feeding experiences (Hoddinott, Craig, Britten, & McInnes, 2012), and barriers to the uptake of HIV services in Tanzania (Gourlay et al., 2014). These studies found that vignettes helped to put interview participants at ease and facilitated in-depth discussions by focusing attention on an unknown third person. They created opportunities for participants to discuss aspects of their own lives because they related to the characters in the vignettes. In this study, low-income women responded to the vignettes in similar ways. It provides an innovative example of how vignettes may be used in realist interviews to 'exchange theories' with programme beneficiaries in an informal way.

This chapter extends the original contribution of this study by integrating the programme theories with three existing behaviour change theories and developing an overarching theoretical model for Healthy Start.

7.3 Integration with existing behaviour change theories

7.3.1 Rationale for using middle-range theories

The role of theory in understanding complex interventions (or programmes) is increasingly recognised and advocated in guidance for researchers and evaluators (Moore et al., 2015; Noyes et al., 2016). Realist researchers strive to develop 'middle-range' theories, which are general or abstract enough to be useful across a range of programmes or contexts (Pawson & Tilley, 1997). This is often a two-way process: using existing middle-range theories to explain what is happening at programme level, and 'zooming out' to see how programme theories might be used to develop middle-range theories. The rationale is that generative mechanisms may be transferable or 'portable' between programmes that use similar strategies to influence behaviour. Therefore, we can learn about programmes through abstraction – the process by which we understand specific instances in terms of broader explanations.

> "Fruitful middle-range concepts will harness together and elucidate many different empirical instances. The same explanation may be located and relocated, used and reused." (Pawson, 2013, p. 89).

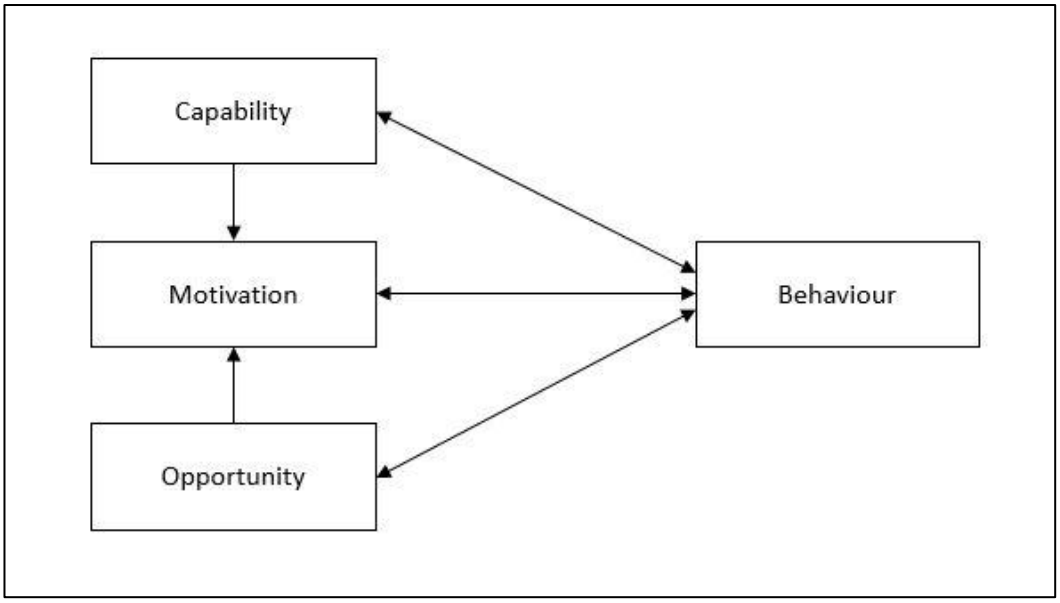
A variety of middle-range theories were considered throughout the study. Economic theories presented a more rational perspective on human decision-making, which was considered less compatible with the realist focus on individual level reasoning and contextual complexity. Behaviour change theories offered deeper psychological explanations for why people behave in certain ways, which helped to identify and articulate the relationships between context, mechanisms and outcomes in realist programme theories. Three behaviour change theories were ultimately selected because they resonated with the evidence-based programme theories in different and complementary ways. The following sections describe how these middle-range theories were integrated with the evidence-based programme theories about how low-income pregnant women use Healthy Start vouchers (referred to as theories 1, 2, 3, 4 and 5).

7.3.2 Behaviour Change Wheel

The Behaviour Change Wheel was considered during the theory development stage of the realist review (chapter 4) and revisited as the programme theories were refined (chapter 6). It provides a systematic way to identify and categorise intervention functions based

on what is understood about the target behaviour (Michie, van Stralen, & West, 2011). At the centre of the Behaviour Change Wheel is the 'COM-B' system, which asserts that an intervention must change at least one of three conditions to generate behaviour change: capability, opportunity or motivation. Figure 15 shows that any of these conditions may influence behaviour (and vice versa) and motivation may be influenced by capability or opportunity. The COM-B system was applied to Healthy Start and the target behaviour of dietary improvements in pregnancy.

Figure 15. The COM-B system (Michie et al., 2011)



Motivation refers to the brain processes that direct the target behaviour, including conscious and subconscious processes (Michie et al., 2011). This was a reminder that 'reasoning' (in the realist definition of mechanisms) is "a catch-all term for 'anything that happens inside the intended beneficiary's head'" (Westhorp, 2014, p. 6). It includes beliefs, values, emotions, impulses and instincts, as well as logical decision making processes. This study suggests that Healthy Start vouchers may work by reinforcing the motivation to eat well during pregnancy (theory 1). This mechanism depends on the context of existing motivation i.e. women who already value healthy eating and aspire to eat well during pregnancy. This is an example of how programmes may work by enabling existing reasoning (as opposed to changing reasoning) inside the mind of the beneficiary.

> "I'd like to do this but I can't because I don't have the resources to do so – this programme provides the resources to do so" (Westhorp, 2014, p. 6).

Opportunity refers to factors outside the individual that make the target behaviour possible (Michie et al., 2011). Interventions or programmes may provide or restrict opportunities to engage in the target behaviour. This study suggests that Healthy Start creates an opportunity for low-income pregnant women to improve their diets by providing additional resources (theory 1). The vouchers make it possible for women to buy and consume more healthy foods by making them more affordable. However, some women perceived different opportunities from the vouchers, such as saving money (theory 3) or stocking up on formula (theory 4). The flexibility of the vouchers enabled women to respond to any of these opportunities depending on their beliefs, values and motivations. As described in the paragraph above, motivation is both context and mechanism; the perceived opportunity associated with the vouchers depends on motivation (context) and has the potential to reinforce motivation (mechanism). This demonstrates a two-way interaction between opportunity and motivation, which differs from the one-way interaction in the COM-B system.

Capability refers to the individual's physical or psychological capacity to engage in the target behaviour (Michie et al., 2011). Psychological capacity includes the ability to engage in the necessary reasoning processes, hence the potential link with motivation. The Healthy Start programme does not directly influence women's knowledge and awareness of the importance of healthy eating in pregnancy because it does not have an education component. It relies on health professionals to provide the necessary information, advice and support. However, this study suggests that support from health professionals may be inadequate or inconsistent in some areas, and low-income pregnant women may not receive clear advice on how to use Healthy Start vouchers to improve their diets (see section 6.4.2). A previous evaluation identified concerns around understaffing, lack of training and insufficient time during appointments to discuss how the vouchers could be used to support a healthy diet (Lucas et al., 2013). Therefore, capability may be underutilised as a behaviour change strategy within the Healthy Start programme.

This COM-B analysis helped to identify sources of behaviour change within the programme theories. The Behaviour Change Wheel suggests nine intervention categories, based on how interventions influence capability, opportunity and motivation to generate behaviour change. The nine categories are: education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling and enablement (Michie et al., 2011). It was difficult to assign Healthy Start to any one of these categories

using the brief definitions provided. It felt over simplistic, having identified that Healthy Start vouchers are likely to influence different women in different ways, depending on aspects of context. This reinforced the decision to consider more than one middle-range theory. Incentivisation was one intervention category that was considered worthy of further consideration.

7.3.3 Incentive theory

Instinctively, any kind of vouchers may be thought of as financial incentives for behaviour change because they have monetary value. Healthy Start fits some definitions of 'incentive' but not others. The Behaviour Change Wheel defines incentives as creating an expectation of a reward (Michie et al., 2011). Another popular definition in the behaviour change literature has two components: incentives are rewarding and contingent on behaviour change (Abraham & Michie, 2008; Adams, Giles, McColl, & Sniehotta, 2014). This kind of incentive includes shopping vouchers for women who stop smoking during pregnancy i.e. rewards for initiating and sustaining behaviour change (Crossland, Thomson, Morgan, Dombrowski, & Hoddinott, 2016). Healthy Start does not fit either of these definitions because the vouchers are provided prospectively (not rewarding) and behaviour change is not a condition of receiving the vouchers (not contingent). A systematic review of financial incentives for dietary behaviour change suggested that vouchers and other types of incentives may be used to facilitate or catalyse behaviour change, rather than to reward it (Purnell, Gernes, Stein, Sherraden, & Knoblock-Hahn, 2014). In the realist literature, incentives are considered even more broadly, as anything that encourages people to adopt certain behaviours (Pawson, 2003).

> "Generically speaking, the working hypothesis is that the incentive offers deprived or recalcitrant subjects the wherewithal to partake in some activity beyond their normal means or outside their normal sphere of influence, which then prompts continued activity and thus long-term benefit to themselves or their community or their organisation." (Pawson, 2013, p. 91).

These broader conceptualisations of incentives mean that Healthy Start may be considered within this category of intervention. The vouchers provide low-income pregnant women with the 'means' or resources to buy more healthy foods, which may facilitate or encourage dietary improvements. However, they do not necessarily help to identify the precise mechanisms through which the incentive operates. Previous studies

have reported similar challenges and this statement indicates the potential contribution of realist studies to enhance knowledge in this area of behaviour change theory.

> "Wide variations in the nature of these interventions make it difficult to draw firm conclusions about what makes an effective incentive, for whom and under what circumstances." (Adams et al., 2014, p. 286).

This study suggests that mechanisms of encouragement may include reinforcing existing motivation and alleviating concerns about the cost of healthy foods, thereby reducing stress associated with healthy eating on a low income (theory 1). The 'reinforcement' mechanism is similar in rewarding incentives, which positively reinforce and validate behaviour change retrospectively. This relates to 'operant conditioning' theory, which suggests that reinforced behaviours tend to be repeated and strengthened (McLeod, 2015). This is akin to 'prompting continued activity' in the realist definition of incentives (Pawson, 2013). Healthy Start may have similar reinforcing effects for some women, but since the incentive is prospective and unconditional, it is unclear whether the strength of effect would be comparable. It has been suggested that financial incentives may have negative consequences if they are perceived as too controlling (Moller, McFadden, Hedeker, & Spring, 2012).

The above statement by Adams et al. (2014) indicates that context or 'circumstances' are likely to be important in determining the effectiveness of incentives. A study of incentives for breastfeeding and smoking cessation in pregnancy noted the complexity of incentive mechanisms, which are unlikely to be similarly effective in all contexts (Morgan et al., 2015). This study identified aspects of context that may influence how women respond to Healthy Start vouchers (at the level of individual reasoning), such as women's beliefs, values and motivations. Therefore, this study adds depth of explanation to the literature on vouchers as incentives for dietary behaviour change.

A previous evaluation highlighted concerns among some health professionals that Healthy Start vouchers could act as an incentive to formula feed (McFadden et al., 2013). While this study focused on pregnant rather than postpartum women, it found that some women used the vouchers to stockpile formula during pregnancy (theory 4), an outcome that was also reported in the McFadden et al. study. Applying the same hypothesis of reinforcement, if women are permitted to use the vouchers to buy infant formula, this may reinforce the decision to formula feed and this could be interpreted as encouragement.

