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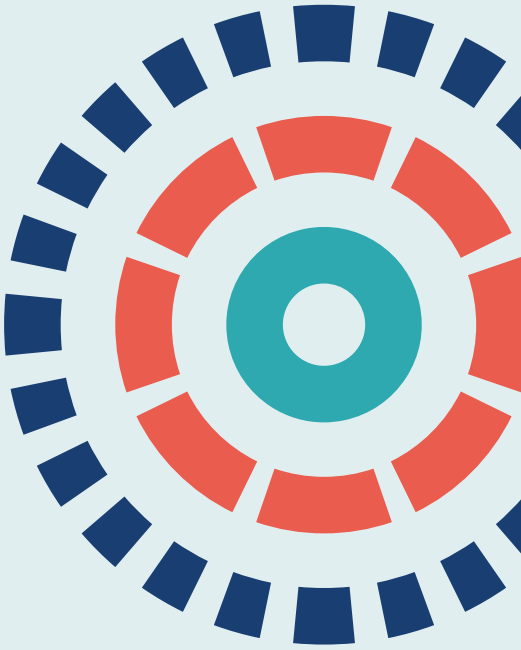

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Acceptability and feasibility of a planned preconception weight loss intervention in women with long-acting reversible contraception: the Plan-it mixed-methods study

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research, or similar, and contains language which may offend some readers.

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Abstract

Acceptability and feasibility of a planned preconception weight loss intervention in women with long-acting reversible contraception: the Plan-it mixed-methods study

Susan Channon,[1*] Elinor Coulman,[1] Rebecca Cannings-John,[1] Josie Henley,[1] Mandy Lau,[1] Fiona Lugg-Widger,[1] Heather Strange,[1] Freya Davies,[2] Julia Sanders,[3] Caroline Scherf,[4] Zoë Couzens[5] and Leah Morantz

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Background: Women with overweight (a body mass index of ≥ 25 kg/m^2) or obesity (a body mass index of ≥ 30 kg/m^2) are at greater risk of experiencing complications during pregnancy and labour than women with a healthy weight. Women who remove their long-acting reversible contraception (i.e. coils or implants) are one of the few groups of people who contact services as part of their preparation for conception, creating an opportunity to offer a weight loss intervention.

Objectives: The objectives were to understand if routine NHS data captured the pathway from long-acting reversible contraception removal to pregnancy and included body mass index; to identify the suitable components of a preconception weight loss intervention; and to engage with key stakeholders to determine the acceptability and feasibility of asking women with overweight/obesity to delay the removal of their long-acting reversible contraception in order to take part in a preconception weight loss intervention.

Design: This was a preparatory mixed-methods study, assessing the acceptability and feasibility of a potential intervention, using routine NHS data and purposefully collected qualitative data.

Participants: The NHS routine data included all women with a long-acting reversible contraception code. There were three groups of participants in the surveys and interviews: health-care practitioners who remove long-acting reversible contraception; weight management consultants; and women of reproductive age with experience of overweight/obesity and of using long-acting reversible contraception.

Setting: UK-based health-care practitioners recruited at professional meetings; and weight management consultants and contraceptive users recruited via social media.

Data sources: Anonymised routine data from UK sexual health clinics and the Clinical Practice Research Datalink, including the Pregnancy Register; and online surveys and qualitative interviews with stakeholders.

Results: The records of 2,632,871 women aged 16–48 years showed that 318,040 had at least one long-acting reversible contraception event, with 62% of records including a body mass index. Given the identified limitations of the routine NHS data sets, it would not be feasible to reliably identify women with overweight/obesity who request a long-acting reversible contraception removal with an intention to become pregnant. Online surveys were completed by 100 health-care practitioners, four weight management consultants and 243 contraceptive users. Ten health-care practitioners and 20 long-acting reversible contraception users completed qualitative interviews. A realist-informed approach generated a hypothesised programme theory. The combination of weight discussions and the delay of long-acting reversible contraception removal was unacceptable as an intervention to contraceptive users for ethical and practical reasons. However, a preconception health intervention incorporating weight loss could be acceptable, and one potential programme is outlined.

Limitations: There was very limited engagement with weight management consultants, and the sample of participating stakeholders may not be representative.

Conclusions: An intervention that asks women to delay long-acting reversible contraception removal to participate in a preconception weight loss intervention would be neither feasible nor acceptable. A preconception health programme, including weight management, would be welcomed but requires risk communication training of health-care practitioners.

Future work: Work to improve routine data sets, increase awareness of the importance of preconception health and overcome health-care practitioner barriers to discussing weight as part of preconception care is a priority.

Trial registration: This trial is registered as ISRCTN14733020.

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/NKIX8285).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

app	application
BASHH	British Association for Sexual Health and HIV
BCT	behaviour change technique
BMI	body mass index
BPAS	British Pregnancy Advisory Service
CI	confidence interval
CMO	context–mechanism–outcome
COM-B	Capability, Opportunity and Motivation to Behaviour
CPRD	Clinical Practice Research Datalink
CTR	Centre for Trials Research
FSRH	Faculty of Sexual and Reproductive Healthcare of the Royal College of Obstetricians & Gynaecologists
GDPR	General Data Protection Regulation
GP	general practitioner
GWG	gestational weight gain
HCP	health-care practitioner
HCPI	health-care practitioner interview
HSE	Health Survey for England
IOM	Institute of Medicine
IU	intrauterine
IUD	intrauterine device
IVF	in vitro fertilisation
iWIP	International Weight in Pregnancy
LARC	long-acting reversible contraceptive
LU	LARC user
LUI	LARC user interview
NICE	National Institute for Health and Care Excellence
NPT	normalisation process theory
PBC	perceived behavioural control
PCC	preconception care
PCOS	polycystic ovary syndrome
PHW	Public Health Wales
PIS	participant information sheet
PPI	participant and public involvement
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	randomised controlled trial
RECORD	REporting of studies Conducted using Observational Routinely-collected Data
RR	relative risk
SAG	Stakeholder Advisory Group
SET	social ecological theory
SHC	sexual health clinic
SHW	Strong Healthy Women
SMG	Study Management Group
SOP	Standard Operating Procedures
SSC	Study Steering Committee
TPB	theory of planned behaviour
WLI	weight loss intervention
WP	work package

Plain English summary

If a woman has overweight or obesity when she is pregnant, then there is a greater risk of health problems for her and her baby. About half of women of childbearing age have overweight or obesity, so we need to find ways of supporting women to lose weight before they become pregnant (described here as 'preconception'). This can be difficult because women do not usually talk to a health-care practitioner (e.g. general practitioners, sexual health doctors, nurses) about becoming pregnant, but one group of women who do are those who need to have a long-acting reversible contraceptive (e.g. a coil or an implant) removed.

This study was designed as preparatory work for a potential future study of a preconception weight loss intervention. We wanted to answer three questions: (1) would women with experience of overweight and of using a long-acting reversible contraceptive think that it would be acceptable to ask women to delay having their long-acting reversible contraceptive removed to take part in a weight loss intervention before pregnancy; (2) what did health-care practitioners think about that idea, and would they be happy to ask women to take part; and (3) can NHS information (routine data) tell us how many women might potentially take part in such an intervention?

We looked at NHS routine data and the research on preconception weight loss interventions. A total of 100 health-care practitioners and 243 users of long-acting reversible contraceptives completed surveys, and 10 health-care practitioners and 20 users of long-acting reversible contraceptives took part in interviews. We found that routine data could not be used to identify people reliably. Designing a weight loss intervention that needed women to delay the removal of a long-acting reversible contraceptive was not acceptable to women. A population-based preconception weight loss intervention with a positive focus was acceptable, but, for such a programme to be delivered by the NHS, health-care practitioners need more knowledge, skills and confidence in talking about weight with patients.

Scientific summary

Background

Women with a raised body mass index (BMI) (i.e. a BMI of 25–29 kg/m^2, classified as overweight, or a BMI of $\geq$ 30 kg/m^2, classified as obese) are at a greater risk of experiencing complications during the antenatal, intrapartum and post-partum periods than women with a BMI of $\leq$ 25 kg/m^2. Those complications include gestational diabetes, shoulder dystocia and venous thrombosis, and there is also increasing evidence of adverse effects of maternal obesity on the longer-term health of the child. Programme development and research in weight management in the context of pregnancy has until relatively recently been focused primarily on the intrapartum period and managing gestational weight gain. However, the evidence thus far is that weight management programmes during pregnancy have limited impact on reducing obesity and the associated complications. Therefore, with the increasing urgency of tackling this problem driven by the rising rates of obesity worldwide, attention has turned to preconception health and the potential to reduce obesity prior to conception.

The development of effective pre-pregnancy weight loss interventions for women with a raised BMI may provide an important step in reducing health risks to mother and child, but there are challenges to be overcome. The preconception period is generally considered a bit of a 'black box' in health terms, as few women actively seek a consultation regarding their preconception health unless there are health concerns or uncertainty regarding fertility. In some countries, such as the Netherlands, preconception clinics are part of routine health services. Elsewhere, there are clinical practice guidelines for health-care practitioners consulting with women of childbearing age with obesity, which include providing information about the risks of obesity and the benefits of weight loss prior to pregnancy. As with pregnancy, the preconception period may be considered a 'teachable moment', during which efforts may be made to positively influence women's diet and health behaviours. However, even when pregnancies are planned, women's enhanced motivation to be healthy may not translate into action because of perceived barriers such as time and relevance. Practitioners also experience barriers to raising weight management in pregnancy-related consultations, including lack of skills, lack of time, the sensitivity of the topic and low confidence in the available interventions.

In countries with no tradition or provision of specific preconception services, women who use long-acting reversible contraception (LARCs) and who require the device to be removed to become pregnant represent a unique group where there is an opportunity for intervention. However, at this point in their reproductive decision-making, it may be difficult to ask women to delay conception through the continued use of their LARC and engage in weight loss programmes, raising pragmatic and ethical issues for both an intervention and any research study designed to establish effectiveness. A small feasibility study of an intensive weight management programme offered to women with a BMI of $\geq$ 30 kg/m^2 attending for LARC removal demonstrated that some women were willing to consider delaying LARC removal for 6 months to participate. This small evidence base suggested that there may be an interest in weight loss and a willingness to delay LARC removal in relevant populations. However, with high rates of non-participation and attrition in the programme, it has not yet been established what, if anything, the nature of an acceptable intervention would be.

Objectives

The aim of the Plan-it study was to establish if it is acceptable and feasible to conduct a study that asks women with overweight/obesity (a BMI of $\geq$ 25 kg/m^2) to delay the removal of their LARC to participate in a targeted pre-pregnancy weight loss intervention.

The study objectives were to identify:

1. the annual number of women of reproductive age (16–48 years) in the UK who request LARC removal and subsequently have a pregnancy
2. means of identifying women with overweight/obesity at study sites who plan to have LARC removal for the purpose of planning a pregnancy and opportunities to intervene
3. suitable and acceptable interventions that could be incorporated into a pre-pregnancy weight loss intervention
4. the willingness of clinicians to raise weight loss in consultations and recruit eligible women to the intervention
5. women's views about the acceptability and feasibility of the proposed intervention
6. potential intervention designs based on their feasibility and acceptability to stakeholders.

Methods

The study took a concurrent mixed-methods approach, incorporating the use of routine NHS data and qualitative data collection and analysis across two work packages. Work package 1 addressed objectives 1 and 2 to establish the feasibility of defining and understanding the population through routine data; and work package 2 addressed objectives 3, 4 and 5, using online surveys in phase 1 and qualitative interviews in phase 2, to provide an understanding of the feasibility and acceptability of a pre-pregnancy weight loss intervention to stakeholders (LARC users and practitioners), in addition to identifying potentially suitable weight loss interventions and the theories underpinning them. The findings from the two work packages were discussed and refined in four stakeholder advisory groups over the course of the study and then integrated to address objective 6, delineating the key design elements of a future intervention.

Three groups of stakeholders were invited to take part in the study: health-care practitioners who insert or remove LARCs were recruited at professional meetings; practitioners who support women with weight management and women of reproductive age who self-identify as having/previously having a raised BMI and experience of having used a LARC were recruited via advertisements on social media.

Results

The online surveys in phase 1 were completed by 100 health-care practitioners, four practitioners who support weight loss as part of their role and 243 LARC users. In phase 2, 10 health-care practitioners and 20 LARC users took part in qualitative interviews.

The key findings of the study are described in relation to the study objectives.

Objective 1

Based on the current routine NHS data sets relating to LARC use and pregnancy, it would not be feasible to reliably identify women who request a LARC removal with an intention to become pregnant. The pathway from LARC removal to pregnancy is not easily captured, with the main barriers being the precision and completeness of the routine data and the lack of connection between the data sets from different parts of the infrastructure (i.e. sexual health services and primary care).

Objective 2

With an average of 62% of women having their BMI recorded within 3 years of a LARC-related consultation, it might be possible to use routine data to identify women of childbearing age who use a LARC and who, based on BMI, would be eligible for a weight loss intervention. However, the limitations of the routine data identified in relation to objective 1 mean that the link between weight, LARC removal and

pregnancy would not be robust enough, and also the acceptability of the intervention to stakeholders (objectives 3–5 below) would preclude this approach to identifying opportunities to intervene.

Objective 3

Research into preconception weight loss interventions has until very recently been dominated by fertility and achieving weight loss in the context of preparation for in vitro fertilisation. The specificity of this context means that the lessons to be learned for a population-based preconception weight loss programme are limited. However, they do provide useful information on the potential parameters of programme duration and achievable weight loss with very motivated participants, suggesting that a clinically significant weight loss of 5–10% within 16 weeks is achievable for women with obesity. The research in managing gestational weight gain is much more developed, with more detail of programme content and underpinning theoretical constructs and mechanisms of change included for some. The main transferable principles in the context of preconception weight loss are the health of the baby as a central motivation for change and the importance of information about general health considerations in pregnancy. The evidence on effective mechanisms underpinning intrapregnancy intervention design is useful to incorporate into a preconception weight loss intervention, with planning and feedback/monitoring being key to success. Our stakeholders identified the key ingredients of a potential programme as diet, exercise, peer group and psychological support. They also shared information about programmes and resources that they had found useful.

Following a realist approach to gathering and synthesising information from the published literature, the lived experiences of our stakeholders and relevant middle-range theories, seven context–mechanism–outcome configurations were developed that, put together as a programme theory, offer possible explanations of how a potential intervention could work.

Reaching out to people

To maximise engagement in a preconception intervention, the design would need to be co-produced with service users to ensure clarity and cultural relevance, have a positive health message and be promoted across multiple platforms and media.

