A realist qualitative study to explore how low-income pregnant women use Healthy Start food vouchers.

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Abstract

Healthy Start is the UK government's food voucher programme for low-income pregnant women and young children. It was introduced in 2006, but the impact of the programme on nutritional outcomes remains understudied. This study sought 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. A realist review preceded this study, in which programme theories were developed and tested using existing evidence. This qualitative study aimed to further refine and consolidate the programme theories from the realist review, while remaining open to new and emerging theories (or hypotheses) about how low-income pregnant women use Healthy Start vouchers. Semi-structured interviews were conducted with 11 low-income women from North West England, who received Healthy Start vouchers during pregnancy. A realist logic of analysis was applied to generate clear and transparent linkages between outcomes and explanations. The findings suggested that some women used the vouchers to improve their diets during pregnancy (intended outcome), whereas some women were diverted towards alternative or unintended outcomes. Women's circumstances, values, beliefs and motivations influenced how they perceived and responded to the vouchers. This paper presents four 'evidence-based programme theories' to explain four contrasting (and potentially overlapping) outcomes: dietary improvements (theory refined from review); shared benefits (new theory); financial assistance (theory refined from review); stockpiling formula (new theory). It considers how the Healthy Start programme could be improved, to increase the possibilities for low-income women to experience the intended outcome of dietary improvements.

Key words: nutrition, realist, qualitative, pregnant, women, vouchers.

Introduction

Healthy Start is the UK government's food voucher programme for low-income pregnant women and young children. 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 receive income-related benefits (NHS, 2017). 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 spent on any combination (one or more) of fruits and vegetables, plain cow's milk or infant formula. Eligible families are also entitled to free vitamins, but this study was concerned only with the food voucher component.

The aims of the Healthy Start programme are to provide a nutritional safety net, improve maternal and child nutrition, promote breastfeeding and reduce health inequalities (DH, 2010; Greenwood, 2017; McFadden et al., 2013). It was introduced in 2006, but its impact on nutritional outcomes remains understudied. The two most recent evaluations of Healthy Start (funded by the Department of Health) explored the views and experiences of programme beneficiaries and other stakeholders (Lucas et al., 2013; McFadden et al., 2013). The perceived outcomes and benefits were similar in both studies and women reported using the vouchers in various 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. 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. It is important to understand how individual women may respond to being given food vouchers, and consider contextual factors that may influence this, in order to maximise programme benefits for low-income families.

Therefore, this study sought to develop in-depth, evidence-based explanations for how low-income pregnant women use Healthy Start vouchers. Realist evaluation was used to explore 'how the programme works, for who, in what circumstances and why' (Pawson & Tilley,

1997). Realist evaluation is a theory-driven approach, which assumes that any social programme is likely to work better for some people than for others. This is because social programmes are introduced into different contexts (reflecting the complexity of the social world) and variations in context are likely to influence programme outcomes. The logic of realist explanation is that programme outcomes (O) are caused by mechanisms (M), and mechanisms may (or may not) be activated in certain contexts. This is known as generative causation, and the mechanisms of interest are 'the reasoning and reactions of individuals in response to the resources offered by the programme' (Pawson, 2006). The goal of realist evaluation is to understand and articulate these underlying causal processes by developing explanatory 'programme theories' (or hypotheses) and testing them using empirical evidence. In accordance with the realist logic described above, realist programme theories tend to be constructed as 'CMO configurations' (or CMOc).

A realist review preceded this study, in which programme theories were developed and tested using existing evidence (Ohly et al., 2017). A total of 38 primary studies were included in the review: four UK studies on Healthy Start and 34 US studies on the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). WIC is the only other national food subsidy programme for low-income women of childbearing age, including pregnant and postpartum women and young children. In realist synthesis, it is common (and recommended) to include studies of similar programmes, which may operate through similar mechanisms to the programme under study. The authors were mindful of key programme differences (such as mandatory nutrition education provided by WIC) and contextual differences between the UK and the US. Despite these differences, relevant evidence from 34 WIC studies was used to support and refute (and thereby refine) programme theories about how low-income pregnant women use Healthy Start vouchers.

