

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

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27

28 **Abstract**

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

50

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

52 **Introduction**

53 Healthy Start is the UK government's food voucher programme for low-income pregnant
54 women and young children. Women are eligible to apply for Healthy Start if they are at least
55 10 weeks pregnant or have a child under four years old, and receive income-related benefits
56 (NHS, 2017). The weekly voucher values are: one voucher per week during pregnancy (£3.10);
57 two vouchers per week for each baby under 1 year (£6.20) and one voucher per week for each
58 child aged 1–4 years (£3.10). The vouchers can be spent on any combination (one or more) of
59 fruits and vegetables, plain cow's milk or infant formula. Eligible families are also entitled to
60 free vitamins, but this study was concerned only with the food voucher component.

61 The aims of the Healthy Start programme are to provide a nutritional safety net, improve
62 maternal and child nutrition, promote breastfeeding and reduce health inequalities (DH, 2010;
63 Greenwood, 2017; McFadden et al., 2013). It was introduced in 2006, but its impact on
64 nutritional outcomes remains understudied. The two most recent evaluations of Healthy Start
65 (funded by the Department of Health) explored the views and experiences of programme
66 beneficiaries and other stakeholders (Lucas et al., 2013; McFadden et al., 2013). The perceived
67 outcomes and benefits were similar in both studies and women reported using the vouchers in
68 various ways: to buy more healthy foods (greater amount, quality or variety), to save money
69 and manage better financially, or to offset the cost of infant formula. However, these studies
70 did not elucidate the reasons why women may have experienced these different outcomes, or
71 the extent to which they may have overlapped. It is important to understand how individual
72 women may respond to being given food vouchers, and consider contextual factors that may
73 influence this, in order to maximise programme benefits for low-income families.

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

77 1997). Realist evaluation is a theory-driven approach, which assumes that any social
78 programme is likely to work better for some people than for others. This is because social
79 programmes are introduced into different contexts (reflecting the complexity of the social
80 world) and variations in context are likely to influence programme outcomes. The logic of
81 realist explanation is that programme outcomes (O) are caused by mechanisms (M), and
82 mechanisms may (or may not) be activated in certain contexts. This is known as generative
83 causation, and the mechanisms of interest are ‘the reasoning and reactions of individuals in
84 response to the resources offered by the programme’ (Pawson, 2006). The goal of realist
85 evaluation is to understand and articulate these underlying causal processes by developing
86 explanatory ‘programme theories’ (or hypotheses) and testing them using empirical evidence.
87 In accordance with the realist logic described above, realist programme theories tend to be
88 constructed as ‘CMO configurations’ (or CMOc).

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

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

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

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

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

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

129 The programme theories presented in the realist review were limited by the primary studies
130 included, which did not have the same in-depth explanatory focus. The realist review was a
131 first step towards theory development, but we felt that additional empirical evidence was
132 needed to better understand how low-income pregnant women use Healthy Start vouchers.
133 Therefore, this study aimed to further refine and consolidate the programme theories from the
134 realist review, while remaining open to new and emerging theories about how low-income
135 pregnant women use Healthy Start vouchers. A realist qualitative study with Healthy Start
136 beneficiaries as the key informants would reveal more nuanced mechanisms relating to why
137 women prioritise in certain ways.

138

139 **Key messages**

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

149

150 **Methods**

151 **Study design and population**

152 This qualitative study was conducted in two areas of North West England. These areas were
153 known to have high claim rates for out-of-work benefits compared to the average for Great
154 Britain (Office for National Statistics, 2017), but no data were available to verify the rate of
155 eligibility for Healthy Start. Women were eligible to participate in this study if they were
156 pregnant and receiving Healthy Start vouchers, or if they had been pregnant within the previous
157 six months ('recently pregnant') and received Healthy Start vouchers during that pregnancy.
158 Ethical approval for this study was obtained in June 2016 from the University of Central
159 Lancashire Science, Technology, Engineering, Medicine and Health Ethics Committee
160 (reference STEMH 486).