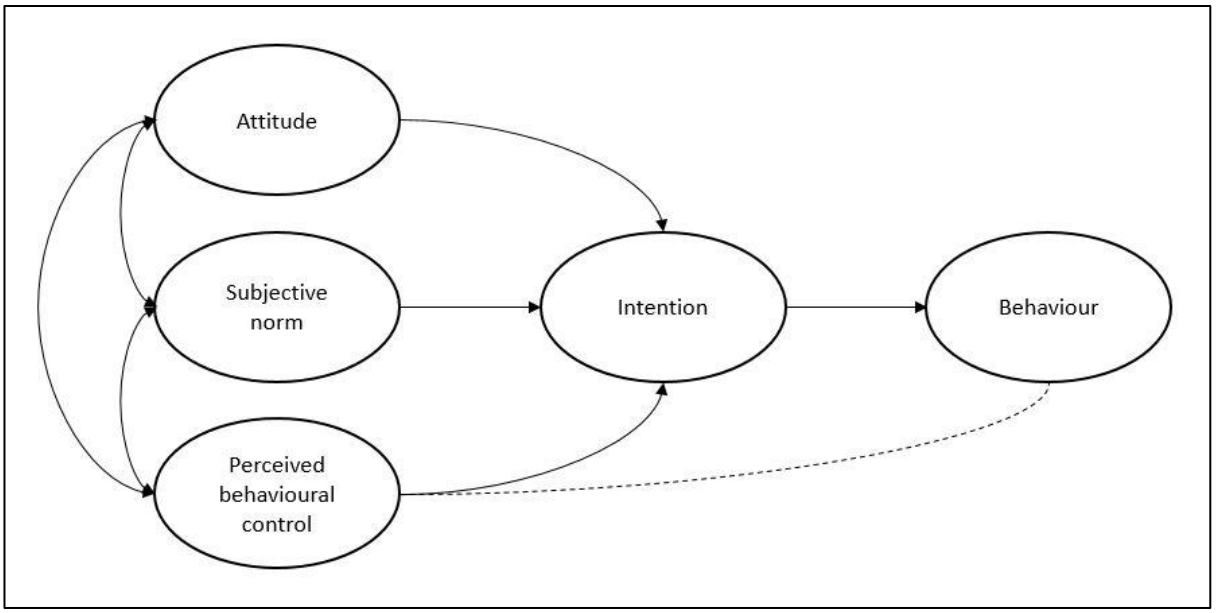
This raises questions about whether Healthy Start conflicts with UK and global public health recommendations to breastfeed exclusively for at least six months.

The integration of incentive theory helped to understand how the Healthy Start programme compares to other types of incentives in terms of resources and mechanisms. The contribution of programme theories from this study was to demonstrate how 'incentive' mechanisms may generate different outcomes depending on the context or pre-existing conditions into which the programme is introduced (Pawson & Tilley, 1997).

7.3.4 Theory of Planned Behaviour

The Theory of Planned Behaviour links human intentions and behaviours with attitudes, subjective norms and perceived behavioural control, as illustrated in Figure 16 (Ajzen, 1991). It is a general theory of behaviour change, which may be applied to different types of interventions or programmes. It asserts that if someone has a favourable attitude towards a behaviour, which is socially accepted, and they believe they can perform that behaviour, they will have greater intention to perform that behaviour. Therefore, when an opportunity arises, they will be more likely to carry out that behaviour.

Figure 16. The Theory of Planned Behaviour (Ajzen, 1991)



The 'determinants of intention' were considered in relation to Healthy Start and the target behaviour of dietary improvements in pregnancy. This study suggests that a 'favourable attitude' among low-income pregnant women would include aspirations to eat well during pregnancy, and being motivated by potential health benefits for mother and baby (theory

1). With a favourable attitude towards healthy eating, women may be more likely to perceive the vouchers as an opportunity to improve their diets.

'Subjective norm' refers to the perceived social pressure to perform or not perform the behaviour (Ajzen, 1991). This includes the perceived behavioural norms of other people who are respected and valued (Malek, Umberger, Makrides, & ShaoJia, 2017). Therefore, women's views on what it means to be 'healthy' and the relative value of healthy eating may be influenced by the perceived views, expectations and behaviours of friends, family members and the wider community. These factors were not fully explored in this study because it was necessary to limit the scope of candidate theories (as described in chapter 4). A previous review of determinants of healthy eating in pregnancy suggested that interpersonal factors, such as social support, may be more influential than individual factors (Fowles & Fowles, 2008). However, it highlighted the lack of high quality research in this area, as did a more recent systematic review on social determinants of diet in pregnancy (Doyle, Borrmann, Grosser, Razum, & Spallek, 2017). Therefore, factors relating to subjective norm would be worthy of exploration in future realist studies of Healthy Start.

'Perceived behavioural control' refers to the perceived ease or difficulty of performing the behaviour, which may reflect past experiences and anticipated experiences (Ajzen, 1991). This study suggests that some women found it difficult to afford fruit and vegetables before they received the vouchers. The vouchers made healthy eating more affordable and achievable because they no longer had to worry about the cost, which demonstrates how attitude and perceived behavioural control may be interrelated. This is an example of how context (in this case perceived difficulty) may be modified by the programme.

In realist terms, attitude, subjective norm and perceived behavioural control are aspects of context – they vary between individuals and they enable or constrain mechanisms. If women aspire to eat well, and these aspirations are supported by social norms and expectations, and they believe the vouchers will make it easier, this enabling context creates an intention to eat well during pregnancy. Therefore, when women receive the vouchers, they are more likely to use them to buy and consume more healthy foods (intended outcome).

However, the same theory may be used to explain why some women may be diverted to the alternative or unintended outcomes of the programme, such as stockpiling formula

(theory 4). Women may have a 'favourable attitude' towards formula feeding, which may be shaped by personal preferences, past experiences or perceptions about 'normal' and socially acceptable infant feeding practices in their community. In this study, some women felt uncomfortable about the idea of breastfeeding in public places because they thought they would be stared at (subjective norm). Some women felt more confident about their ability to bottle feed because they had failed to breastfeed previous babies, or because they had preconceived ideas about breastfeeding being difficult (perceived behavioural control). These contextual factors may constrain or compete with women's aspirations to eat well during pregnancy. They are not mutually exclusive, and this illustrates how women must prioritise resources based on what they feel is most important. The relative value of healthy eating (in the present), compared to formula feeding (in the future), may determine how women use their vouchers in pregnancy.

A cross-sectional study used the Theory of Planned Behaviour to examine the relationship between healthy eating intentions and healthy eating behaviour in pregnant women (n=455) (Malek et al., 2017). It found that the constructs of attitude, subjective norm and perceived behavioural control explained 66% of the total variance in women's healthy eating intentions, but only 3.4% of the total variance in women's adherence to food group recommendations. This suggests that factors that influence intentions to behave in a certain way may not necessarily translate into actual behaviour change. Since this study relied on women's self-reported outcomes, the relationship between intended dietary improvements and actual dietary improvements is unclear.

Despite potential limitations of the theory, its integration with the programme theories in this study helped to elucidate how and why aspects of context may be important in determining which mechanisms are activated when women receive Healthy Start vouchers.

7.4 A theoretical model for Healthy Start

The final stage of theory development was to bring together the main concepts from the evidence-based programme theories and the middle-range theories identified above, into a theoretical model for Healthy Start (Figure 17). The purpose of the model was to illustrate the combination of context and resources needed to generate the intended outcome of dietary improvements for low-income pregnant women, and the mechanisms by which this outcome may be generated. It was informed by the findings of the realist

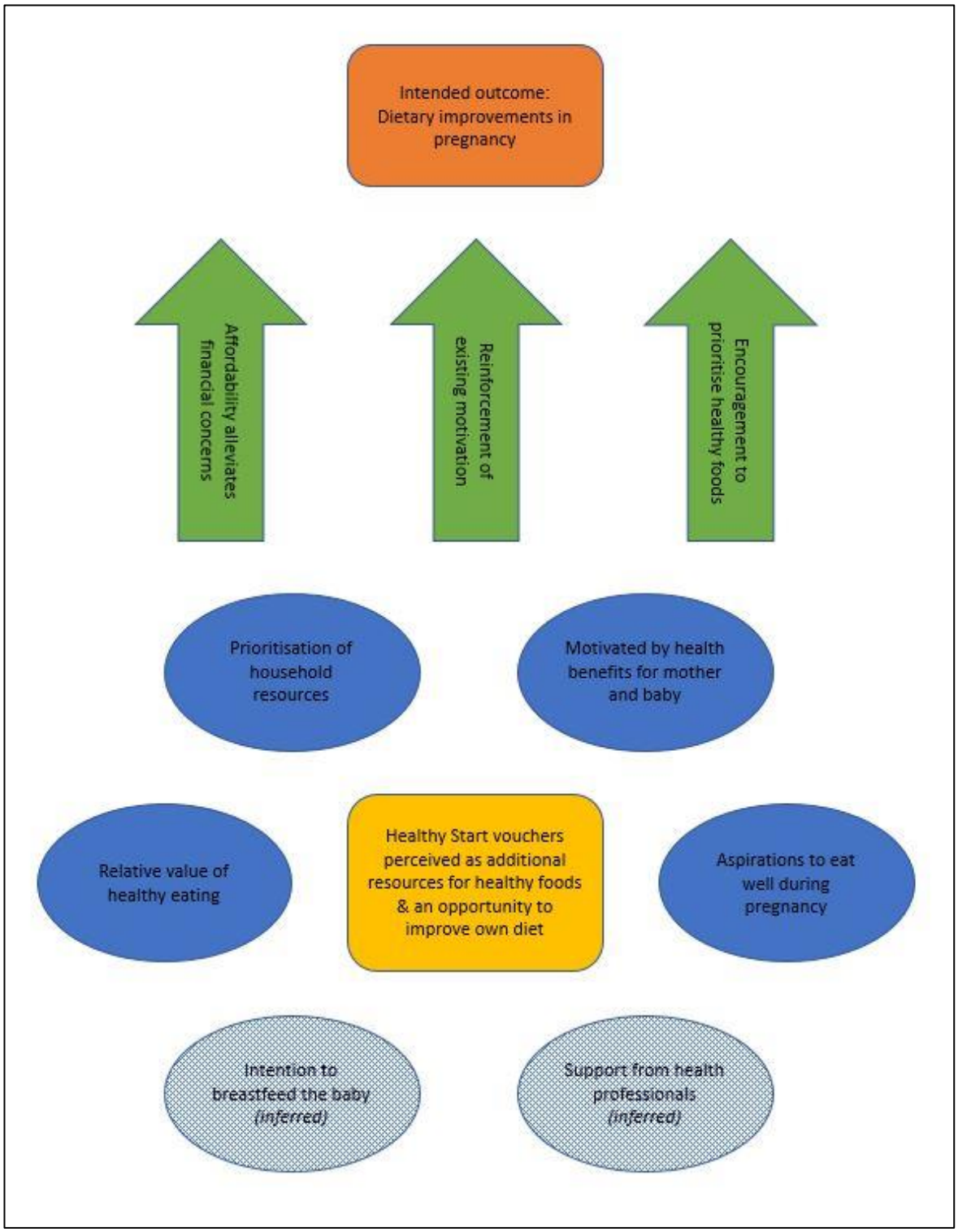
review (chapters 4 and 5), the qualitative study (chapter 6) and insights from three existing behaviour change theories. It presents a positive theory of change for the Healthy Start programme. However, findings and programme theories leading to alternative or unintended outcomes were also used to make inferences about how and why the programme might be successful. The model presents the key findings of this study in terms of what works, for who, in what circumstances and why in relation to how low-income women use food vouchers from the Healthy Start programme.

Fundamentally, this model illustrates that the Healthy Start programme is embedded in the complex social world and therefore its outcomes are dependent on context (Pawson & Tilley, 1997). Context is positioned at the base of the model as the foundation upon which change happens. The programme can only work as intended if the context or conditions into which it is introduced enable certain mechanisms to be activated. Therefore, the mechanisms reflect aspects of context that have been modified or 'enabled' by the programme.

For example, prioritisation of household resources was recognised as context because low-income women must prioritise resources every day, not just when they have the vouchers. Healthy Start influences that ongoing process of prioritisation by making healthy foods more affordable. This may encourage (or incentivise) women to prioritise healthy foods – hence prioritisation has been altered by the programme. However, the success of this strategy may depend on other aspects of context such as women's values, beliefs and motivations, which may also be reinforced by the programme.

This theoretical model offers evidence-based and theory driven explanations about how low-income women use Healthy Start vouchers and why. As anticipated, the answers to these questions are complex and the 'real' explanation for each programme beneficiary will be subtly different. The model should not be interpreted as 'essential conditions for success'. The aspects of context identified in the model will be important for some women and not others. There are likely to be other important aspects of context (and related mechanisms) that have not been identified in this study. Therefore, this model should be considered a first attempt to explain the potential effects of Healthy Start, based on realist assumptions of generative causation. Future studies may choose to explore the prevalence and strength of these proposed effects using different methods, and in different contexts.

Figure 17. A theoretical model for Healthy Start



Colour coding: blue = context; yellow = resources; green = mechanisms; orange = outcomes.

It is important to acknowledge that this theoretical model was largely derived from evidence-based programme theories specific to Healthy Start and it remains a model of Healthy Start. However, the integration of three 'middle-range' behaviour change theories suggests it may also be applied more widely. Generative mechanisms relating to prioritisation of resources and reinforced motivation may be transferable to other food voucher programmes and other types of 'incentives' that are designed to encourage (rather than reward) dietary improvements in pregnancy. Therefore, this study contributes to programme theory and middle-range theory development in this area.

7.5 Implications for policy and practice

This study suggests that participation in the Healthy Start voucher programme may lead to dietary improvements for low-income pregnant women if the following contextual factors enable behaviour change to occur:

- Women value healthy eating and aspire to eat well during pregnancy.
- Women are motivated by potential health benefits for themselves and the unborn baby.
- Women intend to breastfeed, so they do not need to spend money (or vouchers) on infant formula.