The findings of the realist review suggested that some women use Healthy Start vouchers to increase their consumption of healthy foods (intended outcome: dietary improvement) and some women use the vouchers to reduce food expenditure and save money for other things (unintended outcome: financial assistance) (Ohly et al., 2017). Three 'evidence-informed' programme theories proposed plausible and tentative explanations for how and why these outcomes may occur. They identified aspects of context (pre-existing conditions into which the vouchers are introduced) and mechanisms (reasoning and reactions in response to the vouchers) that are likely to be important in determining outcomes.

The first programme theory was named 'prioritisation of resources'; it proposed that the 'relative value' of healthy eating may influence how women prioritise household resources (including the vouchers). If pregnant women value healthy eating and the potential health benefits for the unborn baby, they are more likely to prioritise healthy foods and use the vouchers to buy more fruit and vegetables or cow's milk. However, women may be diverted away from the aspirational outcome of dietary improvement if other things are considered more important or urgent. This is an example of how variations in context may enable or constrain mechanisms.

The second programme theory was named 'bending the rules': it highlighted the role of retailers and shop keepers, who are responsible for checking that women exchange their Healthy Start vouchers for permitted items (any combination of fruits and vegetables, plain cow's milk or infant formula). There is no electronic audit system currently and, therefore, retailers may use their discretion. The review found evidence that some women may put pressure on retailers to 'bend the rules' allowing them to exchange their vouchers for alternative food or non-food items.

The third programme theory was named 'disempowerment': it related to women who may not be empowered to make decisions about household resources or food shopping, such as pregnant

teenagers who live with their parents or women who live in large, multigenerational households. In these circumstances, women may hand over their Healthy Start vouchers to other family members who decide how they are used.

The programme theories presented in the realist review were limited by the primary studies included, which did not have the same in-depth explanatory focus. The realist review was a first step towards theory development, but we felt that additional empirical evidence was needed to better understand how low-income pregnant women use Healthy Start vouchers. Therefore, 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. A realist qualitative study with Healthy Start beneficiaries as the key informants would reveal more nuanced mechanisms relating to why women prioritise in certain ways.

Key messages

1. This was the first study to use realist evaluation, a theory-driven approach to programme evaluation, to explore how low-income pregnant women use Healthy Start vouchers.
2. While some low-income women may use Healthy Start vouchers to improve their diets during pregnancy (intended outcome), some women may be diverted towards alternative or unintended outcomes – if other things are considered more important or urgent than healthy eating.
3. Policy makers should consider programme modifications and additional support for low-income pregnant women, to encourage them to prioritise healthy eating and use Healthy Start vouchers to buy and consume more healthy foods.

Methods

Study design and population

This qualitative study was conducted in two areas of North West England. These areas were known to have high claim rates for out-of-work benefits compared to the average for Great Britain (Office for National Statistics, 2017), but no data were available to verify the rate of eligibility for Healthy Start. 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 ('recently pregnant') and received Healthy Start vouchers during that pregnancy. 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).

Recruitment strategy

Participants were recruited between September 2016 and May 2017. The main strategy was face-to-face recruitment through midwifery services (antenatal clinics) and drop-in sessions (such as breastfeeding support groups) in Sure Start children's centres located in deprived areas. A £10 Love2Shop voucher was offered as an incentive for participation. Additional strategies included posters and flyers displayed around the children's centres, and a 'Healthy Start Study' Facebook page with regular advertisements targeting women aged 16-40 years. Women were asked if they knew anyone else who might be willing to participate. Interviews were arranged at a convenient time and location for the participants. Women were asked to read an information sheet and sign a consent form. They had the option to opt out at any time. Nobody who agreed to participate was excluded.

Data collection

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. A topic guide was used for consistency and transparency. It started with general questions about the participant's age, number of children, stage of pregnancy, and when they started receiving the vouchers. It continued with open questions about what the vouchers were 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?

Secondly, the interviews were realist. 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). Interview techniques such as summarising and paraphrasing were used to ensure that the researcher understood the participants reasoning processes correctly.