161 **Recruitment strategy**

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

172 **Data collection**

173 An innovative combination of interview techniques was used to explore women's views,
174 perceptions, perspectives and experiences of using Healthy Start vouchers during pregnancy
175 and, where applicable, since having their babies. Firstly, the interviews were semi-structured.
176 A topic guide was used for consistency and transparency. It started with general questions about
177 the participant's age, number of children, stage of pregnancy, and when they started receiving
178 the vouchers. It continued with open questions about what the vouchers were used for and what
179 influenced those decisions. The questions and prompts became more in-depth as the interviews
180 progressed. Women were encouraged to explain how they responded to receiving the vouchers
181 and why they used them in certain ways. For example: What made you decide to use the
182 vouchers in that way? Could you tell me more about why you did that?

183 Secondly, the interviews were realist. Realist interviews have been described as a two-way
184 exchange of theories or 'teacher-learner cycle', in which the interviewer explains what they
185 think might be happening within the programme and the participant offers their views in return
186 (Pawson & Tilley, 1997). This differs from traditional interview methods, in which the
187 interviewer adopts a more neutral standpoint (Fielding & Thomas, 2001). Realist interviews
188 are designed to test specific programme theories. Therefore, the interviewer must direct the
189 conversation towards those theories and try to elicit the participant's reasoning processes
190 (Manzano, 2016). Realist interviewers are encouraged to communicate their own ideas, while
191 remaining open and responsive to new or different ideas that might emerge. Therefore, the roles
192 of 'teacher' and 'learner' are interchangeable between the interviewer and the interviewee
193 (Manzano, 2016). Interview techniques such as summarising and paraphrasing were used to
194 ensure that the researcher understood the participants reasoning processes correctly.

195 Thirdly, vignettes were used to present the programme theories in an informal way. Previous
196 qualitative studies have found that vignettes can help participants to reveal things about
197 themselves by focusing the attention on an unknown third person (Gourlay et al., 2014). The

198 vignettes were seven fictional quotations, printed on laminated cards, which represented the
199 CMOc developed during the realist review (Ohly et al., 2017) (Table 1). This included some
200 CMOc that were not substantiated in the review, but were considered worthy of further
201 investigation. In some interviews, all seven vignettes were presented and the participant was
202 prompted to discuss any that were similar (or different) to her own experiences. This strategy
203 was useful for women who were less confident and responded briefly to the opening questions.
204 In other interviews, the conversation flowed naturally and the interviewer directed the
205 participant to relevant vignettes throughout the interview. This helped to elicit in-depth
206 explanatory data at the level of context and mechanisms.

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

214 **Coding and analysis**

215 Interviews were digitally recorded and transcribed verbatim. Participants were allocated a
216 unique code (BL1, BL2 etc.) and a pseudonym for anonymity. The quality and accuracy of
217 transcription was checked by the lead author. All coding and analysis was completed by the
218 lead author. The longest interview transcript (approximately 10% of the data) was formally
219 reviewed by a second author. Furthermore, all the co-authors were involved in regular
220 discussions about coding and analysis; any disagreements or uncertainties were resolved by
221 discussion and consensus. While coding and analysis were distinct tasks in this study, the
222 analysis was also an ongoing and iterative process of internal thought, reflection and dialogue,

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

228 A bespoke Microsoft Excel database was used to extract data and assign codes relating to
229 context (C), mechanisms (M) and outcomes (O). The database and method of analysis was
230 developed by other realist researchers (Punton et al., 2016), who permitted us to adapt it for
231 this study. Each interview transcript was carefully read (at least twice) and annotated with
232 initial thoughts and interpretations. The next task was to identify outcomes relating to how
233 women used their Healthy Start vouchers. An outcome was only coded if there was some
234 degree of explanation within the transcript – how and why did it come about? A separate row
235 was used for each unique outcome, and the adjacent cells in that row were used to enter notes
236 and direct quotations relating to the explanation (C and/or M). Sometimes not all cells were
237 completed, if the participant only provided evidence relating to C/O or M/O (Punton et al.,
238 2016). The database was completed iteratively such that explanations were entered tentatively
239 at first (e.g. entire quotes pasted into cells) and specific codes relating to context and
240 mechanisms were assigned later.