Recognising diversity and wealth of the individuals' experience

The intervention needs to acknowledge and respond to women's experiences of weight management, to maximise their sense of autonomy and competence.

Build health-care practitioners' confidence in and commitment to weight management in preconception care

Practitioners need better information, support and training in talking about weight, and the intervention would need to address the current practical and attitudinal barriers to addressing weight in preconception care.

This is something for me

There needs to be greater awareness of weight as part of preconception health and also more routine weight monitoring as part of contraception consultations.

An intervention that is fit for purpose

A multicomponent intervention that combines nutritional and psychosocial support over several months to enable women to develop effective weight management in order to achieve a clinically significant weight loss of 5–10%.

Building confidence and motivation

Any intervention must take into account the multiple barriers to preconception weight loss and should include recognised key components of behaviour change in successful weight management in other populations, such as goals, planning, feedback and monitoring.

Weight loss discussions should be founded on principles of informed choice and a client-centred approach

Discussing weight is difficult for all parties; any discussion and potential intervention must be based on enabling the service user to make informed choices and be conducted in a sensitive, client-centred way to ensure that it is both ethical and acceptable to the service user.

Objective 4

Practitioners described a willingness to raise weight in consultations with eligible women and recruit them to a preconception weight loss intervention. However, they raised multiple barriers to both, which ranged from the practical, in terms of time, to the sensitivity of the topic, their skills and the appropriateness of the timing of such a discussion at a LARC removal. They also had broader ethical concerns, including whether weight was such a complex issue that it really needed to be raised by the women themselves and that it might not be an appropriate fit with their role to raise it proactively. Although this was not a topic explored extensively in the research literature, the themes from the research resonate with our findings, leading to the conclusion that there are significant attitudinal, knowledge and practical barriers that would need to be overcome for a preconception weight loss intervention to be delivered.

Objective 5

Women had a wide range of views on the acceptability of delaying LARC removal to take part in a preconception weight loss intervention. The key factors that could potentially make this acceptable were sensitive, person-focused communication that acknowledges and works with a woman's prior experience of weight difficulties and puts the woman in control of the decision-making. Significant concerns were expressed about the quality of existing health-care practitioner communication about weight, the practicalities of the intervention in an overstretched service and, crucially, the ethical consideration that the ethos of the intervention undermines a woman's right to choose when she could conceive. On balance, in its basic form, an intervention comprising delaying LARC removal in order to take part in a weight loss programme prior to conception would not be feasible or acceptable to women. However, including this as one option in a preconception health and weight loss programme that is designed with the key principle of informed choice at its heart could be acceptable and potentially feasible.

Objective 6

A potential preconception weight loss intervention is proposed, designed as part of a healthy pregnancy programme. It is based on a broad population-based recruitment approach, signposting to existing programmes but supporting women to feel competent and confident in relation to their weight across the preconception period and pregnancy. It incorporates the opportunity presented by LARC removal, but, in recognition of all the ethical and pragmatic complexities of making that the sole focus, the idea of delaying removal is one potential choice, and the eligibility criteria would be much wider. The focus of the intervention is on introducing change in a 12- to 16-week period pre conception, but it would also incorporate a form of support over a longer period, potentially into pregnancy to support women to consolidate the changes over a longer time frame.

Conclusions

At the present time, developing an intervention that asks women with a raised BMI to delay removal of LARC to participate in a targeted pre-pregnancy weight loss intervention would be neither feasible nor acceptable. However, contraception-related appointments, including LARC removals, do offer an opportunity to engage in discussions about preparation for pregnancy. They could be incorporated into a broader, population-based preconception programme, and one potential model of this type of programme is proposed. For this to succeed, it would need to overcome some current barriers and include training health-care providers in communication about weight (and risk in general) and improving

information relating to the benefits of weight loss prior to conception. The profile of preconception health and its importance needs to be raised in the general population, and the routine data sets in this area need significant improvement, including streamlined coding and links between services.

Future research is needed to explore ways to overcome the barriers experienced by health-care staff in discussing weight as part of preconception care. Very often the focus falls on pragmatic barriers such as time in consultations, but this study has underlined the importance of topics such as professionals' beliefs about the impact of weight on health, their professional remit in relation to weight and the links between contraception services and general health. This needs to be a priority, as, unless these barriers are reduced or removed and the quality of the communication is improved, a population-based preconception weight loss intervention based in the NHS will not be feasible.

Trial registration

This trial is registered as ISRCTN14733020.

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Chapter 1 Introduction and background

The context of obesity in pregnancy

Prevalence and risk

More than 50% of women who gave birth in the NHS between 1 April 2016 and 31 March 2017 had a body mass index (BMI) of ≥ 25 kg/m^2 (which would be classified as being in the overweight range),[1] including 26.7% who had a BMI in the obese category (BMI of ≥ 30 kg/m^2). Obesity levels are expected to continue to rise, with the majority of the UK population expected to be obese by 2050.[2] Obesity places women at a greater risk of experiencing complications during the antenatal, intrapartum and post-partum periods. Maternal risks associated with obesity in pregnancy include backaches, leg pain, increased fatigue, gestational diabetes, miscarriage, pre-eclampsia, thromboembolism, slow labour progress, high caesarean section rates, post-partum haemorrhage, hypertension and maternal death.[3,4]

There is also a generational dimension, as described in the Foresight report,[2] with an increased risk of adverse effects on the child due to biological, social and environmental factors, including child obesity,[4] developing insulin resistance[5] and, for girls, having polycystic ovary syndrome (PCOS).[6] With the increasing evidence of the influence of the periconceptional period on fetal growth and long-term effects on risk factors for non-communicable diseases, it is essential that services incorporate interventions not only to reduce obesity levels of women in the preconception period and maintain weight loss during pregnancy and post partum, but also to prevent this passage of risk to the next generation.[7]

The Southampton Women's Survey reported that, in their community sample, almost half of the women recruited gained excessive weight in pregnancy according to the 2009 Institute of Medicine (IOM) guidelines,[8] and there are health risks associated with gestational weight gain (GWG), irrespective of pre-pregnancy weight status.[9] However, women with overweight or obesity are at greater risk of excessive GWG in early pregnancy. The development of interventions targeting women in the preconception period, with the aim of reducing GWG, may potentially reduce the risks associated with early GWG.[10]

There are clear health gains from a reduction in BMI pre pregnancy. In a population-based study in Canada[11] comprising 226,958 women (64% with normal weight, 20% with overweight and 12% with obesity) with singleton pregnancies, a 10% lower preconception BMI was associated with a clinically meaningful risk reduction in pre-eclampsia, gestational diabetes, preterm delivery, macrosomia and stillbirth.

Excessive GWG is associated with weight retention in the longer term,[12] and women in the post-partum period describe barriers to losing post-partum weight, including depression and a lack of weight management support.[13] The cumulative effects of excessive GWG without post-partum weight loss in multiple pregnancies may, therefore, contribute to obesity. Systematic reviews of weight loss interventions (WLIs) in the post-partum period suggest that WLIs with diet and physical activity components combined or that use diet alone, but not physical activity alone, can contribute to post-partum weight loss.[14] Furthermore, post-partum interventions that have an information or communication technology component may also be effective in increasing weight loss post partum.[15] However, further research and larger, high-quality trials with longer follow-up are required.

Guidelines for health-care practitioners providing care for women before conception and during pregnancy

The risks associated with obesity in pregnancy are reflected in the National Institute for Health and Care Excellence (NICE) guidelines for health-care practitioner consultations with all women before and during a pregnancy.[16] These guidelines make lifestyle recommendations, such as stopping smoking,

taking folic acid and avoiding alcohol, and they include weight management. Specific recommendations are made for consultations with women with a BMI of $\geq$ 30 kg/m^2. Women in this group planning a pregnancy should receive information regarding the risks of obesity during pregnancy and childbirth, and advice and support to help them achieve a healthy weight prior to pregnancy, with the suggestion that losing 5–10% of their body weight would make a significant difference. Once pregnant, women with a BMI of $\geq$ 30 kg/m^2 should be offered tailored information about their diet and exercise. Women should be told about the risks that a raised BMI poses to the pregnancy but also should be told not to diet in pregnancy and that the risks will be managed by the health-care practitioners caring for them. The monitoring of GWG during pregnancy is not advised unless there is a clinical need. These recommendations are supported by the Centre for Maternal and Child Enquiries/Royal College of Obstetricians and Gynaecologists (RCOG)[17] and the RCOG's *Care of Women with Obesity in Pregnancy* guidelines.[18]

NICE guidance also recommends that health-care practitioners be equipped with behaviour change knowledge, skills and competencies and receive communication skills training to be able to discuss weight sensitively with women. However, unlike the IOM guidance in the USA,[19] there are no UK-specific guidelines for recommended optimal weight gain in pregnancy. The FIGO (International Federation of Gynaecology and Obstetrics) guidelines stress that 'management of obesity in pregnancy should be considered in the context of a life course approach, linking with preconception and post-partum and interconception services to prevent excess weight gain before and during pregnancy'.[20]

Interventions in pregnancy

There has been a considerable focus, particularly in the last decade, on weight management interventions in pregnancy. A meta-analysis[21] of individual participant data from 36 randomised controlled trials (RCTs), including 12,000 participants, demonstrated that weight management interventions targeting diet and/or weight management in women across all BMI categories have not been associated with beneficial maternal or child outcomes, with the exception of caesarean section rates. However, weight management interventions in pregnancy were associated with a small but significant reduction in GWG (–0.7 kg),[21] A review of reviews by Farpour-Lambert *et al.*[22] demonstrated moderate- to high-quality evidence of significant reduction in several outcomes in women across all BMI categories receiving a weight management intervention targeting diet and/or physical activity. These included reductions in GWG (–1.8 to 0.7 kg), excessive GWG, caesarean section rates [relative risk (RR) 0.91–0.95] and neonatal respiratory distress syndrome rates in the child (RR 0.56). However, in women with overweight/obesity, the evidence demonstrating beneficial outcomes of weight management interventions was of low to moderate quality. There was also heterogeneity among studies; study methods, intervention settings, target population and main intervention components varied between studies and interventions.

A systematic review by Agha *et al.*[3] across 14 studies in pregnancy and one in the preconception period demonstrated that the techniques most commonly used in interventions effective at reducing GWG included diet and physical activity counselling, motivational counselling, weight monitoring and feedback at appointments with health-care practitioners. In a meta-analysis of 89 RCTs, the authors concluded that although there was no optimal intensity, frequency, duration and delivery method that predicted success, interventions containing a group component or a healthy eating component, no matter the intensity, were more likely to be effective.[23]

The timing of the initiation of a weight management intervention is important. Excessive weight gain in the first trimester is predictive of excessive weight gain throughout pregnancy[24] and gestational diabetes mellitus.[25] This means that starting an intervention in pregnancy may well be too late, as the first point of contact with a health-care practitioner in pregnancy is usually towards the end of the first trimester. Interventions most effective at reducing GWG are those initiated in early pregnancy rather than those delivered later in pregnancy,[3] and in Farpour-Lambert *et al.*'s[22] meta-analyses

investigating the effects of lifestyle interventions on GWG or post-partum weight retention, the authors concluded that weight loss prior to pregnancy is probably required to achieve both GWG goals and optimal pregnancy outcomes.

Given the limited success of interventions for obesity in pregnancy, the issue of timing and the key impact of health behaviours in the very early days of conception, attention has turned to the preconception phase as critical to improving maternal and child health. However, owing to the paucity of WLIs in the preconception stage, evidence of their overall effectiveness or of what intervention components may be beneficial is limited.

Preconception health and care

The preconception period

The World Health Organization defines preconception care (PCC) as:

> *. . . the provision of biomedical, behavioural and social health interventions to women and couples before conception occurs. Its ultimate aim is to improve maternal and child health, in both the short and long term.*
>
> *World Health Organization.[26] Reproduced with permission under the CC BY-NC-SA 3.0 IGO licence*

As highlighted in the 2018 series on preconception health in *The Lancet*[27–29] and by Stephenson *et al.*,[30] preconception is an 'underappreciated period in the life course when health, behavioural, and environmental exposures can have far-reaching consequences, not only for pregnancy outcomes but also for health across generations'.[30] One of the complexities, critical to the clarity of focus of any programme or intervention, is defining the meaning of preconception. Stephenson *et al.*,[27] suggested that there were three perspectives to consider in a discussion of preconception: (1) biological perspective (the days or weeks before the embryo develops), (2) individual perspective (the weeks or months before conception for individuals who have a conscious intent to conceive) and (3) public health perspective, which includes the months or years before conception. Hill *et al.*[31] recognised the value of this classification but felt that it lacked enough specificity to identify the population to be defined and targeted in interventions. They proposed four perspectives, each based on a particular combination of defining attributes: reproductive age, man/woman, not pregnant, sexually active, intent to conceive. Some differences from Stephenson's classification are that the 'public health' group is subdivided into those of reproductive age (public health) or younger (life course) and that the individual perspective is subdivided into those with intent and those without intent (potential preconception). Many preconception interventions target the 'intentional preconception' group, but this excludes those who are sexually active, who may or may not be using contraception, but have not made a conscious decision to conceive.

Healthy diet/nutrition and weight management have been identified as the top two priorities in international preconception research.[32] There are significant gaps in preconception nutritional intake internationally.[33] In the UK it is estimated that 77% of women aged 18–25 years have dietary intakes below Reference Nutrient Intake daily recommendations for iodine and that 96% of women of reproductive age have intakes of iron and folate below the daily recommendations for pregnancy.[27] The situation is not greatly improved in women who are planning a pregnancy: the results of the Southampton Women's Survey showed that only a very small proportion of women planning a pregnancy followed the recommendations for nutrition and lifestyle in the preconception period. For example, only 2.9% of women who became pregnant [95% confidence interval (CI) 1.2% to 6.0%] complied with recommended levels of folic acid supplementation and drank four or fewer units of alcohol a week, compared with 0.66% (95% CI 0.52% to 0.82%; $p < 0.001$) of those women who did not become pregnant.[34]

The lack of engagement with the recommendations may well be due to a lack of knowledge relating to preconception health or, potentially, beliefs relating to the behaviour, as there are indications that smoking, a more commonly known risk behaviour, does reduce before pregnancy.[35] Preconception education and counselling can improve maternal knowledge, self-efficacy and risk behaviour, but the impacts on anthropometric measures and pregnancy outcomes are less clear.[36,37] There may also be demographic differences underlying differential behavioural response to information; for example, younger preconceptional women and women with children were less likely to engage in preconception health behaviours,[38] and women with higher levels of education were more likely to engage.[39,40]

In England, the Preconception Partnership of key stakeholders is working to operationalise policy to ensure that PCC becomes a more integrated part of routine practice. It has proposed an annual report identifying progress on a set of core metrics for agencies, reflecting planning and preparation for pregnancy at an individual and public health level.[30] This would include improving the health environment, putting the importance of preconception health on the school curriculum and embedding it in policy initiatives. On an individual level, the goals include normalising conversations about pregnancy intentions in health care, increasing support for behaviour change to improve preconception health and training health-care providers to have conversations about preconception health.