Furthermore, the programme theories highlighted contextual factors that may limit the potential success of the programme by constraining mechanisms. The following sections consider ways the Healthy Start voucher programme could be improved, to increase the possibilities for low-income pregnant women to experience the intended outcome of dietary improvements.

7.5.1 Clearer guidance on healthy eating for eligible women

This study suggests that Healthy Start vouchers may encourage (or incentivise) low-income pregnant women to buy and consume more healthy foods, by making them more affordable and enabling women to prioritise them (Figure 17). However, some women may be diverted towards alternative or unintended outcomes, such as using the vouchers to feed other family members (theory 2), save money (theory 3), stockpile formula (theory 4) or buy alternative items not permitted by the programme (theory 5).

The evidence-based programme theories explain that women's 'reasoning and reactions in response to the vouchers' (mechanisms) may depend on their existing values, beliefs and motivations, and the extent to which they value healthy eating compared to other things they need to spend money on (context). It may logically be inferred that, if the Healthy Start programme could increase the relative value of healthy eating, more women might improve their diets. In the COM-B analysis, 'capability' was identified as an underutilised behaviour change strategy because Healthy Start does not directly influence women's knowledge and awareness of the important of healthy eating in pregnancy (see 7.3.2).

It has been assumed that health professionals will provide the necessary information, advice and support to low-income pregnant women, to ensure that they are aware of the importance of healthy eating in pregnancy. Guidance for health professionals stated that women eligible for Healthy Start should receive advice on how to use the vouchers to support a healthy diet (National Institute for Health and Care Excellence, 2015). However, this study suggests that support from health professionals may be inconsistent or inadequate in some areas. A previous evaluation identified concerns around understaffing, lack of training and insufficient time during appointments (Lucas et al., 2013).

It would be inappropriate for this study to make specific recommendations to increase the quantity and quality of support provided by health professionals. Health professionals have other important topics to discuss with pregnant women during antenatal appointments and to some extent this will always be a matter of judgement. Policy makers should consider whether it would be feasible to incorporate additional support into the Healthy Start programme. The Healthy Start Discovery project is investigating a range of digital opportunities, including social media campaigns and ways to signpost users to relevant services and information (Department of Health, 2016). These digital solutions could be designed to promote healthy eating messages and clearer guidance on how to use Healthy Start vouchers to support a healthy diet.

In the United States, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) provides mandatory nutrition education in addition to the food package and vouchers. It is delivered in dedicated WIC clinics by trained WIC Nutritionists. A national evaluation of the nutrition education component of the programme is due to be completed in 2017 (Cates et al., 2016). The findings may offer some insights that are

transferable to the Healthy Start programme in the UK. An interim report described the key features of WIC nutrition education (Cates et al., 2016):

- WIC Nutritionists have formal training (mostly dietitians) and extensive experience;
- Primary delivery method is one-to-one counselling;
- Individualised and tailored to the needs of participants;
- Coordinated with other local programmes to ensure consistent messages.

Substantial investment would be needed to replicate this service in the UK.

7.5.2 Greater consistency with guidance on breastfeeding

This study suggests that, if women decide to use infant formula, they may also decide to use Healthy Start vouchers to stockpile formula during pregnancy. This may depend on women's perceptions about the purpose of the vouchers, the relative value of healthy eating (compared to formula feeding) and concerns about the cost of formula. The intention to formula feed may constrain or compete with aspirations to eat well during pregnancy. The voucher value (£3.10 per week) means that stocking up on formula would largely or entirely displace the potential health benefits for themselves and the unborn baby.

The integration of incentive theory (see 7.3.3) highlighted the possibility that Healthy Start vouchers may 'encourage' formula feeding because they facilitate and reinforce the decision and intention to formula feed. This theory warrants further investigation, and policy makers should consider how the programme could be modified to clearly promote and encourage breastfeeding. A previous evaluation of Healthy Start recommended that additional incentives for breastfeeding should be considered, but did not specify how this might be done (McFadden et al., 2013).

A relatively simple solution to the issue of stockpiling formula (theory 4) would be to restrict the vouchers to fruit and vegetables and cow's milk during pregnancy. This would promote a clearer message about the importance of healthy eating in pregnancy (which also relates to the previous recommendation) and remove the constraining context of intention to formula feed (i.e. women may still intend to formula feed but this intention would no longer influence their voucher use during pregnancy).

Better links may be needed with existing breastfeeding support services. This is another area where lessons could be learned from the WIC programme. Its nutrition education component includes breastfeeding promotion and support, and the WIC food package is enhanced (it provides the largest quantity and variety of healthy foods) for women who exclusively breastfeed, which provides a clearer incentive to breastfeed (Institute of Medicine of the National Academies, 2005). A longitudinal survey found that WIC participation was associated with increased probability of breastfeeding initiation (52% compared to 45% in the control group; $p<0.05$); the effect on breastfeeding duration was not significant (Chatterji & Brooks-Gunn, 2004).

The impact of Healthy Start on breastfeeding rates has not been evaluated, despite explicit recommendations to do so (McFadden et al., 2013). While this study focused on pregnant women, future studies might consider exploring the impact of the programme on women's infant feeding practices using similar realist questions: what works, for who, in what circumstances and why (Pawson & Tilley, 1997).

7.5.3 Improved voucher verification system

This study suggests that women may use Healthy Start vouchers to buy alternative items not permitted by the programme. Previous studies also identified this unintended outcome of the programme, but it was unclear how commonly it occurred (Department of Health, 2012; Lucas et al., 2013). While individual aspects of context such as financial pressure may determine why women decide to misuse their vouchers in this way (theory 5), the realist review identified retailer discretion as context that enables women to do so (5.4.5). The current voucher system relies on retailers to verify that the items on the checkout include permitted items (fruits and vegetables, plain cow's milk or infant formula) matching or exceeding the value of the vouchers presented. This must be done visually because the barcodes on the vouchers are not electronically matched to specific items on the till system. Therefore, if retailers decide to use their discretion and 'bend the rules' in response to what their customers want to buy, they are unlikely to be held to account because there is no audit trail of what the vouchers have been exchanged for. This undermines the purpose of the vouchers as a 'nutritional safety net' (Department of Health, 2010) and efforts should be made to prevent it from happening.

It is unclear whether DH intends to digitalise the Healthy Start programme, or how and when this would be implemented (Department of Health, 2016). The WIC programme is

currently transitioning from paper-based vouchers to an Electronic Benefits Transfer (EBT) system, which is mandated to be implemented nationwide by 2020 (United States Department of Agriculture: Food and Nutrition Service, 2016). The transition followed a five-year period of development, implementation and expansion from 2003 to 2008 (United States Department of Agriculture: Food and Nutrition Service, 2006). Its priorities were to maintain the nutritional integrity of the programme, with additional benefits for users (such as convenience, security and discretion) and retailers (such as easy operation and reduced paperwork). The new system will increase accountability and ensure that purchases are restricted to foods authorised by WIC. It will reduce reliance on retailers and opportunities for error or misuse. It has been widely supported, but some smaller retailers expressed concerns about the cost. In response, the government committed to meeting all equipment costs and ongoing maintenance and operational costs associated with the implementation of EBT (United States Department of Agriculture: Food and Nutrition Service, 2016). Similar considerations would need to precede the digitalisation of Healthy Start vouchers, including feasibility and pilot studies.

7.6 Recommendations for further research

The first chapter of this thesis introduced the Healthy Start programme in the context of nutrition inequalities in the UK and the need for targeted support for low-income women and children. Within that wider context, this study has identified several aspects of local and individual context that may influence the effectiveness of the Healthy Start programme, in relation to how low-income pregnant women use food vouchers. Its findings offer in-depth, evidence-based explanations for how the programme works, which provide more nuanced insights into the inner workings of the programme compared to previous studies. This study highlights the complexity of reducing health inequalities and the important contribution of realist evaluation to determine ‘what works, for who, in what circumstances and why’. It suggests that Healthy Start may lead to dietary improvements for some low-income pregnant women, but the overall impact on nutrition inequalities is unclear.

It was necessary to limit the scope of this study to reflect PhD requirements. Future realist studies should continue to explore and develop programme theories about Healthy Start in a wider variety of contexts. Three programme theories were identified but not substantiated in this study, which may be worthy of further investigation: the role of health professionals in supporting the Healthy Start programme; lack of (women’s)

empowerment; stigmatisation associated with using the vouchers. Purposive sampling and in-depth realist evaluation would lead to greater understanding of how to maximise the effectiveness of Healthy Start for low-income women (and families) living in a variety of circumstances.

Findings are anticipated from another evaluation, due to be completed in 2017, which aims to evaluate the extent to which Healthy Start improves the nutrition of pregnant women and the health outcomes of their infants (National Institute for Health Research, 2015). The study design is described as a 'natural experiment' with three comparison groups: recipients of Healthy Start (group 1), eligible non-recipients (group 2), and women who are just outside the eligibility criteria for Healthy Start (group 3). The quantitative component of the evaluation involves the secondary analysis of two existing datasets: Growing Up in Scotland (2011 and 2013) and the Infant Feeding Survey (2010). Therefore, the study is limited by the data available and will not include assessment of food and nutrient intakes. The primary outcomes are vitamin use in pregnancy (maternal outcome) and breastfeeding initiation and duration (infant outcome). Secondary outcomes include child growth, child morbidity, child feeding and maternal health. A gap remains in the evidence base for a national evaluation of the impact of Healthy Start (especially the food vouchers) on the nutritional outcomes of low-income pregnant women and young children, as highlighted in chapter 2.

Therefore, the optimal study design for a future evaluation of Healthy Start would combine a robust quantitative assessment of its impact on nutritional outcomes (including women's food and nutrient intakes, infant feeding practices and children's food and nutrient intakes) and a qualitative study with a subsample of participants to explore how and why those outcomes occur. Ideally, it would be a longitudinal study with a large, nationally representative sample. This study design would enable subgroup comparisons and assessment of short and long-term effects. If the realist evaluation approach was adopted, a multi-method approach would allow further investigation of the linkages between context, mechanisms and outcomes. It would also generate sufficient data to develop cumulative or sequential CMO configurations, to explain how the short-term outcomes of the Healthy Start programme (including those identified in this study for low-income pregnant women) might alter the context in which long-term nutrition and health outcomes are determined.

7.7 Chapter summary

This discussion chapter considered the original contribution of this study – the application of realist evaluation methodology to develop evidence-based programme theories about how low-income pregnant women use food vouchers from the Healthy Start programme. This contribution was extended by integrating the programme theories with existing behaviour change theories (more abstract middle-range theories). The key findings were presented in an overarching theoretical model for Healthy Start. This model illustrates the combination of context and resources needed to generate the intended outcome of dietary improvements for low-income pregnant women, and the mechanisms by which this outcome may be generated. The use of theory in this study sets it apart from previous studies of Healthy Start and marks a turning point in how the programme will be conceptualised. This chapter concluded by discussing the implications of this study for policy and practice, and made recommendations for further research on Healthy Start.

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Appendix A: Publication of realist review in BMJ Open (April 2017)

Open Access Research

BMJ Open

A realist review to explore how low-income pregnant women use food vouchers from the UK's Healthy Start programme

Heather Ohly, Nicola Crossland, Fiona Dykes, Nicola Lowe, Victoria Hall-Moran

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College of Health and Wellbeing, University of Central Lancashire, Preston, UK

Correspondence to
Heather Ohly;
HOhly@uclan.ac.uk

ABSTRACT

Objectives To explore how low-income pregnant women use Healthy Start food vouchers, the potential impacts of the programme, and which women might experience these impacts and why.

Design A realist review.

Eligibility criteria for selecting studies Primary or empirical studies (of any design) were included if they contributed relevant evidence or insights about how low-income women use food vouchers from the Healthy Start (UK) or the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) programmes. The assessment of 'relevance' was deliberately broad to ensure that reviewers remained open to new ideas from a variety of sources of evidence.

Analysis A combination of evidence synthesis and realist analysis techniques was used to modify, refine and substantiate programme theories, which were constructed as explanatory 'context–mechanism–outcome'–configurations.

Results 38 primary studies were included in this review: four studies on Healthy Start and 34 studies on WIC. Two main outcome strands were identified: dietary improvements (intended) and financial assistance (unintended). Three evidence-informed programme theories were proposed to explain how aspects of context (and mechanisms) may generate these outcomes: the 'relative value' of healthy eating (prioritisation of resources); retailer discretion (pressure to 'bend the rules'); the influence of other family members (disempowerment).

Conclusions This realist review suggests that some low-income pregnant women may use Healthy Start vouchers to increase their consumption of fruits and vegetables and plain cow's milk, whereas others may use them to reduce food expenditure and save money for other things.