Thirdly, vignettes were used to present the programme theories in an informal way. 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). The

vignettes were seven fictional quotations, printed on laminated cards, which represented the CMOc developed during the realist review (Ohly et al., 2017) (Table 1). This included some CMOc that were not substantiated in the review, but were considered worthy of further investigation. 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. This strategy was useful for women who were less confident and responded briefly to the opening questions. In other interviews, the conversation flowed naturally and the interviewer directed the participant to relevant vignettes throughout the interview. This helped to elicit in-depth explanatory data at the level of context and mechanisms.

Three pilot interviews were conducted to check that women responded well to the vignettes and the wording was clear. During the main fieldwork period, women were initially asked to participate in one interview. The interviews were all conducted by the lead author, who was heavily engaged with realist networks and sought advice from expects on realist interview techniques. Each interview lasted 30-40 minutes. Later in the study, some participants were invited to participate in a second interview, if the lead author felt that further insights could be gained after the original interviews had been analysed and theory development had progressed.

Coding and analysis

Interviews were digitally recorded and transcribed verbatim. Participants were allocated a unique code (BL1, BL2 etc.) and a pseudonym for anonymity. The quality and accuracy of transcription was checked by the lead author. All coding and analysis was completed by the lead author. The longest interview transcript (approximately 10% of the data) was formally reviewed by a second author. Furthermore, all the co-authors were involved in regular discussions about coding and analysis; any disagreements or uncertainties were resolved by discussion and consensus. 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,

as ideas and theories were gradually assimilated. A realist logic of analysis was consistently applied: outcomes are caused by mechanisms, and mechanisms may (or may not) be 'triggered' in certain contexts (Pawson, 2006). The process always started with an outcome and worked backwards to determine "what caused it (the mechanism) and under what contexts was the mechanism triggered" (p. 2) (Wong, 2015).

A bespoke Microsoft Excel database was used to extract data and assign codes relating to context (C), mechanisms (M) and outcomes (O). The database and method of analysis was developed by other realist researchers (Punton et al., 2016), who permitted us to adapt it for this study. 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 (C and/or M). 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, and sometimes linkages were inferred by drawing together evidence from across an interview transcript (things the participant said at

different times during the interview). Researcher interpretation and iterative theory development is an important element of realist evaluation (Pawson, 2006).

Results

A total of 11 women participated in this study. Their characteristics are summarised in Table 2. Five women were pregnant and receiving Healthy Start vouchers at the time of interview; the other six women had recently been pregnant and received Healthy Start vouchers during that pregnancy. Two women were pregnant for the first time (primiparous); the other nine women had older children as well (multiparous). Seven women were aged 18-25 years (including two pregnant teenagers); the other four women were aged 26-35 years. Six women described themselves as 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. The second interviews enabled the interviewer to further develop and refine some of the CMOc that emerged from the early stages of the analysis. This is an example of iterative theory development in realist evaluation.

The following sections present four evidence-based programme theories (or hypotheses), which propose in-depth, plausible explanations for how low-income pregnant women use Healthy Start vouchers. All four outcomes (one in each theory) were identified in previous studies of Healthy Start, but this study is the first to elucidate possible reasons why women may experience these different outcomes. Table 3 shows which interviews contributed data to support each programme theory.

Programme theory 1 – Dietary improvements

Some women reported that Healthy Start vouchers enabled them to improve their diets during pregnancy (Table 3). This was assumed to be an intended outcome of the programme. These

women valued healthy eating sufficiently that the vouchers were perceived as an opportunity to change their behaviour. 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. It may be inferred that Healthy Start vouchers reinforced the motivation to eat well during pregnancy.

The following CMOc (italics) is supported by examples and quotations, which illustrate the proposed linkages between context, resources, mechanisms and outcomes:

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].

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)

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]. Claire reported eating more fruit and vegetables when she was pregnant, as well as buying more as indicated in this quote:

> "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)

Programme theory 2 – Shared benefits

Some women reported that Healthy Start vouchers enabled them to buy more healthy foods, but these foods were shared with older children (Table 3). These women felt a strong sense of responsibility towards their children and wanted them to benefit from the additional healthy foods. They were willing to make sacrifices for their children, even during pregnancy.