One of the issues that is often cited as the reason for the lack of preconception health care is the number of pregnancies that are planned, often assumed to be small. In a cross-sectional survey[35] of 1288 women conducted in a London maternity centre, 73% had clearly planned their pregnancy and 24% were ambivalent, with only 3% of pregnancies unplanned. These figures would suggest that planning is more common than is often assumed. There are also different types of 'planning', for example women with high levels of pregnancy planning who take up interventions but also those who plan but describe themselves as having poor awareness of preconception actions.[41] However, if the interventions suggested by the Preconception Partnership were put in place and preconception health conversations were more integrated into routine care, the level of positive intention and planning could become less of a barrier.

Preconception and obesity

Until very recently, few studies have targeted obesity in the preconception period; interventions in the preconception period have reported programmes for very specific populations, such as gastric bypass patients,[42] those with diabetes[43] or couples seeking in vitro fertilisation (IVF) treatment,[44] or have been small scale.[45] Two Cochrane reviews[46,47] investigating the effectiveness of preconception and antenatal health programmes and interventions in improving pregnancy outcomes or reducing weight in obese women identified no eligible studies in the preconception phase. In a systematic review[48] of the impact of preconception lifestyle interventions on live birth, birthweight and pregnancy rate, six of the included studies reported participants' weight and BMI, five of which were in the context of assisted reproduction. The Strong Healthy Women (SHW) intervention[49] (a six-session preconception health course with a social cognitive approach[50] to behaviour change in preconceptional and interconceptional women living in low-income rural communities) was excluded from the reviews as it was not possible to identify outcomes by BMI category (see *Studies in progress*).

A more recent scoping review[51] of RCTs of behavioural interventions supporting women of childbearing age in the prevention and treatment of overweight and obesity identified only one intervention in the preconception period, the Prepare study protocol.[52] The Prepare trial is a pre-pregnancy intervention in the USA for women with a BMI of ≥ 27 kg/m^2 identified through routine data. The intervention is based on social cognitive theory, and the intervention group received 6 months of weekly weight management calls from a health coach followed by monthly calls for 1 year. The primary outcome was GWG but with prenatal weight loss as a secondary outcome. In the results, now published,[53] the women receiving the intervention lost an average of 3.5% of their weight before becoming

pregnant (control arm 0.5%; $p < 0.001$). However, by the end of the third trimester, the GWG was the same for both groups, leading the authors to suggest that an intensive weight management approach is needed beyond preconception, and throughout pregnancy, to manage GWG.

One potential reason for the lack of evidence in relation to preconception and obesity is that weight and weight management often do not feature in preconception health programmes that have been evaluated. In a systematic review of studies identifying factors related to preconception health behaviours,[38] weight status was measured in only 3 of the 24 included studies and, therefore, was not identified in the review as one of the six categories of factors. Similarly, in a scoping review of preconception health interventions, only 4 of the 29 included programmes identified weight/obesity as a risk factor to be addressed.[37] More recently, in a published trial protocol concerning the uptake of PCC in the Netherlands,[54] the primary outcome was change in lifestyle behaviours (e.g. folic acid use, smoking and alcohol use) and secondary outcomes were pregnancy outcomes (e.g. miscarriage, preterm birth, gestational diabetes) and the uptake of PCC, but weight management was not included. Overall, the quantity and quality of the evidence in this field is very limited.[36]

Barriers to engaging women in preconception weight loss interventions

With the rising rates of women of childbearing age who are obese,[55] the development of effective preconception WLIs for women with overweight/obesity may provide an important step in reducing the health risks to mother and child. As with pregnancy,[56] the preconception period may be considered a 'teachable moment', during which efforts may be made to positively influence women's diet and health behaviours. However, there are barriers to overcome. As already highlighted, preconception is a difficult time to identify. 'Planning' a pregnancy is often declared only once the pregnancy has been confirmed; prior to this, it is something regarded by many as deeply personal and essentially private.[57] Furthermore, women may not be aware of the importance of preconception health, and they may not perceive there to be risks or that the risks are relevant to them.[45,57] Specific issues for women with overweight/obesity and who are planning a pregnancy include poor uptake of health activities, inaccurate self-categorisation of weight, unsuccessful weight loss attempts and inadequate advice regarding pre-pregnancy weight loss.[58] Often, the complex lifestyle changes required for weight loss before pregnancy are challenging to achieve, but women who recognise that they have knowledge gaps about the impact of obesity in pregnancy are keen to receive information about antenatal, intrapartum and post-partum risks.[43]

The Health Survey for England (HSE)[59] reports that obesity rates for women are higher in areas of highest Index of Multiple Deprivation (39%) than in the least deprived areas (22%). Evidence of obesity rates in ethnic minority groups is scarce, with the exception of the 2004 HSE.[60] These data suggest that obesity rates vary among ethnic groups, with higher rates in black and Pakistani groups and lower rates in Chinese groups than in the general population.[61] Health risks such as diabetes are observed in ethnic groups at lower rates of overweight/obesity than the white European population,[62] and, therefore, reducing obesity levels in ethnic minority groups could be of increased relevance. Uptake and retention of programmes may vary in women of different ethnic backgrounds. In a process evaluation of a postnatal WLI in an ethnically diverse population, non-white British/Irish women were less likely to attend a commercial weight loss management group than white British/Irish women. The women were more likely to describe barriers to attending the sessions, such as time, access and child-care needs, than white British/Irish women.[63] Furthermore, women from ethnically diverse communities reported that they had modest or poor awareness of preconception health issues and that there was little culture of preconception preparation.[64] Therefore, cultural differences would need to be considered and addressed when targeting women from ethnic minority groups and when designing an effective intervention for ethnically diverse populations.

Health-care practitioners also experience barriers to raising weight management during preconception and pregnancy-related consultations, including lack of skills, time, financial reimbursement, sensitivity of topic and confidence in the available interventions.[65–67] Interviews with UK health-care practitioners

showed that there was a low awareness of preconception health issues and confusion about responsibility for delivery of PCC.[35] Taking a broader view of health-care provision, these barriers resonate with those found in a systematic review of the barriers to and enablers of health-care practitioners in delivering behaviour change interventions (diet, physical activity, alcohol reduction, smoking cessation and weight management).[68] Four themes emerged as both barriers and enablers: (1) perceptions of the knowledge or skills needed to support patients' behaviour change, (2) perceptions of their professional role, (3) beliefs about resources needed and (4) practitioners' own health behaviour. Cross-disciplinary barriers included a perceived lack of time, negative attitudes towards patients and perceptions of patients' motivation, including a lack of prioritisation of health behaviour change.[68] Training, context and attitudes towards the intervention were the enablers identified, and any programme of preconception health will need to use these to address individual and systemic barriers if provision is going to change.

Studies in progress

Several trials are in development or pre-reporting that are taking a range of approaches to weight management in the preconception period in different cultural contexts.

Strong Healthy Women was originally a six-session intervention delivered to 692 preconceptional and interconceptional women across 12 weeks in low-income and rural communities. They focused on managing stress, physical activity, nutrition (including folic acid supplementation), preventing gynaecologic infection, tobacco exposure and alcohol use (weight was not included as a focus). Their intervention adopted a social cognitive approach to behaviour change,[50,69] identifying self-efficacy, motivation and intention to change as important determinants of behaviour change. Participants receiving the intervention had improved pre–post intervention outcomes relating to nutrition, physical activity and stress management compared to the control group.[70,71] At the 12-month follow-up, the intervention group had reduced weight (mean group difference of 4.33 lb), reduced BMI (mean difference of 0.75 kg/m^2) and lower GWG in those who became pregnant (mean difference of 17.95 lb).[49] Despite a small sample size, these were promising results. However, the face-to-face nature of intervention delivery was considered resource-intensive and expensive by the research team, and the time investment required for participation was burdensome for some women. The study team have therefore explored a 'smart' version, using qualitative methods to determine which components women would be happy to receive digitally and which to retain face to face.[72]

The INTER-ACT study in Belgium[73] is an interpregnancy study designed to reduce pregnancy complications in women whose pregnancy weight gain exceeds the IOM-recommended levels. The lifestyle intervention incorporates an e-health application (app) and coaching delivered partially post partum and then during the following pregnancy. The women's experience of using the app suggests that combining a personalised app with coaching is a positively received intervention.

The Jom Mama trial in Malaysia[74] is a population-based pre-pregnancy intervention that recruits as couples get married. It is designed to enhance healthy dietary choices, increase exercise and manage stress. It is grounded in the theory of triadic influence and uses behaviour change counselling combined with WhatsApp chat support and an e-health habit formation app.

TOP Mums[75] is a preconception intervention designed to reduce perinatal morbidity for women with a BMI of > 25 kg/m^2 planning to conceive in the next year and is due to report imminently. It is a 26-week programme incorporating motivational interviewing, personalised goals and a health intervention, 'Smarter Pregnancy'. BMI is the primary outcome from baseline to 6 weeks post partum, with GWG one of the secondary outcomes.

Other studies that will involve measurement of pre-pregnancy weight, but do not evaluate population based pre-pregnancy interventions, evaluate the quality of the preconception diet (Healthy for my Baby);[76] the relationship between maternal weight and baby weight;[77] reducing pre-pregnancy and pregnancy weight gain in the context of depression;[78] and reducing the reoccurrence of gestational diabetes.[79]

Users of long-acting reversible contraceptives

The complexities of identifying the preconception population mean that it is difficult to engage with people at the right time to have them consider taking part in a weight reduction programme to improve their preconception health. Women who use long-acting reversible contraception (LARCs) and who require removal of the device to become pregnant represent a unique group in which there is an opportunity for intervention. However, at this point in their reproductive decision-making, it may be difficult to ask women to delay conception through continued use of LARC and engage in weight loss programmes, raising pragmatic and ethical issues for both an intervention and any research study designed to establish effectiveness. A small feasibility study of an intensive WLI offered to women with a BMI of 30 kg/m^2 or more attending for LARC removal[80] demonstrated that some women were willing to consider delaying LARC removal for 6 months to participate. This small evidence base suggests that there may be an interest in weight loss and a willingness to delay LARC removal in relevant populations. However, with high rates of non-participation and attrition from the programme, it has not yet been established what, if anything, the nature of an acceptable intervention would be.

To answer this question, a mixed-methods approach is required, incorporating the use of routine data, qualitative data collection and analysis, and giving a central role to stakeholders. This will lead to a better understanding of the LARC pathway from an individual and population perspective and its interface with weight management. LARC users' and health-care practitioners' experiences of LARC services, decision-making and management of weight around pregnancy will be explored alongside their views of the ethical and methodological issues associated with the timing of informed consent and a potential preconception WLI. Health-care practitioners' LARC practice and consultation patterns regarding LARC use and removal will be identified utilising data sets, collected routinely across the four UK nations, to compare the population across the different health-care settings as well as over time, taking into account factors such as the impact of different general practice incentives on activity and recording.[81] All of this information will be critical to consider when developing a future intervention.

Preconception weight loss as a complex intervention

A preconception weight loss programme would be described as a complex intervention in the terms of the Medical Research Council framework for the development and evaluation of complex interventions,[82,83] which involve multiple interacting components in a complex context and require behaviour change on the part of practitioners and participants. The Medical Research Council framework identifies four phases in the development and evaluation of complex interventions: development, feasibility, evaluation and implementation. The Plan-it study falls into the development phase, exploring an idea for a potential intervention that could be delivered in the NHS. There are, clearly, many generic weight loss programmes that women could access in the preconception phase. The question here is whether or not it is acceptable and feasible to develop a specific preconception weight loss programme that includes a delay to a LARC removal as the entry point to the programme.

As described by O'Cathain *et al.*,[83] the development phase is a dynamic, iterative process that includes seeking feedback from key stakeholders on intervention ideas, reviewing evidence, drawing on theories, exploring context and undertaking some primary data collection. Through this process, the strengths of the idea and the problems can be identified and used to further refine possible intervention designs. Once an idea for an intervention has been developed that is acceptable and feasible in its formulation, it moves to the feasibility phase, when it is tested in practice, followed by an evaluation, potentially by a RCT, to establish its efficacy.

Research objectives

The aim of the Plan-it study is to establish if it is acceptable and feasible to conduct a study that asks women with overweight/obesity (BMI of $\geq$ 25 kg/m^2) to delay removal of LARC to participate in a targeted pre-pregnancy WLI.

The study objectives are to identify:

1. the annual number of women of reproductive age (16–48 years) in the UK who request LARC removal and subsequently have a pregnancy
2. the means of identifying women with overweight/obesity at study sites who plan to have LARC removal for the purpose of planning a pregnancy and opportunities to intervene
3. suitable and acceptable interventions that can be incorporated into a preconception WLI
4. the willingness of clinicians to raise weight loss in consultations and recruit eligible women to the intervention
5. women's views about the acceptability and feasibility of the proposed intervention
6. future potential intervention based on feasibility and acceptability to stakeholders.

Chapter 2 Methods

This chapter provides a detailed description of the study design and a general overview of the study processes. Specific methods relevant to individual study work packages (WPs) are detailed in corresponding chapters.

Study design

The Plan-it study used a concurrent mixed-methods approach, incorporating the use of routine NHS data and qualitative data collection, analysis and synthesis across WPs to address study objectives (see *Chapter 1*).

Work package 1 established the feasibility of defining and understanding the study population through routine data and addressed study objectives 1 and 2 (see *Chapter 3*):

1. to identify the annual number of women of reproductive age (16–48 years old) in the UK who request LARC removal and subsequently have a pregnancy
2. to ascertain opportunities to identify women with overweight/obesity at study sites who plan to have LARC removal for the purpose of planning a pregnancy and opportunities to intervene with a potential preconception WLI.