241 At the analysis stage, rows were filtered so that evidence coded under each outcome could be
242 compared between interviews. This allowed patterns and variations in the explanatory data
243 (context and mechanisms) to be observed. The main advantage of this approach was that
244 proposed linkages between C, M and O were recorded transparently. It was not always possible
245 to find evidence of complete CMOC within one quote, and sometimes linkages were inferred
246 by drawing together evidence from across an interview transcript (things the participant said at

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

249

250 **Results**

251 A total of 11 women participated in this study. Their characteristics are summarised in Table
252 2. Five women were pregnant and receiving Healthy Start vouchers at the time of interview;
253 the other six women had recently been pregnant and received Healthy Start vouchers during
254 that pregnancy. Two women were pregnant for the first time (primiparous); the other nine
255 women had older children as well (multiparous). Seven women were aged 18-25 years
256 (including two pregnant teenagers); the other four women were aged 26-35 years. Six women
257 described themselves as single parents. All 11 women were White British.

258 Six out of 11 women were invited to participate in a second interview, but only three women
259 accepted. The second interviews enabled the interviewer to further develop and refine some of
260 the CMOc that emerged from the early stages of the analysis. This is an example of iterative
261 theory development in realist evaluation.

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

268 **Programme theory 1 – Dietary improvements**

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

271 women valued healthy eating sufficiently that the vouchers were perceived as an opportunity
272 to change their behaviour. The vouchers made healthy foods more affordable, which enabled
273 women to make decisions based on their values, beliefs and motivations, without worrying
274 about the financial implications. It may be inferred that Healthy Start vouchers reinforced the
275 motivation to eat well during pregnancy.

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

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

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

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

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

295 made the higher cost items more affordable [resources] and took away some of the financial
296 stress of being pregnant [mechanism]. She also felt a sense of fairness compared to other
297 women [mechanism] because she could buy the fruit and vegetables she needed [outcome].
298 Claire reported eating more fruit and vegetables when she was pregnant, as well as buying
299 more as indicated in this quote:

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

305 **Programme theory 2 – Shared benefits**

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

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

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

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

324 “I don’t put it in like, you have got £5 and you’ve got £5 we just put it all together in
325 one big shop and we just help ourselves really if we want something you go and get it”
326 (Emily)

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

331 Emma was a single mother of three children (8 weeks, 3 and 7 years) [context]. She was
332 receiving Healthy Start vouchers for the baby and the 3-year-old, and had received them for
333 herself during the recent pregnancy [resources]. She considered her diet to be ‘balanced’ with
334 plenty of fruit and vegetables, and she did not eat differently when she was pregnant [context].
335 Her two sons consumed more cow’s milk, fruit and vegetables than her and enjoyed it more
336 [context], so it was natural for her to prioritise their needs when she felt the voucher intended
337 for herself was surplus to requirement [mechanism]. The combined vouchers enabled her to
338 buy more healthy foods, including a greater variety of fruit and vegetables, most of which were
339 consumed by the children [outcome]. The following series of quotes is an example of how
340 proposed linkages between context, mechanism and outcome were inferred by drawing
341 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:

365 *For women who struggled to manage financially [context], Healthy Start vouchers were*
366 *perceived as a contribution to the household budget [resources], which alleviated some of the*
367 *stress associated with providing for the family [mechanism]. The vouchers were used to deduct*
368 *money from the shopping bill [outcome] and the money saved was redirected towards other*
369 *things [outcome] that were considered more important [context].*

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

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

382 Sophie, who had three children (7 weeks, 3 and 6 years) said she worried about money all the
383 time [context] and constantly had to prioritise what was needed the most [context and
384 mechanism]. Healthy Start vouchers helped to alleviate the stress [mechanism] and she used
385 them to cover the cost of fruit and vegetables that she would have bought anyway [outcome].