The following CMOc (italics) is supported by examples and quotations, which illustrate the proposed linkages between context, resources, mechanisms and outcomes:

For women with older children to feed [context], particularly women who received vouchers for children under 4 as well as for themselves [context], the monthly bundle of vouchers was perceived as being for the family [resources]. Women felt a strong sense of responsibility towards their children [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 older children [outcome].

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]. The following series of quotes is an example of how proposed linkages between context, mechanism and outcome were inferred by drawing together evidence from different parts of an interview transcript.

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

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

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

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

355 **Programme theory 3 – Financial assistance**

356 Some women reported that Healthy Start vouchers were used to subsidise the cost of foods
357 they would have bought anyway, rather than to buy and consume more healthy foods (Table
358 3). The money they saved was redirected to pay for other things. This suggests that financial
359 stress may reduce the relative value or importance of healthy eating, such that Healthy Start
360 vouchers may be perceived as an opportunity to save money, rather than to achieve dietary
361 improvements. The vouchers provided a 'nutritional safety net' because women were able to
362 free up money without having to reduce the amount of healthy foods they bought.

363 The following CMOc (italics) is supported by examples and quotations, which illustrate the
364 proposed linkages between context, resources, mechanisms and outcomes:

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].

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 clothes, days out, just stuff like that, essential other stuff that you need as well." (Emily)

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].

> "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)

Programme theory 4 – Stockpiling formula

Some women reported that Healthy Start vouchers were used to stock up on formula during pregnancy (Table 3). 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. There was no indication in this study that Healthy Start influenced women's decisions to formula feed.

The following CMOc (italics) is supported by examples and quotations, which illustrate the proposed linkages between context, resources, mechanisms and outcomes:

For women who had already decided to formula feed [context], or anticipated that they might need to [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.

Sophie, who was speaking about her recent pregnancy, had already 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)

Discussion

Summary of main findings

In this study, four evidence-based programme theories were developed, tested and refined using qualitative data from interviews with 11 low-income women. They provide in-depth realist explanations about how low-income pregnant women use Healthy Start vouchers and why. Some women used the vouchers to improve their diets during pregnancy (intended outcome), whereas some women were diverted towards alternative or unintended outcomes. Women's circumstances, values, beliefs and motivations (context) influenced how they perceived the vouchers (resources) and how they responded to the vouchers (mechanisms), which ultimately determined the outcomes they experienced.

The 'prioritisation of resources' theory from our realist review (Ohly et al., 2017) was further developed and refined using evidence from this qualitative study. It was separated into two programme theories, leading to two contrasting outcomes. In programme theory 1, women valued healthy eating sufficiently that the vouchers were perceived as an opportunity to afford more healthy foods. The vouchers reinforced their existing motivation to eat well and encouraged them to prioritise healthy foods, leading to dietary improvements during pregnancy. In programme theory 3, financial stress influenced the relative value of healthy eating and the way that resources were prioritised. The vouchers were perceived as an opportunity to reduce the shopping bill and free up money for other things. They helped women

460 to manage better financially, as observed in a previous evaluation of Healthy Start (McFadden
461 et al., 2013). These low-income pregnant women did not experience the intended outcome of
462 dietary improvements as other things were considered higher priority. Their decisions about
463 how to use the vouchers were driven by perceived necessity.

464 This study did not generate evidence to further refine the other two theories from our realist
465 review, 'bending the rules' and 'disempowerment'. This may reflect the small sample size (as
466 acknowledged in the limitations section) and the fact that retailers were not included in this
467 study. However, two new theories emerged from the data. In programme theory 2, women
468 shared the foods purchased using the vouchers with their children. Furthermore, they were
469 willing to sacrifice the intended nutritional benefits to themselves (during pregnancy) so that
470 their children could eat a healthier diet. It may be inferred that children took priority over the
471 unborn baby when resources were limited. Similar choices have been reported in previous
472 studies, such as Latina women enrolled in the WIC programme in the US (n=14) who were
473 willing to go hungry to feed their children, despite concerns about the impact on their unborn
474 babies (Hromi-Fiedler et al., 2009). In programme theory 4, women used the vouchers to
475 stockpile formula during pregnancy, so they felt more prepared for the baby's arrival. This
476 unintended outcome was also observed in a previous evaluation of Healthy Start, which
477 recommended additional support and incentives for breastfeeding mothers (McFadden et al.,
478 2013). These new theories present alternative manifestations of the 'prioritisation' mechanism
479 identified in the realist review. This study enabled us to identify more nuanced mechanisms
480 relating to why women prioritise in certain ways.