Work package 2 identified potentially suitable preconception/pregnancy-related WLIs and the theories underpinning them, using realist methods,[84] in addition to assessing the feasibility and acceptability of a preconception WLI to stakeholders (LARC users and health-care practitioners). Study objectives 3–5 were addressed:

3. to identify suitable and acceptable programme components to be incorporated into a preconception WLI
4. to assess the willingness of health-care practitioners to raise weight loss in consultations and recruit eligible women to the intervention
5. to assess LARC users' views on the acceptability and feasibility of the proposed intervention and of future research.

The findings from the two WPs were collated, and the barriers to and facilitators of a potential future intervention were assessed by stakeholders (see *Chapter 7*), to address objective 6:

6. future potential intervention based on feasibility and acceptability to stakeholders.

Work package 1: defining and understanding the population through routine data

To address study objectives 1 and 2, WP1 used routine data from Welsh sexual health clinics (SHCs) and UK general practices relating to women attending for LARC removal to:

1. understand the pattern of LARC use to identify opportunities to intervene
2. report the annual number of women in the UK requesting removal of LARC without replacing it with an alternative prescribed contraception
3. identify women, who request LARC removal and subsequently become pregnant, who would be eligible for recruitment to a WLI study

4. identify events in general practitioner (GP) and hospital records to explore time from LARC removal to conception or appointments relating to difficulties conceiving (if possible).

Comprehensive WP1 methodologies are described in *Chapter 3*.

Work package 2: understanding context and stakeholder views

Work package 2 was conducted in two phases. Phase 1 comprised scoping work to develop an understanding of the typical preconception pathways related to LARC use/LARC removal and weight from the perspectives of LARC users and service providers and to identify suitable weight loss and weight-related health behaviour interventions and the theories that underpin them using realist synthesis. Phase 2 focused on establishing the acceptability and feasibility of a proposed intervention.

Work package 2 phase 1: realist review – scoping suitable interventions and underlying theories

Programme theories regarding how and when health behaviour interventions in the preconception phase may function were developed, guided by the principles of scientific realism.[84] Studies of WLIs prior to and during pregnancy and relevant behaviour change interventions were identified through literature searches, including searches of systematic reviews, companion papers (e.g. qualitative studies and process evaluations) and grey literature (the search strategy is detailed in *Appendix 6*). These provided an understanding of how and when preconception WLIs might be delivered successfully. Barriers to and facilitators of engagement in preconception health behaviour change interventions and identified health gains or risks to health associated with the intervention were incorporated into the review. The outcome of this review was a set of context–mechanism–outcome (CMO) configurations and key components of the intervention. These were explored in stakeholder advisory groups (SAGs) as the basis of an early overall programme theory, and further developed in phase 2.

Work package 2 phase 1: understanding the preconception pathways relating to LARC

A range of qualitative methods were used to generate a detailed understanding of typical preconception pathways related to LARC use/LARC removal and weight from the perspectives of both service users (LARC users) and service providers (health-care practitioners and weight loss practitioners). LARC removal service contexts, LARC management (in the context of LARC users and health-care practitioners), the inter-relationship between discussions about overweight/obesity and family planning, feasible opportunities to intervene and potential intervention components including additional preconception health-related content were assessed. The phase comprised three components: (1) an analysis of policy documents, (2) engagement with LARC users and (3) service provider engagement (health-care and weight loss practitioners).

Analysis of policy documents

A review of policies, best practice guidelines and other clinical/advisory documents pertaining to the use (and particularly the removal) of LARCs in the UK was conducted to understand how services are expected to approach discussions of weight loss with women with overweight/obesity, how LARC treatment pathways currently operate, guidance on health behaviours prior to conception and the practical/ethical challenges to successful service delivery in current service structures, including equity of access to interventions (for detailed methodologies, see *Chapter 4*).

Engagement with LARC users

Qualitative surveys using closed and open-text questions were utilised to understand women's experiences of discussing weight with health-care practitioners; how, where and when women access preconception WLIs; women's knowledge of the risks of overweight/obesity in pregnancy; the barriers to and facilitators of the introduction of a WLI at LARC removal appointments; and the preferred components of a potential intervention. Detailed methodologies are described in *Chapter 4*.

Engagement with service providers (health-care and weight loss practitioners)

Qualitative surveys with health-care practitioners using closed and open-text questions focused on: PCC provision; the discussion of weight and preconception health both generally and in the specific context of LARC removal; challenges to service delivery; equity of access to interventions; and views on the potential for an intervention postponing LARC removal as part of preconception weight loss plan. Weight loss practitioners (i.e. people who support women to lose weight as part of their role) were recruited via existing contacts and a range of social media platforms. Qualitative surveys with weight loss practitioners addressed the feasibility and experiences/views on the provision of weight loss programmes in the preconception phase. Detailed methodologies are described in *Chapter 4*.

Summary of phase 1 findings

Information gathered in phase 1 was synthesised to describe the core components of a potential intervention, together with the contextual factors likely to be important influences on outcomes and engagement. This was refined through work with two SAGs, a LARC user SAG and a health-care practitioner SAG, recruited through the exploratory work in phase 1. The health-care practitioner SAG was run as part of a Continuing Professional Development event to incentivise health-care practitioners to attend but without disruption to clinical activity. The LARC user SAG took the form of a focus group, held remotely via Zoom (Zoom Video Communications, San Jose, CA, USA). The objectives of both SAGs were to generate the stakeholders' views of the potential intervention components and to consider the key questions to ask participants in phase 2. Detailed methodologies are described in *Chapter 6*.

Phase 2: acceptability and feasibility of proposed intervention

The outputs from phase 1 were explored in phase 2, with targeted qualitative work addressing acceptability and feasibility of a potential WLI to women in the target population and to health-care practitioners. Phase 2 qualitative interview schedules were informed by the feedback from the SAGs, and the interviews further tested and refined the theories developed in phase 1. Interviews with 20 LARC users and 10 health-care practitioners were conducted over the telephone or remotely via Zoom or Microsoft Teams. Health-care practitioners were asked to explore their views regarding the type of intervention and their willingness to recruit women to a potential study. LARC users were asked to explore their views regarding the acceptability and feasibility of the potential WLI. Findings from the targeted qualitative phase 2 work were discussed at LARC user and health-care practitioner SAGs. The SAGs were conducted as a focus group remotely via Zoom or an online group discussion. The findings from phase 2 were collated, and the key design elements of a potential intervention were described.

Study flow

Figure 1 illustrates the Plan-it study flow chart.

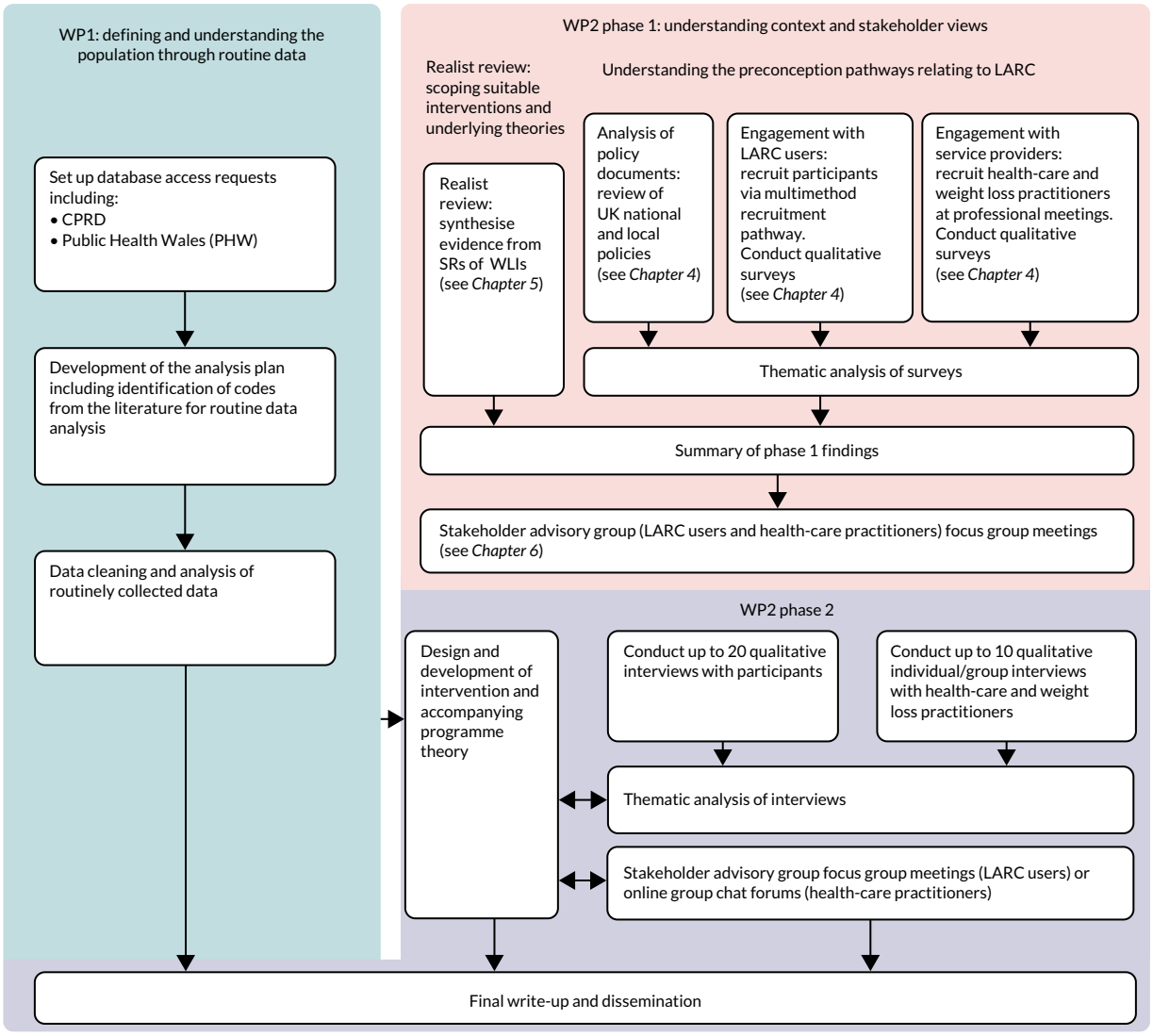

FIGURE 1 Plan-it study flow chart.

Literature review methods

For each of the search strategies (detailed in *Appendix 6*), relevant papers were identified through purposive and snowball searching. A broad search strategy was developed and run in the following search engines: MEDLINE, PubMed and ScienceDirect® (Elsevier, Amsterdam, the Netherlands). Papers were restricted to English language only between set dates. Search strategies were agreed between two members of the team for each search, inclusion criteria were set and the relevance of each paper was assessed. Data to be extracted were agreed prior to analysis and a sample of data extraction was double checked by a second member of the study team. Quality was assessed and integrated into the analysis and synthesis to ensure that the findings were not overinterpreted.

Study setting and participant selection/recruitment

The study setting and participant population is described in *Table 1*.

TABLE 1 Study setting and participant selection/recruitment processes

Study stage	Participant population	Setting
WP1	Participants will be included in routine data sets if they met eligibility criteria	N/A
WP2 phase 1	LARC users of reproductive age who self-identify as having/previously having overweight/obesity	Identified via social media/online platforms. Recruited online via Cardiff Online Surveys (formerly Bristol Online Surveys)
	Health-care practitioners who insert or remove coils as part of their role	Identified at up to eight professional meetings. Recruited online via Cardiff Online Surveys or face to face
	Weight loss practitioners who support women to lose weight as part of their role	Identified via existing contacts or social media/online platforms. Recruited online via Cardiff Online Surveys
WP2 end of phase 1 SAGs	LARC users of reproductive age who self-identify as having/previously having overweight/obesity	Purposively sampled from the WP2 phase 1 participant population, who had agreed to be contacted by the study team
	Health-care practitioners who insert and/or remove coils as part of their role	Identified and recruited at a BASHH audit-focused professional meeting
WP2 phase 2 interviews	LARC users of reproductive age who self-identify as having/previously having overweight/obesity	Purposively sampled from the WP2 phase 1 participant population, who had agreed to be contacted by the study team, excluding members of the phase 1 SAG
	Health-care practitioners who insert and/or remove coils as part of their role	Purposively sampled from the WP2 phase 1 participant population, who had agreed to be contacted by the study team
WP2 end of phase 2 SAGs	LARC users of reproductive age who self-identify as having/previously having overweight/obesity	Purposively sampled from the WP2 phase 1 participant population, who had agreed to be contacted by the study team
	Health-care practitioners who insert and/or remove coils as part of their role	WP2 phase 1 participant population, who had agreed to be contacted by the study team

N/A, not applicable.

Eligibility criteria

Participants were included in routine data sets if they met the eligibility criteria and in the online surveys if they self-identified as meeting the eligibility criteria. See *Chapter 4* for a detailed description of LARC user and health-care practitioner eligibility criteria and *Chapters 6* and *7* for relevant LARC user and health-care practitioner sampling criteria.

Informed consent

For the surveys, all inclusion and exclusion criteria were specified in publicity materials, and for the surveys, interviews and SAGs all participants were provided with a participant information sheet (PIS) and followed a consent procedure (see *Chapters 4*, *6* and *7*).

Data management and confidentiality

All procedures for data storage, processing and management complied with the Centre for Trials Research (CTR) Standard Operating Procedures (SOPs), Clinical Practice Research Datalink (CPRD) and Public Health Wales (PHW) data-sharing agreements and the General Data Protection Regulation (GDPR),[85]

as appropriate. A full Data Management Plan was developed, and all data will be kept for 15 years on a Cardiff University secure server, in line with Cardiff University's Research Governance Framework Regulations for clinical research.

The online survey was hosted by Cardiff Online Surveys (previously Bristol Online Surveys) on a Cardiff University secure server, and access was password protected. A member of the research team acted as administrator.

Hard-copy consent forms were stored in a locked filing cabinet. All electronic data, including consent/contact details, were stored in password-protected servers maintained on Cardiff University networks. All electronic identifiable data (consent, contacts forms) were stored separately from interview data. Interviews and SAGs were recorded on encrypted password-protected audio recorders, and voice files remained password protected and were accessible only to relevant members of the research team once transferred to secure Cardiff University servers. Recordings were transcribed and pseudonymised in line with the CTR SOPs. All essential documents generated by the study were kept in the study master file and/or on the electronic study master file.

Analysis

Findings from iterative literature searches were synthesised using a realist approach to evaluation.[84,86] The extracted information was summarised descriptively in explanatory accounts and then consolidated to generate potential CMO configurations to be explored in phase 2 stakeholder interviews.