386 “All the time. All the time. Some weeks you’ve got to think about buying all your food
387 but I always think she’s growing, how am I going to buy next size of clothes if I’m

388 buying her nappies and milk. I don't want to borrow money for clothes. You want to
389 treat your kids all the time, but you've got to think about what you need first." (Sophie)

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

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

393 (Sophie)

394 **Programme theory 4 – Stockpiling formula**

395 Some women reported that Healthy Start vouchers were used to stock up on formula during
396 pregnancy (Table 3). This outcome is within the legitimate use of the vouchers because the
397 range of permitted foods is the same for pregnant women, babies and children under 4 (any
398 combination of plain cow's milk, fruit and vegetables and infant formula). However, it is
399 unlikely that policy makers anticipated this outcome, which displaces the potential health
400 benefits for low-income pregnant women and children. There was no indication in this study
401 that Healthy Start influenced women's decisions to formula feed.

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

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

410 Sophie, who was speaking about her recent pregnancy, had already decided to formula feed
411 before the baby was born [context]. She felt uncomfortable and embarrassed about the idea of

412 breastfeeding and wanting her partner to be able to contribute to feeding the baby [context].
413 Her view was that she did not need the vouchers (and by implication healthy foods) as much
414 as the baby would need infant formula [mechanism]. She knew that the vouchers she would
415 receive for the baby (worth £6.20/week) would not cover the cost of formula she would need
416 [resources] and therefore she wanted to get ahead of those costs [mechanism]. If she invested
417 the vouchers in the baby's food during pregnancy [outcome], she felt more prepared and less
418 worried about affording it in the future [mechanism].

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

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

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

434 "If I couldn't breastfeed I needed milk. With my oldest I tried to breastfeed and he
435 wouldn't latch on. I thought if he will be the same I needed to be ready and I didn't

436 have time to rush around just having a new born being a single mum, I wouldn't have
437 time to run around trying to get money to get milk. I did breastfeed him for three weeks
438 and then he lost quite a bit of weight so I lost my confidence in doing it so I did a bit of
439 both and then I just did the formula.” (Anna)

440

441 **Discussion**

442 **Summary of main findings**

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

451 The 'prioritisation of resources' theory from our realist review (Ohly et al., 2017) was further
452 developed and refined using evidence from this qualitative study. It was separated into two
453 programme theories, leading to two contrasting outcomes. In programme theory 1, women
454 valued healthy eating sufficiently that the vouchers were perceived as an opportunity to afford
455 more healthy foods. The vouchers reinforced their existing motivation to eat well and
456 encouraged them to prioritise healthy foods, leading to dietary improvements during
457 pregnancy. In programme theory 3, financial stress influenced the relative value of healthy
458 eating and the way that resources were prioritised. The vouchers were perceived as an
459 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.

485 **A theoretical model for Healthy Start**

486 Figure 1 illustrates the combination of context and resources needed to generate the intended
487 outcome of dietary improvements for low-income pregnant women, and the mechanisms by
488 which this outcome may be generated. Context is positioned at the base of the model as the
489 foundation upon which change happens. The programme can only work as intended if the
490 context or conditions into which it is introduced enable certain mechanisms to be activated.
491 This theoretical model presents a positive theory of change for Healthy Start. It highlights
492 aspects of context and mechanisms that may lead to the intended outcome of dietary
493 improvements in pregnancy. Some aspects of the model were not directly supported by
494 evidence from this study – but our programme theories were used to make inferences about
495 how and why (and for who) the programme might be successful. For example, programme
496 theory 4 relates to low-income pregnant women who have already decided to formula feed, or
497 anticipate that they might need to. We used this hypothesis to suggest, conversely, that low-
498 income pregnant women who intend to breastfeed may be less likely to use the vouchers to
499 stock up on formula and more likely to spend them on healthy foods.