481 Most of the women in this study reported more than one outcome (Table 3). This indicates that
482 women used the vouchers in different ways at different times, as changes in context altered the
483 mechanisms activated. It was not clear how women's outcome patterns changed over time (or
484 overlapped) and this would be worthy of further investigation.

A theoretical model for Healthy Start

Figure 1 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. 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. This theoretical model presents a positive theory of change for Healthy Start. It highlights aspects of context and mechanisms that may lead to the intended outcome of dietary improvements in pregnancy. Some aspects of the model were not directly supported by evidence from this study – but our programme theories were used to make inferences about how and why (and for who) the programme might be successful. For example, programme theory 4 relates to low-income pregnant women who have already decided to formula feed, or anticipate that they might need to. We used this hypothesis to suggest, conversely, that low-income pregnant women who intend to breastfeed may be less likely to use the vouchers to stock up on formula and more likely to spend them on healthy foods.

This theoretical model proposes 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.

While this model was based on evidence-based programme theories about the Healthy Start programme, similar mechanisms relating to prioritisation and reinforced motivation may be

transferable to other food voucher programmes, and perhaps other types of financial support programmes designed to encourage dietary improvement.

Implications for policy and practice

This study has highlighted contextual factors that may influence the potential success of the Healthy Start programme by enabling or constraining mechanisms. This section considers how the programme could be improved, to encourage low-income women to prioritise healthy eating and use Healthy Start vouchers to buy and consume more healthy foods – to generate the intended outcome of dietary improvements during pregnancy.

First, this study has identified the relative value of healthy eating as an important aspect of context. Therefore, if the Healthy Start programme could offer additional support to low-income pregnant women, with the aim of increasing the relative value of healthy eating, this would encourage women to use the vouchers to improve their diets during pregnancy (as outlined in programme theory 1). 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). There was insufficient evidence in this study to substantiate a programme theory relating to support from health professionals. However, a previous evaluation identified concerns around understaffing, lack of training and insufficient time during appointments (Lucas et al., 2013). This is an area worthy of further investigation. In the US, the WIC programme provides mandatory nutrition education to beneficiaries. A recent report described its key features: WIC nutritionists have formal training (most are dietitians) and extensive experience; the primary delivery method is one-to-one counselling; it is tailored to the needs of participants; it is

coordinated with other local programmes to ensure consistent messages (Cates et al., 2016). Substantial investment would be needed to replicate this service in the UK.

Second, this study suggests that women who intend to formula feed may use Healthy Start vouchers to stockpile formula during pregnancy. We did not explore women's infant feeding decisions and intentions in our interviews, and there was no indication that Healthy Start influenced women's decisions about whether to breastfeed or formula feed. However, for women who had already decided to formula feed (or thought they might need to), this context influenced how they used the Healthy Start vouchers. Therefore, 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 pregnant women and their unborn babies. This raises questions about whether Healthy Start conflicts with UK and global public health recommendations to breastfeed exclusively for six months. A relatively simple modification 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 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. It includes breastfeeding promotion and support, and the WIC food package is enhanced (larger 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).

Finally, this study found that some low-income pregnant women shared the foods purchased using the vouchers with their children. This suggests that they did not have sufficient resources (even with the vouchers) to afford healthy foods for themselves and their children. They were

559 forced to make tough choices and they prioritised the children over their own diet, and the
560 potential benefits for the unborn baby. The value of Healthy Start vouchers has not increased
561 since 2009 and eligible pregnant women only receive £3.10 per week. A previous evaluation
562 of Healthy Start raised concerns about this: "if the value of the vouchers themselves does not
563 keep pace with the rising cost of food, the nutritional safety net will be eroded" (McFadden et
564 al., 2013). This study provides further evidence to support a review of the value of Healthy
565 Start vouchers, to ensure that low-income pregnant women can afford to prioritise their own
566 health and use the vouchers to buy more healthy foods for themselves.