Survey responses were downloaded. Responses to closed or multiple-choice questions were described. For each qualitative data collection method (open-text questions in survey responses, interviews or SAGs), responses were thematically analysed in each group of participants (LARC users, health-care practitioners and weight loss practitioners) separately. Qualitative synthesis across all interviews provided an overarching synthesis of LARC users' and service providers' perceptions related to the study objectives. A full qualitative analysis plan was written by the qualitative researcher and approved by the Study Management Group (SMG) and Study Steering Committee (SSC) prior to analysis taking place.

Withdrawal

For WP1, data were aggregated and anonymised, and, therefore, it was not possible to remove records once an extract had been produced. Participants in the WP2 surveys and qualitative interviews were able to withdraw at any time prior to analysis by contacting the study team. Participants in SAGs were able to withdraw at any time by leaving the SAG meeting. However, the nature of a focus group meant that any contribution thus far was unable to be withdrawn.

Ethics

Ethics approval for this study was given by the Cardiff University School of Medicine Research Ethics Committee on 30 April 2019, reference number 19/42 (see *Report Supplementary Material 1*).

Participant and public involvement

Participant and public involvement (PPI) representatives contributed to both the SMG and the SSC (one PPI member in each committee) and took an advisory role in study design, study progress and results dissemination.

At the end of each phase of WP2, PPI input took the form of SAGs whose role was to:

1. refine findings from WP2 phase 1 to generate potential intervention components, collaboratively with the research team, and to consider key questions to take forward in phase 2 (phase 1)
2. discuss findings from the targeted qualitative phase 2 work to describe the key design elements of a potential intervention or the reasons why a trial is currently not feasible to deliver (phase 2).

Changes to the protocol

Three changes were made to the original study protocol. (1) Phase 1 engagement with health-care practitioners via qualitative individual interviews and a qualitative survey was changed to solely the qualitative survey. This was for two reasons. First, conducting qualitative interviews during professional events proved to be impractical and, second, the study team felt that the in-depth nature of individual qualitative interviews was not required in addition to the survey at stage 1. (2) In-depth interviews with weight loss practitioners who support women to lose weight were not conducted in WP2, phase 1, as planned. This was due to a poor response rate to the phase 1 online survey and resulting limited number of participants to sample. (3) COVID-19-related restrictions led to the phase 1 LARC user SAG and the phase 2 SAGs being conducted remotely (via Zoom or Padlet) rather than face to face.

Chapter 3 Routine data work package

Introduction

Aims of the chapter

The Plan-it routine data WP used anonymised routinely collected data from SHCs in England, Wales and Scotland and the CPRD linked to the Pregnancy Register to determine the most appropriate LARC removal settings, the annual numbers of potential participants available to be recruited and an indicative time frame for recruitment.

The objectives were to set up access to anonymised data from multiple health settings to:

- understand the pattern of LARC use (removal/insertion/in situ) to identify opportunities to intervene
- identify women, who request LARC removal and subsequently become pregnant, who would be eligible for recruitment to a WLI study
- report the annual number of women in the UK requesting removal of LARC without replacing it with an alternative prescribed contraception
- identify events in GP and hospital records to explore time from LARC removal to conception or appointments relating to difficulties conceiving (if possible).

The outcomes identified were:

- rates of women in the UK who request LARC removal and subsequently have a pregnancy from routine data
- identification of opportunities to intervene in the preconception pathway.

Methods

Study design/setting

Routine data providers and data sets

Clinical Practice Research Datalink

The CPRD provides UK-wide individual anonymised patient GP data. Data cover > 20% of general practices in the UK and are representative of practices by country, rurality and deprivation quintiles.[87] Anonymised primary care patient data requested from CPRD include data linked to secondary care and other health-based data sets, including the Pregnancy Register. The Pregnancy Register is created by an algorithm that lists all pregnancies identified in the CPRD database.[88] For pregnancies resulting in live births, deidentified information of the linked babies in the CPRD Mother Baby Link were also provided (baby ID, baby month and year of birth, pregnancy start and end dates, gestational age of baby, and mother's age at pregnancy). LARC-related Read codes were identified using the Read code dictionary and from the literature and reviewed by the clinical co-investigators for accuracy and inclusivity of all possible codes. Cardiff University held an Academic Risk Sharing Licence with CPRD and following Independent Scientific Advisory Committee approval, and data were made available via a Cardiff University-employed data analyst.

Sexual health clinic data

Sexual health clinic data are collected and held separately in Wales, England and Scotland. Public Health Wales holds individual-level patient data from all SHCs in Wales (from 2012), and these were made available to the study team in an aggregate format based on data requirements. Aggregated data from PHW were transferred to Cardiff University servers on agreement of data release. The required tabulations of outputs were agreed with PHW to ensure that the eligibility applied to CPRD patients was applied to the SHC data. In Scotland and England, SHC data are collated and reported by NHS National Services Scotland and NHS Digital, respectively. National statistics annual reports on sexual health service use provide open data tables that were used as a national comparison with Wales (with no formal data access requests required for these open data tables).[89,90]

Study population

Clinical Practice Research Datalink

The Plan-it Study was interested in identifying women with overweight or obesity who had their LARC removed for the purpose of conception and were, therefore, eligible for a targeted pre-pregnancy WLI. The predefined study population was women of reproductive age (16–48 years inclusive) with at least one LARC event between 1 January 2009 and 31 December 2018.

Defining a LARC event

A list of LARC events was prespecified from the Clinical (medical history data entered on the GP system), Referral (referral details recorded on the GP system) and Therapy (all prescriptions issued by the GP on the GP system) data sets in the CPRD and agreed by the SMG (see *Appendix 1*). These were categorised as followed: LARC insertion, in situ (checks), removal. LARC event codes that belonged to males or to women who were under 16 or over 48 years old at the date of consultation, those for events before 2009 or after 2018, those with no consultation date, duplicate codes (same code recorded on the same day) or those that belonged to women who were not in the predefined study population were excluded.

Identifying women who were planning a pregnancy following LARC removal

The study population were grouped as follows:

- Group 1 – planning a pregnancy
- Group 2 – possibly planning a pregnancy
- Group 3 – probably not planning a pregnancy.

Table 2 shows the algorithm used to define these groups based on the initial LARC event, a consultation code following the LARC event that either confirmed or refuted planning a pregnancy, and a confirmation of a pregnancy. Codes to refute or confirm that a pregnancy was planned are in *Appendix 3*.

Identifying a pregnancy

We requested Pregnancy Register data on the predefined population and used the estimated pregnancy start date provided as the index date at which to examine prior LARC use. The estimated pregnancy start date was estimated using the timing of the start of pregnancy (first day of their last menstrual period) and additional data from 'Additional Clinical Details' files. In the absence of such data, pregnancy start dates were imputed according to the type of pregnancy outcome. We excluded pregnancies that had a defined start date occurring before 2009 or after 2018, duplicate events (repeated events, overlapping events, and events that had a start date within 31 days of the previous start date).

Identifying clinical events after the LARC removal

The clinical events between the two events (LARC removal and pregnancy start date) or following the LARC event were examined to either confirm or refute that a pregnancy had been planned.

TABLE 2 Defining the study population into groups: those planning a pregnancy and those not

Group	Group description	LARC event	Consultation following LARC event (and prior to pregnancy if applicable)	Pregnancy event
1	Planning a pregnancy	LARC removal/ inserted/in situ	Read code indicating a pregnancy was being planned	Yes
1	Planning a pregnancy	LARC removal/ inserted/in situ	Read code indicating a pregnancy was being planned	No
2	Possibly planning a pregnancy	LARC removal/ inserted/in situ	No code present to indicate that the woman was planning a pregnancy or not. No code present to indicate an unplanned pregnancy	Yes
3	Probably not planning a pregnancy	LARC removal/ inserted/in situ	Code to indicate a pregnancy was not being planned (e.g. alternative contraception), menopause indication (e.g. blood tests)	Yes
3	Probably not planning a pregnancy	LARC inserted/ in situ	No code present to indicate that the woman had a LARC removed or was planning/not planning a pregnancy	No
3	Probably not planning a pregnancy	LARC removal/ inserted/in situ	Code to indicate a pregnancy was not being planned (e.g. alternative contraception), menopause indication (e.g. blood tests)	No
Not enough information		LARC removal	No code present to indicate that the woman was planning/not planning a pregnancy	No

These events were identified from the Clinical file in CPRD (see *Appendix 2* for the list of Read codes that were prespecified and agreed by the SMG):

- refuting a planned pregnancy – an alternative prescribed contraception (see *Appendix 2*, *Table 23*), indication of the menopause (see *Appendix 3*, *Table 24*), and an unplanned pregnancy (see *Appendix 3*, *Table 26*)
- confirmation of a planned pregnancy – indicating trying to get pregnant, a planned pregnancy (see *Appendix 3*, *Tables 25* and *26*).

The following assumptions were agreed by the Plan-it study team in advance:

- For those with a pregnancy, only codes that were within the 456 days (1 year and 3 months) prior to the pregnancy start date were investigated. For those with no pregnancy, only codes that were within 456 days of the LARC event were investigated.
- If the gap between a LARC removal and LARC situ events was < 28 days, it was assumed that the woman was having a LARC check-up. These two events were combined as one rather than included twice.
- For a woman who had the LARC in situ/insertion and LARC removal event on the same date, LARC replacement was assumed and the LARC removal event was excluded.
- For clinical codes that appeared between a pregnancy start and end, only the planned pregnancy and unplanned pregnancy code were included.
- LARC in situ or insertion within a week of a pregnancy start was coded as unplanned pregnancy.
- For a woman with their first LARC code between a pregnancy start and end and after a week of a pregnancy start, the whole event was excluded.
- For a woman who has both unplanned and planned pregnancy code between LARC removal and pregnancy start, the code that was closest to the pregnancy start was used as an indicator for grouping the woman.

- For a woman who had both the alternative contraception and the trying/difficult to get pregnant code on the same day, the trying/difficult to get pregnant code was used as an indicator and the contraception code excluded.
- Women with too many planned/unplanned codes were coded as Unable to code.

Body mass index

Weight and height data were selected from the 'Additional Clinical Details' file in CPRD (Entity Type 13 and 14). The BMI was generated following the method described in Bhaskaran *et al.*[92] (representativeness). Only BMIs that were recorded within 3 years of either the pregnancy start date or the last LARC event for those with no associated pregnancy were included. *Appendix 5* depicts the data flow for BMI.

Sexual health clinic data

Women of reproductive age (i.e. 16–48 years old) with at least one LARC event (inserted, removed or in situ) between 1 January 2012 and 31 December 2018 were included. Data were sourced from the Sexual Health in Wales surveillance system. Data on patients who attended a SHC in Wales were recorded and coded by front-line SHC staff and then collated by PHW. Data fields of relevance to this project included date of birth (for age to be calculated), date of attendance (for year to be derived), main contraception method [CM2: implant; CM3: intrauterine device (IUD); CM4: intrauterine (IU) system], health board and deprivation quintile.

Statistical methods

For the individual anonymised data from CPRD, rates of fitting and removal of LARC in general practice were calculated and reported over time (either quarterly or annually, depending on numbers). Rates were calculated as the number of LARCs fitted and removed as a proportion of all women of reproductive age.

Trends in rates were examined by country, LARC type and, where available, attendance type (pre-booked vs. walk-in consultations). Similarly, we examined trends using the Welsh SHC data. This enabled a comparison of the case mix of women recorded for a LARC removal in general practice and those who visit a SHC by age, ethnicity, BMI and deprivation. The data from SHCs in Scotland and England were in aggregate format at NHS Sexual and Reproductive Service provider level and reported rates of fitting and removal annually. Trends in rates by age group at time of fitting or removal, change of contraception method from/to a LARC and, if recorded, BMI category and deprivation quintile were explored. These rates were compared with those arising from the SHC data in Wales. The quality of recording of BMI in all data sets was explored. Previous work in the CPRD shows that completeness of BMI has increased over time (to around 77%) and was higher in female individuals, especially those of reproductive age.[92]

Analysing these data sets identified variation in the numbers, pattern and duration of use of LARCs in the different health settings, geographical areas (rural/urban) and demographic groups. It was possible to consider what opportunities (e.g. consultation types, frequency of consultations) are available to intervene in the different service delivery designs across the UK. The routine data analysis determined the most appropriate LARC removal settings, the annual numbers of potential participants available to recruit and an indicative time frame for recruitment.

For patients attending their GP for the fitting or removal of their LARC, the data allowed exploration of the duration of LARC use prior to removal and the changes to contraception use over time; through linking to the Pregnancy Register algorithm, a pregnancy episode related to the women in the cohort (estimated start of pregnancy) was flagged. Accessing these data will enable a broader understanding of the population for whom this intervention will be targeted and, potentially, identify those who had a LARC removed for the purpose of planning a pregnancy. An examination of how time to conception may differ between BMI and age categories was also possible. For women whose pregnancy was identified following a LARC removal, the natural distribution of the time between the two events (LARC end and pregnancy start) was examined to assess whether or not a rule could be applied to indicate that the pregnancy and LARC removal were associated.

Although the data between GP surgeries and SHC data could not be linked, the recording of a LARC removal in a SHC setting was explored in the GP notes. Previous work using an alternative primary care data source (The Health Improvement Network) identified that 24% of LARC-related records in primary care came from SHC letters.[93] The reporting of routine data was in accordance with RECORD (REporting of studies Conducted using Observational Routinely-collected Data).[94]

Data access, linkage and cleaning methods

At the time of the project, Cardiff University held a licence with CPRD that allowed approved university staff members to access the CPRD GOLD database. The population relevant to this study was identified using the agreed code list (see *Defining a LARC event*). This list of patients was then linked to the Pregnancy Register (this linkage is completed by CPRD and not by Cardiff University staff). Once linked, these data sets were made available to the project staff.

Ethics

Data access requests to CPRD were reviewed by the Independent Scientific Advisory Committee (Protocol: 19_188). The CPRD has broad National Research Ethics Service Committee ethics approval for purely observational research using the primary care data and established data linkages. No further ethical review was required for this element of the project.

Results

Defining the study population in the Clinical Practice Research Datalink

The study population generation is reported in *Figure 2*. The study population was identified using the CPRD Patient file, which included just over 20 million patient records. Practices were excluded from the study population if the practice's last contribution date was before 2009 or their up-to-standard date was after 2018. Practices with < 1 year between their last contribution date and their up-to-standard date (< 1 year of data available) and those not meeting the criteria in the specified years were also excluded. The following patient groups were excluded: male patients; patients of unknown or indeterminate gender; patients whose data were outside the up-to-standard date; patients whose year of birth was outside 1961–2002; patients who had died before 2009; patients registered with the practice after 2018; and patients whose current period of registration with the practice was after 2018.