500 This theoretical model proposes evidence-based and theory-driven explanations about how
501 low-income women use Healthy Start vouchers and why. As anticipated, the answers to these
502 questions are complex and the ‘real’ explanation for each programme beneficiary will be subtly
503 different. The model should not be interpreted as ‘essential conditions for success’. The aspects
504 of context identified in the model will be important for some women and not others. There are
505 likely to be other important aspects of context (and related mechanisms) that have not been
506 identified in this study. Therefore, this model should be considered a first attempt to explain
507 the potential effects of Healthy Start, based on realist assumptions of generative causation.

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

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

512 **Implications for policy and practice**

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

518 First, this study has identified the relative value of healthy eating as an important aspect of
519 context. Therefore, if the Healthy Start programme could offer additional support to low-
520 income pregnant women, with the aim of increasing the relative value of healthy eating, this
521 would encourage women to use the vouchers to improve their diets during pregnancy (as
522 outlined in programme theory 1). It has been assumed that health professionals will provide
523 the necessary information, advice and support to low-income pregnant women, to ensure that
524 they are aware of the importance of healthy eating in pregnancy. Guidance for health
525 professionals stated that women eligible for Healthy Start should receive advice on how to use
526 the vouchers to support a healthy diet (National Institute for Health and Care Excellence, 2015).
527 There was insufficient evidence in this study to substantiate a programme theory relating to
528 support from health professionals. However, a previous evaluation identified concerns around
529 understaffing, lack of training and insufficient time during appointments (Lucas et al., 2013).
530 This is an area worthy of further investigation. In the US, the WIC programme provides
531 mandatory nutrition education to beneficiaries. A recent report described its key features: WIC
532 nutritionists have formal training (most are dietitians) and extensive experience; the primary
533 delivery method is one-to-one counselling; it is tailored to the needs of participants; it is

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

536 Second, this study suggests that women who intend to formula feed may use Healthy Start
537 vouchers to stockpile formula during pregnancy. We did not explore women's infant feeding
538 decisions and intentions in our interviews, and there was no indication that Healthy Start
539 influenced women's decisions about whether to breastfeed or formula feed. However, for
540 women who had already decided to formula feed (or thought they might need to), this context
541 influenced how they used the Healthy Start vouchers. Therefore, intention to formula feed may
542 constrain or compete with aspirations to eat well during pregnancy. The voucher value (£3.10
543 per week) means that stocking up on formula would largely or entirely displace the potential
544 health benefits for pregnant women and their unborn babies. This raises questions about
545 whether Healthy Start conflicts with UK and global public health recommendations to
546 breastfeed exclusively for six months. A relatively simple modification would be to restrict the
547 vouchers to fruit and vegetables and cow's milk during pregnancy. This would promote a
548 clearer message about the importance of healthy eating in pregnancy and remove the
549 constraining context of intention to formula feed (i.e. women may still intend to formula feed
550 but this intention would no longer influence their voucher use during pregnancy). Better links
551 may be needed with existing breastfeeding support services. This is another area where lessons
552 could be learned from the WIC programme. It includes breastfeeding promotion and support,
553 and the WIC food package is enhanced (larger quantity and variety of healthy foods) for women
554 who exclusively breastfeed, which provides a clearer incentive to breastfeed (Institute of
555 Medicine of the National Academies, 2005).

556 Finally, this study found that some low-income pregnant women shared the foods purchased
557 using the vouchers with their children. This suggests that they did not have sufficient resources
558 (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.

- 607 • Women intend to breastfeed, so they do not need to spend money (or vouchers) on
608 infant formula.

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

612

613 **References**

614 Cates, S., Capogrossi, K., Sallack, L., Deehy, K., Eicheldinger, C., Karns, S., . . . Brophy, J.
615 (2016). WIC nutrition education study: Phase I report. Alexandria, VA: United States
616 Department of Agriculture.

617 Dalkin, S. M., Greenhalgh, J., Jones, D., Cunningham, B., & Lhussier, M. (2015). What's in a
618 mechanism? Development of a key concept in realist evaluation. *Implementation
619 Science*, 10, 49.