567 **Strengths and limitations**

568 This was the first study to use realist evaluation to explore how low-income pregnant women
569 use Healthy Start vouchers. An innovative combination of realist interviews and vignettes was
570 used to communicate and exchange theories with low-income women. The methods were
571 closely aligned with quality standards for realist evaluations (RAMESES, 2017). This study
572 has highlighted a range of possible outcomes and plausible, evidence-based explanations for
573 how and why those outcomes may occur. The realist approach to data collection, coding and
574 analysis illuminated individual level mechanisms i.e. how the vouchers influenced women's
575 decision-making processes, and which aspects of context may have enabled or constrained
576 those processes. In addition to context, mechanisms and outcomes, the CMOc indicate
577 'resources' and how they were perceived by women. This alternative configuration helps to
578 clarify that programme resources are introduced into a context, which leads to a change in
579 reasoning (Dalkin et al., 2015). The richness of the interview data made this distinction clearer
580 than it was during the realist review. The study findings may be used to inform the design of
581 any future evaluations of Healthy Start.

582 The main limitations of this study were its small sample size and lack of ethnic diversity.
583 Recruitment was challenging and the recruitment rate was around 5% of women approached,

584 despite focusing on children's centres in deprived areas. Most women were not eligible to
585 participate because they were not eligible for Healthy Start, although it is possible that some
586 women did not want to disclose their eligibility. Historically, data on Healthy Start eligibility
587 have not been publicly available. However, in March 2017, we obtained data from the UK
588 Government's Healthy Start Issuing Unit (via personal communication) on the number of
589 beneficiaries in the two study areas. This showed that, in both study areas, less than 5% of
590 beneficiaries were pregnant women and the majority were children aged over one year. This
591 explained why it had been so difficult to recruit women who were using (or had recently used)
592 Healthy Start vouchers during pregnancy.

593 Only three women agreed to participate in second interviews, which limited the potential for
594 further insights and theory development in the second round of analysis. Data saturation was
595 not reached, and additional programme theories (or hypotheses) may have emerged from a
596 larger and more diverse sample. Therefore, the evidence-based programme theories presented
597 in this study are unlikely to represent all low-income pregnant women who are beneficiaries of
598 the Healthy Start programme. It is also important to acknowledge that this study cannot draw
599 any conclusions about the prevalence of outcomes.

600

601 **Conclusion**

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

605 • Women value healthy eating and aspire to eat well during pregnancy.
606 • 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.

Policy makers should consider programme modifications and additional support for low-income pregnant women, to encourage them to prioritise healthy eating and use Healthy Start vouchers to buy and consume more healthy foods.

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665 Table 1. Vignettes used in the realist interviews

Vignette (fictional quote)	**Development of vignette**
"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."	Programme theory 1 from realist review: prioritisation of resources (intended outcome: dietary improvements)
"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."	Programme theory 1 from realist review: prioritisation of resources (unintended outcome: financial assistance)
"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."	Programme theory 2 from realist review: bending the rules (unintended outcome: financial assistance/alternative items)
"Mum does the shopping, so I give her the vouchers. I don't know what she spends them on."	Programme theory 3 from realist review: disempowerment (unintended outcome: vouchers handed over to others)
"The midwife explained about growth and development, and how the baby gets vitamins from my food. Healthy eating seemed more important after that."	Candidate theory from realist review (not substantiated)

“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.”	Candidate theory from realist review (not substantiated)
“I mainly use the vouchers for infant formula because I want to be ready when the baby comes.”	Candidate theory from realist review (not substantiated)

666

667 Table 2. 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
Area 1 (BA)	✓	✓	✓	✓	✓	✓	✓				
Area 2 (BL)								✓	✓	✓	✓
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		✓		✓			✓				

668 Table 3. 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
Programme theory 1	✓	✓	✓	✓				✓		✓	✓
Programme theory 2				✓		✓	✓		✓	✓	✓
Programme theory 3		✓			✓		✓		✓	✓	
Programme theory 4	✓		✓		✓		✓		✓		

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