This left 2,632,871 women at reproductive age in the study denominator. However, 2,314,831 were excluded as they were not in the predefined study population (i.e. with one LARC event), leaving 318,040 eligible women of reproductive age in the study population. The rate of women at reproductive age in the study denominator was constant over the time period 2009–18 (*Table 3*).

Objective 1: understand the pattern of LARC use (removal/insertion/in situ) to identify opportunities to intervene

Women attending general practice for a LARC-related consultation

To identify women who attended a GP surgery for a LARC event, a combination of Read and prescription codes were used. The flow chart (see *Figure 2*) shows that, from using these codes for LARC, 929,099 codes were present in the study population of 315,755 women. *Table 4* shows these data broken down by LARC consultation type and type of LARC. Women in our study population could experience more than one code over the study period. For example, among the 127,909 women who had at least one LARC in situ code, 49,285 (39%) had more than one code recorded over the study period. Of those 269,999 women who had a LARC insertion, 182,090 (67%) had more than one LARC insertion code recorded over the study period. Of those 108,987 women who had a LARC removal, 12,615 (12%) had more than one LARC removal code recorded during the study period.

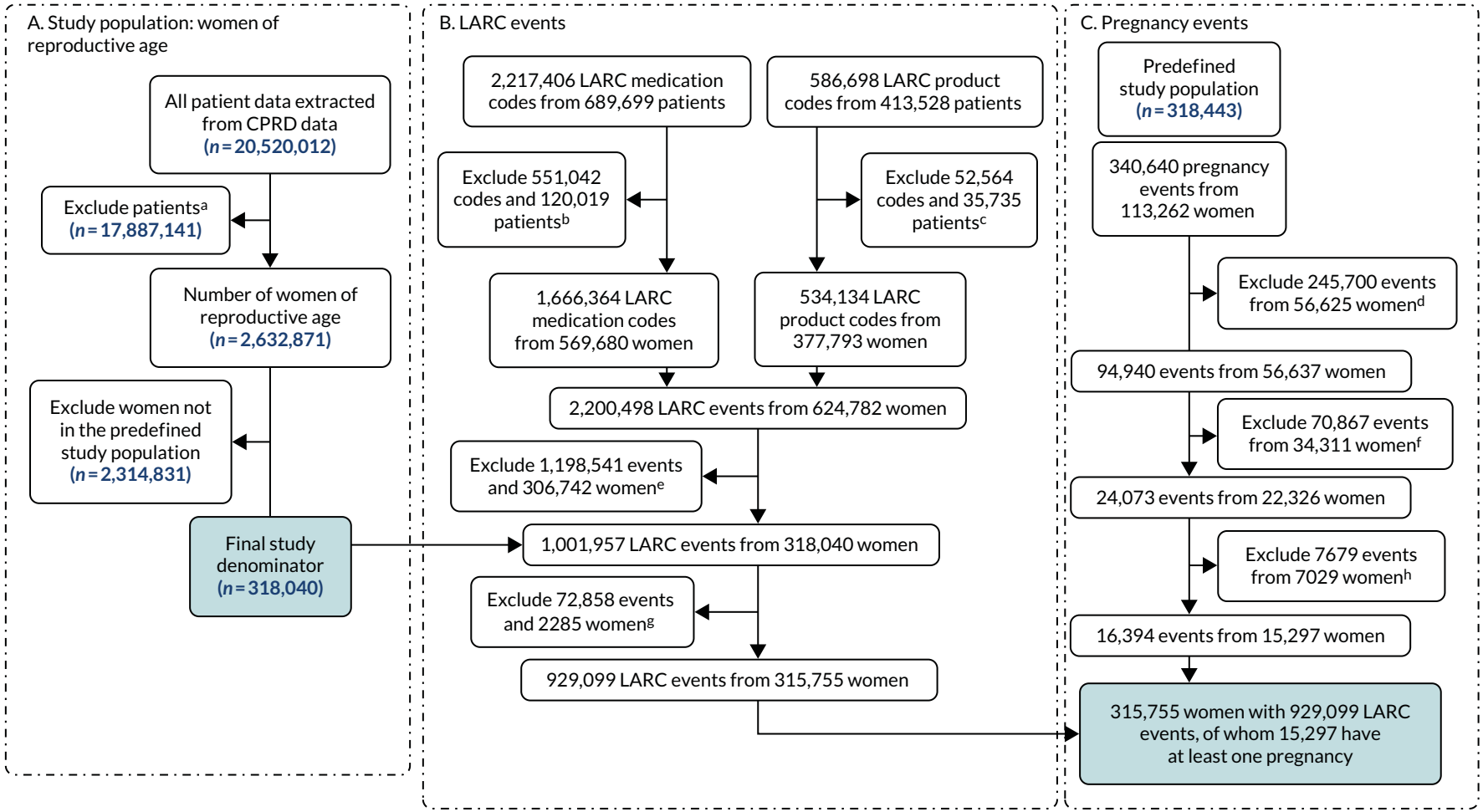

FIGURE 2 Participant flow diagram. Reproduced with permission from Channon *et al.*[91] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original figure. (*continued*)

<table>
<tr><th>CPRD data[a]</th><th>LARC medication codes[b]</th><th>LARC product codes[c]</th><th>Pregnancy registry[d]</th></tr>
<tr><td>• Male or indeterminate or unknown gender (9,806,591)
• Patient CPRD date not up to standard (1,406,355)
• Year of birth before 1961 or after 2002 (3,895,933)
• Died before 2009 (25,917)
• Patient registered with practice after 2018 (48,068)
• Patient current period of registration with the practice after 2018 (8941)
• Patient transferred out the practice before 2009 (2,229,378)
• Practice last data collection date ended before 2009 (95,446)
• Practice up-to-standard date begin after 2018 (63,904)
• With less than 1-year data available (88,242)
• Not met the criteria in the specified years (218,366)</td><td>• Male (37,147 codes from 113,919 patients)
• Year of birth before 1961 or after 2002 (421,288 codes from 5918 patients)
• Code with no event date (1839)
• Same code on the same date (90,768)</td><td>• Male (356 codes from 169 patients)
• Year of birth before 1961 or after 2002 (48,511 codes from 35,566 patients)
• Same code on the same date (3697)</td><td>• Exclude pregnancy before 2009 or after 2018 (232,410 events)
• Exclude events that were duplicated or < 31 days or overlapped events (13,290 events)</td></tr>
<tr><th>Merged LARC medication and LARC product codes[e]</th><th colspan="3">Pregnancy registry in study population[f]</th></tr>
<tr><td>• Women not in the pre-defined study population (867,870 codes)
• Event before 2009 or after 2018 (330,671 codes)</td><td colspan="3">• Pregnancy events belong to women with no LARC event (235)
• First pregnancy event before the first LARC (62,160)
• First LARC code between pregnancy start and end (3625)
• Multiple pregnancy events after one LARC event (4847)</td></tr>
<tr><th>LARC code and CPRD data[g]</th><th colspan="3">LARC code and pregnancy registry[h]</th></tr>
<tr><td>• Excluded LARC event happened before age 16 or after age 48 (8482 codes within 1927 women)
• Excluded LARC removal codes that are ≤ 28 days between the next LARC in situ or LARC insertion code (LARC replacement) (62,026 codes)
• Excluded LARC code in between pregnancy start and end (2350 codes)</td><td colspan="3">• Excluded pregnancy events that were 1 year and 3 months after the LARC events (7679 events within 7,029 women)</td></tr>
<tr><td colspan="4">Predefined study population: women of reproductive age (16–48) with at least one LARC event between 1 January 2009 and 31 December 2018</td></tr>
</table>

FIGURE 2 Participant flow diagram. Reproduced with permission from Channon *et al.*[91] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original figure.

TABLE 3 Study denominator by year

Year	Number of women aged 16–48 years (study denominator)	Number of general practices with data available	Rate of women per practice per 10,000
2009	1,413,791	738	5.22
2010	1,408,118	728	5.17
2011	1,380,332	713	5.17
2012	1,355,832	699	5.16
2013	1,330,823	680	5.11
2014	1,244,434	645	5.18
2015	1,108,991	580	5.23
2016	914,755	491	5.37
2017	812,739	437	5.38
2018	741,453	397	5.35

TABLE 4 The LARC events by consultation and LARC type

	Unique number of events	Number of women with at least one event
LARC consultation type[a]	**n = *938,161***	
In situ	222,555	127,909
Insertion	592,402	269,999
Removal	123,204	108,987
Type of LARC	**n = *934,903***	
IUD	411,514	167,008
IU system	308,058	131,889
Implant	215,331	125,497

a *n* = 9062 codes were double counted owing to three codes [IUD – not otherwise specified (NOS), subcutaneous contraceptive NOS, and subcutaneous contraceptive] being coded as both LARC in situ and LARC insertion.

The number of women in the study population decreased over time due to the number of practices contributing to the CPRD declining; the rate of women per practice was constant (*Figure 3* and *Table 5*). The proportion of women with one or more LARC consultations decreased over time, from 2.2% in 2009, which is approximately 42 LARC events per practice, to 1.3% in 2018, 24 LARC events per practice. By contrast, the Wales SHC data show a different picture (*Figure 4*); in 2018 the rate of women with SHC contact for LARC use out of contacts for any contraception was higher, at 24%.

To further understand LARC use in general practice and SHCs, patterns were examined by LARC consultation type (insertion, in situ, removal), type of LARC used (IUD, IU system, implant) and age group type to identify opportunities to intervene. SHC data were obtained from open-access sources, and extracts are presented in *Appendix 4*. LARC insertions are most frequently performed in general practice (see *Figure 4*) (see *Appendix 3* for details of type of LARC use over time).

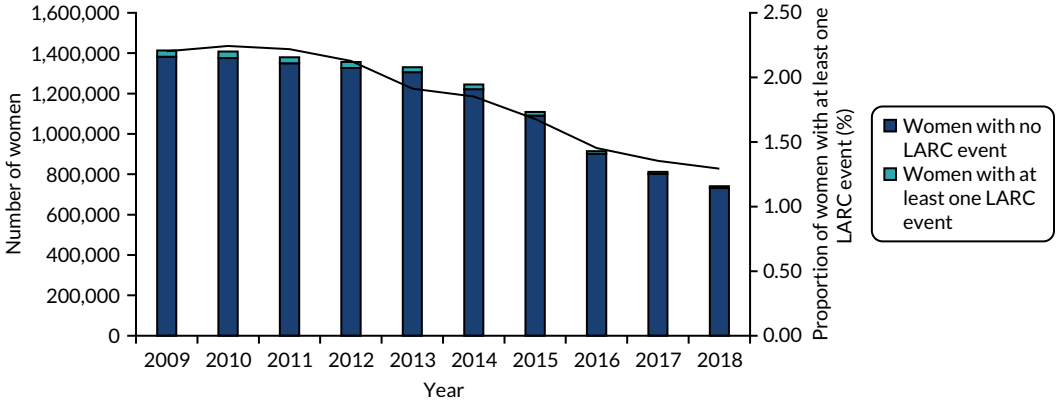

FIGURE 3 LARC users over time: CPRD (2009–18).

Objective 2: identify women requesting LARC removal who subsequently become pregnant who would be eligible to recruit to a weight loss intervention study

To identify eligible women to recruit to a WLI study, several stages need to be established (*Figure 5*):

- LARC use (objective 1)
- pregnancy within 1 year and 3 months
- codes to refute or confirm that the pregnancy was planned
- BMI status.

Identifying a pregnancy

A total of 340,640 pregnancy events were identified from 113,262 (35.5% of predefined study population) women. After excluding 245,935 events that were outside the study period (before 2009 or after 2018) and duplicate entries, we have 94,705 pregnancy events from 56,637 women. A further 70,632 events were excluded, leaving 24,073 pregnancy events from 22,326 (7.0%) women in the study population.

LARC removal for the purposes of planning a pregnancy

In the 24,073 pregnancy events from 22,326 (7.0%) women in the study population, 11,381 (47.3%) conceptions occurred within the window of 1 year and 3 months (456 days), and 3090 (12.8%) occurred outside the window of 1 year and 3 months. With regard to the 411 (1.7%) pregnancy events with a removal code between pregnancy start and pregnancy end, we considered them as an unplanned pregnancy if the removal code was within 7 days after pregnancy start; otherwise, we would investigate other LARC code (if any) or exclude the pregnancy event and the removal code in between. For the 9191 (38.2%) pregnancy events with no removal code between start and end date, we included the event if the pregnancy start date was within the window of 1 year and 3 months after the last LARC in situ or LARC insertion date; otherwise, the pregnancy event would be excluded.

Among the 315,755 women in the study population with a LARC event, 15,297 women had at least one pregnancy, with 16,394 pregnancy events (*Table 6*). Of those, 4753 (29.0%) pregnancy events did not have a LARC removal code before pregnancy started and 299 (1.8%) had a removal code between pregnancy start and end. The number and percentage of the 16,394 pregnancy outcomes are described in *Table 6*. For the remaining 11,342 events, the median time to conception was 109 days (25th to 75th centiles = 47 to 220 days) (*Figure 6*).

We have defined 479,044 different scenarios or pathways to a pregnancy event or not among 317,684 women (note that women can have more than one scenario). The number of scenarios and number of women in each group are summarised in *Table 7*.

TABLE 5 Number of LARC events and type of LARC between 2009 and 2018: CPRD

	Study denominator		Study population													
			Year of first LARC consultation[a]		LARC consultation type[b]						Type of LARC					
					In situ		Insertion		Removal		IUD		IU system		Implant	
Year	Women aged 16–48 years (*n*)	Consultations (*n*)	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
2009	1,413,791	2,253,647	61,440	4.3	31,074	1.4	65,523	2.9	11,293	0.5	58,232	2.6	27,390	1.2	21,814	1.0
2010	1,408,118	2,385,300	51,850	3.7	31,479	1.3	75,430	3.2	12,402	0.5	58,576	2.5	35,194	1.5	25,222	1.1
2011	1,380,332	2,474,914	43,456	3.1	30,540	1.2	72,290	2.9	13,891	0.6	56,355	2.3	33,977	1.4	26,207	1.1
2012	1,355,832	2,561,659	36,994	2.7	28,768	1.1	72,904	2.8	14,150	0.6	51,866	2.0	37,175	1.5	26,387	1.0
2013	1,330,823	2,485,337	32,975	2.5	25,384	1.0	71,152	2.9	14,735	0.6	46,513	1.9	38,469	1.5	26,058	1.0
2014	1,244,434	2,353,969	26,816	2.2	22,996	1.0	64,713	2.7	14,283	0.6	41,533	1.8	36,231	1.5	23,945	1.0
2015	1,108,991	2,149,417	21,344	1.9	18,558	0.9	55,091	2.6	13,410	0.6	33,673	1.6	32,266	1.5	20,780	1.0
2016	914,755	1,751,839	15,662	1.7	13,258	0.8	42,554	2.4	10,985	0.6	24,542	1.4	25,507	1.5	16,365	0.9
2017	812,739	1,479,553	13,268	1.6	10,972	0.7	38,001	2.6	9585	0.6	21,364	1.4	21,983	1.5	14,881	1.0
2018	741,453	1,304,630	11,950	1.6	9526	0.7	34,744	2.7	8470	0.6	18,860	1.4	19,866	1.5	13,672	1.0

a Year of first LARC consultation for women in the study population ($n = 315,755$). Percentage based on the number of women at the study denominator.
b Percentage based on the number of consultations at the study denominator.