Strengths and limitations of this study

- First study to articulate, develop and test programme theories about Healthy Start.
- Inclusion of relevant studies from a similar programme in the USA (Women, Infants and Children).
- Some evidence not transferable due to population and programme differences.
- Insufficient evidence to link context–mechanism–outcome configurations to sociodemographic and cultural characteristics.

BACKGROUND

Healthy Start is the UK government's food voucher programme for low-income pregnant women and young children. It was introduced in 2006, after the Acheson Review drew attention to income as one of the major determinants of health (and nutrition) inequalities, and highlighted the importance of nutrition for women of childbearing age and their children.[1] The Committee on Medical Aspects of Food and Nutrition Policy was asked by the government to review the long-standing Welfare Food Scheme, which was subsequently replaced by Healthy Start.[2]

Women are eligible for Healthy Start if they receive income-related benefits or child tax credit and an annual household income of £16 190 or less. Pregnant women aged under 18 are eligible regardless of their income. The weekly voucher values are: one voucher per week during pregnancy (£3.10); two vouchers per week for each baby under 1 year (£6.20) and one voucher per week for each child aged 1–4 years (£3.10). The vouchers can be exchanged for fruits and vegetables, plain cow's milk or infant formula. Retailers must be registered with the scheme to accept and claim payment for the vouchers. Healthy Start also offers free vitamins for eligible women and children, but there have been problems with uptake of vitamins.[3] Some areas offer free vitamins to all pregnant women and young children and the option of universalising Healthy Start vitamins remains under review (at the time of writing) by the chief medical officer. Therefore, this review focused on the food voucher component of the programme and low-income pregnant women as the first beneficiaries.

Healthy Start aims to provide a 'basic nutritional safety net' and to encourage 'women and families to make positive nutritional choices affecting their longer term health' (p 4).[4] Therein lies an implicit programme assumption that women will use the vouchers to purchase target foods (ideally in greater quantities than they did before) leading to dietary improvements. The vouchers may have been conceived as a financial incentive for dietary improvements, although this was not explicit in policy documentation. Since the introduction of Healthy Start in 2006, there has been no robust evaluation of its impact on nutritional outcomes—despite recommendations published in an early scoping review.[5] However, qualitative studies have indicated a range of experiences, motivations and perceived outcomes, with not all low-income women using the vouchers to improve their diets.[6 7] This review was undertaken to explore how low-income pregnant women use Healthy Start food vouchers, the potential impacts of the programme, which women might experience these impacts and why.

The realist approach was adopted because it is based on the understanding that different individuals or groups of individuals are likely to respond to any programme (or intervention) in different ways. It is a theory-driven approach that seeks to explore outcome patterns (or demiregularities) and offer plausible explanations for how and why they occur. The purpose of realist synthesis is to 'articulate underlying programme theories and then to interrogate the existing evidence to find out whether and where these theories are pertinent and productive' (p 74).[8] The stages of conducting a realist review tend to be iterative and overlapping—a gradual process of developing, testing and refining programme theories. Evidence may be obtained from studies of the programme itself, or more widely from similar programmes that are thought to work in similar ways. Reviewers may adapt and modify existing theoretical frameworks or 'middle-range' theories to help develop their own explanations. The unit of analysis is the programme theory (rather than the specific programme) and this can be considered at different levels of abstraction.

Programme theories are often constructed as 'context–mechanism–outcome' (CMO) configurations, and evidence is sought to substantiate the causal linkages. The logic of realist explanation is that outcomes are caused by mechanisms, and mechanisms may (or may not) be 'triggered' in certain contexts.[8] Context refers to the pre-existing conditions into which the programme is introduced, and there are four layers of context: individual, interpersonal, institutional and infrastructural. Mechanisms are defined as the reasoning and reactions of individuals in response to the resources offered by the programme. A core principle of realism is that mechanisms generate outcomes—they are not a direct result of the programme.

This realist review aimed to explore the following questions:

1. How do low-income pregnant women use Healthy Start vouchers?
2. What are the intended and unintended outcomes of the programme?
3. What are the underlying mechanisms and how do variations in context influence (enable or constrain) these mechanisms?

A preliminary search confirmed the paucity of empirical studies on Healthy Start and we felt that additional sources of empirical evidence would be needed to explore these research questions. The most obvious source of potentially relevant evidence was the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) in the USA. WIC is the only other national food subsidy programme for low-income women of childbearing age, including pregnant and postpartum women and young children. It was first introduced in 1972 and revised in 2009 to reflect current dietary guidelines.[9] The WIC food package for pregnant women is different to Healthy Start, with 'maximum monthly allowances' for a range of foods (reduced-fat milk, whole grain cereals, eggs and pulses) and 'cash value vouchers' for fruits and vegetables. The other main programme difference is mandatory WIC nutrition education for all beneficiaries. There are also many contextual differences between the USA and the UK, such as sociodemographic, cultural, geographical and political characteristics. Despite these differences, there are also likely to be similarities in terms of how low-income women respond to the programme (ie, mechanisms).

METHODS

Study protocol and ethical approval

The protocol for this realist review was registered with the International Prospective Register of Systematic Reviews (PROSPERO 2014: CRD42014015050). There were no changes to the review process since this protocol was published. Ethical approval was obtained from the University of Central Lancashire Science, Technology, Engineering, Medicine and Health Ethics Committee in May 2015.

Programme theory development

This review is about a programme that already exists, with implicit theories and assumptions about how it works and what effects it may have on beneficiaries.[8] Therefore, we used a 'bottom up' approach to theory development in this review, as described by Shearn and Allmark (Realist Research Seminar Series, Sheffield Hallam University, 2016). In other words, we developed theories using information about the Healthy Start food voucher programme rather than theorising at a more abstract level. Candidate theories (or initial, untested theories) were identified and prioritised using information derived from academic and grey literature on Healthy Start, an intervention mapping exercise, existing knowledge, creative thinking, consultations with stakeholders (in person and by email) and discussions among the review team. The stakeholder group included six midwives, two academics and two

public health practitioners, who all shared first-hand experiences and insights about how the Healthy Start programme works in practice.

We developed candidate theories about how low-income pregnant women might experience Healthy Start and what contextual factors might influence their reasoning and reactions (mechanisms) at each of the following stages: access to the programme starting at the first trimester antenatal appointment (eg, issues around clear communication and understanding of eligibility criteria and entitlement); the application process (eg, barriers and facilitators to successfully receiving the vouchers); whether and where women use the food vouchers (eg, issues around convenience and stigmatisation); and how women use the food vouchers (eg, to buy more of the target foods or to save money). We decided to prioritise the last stage of the programme pathway: once an eligible pregnant woman has received the food vouchers, how does she use them and why? This decision reflected the research priorities identified from the literature, the interests of the research team and the time and resources available to conduct this review. The candidate theories we tested were proposed explanations for why women might use Healthy Start to improve their diets during pregnancy, such as motivations and values relating to health benefits. We also considered reasons why women might use their vouchers in alternative ways, including prioritisation of resources, pressure to bend the rules and disempowerment.

Search strategy

Separate searches were conducted for Healthy Start and WIC:

Healthy Start

Studies were identified through manual, purposive, snowball and citation searches (January to March 2015). The search terms used initially were 'Healthy Start' and 'UK' because there is another programme called Healthy Start in the USA, which aims to prevent infant mortality. More precise search terms were not needed due to the paucity of empirical studies and familiarity with the literature.

Program for Women, Infants and Children

A broad search strategy was devised in collaboration with an information specialist in the Collaboration for Leadership in Applied Health Research and Care North West Coast. This strategy was adapted and run in six electronic databases in September 2015: MEDLINE, EMBASE, CINAHL, Open Grey, ETHOS and PubMed. Table 1 shows the search terms used in MEDLINE. No date or language restrictions were used. Reference lists of included studies were checked for additional studies. An online list of WIC studies was also checked for additional studies.[10]

Inclusion criteria

Primary or empirical studies (of any design) were included if they contributed relevant evidence or insights about how low-income women use food vouchers from the Healthy Start (UK) or WIC (USA) programmes. An assessment of 'relevance' is essential in realist synthesis to ensure that all included studies contribute to theory development, refinement and testing.[8 11] In this review, the interpretation of 'relevance' was deliberately broad to ensure that reviewers remained open to new ideas from a variety of sources of evidence. A bespoke system was used to maintain a consistent and transparent approach. Table 2 shows the questions used to assess relevance. These questions were developed by the review team and finalised towards the end of the theory development stage to ensure they reflected the candidate theories we wanted to test. Studies that scored 5/8 or more (based on the total number of yes answers) were included.

Table 1 Search strategy used in MEDLINE to identify women, infants and children (WIC) studies

#	Search terms	Results
1	WIC.tw.	1008
2	(nutrition or food or voucher or 'nutrition program').tw.	377 002
3	1 and 2	599
4	(Special* adj4 Supplement* adj4 Nutrit* adj4 Program* adj4 Women* adj4 Infant* adj4 Child*).tw.	415
5	3 or 4	688

Study selection

Results from the WIC database searches were uploaded into RefWorks (web version; ProQuest; Michigan, USA) and screened using titles and abstracts. Studies that appeared to meet the inclusion criteria were obtained

Table 2 Questions used to assess the relevance of primary studies

#	Question
1	Do the research questions or study aims refer to Healthy Start or Women, Infants and Children (WIC)?
2	Does the study focus on the food voucher (cash value voucher or food package for WIC) component of the programme?
3	Does the study focus on beneficiaries (women who were receiving the vouchers) rather than eligibility status (women who were eligible to receive the vouchers)?
4	Does the sample include pregnant women?
5	If the sample does not include pregnant women, could some of the findings be generalisable to pregnant women?
6	Does the study report women's food or nutrient intakes (measured or perceived)?
7	Does the study provide any insights about how food vouchers are used?
8	Does the study provide any insights about which women may benefit most/least and why?

as full-text articles. Studies for which insufficient information was available to determine relevance were also obtained as full-text articles. The full-text screening process was fully documented using Microsoft Excel 2013 V.15.0.4815.1001, including assessments of relevance and reasons for exclusions. The same criteria were applied to studies of Healthy Start. Study selection was completed by the lead reviewer (HO) and double checked by a second reviewer (VM). Any disagreements were resolved by discussion.

Data extraction

Quantitative data on women's nutritional outcomes were extracted using bespoke tables in Microsoft Word 2013 V.15.0.4815.1001. Other non-relevant data were not extracted. Qualitative data, textual descriptions of findings and author interpretations were extracted using MAXQDA V.11. A coding system was created with three main headings: context, mechanisms and outcomes. Subheadings were added deductively (based on candidate theories) and inductively (as new themes emerged from the data). Data extraction was completed by the lead reviewer (HO), and a sample was double checked by a second reviewer (NC).

Quality appraisal

Studies were not formally appraised at the data extraction stage, as would be the case in traditional systematic reviews. Instead, an assessment of 'rigour' was used to judge the credibility and trustworthiness of the evidence as it was integrated into the analysis and synthesis.[8 11] This assessment was not scored because weaker studies were still included, but it meant that methodological limitations were acknowledged and study findings were not overinterpreted. Table 3 shows the questions used to assess rigour. Quality appraisal was completed by the lead reviewer (HO) and double checked by second reviewers (NL/VM).

Analysis and synthesis

This process involved gradual and iterative theory development, whereby evidence from primary studies was used to modify, refine and substantiate programme theories about how low-income pregnant women use Healthy Start vouchers, in what circumstances and why. Theories were constructed as explanatory CMO configurations, usually by starting with the outcome and working backwards to determine 'what caused it (the mechanism) and under what contexts was the mechanism triggered'.[12] The main focus of the analysis was searching for evidence to support and refute the proposed causal linkages between context, mechanisms and outcomes. A combination of evidence synthesis and realist analysis techniques was used:

1. Narrative synthesis of quantitative data on women's nutritional outcomes; meta-analysis was not appropriate due to heterogeneity of study designs and data collection methods (and was beyond the scope of this review).
2. Thematic synthesis of qualitative data, by creating codes and themes (as described under data extraction) and then 'going beyond' the interpretations of the original studies to generate new understandings or hypotheses.[13]
3. Creative theorising or 'retroduction' by the lead reviewer (HO) in collaboration with the review team and the stakeholder group. This involved in-depth reflection and discussions (throughout the review) about the underlying causes of outcome patterns, at the level of generative mechanisms and explanatory context. The data from included studies did not always provide such in-depth insights and explanations. Where individual extracts of data only supported part of the CMO configuration, it was necessary to make logical inferences about the complete causal pathways and explanations.[14]

Table 3 Questions used to assess the rigour of primary studies

#	Question
1	Are the study methods clearly reported (including study design, recruitment, data collection and analysis)?
2	Are the study methods appropriate to answer the research questions?
3	Are the sample characteristics reported to enable judgements about generalisability?
4	Are the study findings and conclusions supported by raw data?
5	Are the study limitations acknowledged and clearly reported?