620 Department of Health. (2010). *Healthy Start: Equality impact assessment*. London:
621 Department of Health.

622 Fielding, N., & Thomas, H. (2001). Qualitative interviewing. In N. Gilbert (Ed.), *Researching
623 social life*. London: SAGE.

624 Gourlay, A., Mshana, G., Birdthistle, I., Bulugu, G., Zaba, B., & Urassa, M. (2014). Using
625 vignettes in qualitative research to explore barriers and facilitating factors to the uptake
626 of prevention of mother-to-child transmission services in rural Tanzania: A critical
627 analysis. *BMC Medical Research Methodology*, 14, 21.

628 Greenwood, P. (2017). Public Health England blog: Healthy start – supporting families to give
629 their children the best start in life. Retrieved from
630 <https://vivbennett.blog.gov.uk/2017/07/06/healthy-start-penny-greenwood/>

631 Hromi-Fiedler, A., Bermúdez-Millán, A., Segura-Pérez, S., Damio, G., & Pérez-Escamilla, R.
632 (2009) Adaptation of the U.S. Food Security Survey Module for Low-Income Pregnant
633 Latinas: Qualitative Phase. *Journal of Hunger & Environmental Nutrition*, 4(1): 62–80.

634 Institute of Medicine of the National Academies. (2005). *WIC food packages: Time for a*
635 *change*. Washington, DC: The National Academies Press.

636 Lucas, P. J., Jessiman, T., Cameron, A., Wiggins, M., Hollingworth, K., & Austerberry, C.
637 (2013). *Healthy Start vouchers study: The views and experiences of parents,*
638 *professionals and small retailers in England*. School for Policy Studies, University of
639 Bristol.

640 Manzano, A. (2016). The craft of interviewing in realist evaluation. *Evaluation*, 22(3), 342-
641 360.

642 McFadden, A., Fox-Rushby, J., Green, J. M., Williams, V., Pokhrel, S., McLeish, J., . . .
643 Renfrew, M. J. (2013). *Healthy Start: Understanding the use of vouchers and vitamins*.
644 College of Medicine, Dentistry and Nursing, University of Dundee.

645 National Health Service. (2017). Healthy Start. Retrieved from
646 <https://www.healthystart.nhs.uk/>

647 National Institute for Health and Care Excellence. (2015). Nutrition: Improving maternal and
648 child nutrition. NICE quality standard [QS98]. Retrieved from
649 <http://www.nice.org.uk/guidance/qs98>

650 Office for National Statistics. (2017). Nomis official labour market statistics. Retrieved from
651 <https://www.nomisweb.co.uk/>

652 Ohly, H., Crossland, N., Dykes, F., Lowe, N., Hall Moran, V. (2017) A realist review to explore
653 how low-income pregnant women use food vouchers from the UK's Healthy Start
654 programme. *BMJ Open*, 7(4) doi:10.1136/bmjopen-2016-013731

655 Pawson, R., & Tilley, N. (1997). *Realistic evaluation*. London: Sage.

- 656 Pawson, R. (2006). *Evidence-based policy: A realist perspective*. London: Sage.
- 657 Punton, M., Vogel, I., & Lloyd, R. (2016). *Centre for development impact practice paper.*
658 *reflections from a realist evaluation in progress: Scaling ladders and stitching theory.*
659 (No. 18). Brighton: Institute of Development Studies.
- 660 RAMESES. (2017). Quality standards for realist evaluations. Retrieved from
661 [http://ramesesproject.org/media/RE_Quality_Standards_for_evaluators_and_peer_r](http://ramesesproject.org/media/RE_Quality_Standards_for_evaluators_and_peer_reviewers.pdf)
662 [eviewers.pdf](http://ramesesproject.org/media/RE_Quality_Standards_for_evaluators_and_peer_reviewers.pdf)
- 663 Wong, G. (2015). Special invited editorial: Getting started with realist research. *International*
664 *Journal of Qualitative Methods*, 14(5) doi:10.1177/1609406915621428

665 Table 1. Vignettes used in the realist interviews

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

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

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	✓		✓		✓		✓		✓		

669