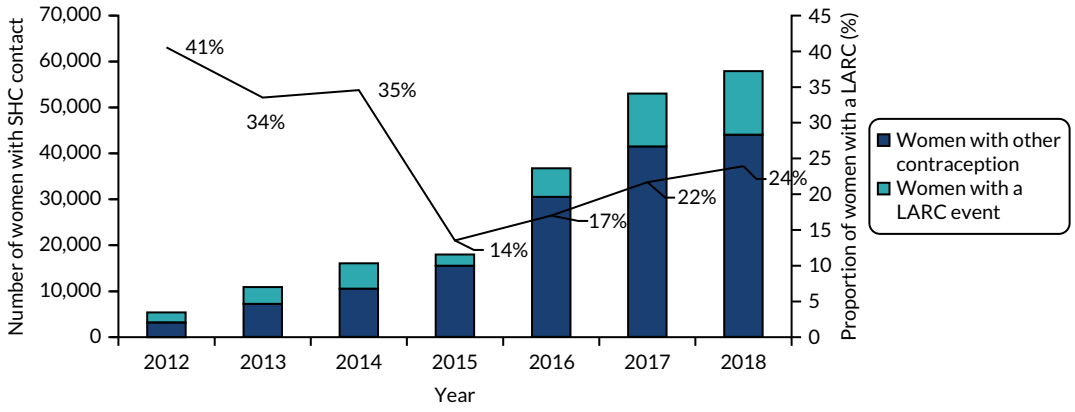

FIGURE 4 LARC users over time: Wales SHC data (2009–18). Note: data from 2012 to 2015 are unreliable due to under-reporting by some health boards.

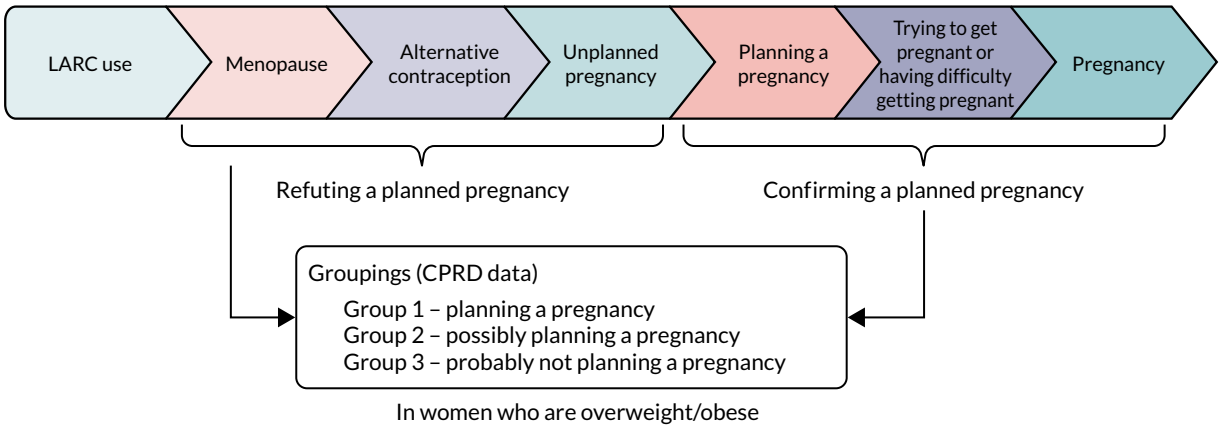

FIGURE 5 Stages of identifying women for a WLI study.

TABLE 6 Pregnancy outcomes ($n = 16,394$)

Pregnancy outcome	Frequency (*n*)	%
Live birth	8910	54.3
Stillbirth	33	0.2
Miscarriage	1700	10.4
TOP	241	1.5
Miscarriage or TOP or ectopic	1231	7.5
Ectopic	163	1.0
Molar	6	0.0
Blighted ovum	5	0.0
Unspecified loss	107	0.7
Delivery based on a third-trimester pregnancy record	278	1.7
Delivery based on a late-pregnancy record	46	0.3
Outcome unknown	3674	22.4
Total	16,394	

TOP, termination of pregnancy.

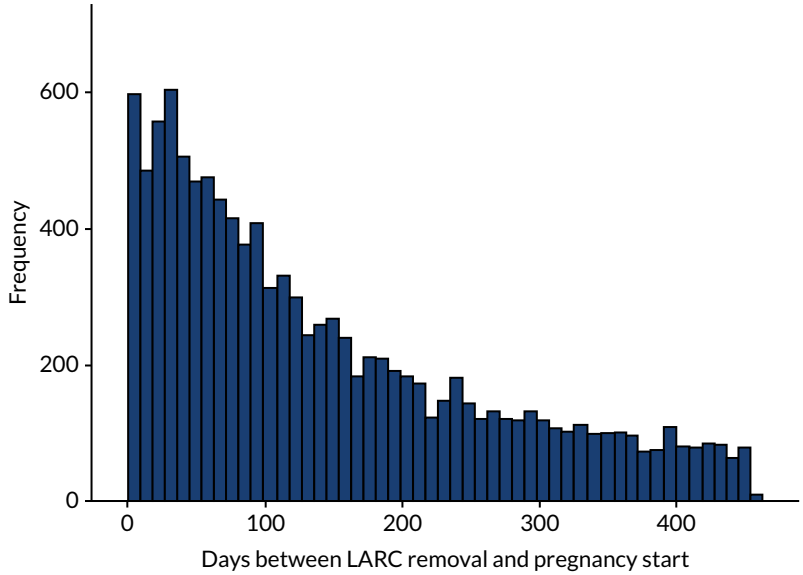

FIGURE 6 Conception time for events within 456 days ($n = 11,342$).

TABLE 7 Defining the groups based on LARC use, events related to planning a pregnancy and contrary events, and conception

LARC use	Read code indicating an event	Pregnancy	Group	Number of scenarios	Number of women	Age (years), mean (SD)
1: LARC removal/ inserted/in situ	A Read code to indicate the pregnancy was being planned (planned pregnancy code or trying/difficult to get pregnant) either between a LARC (removal/inserted/in situ) and pregnancy start, or between a pregnancy start and end	Yes	1: planning a pregnancy	1635	1616	29.0 (5.81)
2: LARC removal/ inserted/in situ	No Read code to indicate that the pregnancy was planned (planned pregnancy code or trying or difficult to get pregnant) or not planning a pregnancy (alternative contraception and menopause). No Read code to indicate that this pregnancy was unplanned (unplanned pregnancy code)	Yes	2: possibly planning a pregnancy	10,902	10,387	28.5 (6.06)
3: LARC removal/ inserted/in situ	A Read code to indicate that a pregnancy was not being planned (alternative contraception and menopause)	Yes	3: probably not planning a pregnancy	3851	3761	26.5 (5.98)
4: LARC removal/ inserted/in situ	A Read code to indicate that a pregnancy was being planned (planned pregnancy code or trying/difficult to get pregnant)	No	1: planning a pregnancy	4871	4717	30.6 (7.26)
5: LARC removal	After a LARC removal code, no Read code or a Read code present to indicate that the woman was planning/not planning a pregnancy	No	Not enough information	73,290	69,455	32.4 (9.03)

TABLE 7 Defining the groups based on LARC use, events related to planning a pregnancy and contrary events, and conception (*continued*)

LARC use	Read code indicating an event	Pregnancy	Group	Number of scenarios	Number of women	Age (years), mean (SD)
6: LARC inserted/ in situ	No code present to indicate that the woman had a LARC removed or was planning/not planning a pregnancy	No	3: probably not planning a pregnancy	379,495	277,144	33.0 (9.22)
7: LARC removal/ inserted/in situ	Code to indicate a pregnancy was not being planned (e.g. alternative contraception), menopause indication (e.g. blood tests)	No	3: probably not planning a pregnancy			
8		Yes	Unable to code	6	6	
9		No	Unable to code	59	59	

SD, standard deviation.

Table 8 shows, for each group, the number of LARC events, the proportion with a valid BMI measurement broken down by BMI categories: ≥ 25 kg/m^2 (overweight and obese), ≥ 30 kg/m^2 (obese) and ≥ 40 kg/m^2 (morbidly obese). Of all 474,044 LARC events with a valid BMI measurement, a small proportion (1.4%, $n = 6506$) were removed for planning a pregnancy, 10,902 (2.3%) were possibly planning a pregnancy and 383,346 (80.9%) were probably not having a pregnancy; 73,290 (15.5%) could not be grouped because of insufficient information. A total of 62% of women had a BMI recorded within 3 years of their LARC event, and this was similar across all groups (range 60–67%), with a 5% difference between women not planning a pregnancy and those planning a pregnancy (62% vs. 67%). Around 50% of women had a BMI of ≥ 25 kg/m^2, around 28% had a BMI of ≥ 30 kg/m^2 and < 5% had a BMI of ≥ 40 kg/m^2. Among those planning a pregnancy, 54% had a BMI of ≥ 25 kg/m^2, 28% had a BMI of ≥ 30 kg/m^2 and < 5% had a BMI of ≥ 40 kg/m^2.

Objective 3: report the annual number of women in the UK requesting removal of LARC without replacing it with an alternative prescribed contraception

For this objective, we are interested in events of LARC removal without replacement with an alternative contraception (see *Appendix 2*, *Table 23*, for alternative contraception code). Of the 123,204 LARC removal events in the study population, 24,777 were followed by an alternative contraception code (20.1%). The time between LARC removal and alternative contraception ranged from 0 to 35.84 months, with a mean of 4.38 months (standard deviation 4.76 months) and a median of 2.73 months (interquartile range 0–7.82 months) (*Figure 7*).

Based on this information, and without a clear cut-off point identified from clinical practice, we decided to use 4 months as a cut-off point and considered contraception events outside this window as LARC removal events without replacement with an alternative contraception. Overall, there were 14,368 (58.0%) LARC removal events without replacement with an alternative contraception (*Table 9*).

Objective 4: identify events in general practitioner and hospital records to explore time from LARC removal to conception or appointments relating to difficulties conceiving (if possible)

For these 24,073 pregnancy events, we aimed to calculate an accurate time from LARC removal to conception. We could not calculate an accurate conception time for 9602 (39.9%) pregnancy events [411 events had a LARC removal event between the estimated pregnancy start and end date; 9191 events had no LARC removal code (presumed to be because the LARC was removed elsewhere) before a pregnancy start]. For the remaining 14,471 (60.1%) valid pregnancy events following a LARC removal, the median time to conception following LARC removal was 160 days (25th to 75th centiles = 62 to 398 days) (see *Figure 11*). In total, 1861 (12.9%) were within the first month, 3562 (24.6%) were within

TABLE 8 Completeness of BMI and BMI categories

		With BMI			BMI ≥ 25 kg/m²			BMI ≥ 30 kg/m²			BMI ≥ 40 kg/m²		
Group	**Events, *n* (%)**	**Category**	***n***	**%**	**Category**	***n***	**%**	**Category**	***n***	**%**	**Category**	***n***	**%**
1: planning a pregnancy	6506 (1.4)	Yes	4328	66.5	< 25	2014	46.5	< 30	3130	72.3	< 40	4124	95.3
		No	2178	33.5	≥ 25	2314	53.5	≥ 30	1198	27.7	≥ 40	204	4.7
2: possibly planning a pregnancy	10,902 (2.3)	Yes	7034	64.5	< 25	3480	49.5	< 30	5368	76.3	< 40	6844	97.3
		No	3868	35.5	≥ 25	3554	50.5	≥ 30	1666	23.7	≥ 40	190	2.7
3: probably not planning a pregnancy	383,346 (80.9)	Yes	237,155	61.9	< 25	112,472	47.4	< 30	176,619	74.5	< 40	227,618	96.0
		No	146,191	38.1	≥ 25	124,683	52.6	≥ 30	60,536	25.5	≥ 40	9537	4.0
Not enough information	73,290 (15.5)	Yes	44,286	60.4	< 25	20,629	46.6	< 30	32,535	73.5	< 40	423,89	95.7
		No	29,004	39.6	≥ 25	23,657	53.4	≥ 30	11,751	26.5	≥ 40	1897	4.3
Total	474,044	292,803 (62%)											

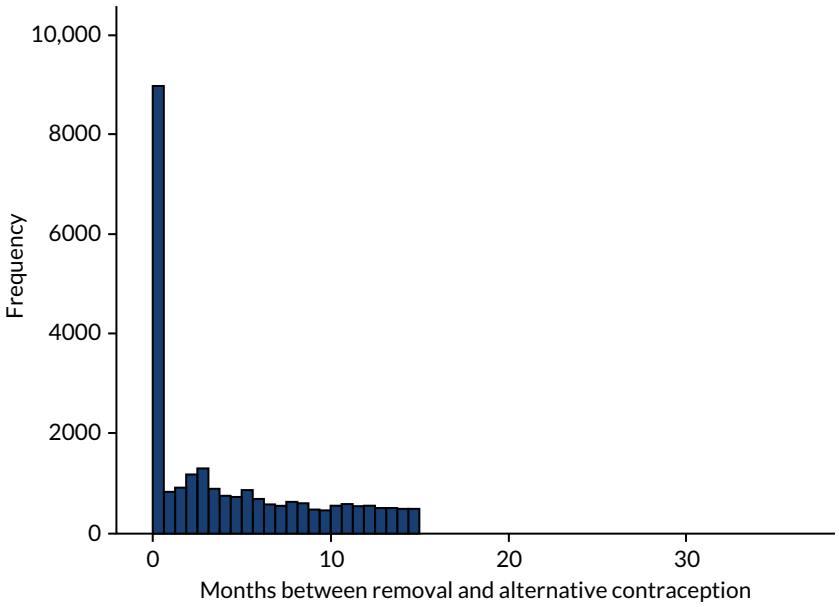

FIGURE 7 Time between LARC removal and alternative contraception (months) ($n = 24,777$).