RESULTS

Search results and study characteristics

A total of 908 records were identified through the two separate searches. After screening titles and abstracts, 88 records were obtained in full-text format. Fifty full-text articles were excluded based on the assessment of relevance (n=33) or because they were not primary studies (n=15) or the findings were duplicated (n=2). Therefore, 38 primary studies were included in this review: four UK studies on Healthy Start[6 7 15 16] and 34 US studies on WIC[17–50] (see online PRISMA Flow Diagram and online supplementary file 1).

Identification of outcomes and supporting evidence

Two main outcome strands emerged during the theory development stage and were further substantiated using evidence from primary studies:

1. Women use vouchers to increase consumption of target foods—dietary improvements.
2. Women use vouchers to reduce food expenditure—financial assistance.

For the purposes of this review, we have assumed that strand 1 is the intended outcome of the programme and strand 2 is an unintended outcome. This was not explicit

in policy documentation, but there were references to dietary improvements which were thought to be achieved by enabling low-income women to access healthier foods and encouraging positive nutritional choices.[4] The included studies provided support for both outcome strands. The next section provides an overview of the available evidence on women's outcomes (intended and unintended) and highlights the relative contribution of evidence from Healthy Start and WIC studies. It also helps to illustrate how we worked backwards from outcomes to identify generative mechanisms and related aspects of context.

A total of 25 studies reported women's nutritional outcomes: three studies on Healthy Start and 22 studies on WIC. The Healthy Start studies reported perceived outcomes only; some women said they consumed more cow's milk, fruits and vegetables after receiving Healthy Start vouchers,[6 7 16] whereas other women said the vouchers 'freed up money to do other things' and 'helped them to manage better financially' (p 59).[7] The WIC studies were published between 1981 and 2015, but the most useful data was extracted from two studies comparing women's diets before and after the 2009 WIC revisions when the 'cash value vouchers' for fruits and vegetables were introduced (there was no allowance for fresh fruits and vegetables before 2009). A longitudinal study of African–American and Hispanic women from WIC clinics in Chicago (n=273) found significant dietary improvements for Hispanic mothers who reported consuming more fruit, more reduced fat milk less whole milk and less saturated fat (all p<0.05).[39] African–American mothers reported consuming less whole milk (p=0.02) but no other changes were statistically significant.[41] There were no sustained dietary improvements in either group compared with baseline at 18 months.[38] A cross-sectional study comparing two random samples of WIC participants in California (both 80% Hispanic) found that women assessed 6 months after the changes (n=2996) reported consuming significantly more whole grains, reduced-fat milk and vegetables and less whole milk compared with women assessed before the changes (n=3004) (all p<0.001).[42]

Five studies reported electronic sales data from WIC retailers (one large supermarket chain) in New England, which showed that women's purchasing patterns shifted towards items provided in the WIC package after the 2009 revisions—fruits and vegetables, reduced-fat milk, brown rice, whole grain cereals and bread replaced less nutritious options.[18–22] One study (n=2137) showed that, while total spending on fruits and vegetables increased between 2009 and 2010 (p<0.001), up to 13% fewer purchases were made using non-WIC funds.[22] This implies that some women 'substituted' the method of payment, rather than using WIC to increase the amount of fruits and vegetables purchased. None of these studies reported sample characteristics such as ethnicity. Finally, a mixed-methods study of Hispanic and African–American pregnant women (n=313) found that two-thirds of women reported using WIC vouchers to reduce food expenditure.[35] The money they saved was used to purchase items for the unborn baby, other foods and for bills and emergencies.

These findings suggest that food vouchers may lead to dietary improvements for some, but not all women. This may be because some women use the vouchers to pay for foods they would previously have bought using cash. The WIC studies described above were not representative of ethnic groups in the UK, and the samples included mothers as well as pregnant women. However, these studies provide much needed evidence on the potential impact of food vouchers for low-income women, which was not available from the Healthy Start literature alone.

Evidence-informed programme theories

This section presents three evidence-informed programme theories, which help to explain why different women receive the same Healthy Start vouchers and yet experience different outcomes because of variations in context and mechanisms. Figure 1 illustrates the key aspects of context, mechanisms and outcomes identified and the proposed causal pathways linking them together. These causal pathways are explained as CMO configurations and illustrated using quotations from included studies under each theory. Although low income is clearly an important aspect of context, we have not included it in our programme theories because it applies to all women who receive Healthy Start vouchers (apart from under 18s). As the programme theories explain, some women may achieve dietary improvements despite low income,

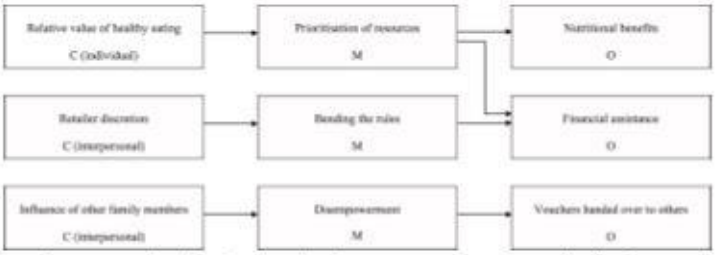

Figure 1 Summary of programme theories about how low-income pregnant women use Healthy Start vouchers.

and other women may not—this divergence depends on other aspects of context.

Prioritisation of resources

Women living on low income must constantly prioritise how they spend their money. Food vouchers may be considered as one part of the household resources and decisions must be made about how best to use the vouchers. A key aspect of individual level context is the 'relative value' of healthy eating (compared with other things women value), which can lead women to prioritise in different ways. Context is not static and women's values may change over time, so we propose that some women may fluctuate between the mechanisms (ways of prioritising) outlined in these two contrasting CMO configurations.

Women who value healthy eating and aspire to eat well during pregnancy (context)[47] are more likely to perceive Healthy Start vouchers as an opportunity to achieve health benefits for themselves and their unborn baby (mechanism).[6] The vouchers alleviate the financial barrier associated with healthy eating and make healthy foods seem more affordable (mechanism).[6] Therefore, women who value healthy eating are more likely to prioritise healthy eating (mechanism) and use Healthy Start vouchers to increase consumption of target foods—fruits and vegetables or cow's milk (outcome).[6]

'I have them at Asda when I do my shop, and I think how many vouchers I've got and I buy the veg that I have the vouchers for. I suppose if I didn't have the vouchers, I would just pick out the little things. I don't think if I didn't have the vouchers I'd buy half as much, no.' (Mother, UK; p 50)[6]

Alternatively, women may value healthy eating less than other things they want or need to spend money on, which are considered more important or urgent (context).[6 7] They are more likely to perceive Healthy Start vouchers as a way to save money, which can be redirected and prioritised in other ways (mechanism).[6 7] These women are more likely to use Healthy Start vouchers to deduct money from the shopping bill, with no increase in consumption of target foods (outcome).[6 7 33]

'Women are often in a dilemma about whether they should or shouldn't eat healthy foods because something else is needed more. Their own health and maybe the health of their younger children are on the back burner because something else is more pressing.' (Midwife, UK; page 35)[6]

Bending the rules

The Healthy Start voucher exchange system relies on registered retailers to verify (visually) at the checkout that women have selected appropriate amounts of appropriate items—fruits and vegetables, plain cow's milk or infant formula. The vouchers are processed by swiping a bar code that subtracts the voucher value (£3.10) from the total. They are not electronically matched to specific food items. There is a reminder printed on each voucher about which foods may be purchased, along with a warning about prosecution, but the evidence suggests that some customers and retailers appear to disregard this information.

Retailers who are registered to accept Healthy Start vouchers have some discretion over how vigilantly they check what vouchers are spent on (context).[6 15] Women may put pressure on retailers to 'bend the rules' or make exceptions (mechanism).[6 15–17 32] Some retailers may decide to 'turn a blind eye' because they feel duty bound to help families in whatever ways they can (mechanism)[6] or because they prefer to avoid conflict (mechanisms).[16] This enables women to exchange the vouchers for alternative food or non-food items (outcomes).[6 16]

'But you have to realise that I get people coming in here, they are buying £1 pound of electricity every day. £1. That must run out after an hour. How do they live? And in the winter, it really does get very cold and they come in and ask me if they can use the voucher for electricity. What can I do? I can't see them living in the flat with young children, with no heating, it's so cold. So I do let them do that. They come in and show me their empty wallet and I have to believe them and I do sell gas and electricity for the voucher. You can report that back. I don't care, what can I do?' (Retailer, UK; p 69)[6]

Disempowerment

Pregnant women (and later their young children) are the intended beneficiaries of Healthy Start, but some women may not be empowered to make decisions about how to use the vouchers themselves. The vouchers are posted to women at their home address, but there is no name printed on the actual vouchers and no identification is required at the checkout, so there is nothing to stop other people from using them. Regardless of what is bought with the vouchers, and who benefits, this would surely be considered an unintended outcome of the programme.

Women may not be empowered to make decisions about household resources or food shopping, such as pregnant teenagers who live with their parents (context)[6 47] or women who live in large, multigenerational households (context).[48] Women who are disempowered are more likely to hand over their Healthy Start vouchers to other family members (mechanism)[48] who then decide how they are used (outcome).[48]

'She (mom) makes most of the decisions. We get the same thing every time we go shopping.' (African–American mother living in multigenerational household, USA; p5).[48]

DISCUSSION

Statement of principal findings

This realist review identified two main outcome strands for low-income pregnant women using food vouchers from the Healthy Start programme: dietary improvements (intended) and financial assistance (unintended). Three evidence-informed programme theories were developed

and refined to explain how aspects of context (and mechanisms) may generate these outcomes: the 'relative value' of healthy eating (prioritisation of resources); retailer discretion (pressure to 'bend the rules'); the influence of other family members (disempowerment).

Strengths of this review

This was the first study to use a realist, theory-driven approach to investigate how low-income pregnant women use Healthy Start vouchers, in what circumstances and why. The inclusion of relevant studies from a similar programme in the USA (WIC) provided insights and explanations beyond what was available from the Healthy Start literature. This was the first time that researchers have attempted to articulate, develop and test programme theories about how Healthy Start works. Our findings suggest that Healthy Start vouchers are not always used to achieve dietary improvements. Some low-income pregnant women may need to receive more support to increase the perceived value of healthy eating. Modifications to the voucher verification system would help to prevent the vouchers being used by other people and exchanged for alternative items. We hope this review will stimulate discussions about future evaluation needs and programme development.

Limitations of this review

We were aware from the outset that some of the evidence from WIC studies would not be transferable to Healthy Start due to population and programme differences. Further evidence from the UK is needed to develop some of the other candidate theories we identified. This review focused on women's outcomes from the programme, and the aspects of context explored in our theories were individual (women's values and perceptions) and interpersonal (interactions with retailers and other family members).[8] We did not find sufficient evidence to link our CMO configurations with sociodemographic and cultural characteristics, such as which groups of women are more/less likely to value healthy eating. Future reviews in this area could include wider evidence on voucher programmes to provide insights about how the mechanisms we have identified might operate in different contexts and different programmes. This was beyond the scope of this review due to time and resource limitations. Finally, we did not explore theories relating to Healthy Start vitamins, women's decisions about infant feeding or children's outcomes. These would all be worthy areas for realist investigations.

Comparisons with existing literature and theories

This study builds on two previous evaluations of Healthy Start, which highlighted different ways of using the food vouchers: some women used the vouchers to access healthy foods that they otherwise could not afford, whereas other women used them to save money on foods they had already planned to buy and reallocated the money for other things.[6 7] Our realist review has shown how 'substitution effects' (ie, using the vouchers as an alternative method of payment) may reduce the potential impact on women's nutritional outcomes and some women may experience no dietary improvements at all. In addition, we have identified aspects of context and causal mechanisms that are likely to be important in determining outcome patterns for low-income pregnant women.

Our first programme theory relates to the economics of decision making. If women value healthy eating and want to do everything they can to give their baby the best possible start in life, these beliefs and motivations will influence the decision-making process when it comes to using the vouchers. However, other factors will also influence the decision-making process and women must consider whether additional fruits and vegetables (or cow's milk) are the most important things they need. Frick considered the everyday economic analyses that take place at family level in relation to infant and young child feeding, whereby mothers and other family members must decide how to allocate financial resources, weighing up food choices and nutrition against a range of other considerations.[51] He described how societal and individual values influence these trade-offs between nutrition and other priorities. Decisions about how to use Healthy Start vouchers are subject to similar trade-offs through the mechanism of prioritisation. Aufree found that low-income women 'strategically adjust' to poverty by prioritising or 'juggling' what they spend money on.[52] Food may be ranked below other basic needs such as rent and household bills, with more flexibility to cut back on healthy items like fruits and vegetables. Therefore, Healthy Start may be seen as a way to manage financially by reducing food expenditure. The programme provides additional resources to (ideally) enable low-income pregnant women to improve their diets, but only women who value healthy eating (and the associated health benefits for mother and child) are likely to use the vouchers in this intended way. A recent taxonomy of behaviour change techniques defined 'incentives' as rewarding and contingent on behaviour change.[53] Healthy Start does not fit this definition and should not be assumed to encourage healthy choices for all beneficiaries.

Our second programme theory relates to retailers who misuse the Healthy Start programme by allowing women to exchange vouchers for alternative items. It is presented under the context of retailer discretion, which highlights weaknesses in the system, but this theory also relates to the context of women who value other things above healthy eating. The evidence suggests that some retailers may bend the rules because they feel they are acting in the best interests of the customer. This is similar to 'responsible subversion' identified among health professionals who admitted to bending or breaking the rules for what they perceived to be patient benefits, despite contravening evidence-based practice guidance.[54] However, there may be other (unscrupulous) reasons why retailers bend the rules and

further evidence is needed to develop and explore this programme theory more fully.

Finally, our third programme theory relates to women who may not be empowered to decide how to use their Healthy Start vouchers. Their choices may be heavily influenced (or constrained) by significant others, for example a partner, mother or mother-in-law, who may take charge of food shopping and allocation of household resources. Similar issues have been identified in relation to decisions about infant feeding: women are surrounded by networks of people who participate in decision making, so they may be unable to exercise their 'right to choose' despite knowing what the options are and possessing their own opinions.[55] This may be particularly the case in communities where there are high levels of interdependence within the extended family network.

Healthy Start is dependent on individual agency to achieve dietary improvements, in contrast with other types of nutrition interventions that can be said to be less dependent on individual agency (such as food fortification). Our evidence-informed programme theories illustrate how aspects of context may enable or constrain women's agency. A recent paper by the Centre for Diet and Activity Research considered the role of individual agency in public health interventions, concluding that 'low agency' interventions are more likely to be effective and equitable by reducing the need for individual decisions.[56] Food vouchers for free fruits and vegetables were positioned in the middle of a continuum of the degree of agency required to benefit from the intervention. This review highlights some ways in which the level of agency required could be reduced in the Healthy Start programme, such as by 'tightening up' the system for verifying who uses the vouchers and what they are exchanged for. However, agency cannot be eliminated from food voucher programmes and therefore this review contributes to ongoing debates about how public health interventions should be designed to maximise outcome effectiveness.

Agency is synonymous with realist mechanisms (the reasoning and reactions of individuals in response to the resources offered by the programme), and this review illustrates the contribution of realist methodology to understanding the differential impacts of public health interventions or programmes.

CONCLUSION

This realist review suggests that some low-income pregnant women use Healthy Start vouchers to increase their consumption of fruits and vegetables and plain cow's milk (intended outcome: dietary improvements), whereas other women use them to reduce food expenditure and save money for other things (unintended outcome: financial assistance). We have identified some aspects of context (the 'relative value' of healthy eating, retailer discretion and the influence of other family members) and mechanisms (prioritisation of resources, pressure to 'bend the rules' and disempowerment) that are likely to be important in determining these outcomes. Further evidence is needed to understand how low-income pregnant women could be better supported to prioritise healthy eating and use Healthy Start vouchers to improve their diets during pregnancy— in particular to buy more fruits and vegetables. This may include ways of 'tightening up' the programme to reduce the amount of agency required but also considering ways in which women may be supported to become more empowered to choose.

Contributors HO was the lead reviewer, while other authors completed the second reviewer tasks (as indicated in the Methods). All authors contributed to the development of programme theories through regular discussions. HO drafted the initial manuscript and all authors contributed to the final manuscript.

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Appendix B: Consultation document prepared for study advisory group

Dear Advisory Group members,

For the first stage of my PhD, I have decided to conduct a realist review to explore the impact of Healthy Start on the diets of low income women. I have prepared this document to briefly explain the principles of realist synthesis, the purpose of this review and how I would like you to contribute at this stage.

Realist methodology is derived from the realist traditions in social science and philosophy. In the last decade or so it has increasingly been applied to the development and evaluation of complex social interventions and evidence-based policy. The central premise of realist methodology is that interventions (or 'programmes') are dependent on **context and implementation** (Pawson, Greenhalgh, Harvey, & Walshe, 2005). Therefore, an intervention may be successful in certain circumstances, for certain people, under certain conditions – so it is important to know what these parameters are and, crucially, **how** they influence the success of the intervention in terms of specific outcomes.

Realist synthesis offers an alternative approach to evidence synthesis, recognising the limitations of more conventional systematic review, meta-analysis and narrative review methods (Pawson, 2006). It seeks to identify the **causal or generative mechanisms** underpinning an intervention – what works, how, in what circumstances and for whom. This is done by developing and then testing **programme theories,** which may be defined as assumptions about how the intervention works. The testing phase involves systematic processes to identify, select, appraise and synthesise evidence to support/challenge each programme theory. In this way the programme theories are iteratively developed, with the end result being **evidence-informed programme theories** about an intervention.

In order for programme theories to adequately explain how an intervention works, they must take into account context (C), mechanisms (M) and outcomes (O). These components are usually linked together in **CMO configurations,** which provide a logical narrative on what the intervention is 'supposed to do' to achieve its objectives. The first task for a realist reviewer is to identify which programme theories they wish to test. An intervention may have many programme theories depending on the complexity of its context and implementation pathways.

In the case of Healthy Start, there are several stages in the intervention process and each stage influences the final outcomes. As a nutritionist, I am interested in the **nutritional outcomes** i.e. does Healthy Start improve the food and nutrient intakes of women and children; does it succeed in its aim to be a 'nutritional safety net' for low income families? These are big questions and previous studies have identified the need for a national evaluation of Healthy Start (Dyson et al., 2007; McFadden et al., 2013). This is beyond the scope of my PhD, but it is also important to explore **how** these outcomes are generated and **how** Healthy Start can be optimised to maximise the potential for nutritional improvements.

So far in my realist review, I have used the existing literature on Healthy Start to identify **candidate programme theories** about what the intervention is 'supposed to do' and alternative hypotheses about what may actually happen in practice. These are represented as CMO configurations in the other attached document – but actually these are **CRMO configurations** with resources (R) considered separately. A recent paper recommended this distinction to avoid conflating the intervention strategy (i.e. resources) with the individual's reasoning and responses to the intervention (i.e. mechanisms) (Dalkin et al., 2015). Both of these components interact with pre-existing social/cultural/economic conditions (i.e. context) to generate outcomes.

1

I have presented two candidate programme theories for two different stages (and objectives) of the intervention process:

PT1: To encourage and enable eligible pregnant women to apply for Healthy Start

PT2: To improve the nutritional outcomes of pregnant women using Healthy Start vouchers

I decided to focus on **pregnant women** as they are the first people to benefit from Healthy Start and during pregnancy the benefits are intended for them. After the baby is born, women have more complicated decisions to make about how to spend the vouchers and all sorts of new contextual factors come into play.

My preference is to focus on PT2 – what happens after eligible women receive their Healthy Start vouchers; what influences how the vouchers are used; are they used to increase women's consumption of target foods? There is limited evidence on what happens at this stage of the intervention. In contrast, two recent studies on Healthy Start focussed on the earlier implementation stages and provided rich qualitative evidence and recommendations on issues around eligibility, the application process, support from health professionals, integration with other services, poor distribution of vitamins etc. (Lucas et al., 2013; McFadden et al., 2013).

I would like to ask for your opinions on the **logic and completeness** of my candidate programme theories. Do they represent what Healthy Start sets out to achieve? Do they take account of the main contextual factors you are aware of? Have I considered the main barriers and challenges that you are aware of from your work? Remember that they do not need to be perfect as this stage – they will evolve as I go through the review process.

I am also planning consultations with midwives and low income women (eligible for and/or receiving Healthy Start) once I have received ethical approval. This will be done through small discussion groups and will help me to refine my candidate programme theories further and prioritise which ones to test.

Thank you in advance for your contributions.

Heather

Appendix C: Guest blog for The Realist Hive

Posted on 17th Jul, 2015 by Rebecca Jane Louise Hardwick

← Previous Next →

Guest Blog from Heather Ohly, PhD student, University of Central Lancashire. Support Networks for Novice Realist Researchers.

When I started my PhD in October 2014, I had barely heard of realism and was much more inclined to do a standard systematic review, having recently worked on two at the University of Exeter. So it was with some trepidation that I started to explore realist synthesis…only to discover that its core principles and approach did seem to suit my research project.

Here goes, I thought. My supervisors were enthusiastic and supportive, but none of them had ever used realist methodology. I felt like I was fumbling around in the dark for quite a while. Was this really a good idea? Can my brain think in this way?

Fortunately, I discovered that there are great support networks out there for novices like me. This blog post aims to encourage others to make the most of such networks and develop their own, to minimise and cope with the confusion that inevitably occurs when you try to learn how to do something that is at once creative, scientific, theory-driven and evidence-based.

I have benefited from three support networks so far in my journey:

RAMESES

A virtual network managed through an email distribution list that anyone can join and contribute to: https://www.jiscmail.ac.uk/RAMESES

Anyone can post a question, either about realist methodology or about your own project, and without fail you will get a thoughtful and considered response (often several) within 24 hours. This often leads to fairly high level discussions between experts from around the world, and it is fascinating to (try to) follow these and benefit from their wisdom and experience. The diverse range of contributors and questions demonstrates the scope of the realist approach and how it is gaining momentum in different disciplines. It was reassuring for me to discover that so many other people are applying it for the first time and experiencing similar uncertainties.

Frequently, some kind person will take the trouble to explain something in detail for the benefit of others. One example that I found really useful was when Peter O'Halloran from Queen's University, Belfast outlined some of the key concepts in critical realism that have helped to shape the definitions of 'context' and 'mechanism' used in scientific realism (posted 10th March 2015). As someone without a social science background, this brief introduction to 'social structure' and 'human agency' enabled me to think about my project through a different lens. Peter also made the point that there may be "a relatively small number of mechanisms at work in relation to agency (because there is a commonality in human nature) but a myriad social structures in a given context". This resonated with me and made the process of abstraction to middle range theory seem a little less daunting.

CARES

The University of Liverpool's Centre for Advancement of Realist Evaluation and Synthesis organises regular realist workshops and an annual realist summer school. These events provide an opportunity to meet other realist researchers, from novice to expert, all of whom are keen to share their experiences and learn from each other. The events are reasonably priced and usually located in Liverpool or London.

When I attended the two-day realist workshop in March 2015, I was still very unsure about what I was doing with my realist synthesis and just absorbed as much information as possible. By the time I returned for the three-day realist summer school in June 2015, I had a much better understanding and felt confident enough to share my candidate programme theories. I received individual advice and feedback from three experts: Justin Jagosh, Geoff Wong and Sonia Dalkin, and came away feeling motivated and reassured.

At both events, the groups were well-attended and cross-disciplinary. I think we all found it interesting and challenging working through examples of CMO configurations from projects very different to our own. It helped me to see the logic of the realist approach shining through and also to appreciate its strengths and limitations compared to alternative research methods. A previous blog post by David Blane summarised his experience of the 2014 summer school and I would echo his sentiments about the 'mechanisms' of a supporting environment in which to learn – more on that later.

'Realist club'

At the first CARES event I attended, I connected with two other researchers called Sue Mann (UCL) and Katie Shearn (Sheffield Hallam University) and we decided to stay in touch and share our realist journeys through monthly Skype chats. Our projects have some similarities and many differences, but we are all using realist methods for the first time. We take turns to discuss our own programme theories and CMO configurations, and my experience has been that I benefit just as much from discussing their projects as my own.

One thing we are all finding challenging is defining the scope and limitations of what we can do with the time and resources we have – this is very different for Katie and I as PhD students, compared to Sue who is managing a large programme of work across several developing countries – each challenging in its own way. It helps to communicate the logic of what you have done and gain fresh perspectives from people who are detached from your project. Tomorrow we are discussing Katie's project and she has sent us a fascinating collection of slides entitled 'conceptualising context and time'.
A small group seems to work well because we all get regular individual attention! However, we have been thinking about ways to share our discussions more widely, such as recording our Skype chats and developing a Wiki resource.

Programme theory?!

Building on David Blane's ideas about context, mechanisms and outcomes for the CARES summer school, I'd like to propose a candidate programme theory (yes, my arm was twisted to do this):

Realist methodology is flexible, iterative and evolving (context). This means it can be confusing, especially the first time it is used (context). Support networks provide opportunities for shared learning and promotion of best practice with regards the core principles of realist methodology (mechanism: resource). This helps novice researchers to feel confident in their work and stay motivated (mechanism: response), which ultimately means they produce higher quality work and become better realist researchers (hopeful outcomes).

This is probably way too simplistic and I'm sure many people could articulate this better than me, but hey at least I'm confident to try now…so maybe confidence should have been the outcome…??

Heather Ohly, PhD student, University of Central Lancashire
Find me on Linked-In
Follow me on Twitter @heatherohly
Review registered on Prospero, Reference No. CRD42014015050. A realist review to explore how low-income pregnant women use good vouchers from the UK's Healthy Start programme.

This entry was posted in **Uncategorized** by **Rebecca Jane Louise Hardwick**. Bookmark the **permalink**.

Appendix D: Assessment of relevance in realist review (full text screening of WIC studies)

Authors, Primary	Title Primary	Periodical Full	Pub Year	FT found HO	FT found EK	Notes on FT	Study design	Primary study WIC	R1	R2	R3	R4	R5	R6	R7	R8	Relevance score	Included?	#	PRISMA reason for exc
Adedze,P.;Chapman-I	Knowledge, attitudes	Family & community	2011	No	Yes		Quant	Yes	Yes	No	Yes	No	No	No	No	No	2	No		Relevance score 4/8 or less
Anderson,C. K.;Walch	Excess Gestational W	Journal of Nutrition E	2015	Yes	NA		Qual	Yes	No	No	No	Yes	.	Yes	No	Yes	3	No		Relevance score 4/8 or less
Andreyeva,T.;Luedick	Incentivizing fruit an	Public health nutritic	2015	No	Yes		Quant	Yes	Yes	Yes	Yes	Unclear	Yes	No	Yes	No	5	Yes	1	
Andreyeva,T.;Luedick	Federal food packag	American Journal of I	2013	Yes	NA		Quant	Yes	Yes	Yes	Yes	Unclear	Yes	No	Yes	No	5	Yes	2	
Andreyeva,T.;Luedick	The positive effects (	Journal of the Acade	2014	Yes	NA		Quant	Yes	Yes	Yes	Yes	Unclear	Yes	No	Yes	No	5	Yes	3	
Andreyeva,T.;Luedick	Grocery store bevera	American Journal of I	2012	Yes	NA		Quant	Yes	Yes	Yes	Yes	Unclear	Yes	No	Yes	No	5	Yes	4	
Andreyeva,T.;Luedick	Positive influence of	Journal of the Acade	2012	Yes	NA		Quant	Yes	Yes	Yes	Yes	Unclear	Yes	No	No	No	4	No		Relevance score 4/8 or less
Andreyeva,T.;Luedick	Effects of reduced jui	Pediatrics	2013	Yes	NA		Quant	Yes	Yes	Yes	Yes	Unclear	Yes	No	Yes	No	5	Yes	5	
Andreyeva,T.;Middlet	Food retailer practice	Public health nutritic	2011	Yes	NA		Quant	Yes	Yes	Yes	Yes	Unclear	Yes	No	Yes	No	5	Yes	6	
Anliker,J.;Damron,D.;	Using peer educators	Journal of Nutrition E	1999	No	Yes		Mixed	WIC 5 a day	Yes	No	Yes	Unclear	Yes	No	No	No	3	No		Relevance score 4/8 or less
Au,L.;Whaley,S.;Rosei	A randomized contro	FASEB Journal	2015	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Ayala,G. X.;Laska,M. I	Stocking characterist	Public health nutritic	2012	Yes	NA		Quant	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	5	Yes	7	
Bensley,J.;Anderson,'	Impact of Internet vs	Journal of the Americ	2011	Yes	NA		Quant	WIC education	Yes	No	Yes	No	Yes	Yes	No	No	4	No		Relevance score 4/8 or less
Berkenfield,J.;Schwai	Nutrition interventio	New England Journal	1980	No	Yes		Not research	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Bertmann,F. M.;Barro	Women, infants, and	Journal of Nutrition E	2014	Yes	NA		Qual	Yes	Yes	Yes	Yes	Yes	.	No	Yes	Yes	6	Yes	8	
Bertmann,F. M.;Barro	A Study Assessing Pe	Journal of the Acade	2014	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Birkett,D.;Johnson,D.	Reaching low-income	Journal of the Americ	2004	No	Yes		Qual	Yes	Yes	No	Yes	No	Yes	No	No	No	3	No		Relevance score 4/8 or less
Black,A. P.;Brimbleco	Food subsidy prograr	BMC Public Health	2012	Yes	NA		Review	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Black,M. M.;Hurley,K.	Participants' commer	Journal of the Americ	2009	Yes	NA		Mixed	Yes	Yes	Yes	Yes	Yes	.	No	Yes	No	5	Yes	9	
Blankenbaker,R. G.	WIC: a food program	Journal of the Indian	1981	Yes - ILL	No		Not research	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Carroll,J. M.;Stein,C.;E	Using interactive mu	Journal of Nutrition E	1996	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Chang,M. W.;Nitzke,S	Motivators and barri	Journal of the Americ	2008	Yes	NA		Qual	Yes	No	No	Yes	No	Yes	No	No	No	2	No		Relevance score 4/8 or less
Chen,D. Y.;Gazmarari	Impact of personal p	Journal of Nutrition E	2014	Yes	NA		Quant	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	6	Yes	10	
Emerson,J. S.;Towns,I	Racial/ethnic and W	Journal of Health Car	2015	Yes	NA		Quant	Yes	Yes	Yes	Yes	No	No	No	No	Yes	4	No		Relevance score 4/8 or less
Emmons,L.	Food procurement ar	Journal of the Americ	1986	Yes - ILL	No		Quant	No	No	No	No	Unclear	No	Yes	No	No	1	No		Not primary study
Endres,J.;Dunning,S.;I	Older pregnant wom	Journal of the Americ	1987	Yes - ILL	No		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	No	Yes	6	Yes	11	
Endres,J. M.;Sawicki,I	Dietary assessment (	Journal of the Americ	1981	Yes - ILL	No		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	No	No	5	Yes	12	
Farrior,E. S.;Ruwe,C. I	Women, infants and	Nutrition Research	1987	No	Yes		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	No	No	5	Yes	13	
Greenblatt,Y.;Gomez,	Optimizing nutrition	FASEB Journal	2015	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Greig,E.;Davis,S.;Myei	Women Infants and (	Journal of Investigati	2011	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Hamilton,C. Y.;Schille	Nutrition attitudes, p	Journal of the Americ	1994	No	Yes		Quant	Yes	Yes	No	Yes	No	No	No	No	Yes	3	No		Relevance score 4/8 or less
Havas,S.;Treiman,K.;L	Factors associated w	Journal of the Americ	1998	Yes	NA		Quant	WIC 5 a day	Yes	No	No	Yes	.	Yes	No	Yes	4	No		Relevance score 4/8 or less
Herman,D. R.;Harriso	Effect of a targeted s	American Journal of I	2008	Yes	NA		Quant	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	5	Yes	14	
Herman,D. R.;Harriso	Choices made by low	Journal of the Americ	2006	Yes	NA		Quant	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	6	Yes	15	
Hillier,Amy;McLaughl	The Impact of WIC Fo	Journal of Nutrition E	2012	Yes	NA		Quant	Yes but not all WI	Yes	Yes	No	No	Yes	No	No	No	3	No		Relevance score 4/8 or less
Horswill,L. J.;Yap,C.	Consumption of food	Journal of the Americ	1999	Yes	NA		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	No	Yes	6	Yes	16	
Huber,C.	WIC update: the phys	Wisconsin medical jo	1995	Yes - ILL	No		Not research	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Joyce,T.;Racine,A.;Yur	Reassessing the WIC	Journal of Policy Ana	2008	No	Yes	Found worki	Quant	Yes	Yes	Yes	Yes	Yes	.	No	No	No	4	No		Relevance score 4/8 or less
Kane,A.	The Women, Infants,	International Journa	1999	No	Yes		Not research	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Keane,P.	Barriers and facilitat	FASEB Journal	2014	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Kim,L.;Koleilat,M.;Wh	Qualitative evaluatic	FASEB Journal	2014	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Kim,L. P.;Whaley,S.;He	Using mixed method	FASEB Journal	2011	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Koleilat,M.;Vargas,N.	Beliefs regarding we	FASEB Journal	2015	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Koleilat,M.;Whaley,S	Gestational weight g	FASEB Journal	2012	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only

Authors, Primary	Title Primary	Periodical Full	Pub Year	FT found HO	FT found EK	Notes on FT	Study design	Primary study WIC	R1	R2	R3	R4	R5	R6	R7	R8	Relevance score	Included?	#	PRISMA reason for exc
Koleilat,M.;Whaley,S	Trends and predictor	Maternal & Child Hea	2013	No	Yes		Quant	Yes	Yes	Yes	Yes	Yes	.	No	No	No	4	No		Relevance score 4/8 or less
Kong,A.;Odoms-Youn	Racial/ethnic differe	Journal of Nutrition E	2013	Yes	NA		Quant	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	6	Yes	17	
Kong,A.;Odoms-Youn	The 18-month impact	American Journal of I	2014	Yes	NA		Quant	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	5	Yes	18	
Kropf,M. L.;Holben,D.	Food security status	Journal of the Americ	2007	Yes	NA		Quant	WIC and FMNP	Yes	No	Yes	Yes	.	Yes	No	No	4	No		Relevance score 4/8 or less
Laska,M. N.;Caspi,C. E	Lack of Healthy Food	Preventing Chronic Di	2015	Yes	NA		Quant	No	Yes	No	No	Unclear	Yes	No	No	No	2	No		Not primary study
Lewis,M. T.	Special supplementa	Tennessee Medicine	2003	Yes - ILL	No		Not researcl	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Lindsay,A. C.;Sussner	Influence of social c	Health Education & B	2009	Yes	NA		Qual	No	No	No	No	No	No	No	No	No	0	No		Relevance score 4/8 or less
Mangels,Reed	Revisions to the WIC	Vegetarian Journal	2014	Yes	NA		Not researcl	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Mathews,L.;Morris,M	The relationship bet	Journal of Hunger an	2010	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Meiqari,L.;Torre,L.;Ga	Exploring the Impact	Journal of Health Car	2015	Yes	NA		Quant	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	6	Yes	19	
Morgan, R.	Perceptions of the Ac	Journal of Nutrition E	2012	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Navaie,M.;Glik,D.;Sal	Communication effec	Journal of Nutrition E	1994	No	Yes		Qual	Yes	Yes	No	Yes	No	Yes	No	No	No	3	No		Relevance score 4/8 or less
Nestor,B.;McKenzie,J.	Client satisfaction w	Journal of Nutrition E	2001	No	Yes		Mixed	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes	5	Yes	20	
Nunnery,D.;Dharod,J.	Prenatal food insecu	FASEB Journal	2015	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Odoms-Young,A.;Kon	Evaluating the initial	Public health nutritic	2014	Yes	NA		Quant	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	Yes	21	
Park,H.;Kim,J.;Uhm,S.	Nutrition education a	The FASEB Journal	2009	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Pelto,J. M.	Results of a nutritior	Alaska Medicine	1982	Yes - ILL	No		Review	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Perez-Escamilla,R.;Sc	Place of residence m	Journal of Immigrant	2011	Yes	NA		Quant	Yes	Yes	No	Yes	No	No	No	No	No	2	No		Relevance score 4/8 or less
Peterman,J.;Cordeiro,	Healthful cultural for	FASEB Journal	2014	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Reyes,N. R.;Klotz,A. A	A qualitative study o	Journal of the Acade	2013	Yes	NA		Qual	Partial WIC sampl	No	Yes	No	Yes	.	Yes	Yes	Yes	5	Yes	22	
Ritchie,L. D.;Whaley,S	Satisfaction of Califo	Journal of Nutrition E	2014	Yes	NA		Quant	Yes	Yes	Yes	Yes	Yes	.	No	No	No	4	No		Relevance score 4/8 or less
Ritchie,L. D.;Whaley,S	Favorable impact of t	Journal of Nutrition E	2010	Yes	NA		Quant	Yes	Yes	No	Yes	Yes	.	Yes	No	No	4	No		Relevance score 4/8 or less
Rush et al.	The National WIC Eva	American Journal of (	1988	No	Yes		Quant	Yes	.	.	.	.	.	.	.	.	.	No		Duplication
Rush,D.;Horvitz,D. G.;'	The National WIC Eva	American Journal of (	1988	Yes	NA		Quant	No methods only	.	.	.	.	.	.	.	.	.	No		Not primary study
Rush,D.;Kurzon,M. R.;'	The National WIC Eva	American Journal of (	1988	Yes	NA		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	Yes	7	Yes	23	
Rush,D.;Sloan,N. L.;Le	The National WIC Eva	American Journal of (	1988	Yes	NA		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	No	Yes	6	Yes	24	
Schneider, J.	WIC Participants' Per	Journal of Nutrition E	2012	No	No	Abstract only	.	.	.	.	.	.	.	.	.	.	.	No		Abstract only
Schultz,D. J.;Byker Sha	The Impact of the 200	J Acad Nutr Diet	2015	Yes	NA		Review	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Seth,J. G.;Isbell,M. G.	Addressing language	Health Promotion Pra	2015	No	Yes		Quant	Yes	Yes	No	No	No	No	No	No	No	1	No		Relevance score 4/8 or less
Sigman-Grant,M.;Rye	How to strengthen ar	Journal of Nutrition E	2008	Yes	NA		Not researcl	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Slonim,A. B.;Kolasa,K	The cultural appropri	Journal of the Americ	1981	Yes - ILL	No		Mixed	Yes	Yes	Yes	Yes	Yes	.	No	No	No	4	No		Relevance score 4/8 or less
Smith,A. L.;Branch,G.;'	Effectiveness of a nu	Journal of the Americ	1986	Yes - ILL	No		Quant	WIC and more	Yes	No	Yes	No	No	Yes	No	Yes	4	No		Relevance score 4/8 or less
Spellacy,W. N.	Why WIC (Women, In	American Journal of (	1996	No	Yes		Not researcl	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Swensen,A. R.;Harnac	Nutritional assessm	Journal of the Americ	2001	No	Yes		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	No	No	5	Yes	25	
Tuori,J. L.	WIC knows no bound	Nursing Spectrum -- N	2004	No	No	Not found	Not researcl	No	.	.	.	.	.	.	.	.	.	No		Not primary study
Walker,J. L.;Holben,D	Household food inse	Journal of the Americ	2007	Yes	NA		Quant	WIC and FMNP	Yes	Yes	Yes	Yes	.	No	No	No	4	No		Relevance score 4/8 or less
Watts,V.;Rockett,H.;B	Assessing diet quali	Maternal & Child Hea	2007	No	Yes		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	No	Yes	6	Yes	26	
Webber,C. B.;Rojhani	Food or fuel: Rising g	Journal of Hunger an	2010	No	No	Not found bu	Qual	Yes	Yes	No	Yes	Unclear	Yes	Yes	No	No	4	No		Relevance score 4/8 or less
Whaley,S. E.;Ritchie,L	Revised WIC food pa	Journal of Nutrition E	2012	Yes	NA		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	No	No	5	Yes	27	
Wheeler,A. L.;Chapm	Farmers' markets: co	Journal of Nutrition E	2014	Yes	NA		Quant	WIC and FMNP	Yes	No	Yes	Unclear	Yes	Yes	No	No	4	No		Relevance score 4/8 or less
Woelfel,M. L.;Abusab	Barriers to the use of	Journal of the Americ	2004	Yes	NA		Mixed	Yes	Yes	Yes	Yes	Unclear	Yes	No	No	No	4	No		Relevance score 4/8 or less
Wunderlich,S. M.;Hor	Nutrient intake and r	Topics in Clinical Nut	1996	No	Yes		Quant	Yes	Yes	Yes	Yes	Yes	.	Yes	No	No	5	Yes	28	
Zenk,S. N.;Odoms-Yo	Fruit and vegetable a	American Journal of I	2012	Yes	NA		Quant	Yes	Yes	Yes	No	No	No	No	No	No	2	No		Relevance score 4/8 or less

Appendix E: Assessment of rigour in realist review

Assessment of rigour for included studies of Healthy Start (n=4)

Authors (year)	Ri1	#2	#3	#4	#5
Hills (2006)	Partial	Unclear	Partial	Yes	Partial
DH (2012)	No	Unclear	No	No	No
Lucas et al. (2013)	Yes	Yes	Yes	Yes	Unclear
McFadden et al. (2013)	Yes	Yes	Yes	Yes	Yes

DH = Department of Health

Assessment of rigour for included studies of WIC (n=34)

Authors (year)	#1	#2	#3	#4	#5
Endres et al. (1981)	Yes	Yes	Partial	Yes	No
Bailey et al. (1983)	Yes	Yes	Yes	Yes	No
Endres et al. (1987)	Partial	Yes	Partial	Yes	Partial
Farrior et al. (1987)	Yes	Yes	Yes	Yes	No
Rush et al. (1988a)	Yes	Yes	Yes	Yes	Yes
Rush et al. (1988b)	Partial	Yes	No	Yes	Partial
Treiman et al. (1996)	Yes	Yes	Yes	Yes	Yes
Wunderlich et al. (1996)	Partial	Yes	Yes	Yes	No
Horswill et al. (1999)	Yes	Partial	Yes	Partial	No
Nestor et al. (2001)	Yes	Yes	Yes	Yes	Yes
Pehrsson et al. (2001)	Yes	Yes	Yes	Unclear	Unclear
Swensen et al. (2001)	Yes	Yes	Yes	Yes	Yes
Herman et al. (2004)	Yes	Partial	Yes	Partial	Yes
Herman et al. (2006)	Yes	Yes	Yes	Yes	Yes
Watts et al. (2007)	Yes	Yes	Yes	Yes	Yes
Herman et al. (2008)	Yes	Yes	Yes	Yes	Yes
Black et al. (2009)	Yes	Yes	Yes	Yes	Yes
Andreyeva et al. (2011)	Yes	Yes	Yes	Yes	Yes
Andreyeva et al. (2012)	Yes	Yes	Yes	Yes	Yes
Alaya et al. (2012)	Yes	Yes	Yes	Yes	Yes
Gittelsohn et al. (2012)	Yes	Yes	Yes	Yes	Yes
Whaley et al. (2012)	Yes	Partial	Yes	Yes	Yes
Andreyeva et al. (2013a)	Yes	Yes	Yes	Yes	Yes
Andreyeva et al. (2013b)	Yes	Yes	Yes	Yes	Yes
Ettienne-Gittens et al. (2013)	Yes	Yes	Yes	Yes	Yes
Kong et al. (2013)	Yes	Yes	Yes	Yes	Yes
Reyes et al. (2013)	Yes	Yes	Yes	Yes	Yes
Andreyeva et al. (2014)	Yes	Yes	Yes	Yes	Yes
Bertmann et al. (2014)	Yes	Yes	Yes	Yes	Yes
Chen et al. (2014)	Yes	Yes	Yes	Yes	Yes
Kong et al. (2014)	Yes	Yes	Yes	Yes	Yes
Odoms-Young et al. (2014)	Yes	Yes	Yes	Yes	Yes
Andreyeva et al. (2015)	Yes	Yes	Yes	Yes	Yes
Meiqari et al. (2015)	Yes	Partial	Yes	Yes	Partial

Appendix F: Example of flyer used for recruitment in children's centres

HEALTHY START

uclan
University of Central Lancashire

Do you receive Healthy Start vouchers?

Are you currently pregnant?

Or were you pregnant less than 6 months ago?

I'm a research student from the University of Central Lancashire. I have been talking to women in the Blackburn area about their experiences of using food vouchers from Healthy Start during pregnancy.

Would you like to participate in a short interview with me?

We can meet at the children's centre or somewhere more convenient and it will only take around 20 minutes. You will receive a £10 LovetoShop voucher by way of thanks.

Please contact Heather Ohly

07866 318014

I'd be happy to answer any further questions before you agree!

Please note that not all volunteers will be selected for interview.

Appendix G: Example of Facebook post targeting women in Blackburn

Appendix H: Information sheet for qualitative study

VERSION 3 DATED 22/09/16

INFORMATION SHEET

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

Project title
A realist investigation of the impact of Healthy Start on the diets of pregnant women.

What is the purpose of the project?
This is the second stage of a three-year research project. We are interested in finding out about how pregnant women use their Healthy Start vouchers. We have some ideas that we would like to share with you, so that we can learn from your experiences and develop our ideas further.

Why have I been invited?
If you are currently pregnant and receiving Healthy Start vouchers (or were recently pregnant and received them during pregnancy) we would like to invite you to participate in this research.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the support you receive from the place where we approached you (e.g. community group).

What will I be asked to do?
We will invite you to take part in an interview about Healthy Start. The date, time and location of the interview will be arranged to suit you. Before the interview, you will be given another copy of this information sheet to read and asked to sign a consent form. The interview will last around 20-30 minutes and will be recorded using a digital Dictaphone.

What if I want to participate?
That's great. Please contact the researcher, Heather Ohly who will give you further details:
Telephone: 07866 318 014
Email: HOhly@uclan.ac.uk

What are the possible disadvantages of taking part?
A possible disadvantage of being part of this project is the time and hassle involved. We will make every effort to arrange the interview at a convenient time to minimise any disruption to your routine.

What will happen to the results of the research project?
The results of this project will be used to make recommendations for further research on Healthy Start and also recommendations on how the scheme might be improved. You will not be identified in any publications or reports printed or published as part of this research.

1

Will my taking part in this project be kept confidential?
All information collected from you will be kept strictly confidential and your views will be reported anonymously in any publications.

What are the benefits of taking part?
You will receive a £10 voucher to say thank you at the end of the interview. More importantly, you will be helping us to find out more about how Healthy Start works and we will use this information to make recommendations on how the scheme might be improved. We also hope that you will enjoy taking part in the interview. If you would like to see our findings from this research, we will send you a summary at the end of the project.

What if I want to withdraw from the study?
You are free to withdraw at any time and without giving a reason. If you withdraw during or after the interview, we will ask you if the information you have shared with us so far can still be used. If you do not want the information to be used, your wishes will be respected and all data destroyed.

Who is organising and funding the research?
This research is being conducted by Heather Ohly, a full-time PhD student at the University of Central Lancashire. Heather is an experienced researcher and Registered Nutritionist (RNutr). The project is funded by the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North West Coast, which is a partnership between local Universities and the NHS.

Who has reviewed this project?
All proposals for research using human subjects are reviewed by an ethics committee before they can proceed. This research was reviewed by the University of Central Lancashire's Research Ethics Committee (STEMH) in June 2016. The study reference number is 486.

Further information
Should you require further information regarding this research, please contact the research supervisor: Dr Victoria Moran, School of Health, University of Central Lancashire.
Telephone: 01772 89 3830
Email: VLMoran@uclan.ac.uk

In case of complaints
Should you wish to complain directly to the University about any aspect of this research, please contact: OfficerForEthics@uclan.ac.uk

Thank you for reading this information sheet.

Heather Ohly

Appendix I: Consent form for qualitative study

VERSION 3 DATED 22/09/16

CONSENT FORM

Study title
A realist investigation of the impact of Healthy Start on the diets of pregnant women.

Investigators
Heather Ohly, PhD Student, School of Health, University of Central Lancashire
Victoria Hall Moran, School of Health, University of Central Lancashire
Fiona Dykes, School of Health, University of Central Lancashire
Nicola Lowe, School of Sport, Tourism and the Outdoors, University of Central Lancashire
Nicola Crossland, School of Health, University of Central Lancashire

	Please tick box
1. I confirm that I have read and understand the information sheet dated 22/09/16 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason. I understand that any information I have shared up to that time may be used in the research (unless I request it to be destroyed).	☐
3. I understand that this interview will be recorded and that my data will be securely stored for up to five years at the University.	☐
4. I agree to take part in the above study.	☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of researcher	Date	Signature

Appendix J: Interview topic guide for qualitative study

General questions to get her talking:

- Could you tell me a bit about yourself and your family?
- Is this your first pregnancy or do you have older children?
- How many weeks pregnant are you?
- When did you start receiving Healthy Start vouchers? (min. 4-6 weeks ago)
- So you first received them at around __ weeks of pregnancy.

Broad questions about voucher use:

- What do you tend to buy with your Healthy Start vouchers?
- What made you decide to buy _____?
- Do you think you buy more _____ than you did before, or do the vouchers just bring down the cost?
- That's interesting. Can you tell me more about that?

Ask her to read the 'scenarios' and pick out any that seem familiar:
Direct to particular ones (based on previous answers) and ask her opinions:

- Have you experienced anything like this?
- Why do you think that happened?
- How did that make you feel?

Explore practical issues that arose in previous interviews:

- Have you had any problems or frustrations with using the vouchers?
- Did they scan OK at the checkout?
- Which shops do you use them in?
- Have you ever tried using them in smaller shops?

Finally, move into more open questions:

- What do you think about Healthy Start overall?
- How would you improve the scheme?

If she is NOT currently pregnant:

- Can you remember if you did anything different with the vouchers when you were pregnant?

Appendix K: Vignettes used in realist interviews

“I wanted to eat healthier during pregnancy. Now that I have the vouchers, I can afford the extra fruits and vegetables without having to worry about the cost.”

“The midwife explained about growth and development, and how the baby gets vitamins from my food. Healthy eating seemed more important after that.”

“The vouchers are for me, but I don’t just shop for me – I’ve got other mouths to feed. I definitely eat some of the vegetables, but so do the kids. As a mother I share with my children and I want them to eat well too.”

“I don’t buy more of the healthy foods than I did before. The main thing for me is saving money – I never say no to any discounts because money is always so tight. The vouchers really help.”

“My local shopkeeper doesn’t make a fuss if I want to spend my vouchers on something else. He just scans the voucher and puts it away.”

“Mum does the shopping, so I give her the vouchers. I don’t know what she spends them on.”

“I mainly use the vouchers for infant formula because I want to be ready when the baby comes.”