TABLE 9 Time between LARC removal and alternative contraception

	Events
LARC removal event in study population	123,204
LARC removal event with alternative contraception code	24,777, 20.1%
Within 4 months: replacing with alternative contraception	14,368, 58.0%
Outside 4 months: not replacing with alternative contraception	10,409, 42.0%

the first 2 months and 5021 (34.7%) were within the first 3 months following LARC removal (*Figure 8*) (see *Appendix 3* for the details of time to conception for women in different age and BMI categories, as well as additional analysis on further contraception patterns).

Discussion

The aim of this WP was to use routine data to determine the most appropriate LARC removal settings, the annual numbers of potential participants available to be recruited and an indicative time frame for recruitment. The records of 318,040 women of reproductive age (i.e. 16–48 years old) with at least one LARC event (where consultation type is insertion, removal or a check/in situ) between 1 January 2012 and 31 December 2018 were examined using the CPRD. Women frequently visit their general practice for LARC, and this is where insertions are most frequently performed, in particular in the 25–34 years age group. The insertion of IUDs has fallen since 2009, with an increase seen in IU systems. LARC removals were least frequently carried out in the general practice setting. No comparable open-source data from SHCs across England, Scotland and Wales were available on LARC consultation type (insertion, removals or in situ), but a mixed pattern in the type of LARC used in clinics was observed. A higher proportion of women in the 25–44 years age group consulted their GP regarding LARC use, whereas younger age groups (i.e. aged < 24 years) are more likely to attend SHCs. Across both settings, consultations for LARC were lowest in the ≥ 45 years age group. Using the Pregnancy Register, we were able to determine that only 1.4% of LARCs were removed for the purpose of planning a pregnancy, with an additional 2% when potentially planning a pregnancy; 16% could not be because of insufficient information.

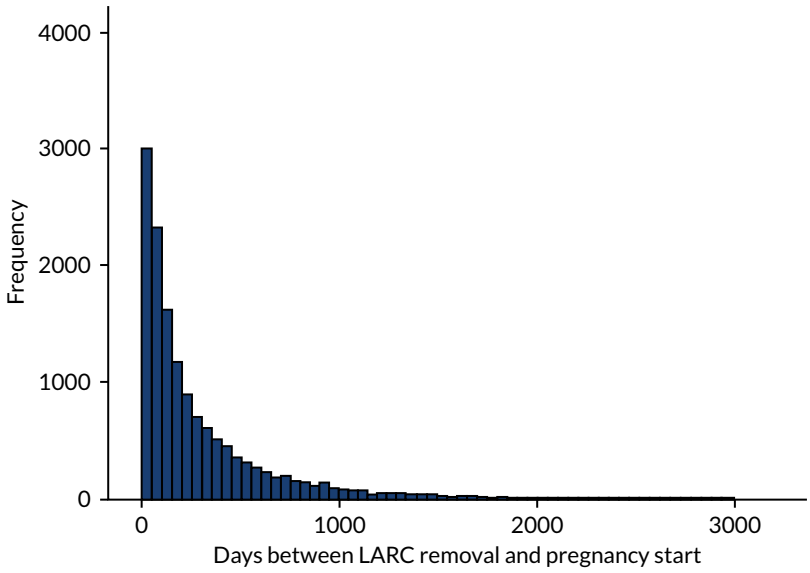

FIGURE 8 Time from LARC removal to pregnancy start (days) ($n = 14,471$).

Among those planning a pregnancy, 54% had a BMI of ≥ 25 kg/m^2, 28% had a BMI of ≥ 30 kg/m^2 and $< 5\%$ had a BMI of ≥ 40 kg/m^2. For valid pregnancy events following a LARC removal, the median time to conception was 160 days; 13% were within the first month and 25% within the first 2 months following LARC removal.

Our large sample size from the CPRD database improves the representativeness of our findings in terms of the British population, and its linkage with the Pregnancy Register made this work viable. We were able to examine the data from both general practices and SHCs; however, their current structure does not enable the sequential relationship between removal of LARC and subsequent pregnancy in different settings to be reliably determined. We developed comprehensive coding lists to identify nodes/stages that either confirm or refute pregnancy or the planning of pregnancy to enable women to be grouped based on whether or not the LARC was removed for pregnancy. However, the labour-intensive methods used to define women requesting LARC removal for the purpose of pregnancy, alongside the non-contemporaneous nature of the data, do not make routine data a feasible option for reliably identifying women who are in the overweight or obese category and plan to have LARC removal for the purpose of planning a pregnancy.

Chapter 4 Understanding preconception pathways relating to LARC through qualitative surveys and analysis of policy documents

Introduction

To establish the feasibility and acceptability of introducing a preconception WLI at LARC removal appointments, it is first necessary to develop an understanding of the LARC pathway from an individual perspective and its interface with weight management.

Study objectives to be addressed

Study objectives 4 and 5 are addressed directly:

4. to assess the willingness of health-care practitioners to raise weight loss in consultations and recruit eligible women to the intervention
5. to assess LARC users' views as to the acceptability and feasibility of the proposed intervention and of future research.

The findings from this chapter will also map onto study objectives 2 and 3:

2. to identify opportunities to identify women with overweight/obesity who plan to have LARC removal for the purpose of planning a pregnancy and opportunities to intervene with a potential preconception WLI
3. to identify suitable and acceptable interventions to be incorporated into a preconception WLI.

Aims of the chapter

To answer the study objectives, the aims were to:

(a) develop an understanding of how health-care services are expected to approach discussions of weight loss with women with overweight/obesity
(b) develop an understanding of how LARC treatment pathways currently operate through an analysis of policy documents
(c) assess current practice of how health-care practitioners approach discussions of weight loss with women with overweight or obesity and the inter-relationship between discussions about overweight/obesity and family planning through qualitative surveys with LARC users and health-care practitioners
(d) assess the barriers to and facilitators of, including practical and ethical considerations, introducing weight and the option of delaying LARC removal during health-care consultations from the perspective of LARC users and health-care practitioners
(e) identify feasible opportunities to intervene with a potential preconception WLI
(f) assess the desired characteristics of a potential preconception WLI from the perspective of LARC users and health-care practitioners.

Methods

To address these aims, a range of qualitative methods were used, including (1) an analysis of policy documents, (2) engagement with LARC users via a qualitative survey and (3) service provider engagement (health-care practitioners and weight loss consultants) via qualitative surveys.

Analysis of policy documents

A review of policies, best practice guidelines, other clinical/advisory documents and grey literature pertaining to the use (and particularly the removal) of LARCs in the UK was conducted to meet aims A and B. Relevant data were identified via searches of websites and/or online document repositories belonging to four key organisations: Faculty of Sexual and Reproductive Healthcare of the Royal College of Obstetricians & Gynaecologists (FSRH), RCOG, NICE and British Pregnancy Advisory Service (BPAS) (the search strategy is detailed in *Appendix 6*). The initial results were presented to the SSC to ensure that all relevant policies had been included. A full-text analysis of included documents was conducted: key statements and/or excerpts relating to aims A and B were extracted.

Qualitative online surveys

Qualitative online surveys with LARC users and service providers (health-care practitioners and weight loss practitioners) were used to meet aims C, D, E and F.

Engagement with LARC users through qualitative surveys

An online qualitative survey (see *Report Supplementary Material 2*) using closed and open-text questions was utilised to understand women's experiences of discussing weight with health-care practitioners; their knowledge of the risks of overweight/obesity in pregnancy; barriers to and facilitators of the introduction of a WLI at LARC removal appointments; feasible opportunities to intervene in the LARC pathway with a preconception WLI; and preferred components of a potential intervention. The survey for women of reproductive age who self-identify as having/previously having overweight/obesity was advertised on a range of relevant social media platforms. A range of 200–500 responses was specified, and data collection was to cease when sufficient 'information power' had been generated.[95]

Engagement with service providers (health-care and weight loss practitioners)

Health-care practitioners who insert and/or remove coils as part of their role were identified and recruited at relevant professional events. A qualitative survey with health-care practitioners (see *Report Supplementary Material 3*) using closed and open-text questions focused on the discussion of weight and preconception health both generally and in the specific context of LARC removal; challenges to service delivery; barriers to and facilitators of the introduction of a WLI at LARC removal appointments; feasible opportunities to intervene in the LARC pathway with a preconception WLI; and preferred components of a potential intervention. Weight loss practitioners (people who support women to lose weight as part of their role, e.g. weight loss programme consultants, personal trainers, dieticians) were recruited via existing contacts or a range of social media platforms; a qualitative survey (see *Report Supplementary Material 4*) addressed their views on the provision of a WLI in the preconception phase.

Qualitative survey development

The online surveys were developed in Cardiff Online Surveys. The survey questions were developed by the research team, aligned with evidence from initial literature searches and the studies' research questions. The surveys were piloted with contacts of the study team and signed off by the SMG, including the health-care practitioners and the study lay member.

Participant identification/selection

LARC users responded to advertisements in a broad range of targeted, relevant, online social spaces, including Facebook (Meta Platforms, Inc., Menlo Park, CA, USA), Twitter (Twitter, Inc., San Francisco, CA, USA) and Netmums (London, UK), and via Healthwise Wales (a national registry).[96]

Health-care practitioners were recruited via professional events targeted at clinicians with a sexual health role, which were attended by the study team. Weight loss practitioners who support women to lose weight as part of their role were recruited via existing contacts of the study team and targeted Facebook advertisement.

Participant informed consent

On accessing the online survey, participants were taken to a page where information was provided about the study in the form of a PIS. Participants were instructed to take as much time as required to consider the information before taking part in the study. To proceed to survey questions, participants were screened by answering inclusion questions (*Table 10*). If participants were ineligible, they were redirected to an online page thanking them for their time. If participants were eligible and consented electronically, they were able to complete the online survey. Participants were invited to consent to future contact by the research team and also to be entered into a prize draw for £100-worth of high-street vouchers. Participants provided their contact details if applicable. There were no follow-up assessments.

For health-care practitioner surveys only, participants were recruited face to face at relevant professional events. Study team members were available to explain the study to participants and to answer any questions before the participant completed either a paper or an online version of the eligibility form, consent form and survey.

Data collection

The online surveys were hosted by Cardiff Online Survey on secure Cardiff University servers. Data were exported from Cardiff Online Surveys at the end of the data collection period in a Microsoft Excel® and Microsoft Word® (both Microsoft Corporation, Redmond, WA, USA) file, uploaded to NVivo (QSR International, Warrington, UK) and stored on secure, restricted-access folders on Cardiff University servers.

Analysis

Responses to closed questions in the survey were reported descriptively as numbers and percentages. A computer-assisted qualitative data analysis software package (NVivo) was used to manage open-text qualitative survey data. Data were subsequently analysed thematically and coded inductively. Inductive thematic analysis was considered appropriate as this approach is known to facilitate the exploration of similarities and differences across large data sets,[97] allowing variation in responses within and between LARC users and health-care practitioners to be identified and explored. The six phases of thematic analysis proposed by Braun and Clarke[97] were used to guide the analytic process, the results of which were discussed at regular team meetings. The LARC user and health-care practitioner data sets were coded separately during the first stage of analysis. Once each data set had been fully coded, a copy of each was merged. The resulting coding framework and data set was considered as a whole to identify key and cross-cutting themes and to highlight areas of similarity and difference across the LARC user and health-care practitioner groups.

TABLE 10 Survey participants eligibility criteria

Participants	Inclusion criteria	Exclusion criteria (same for all groups)
LARC users	Women of reproductive age (16–48 years old) who: • Currently live in the UK • Have experience of using LARC in the past 10 years • Who believe either that their current weight would put them in the overweight/obese category or that their weight in the past would have put them in the overweight/obese category • Are currently pregnant, are planning to get pregnant within 5 years or have had pregnancies in the past	Sufficient written English to participate in online surveys and consent to participate in the study
Health-care practitioners	Practitioners who insert and/or remove LARC as part of their clinical role	
Weight loss practitioners	Practitioners who support women to lose weight as part of their role	

Results

Both the policy documentation and the survey results are discussed in the context of the aims of the chapter. Where content from the surveys is quoted, the abbreviations HCP for health-care practitioner and LU for LARC user survey responses are used.

Analysis of policy documents

A total of 15 documents were included in the review: 13 were identified via the search strategy detailed in *Appendix 6* and two were identified subsequently by study team members. The document types identified included FSRH clinical guidance, FSRH Clinical Effectiveness Unit-produced statements, NICE public health guidelines and clinical guidance, RCOG Green-top Guidelines, and BPAS and RCOG press releases (see *Appendix 7*).

Aim A: develop an understanding of how health-care services are expected to approach discussions of weight loss with women with overweight/obesity

Two main themes were identified in relation to how health-care practitioners are expected to approach discussions of weight loss with women with overweight or obesity. First, clinical encounters where preconception and/or contraception is discussed were characterised as key moments in which strategies for minimising some of the clinical risks associated with maternal obesity/overweight could and should be discussed. Specific mention of 'obesity' or 'overweight' was not typically advocated, with guidance instead referring to weight optimisation and the inclusion of general dietary and exercise-related advice:

> *Primary care services should ensure that all women of childbearing age have the opportunity to optimise their weight before pregnancy. Advice on weight and lifestyle should be given during preconception counselling or contraceptive consultations.*
>
> *Denison* et al.[98]

Second, although it was not explicitly stated whether or how health-care practitioners should inform women of the underlying evidence, policy guidance aimed at health-care practitioners placed emphasis on (1) the safety of LARC use in women with overweight/obesity[99] and (2) the current lack of evidence of a causal association between the use of IU contraception and weight gain.[100]

The LARC removal event itself was highlighted as an opportunity for providing behavioural and lifestyle-related advice, including the need to provide dietary advice.[100]

Aim B: develop an understanding of how LARC treatment pathways currently operate through analysis of policy documents

Information on how LARC treatment pathways currently operate (particularly in relation to LARC removal) was retrieved from the documents reviewed. The FSRH documents clarified that no formal training, beyond gynaecological skills and contraceptive knowledge, is required of health-care practitioners for LARC removal.[100]

The need to discuss LARC removal with women was highlighted in the FSRH documents, but the guidance was minimal in scope, with very limited information on when or how such discussions should take place.

Engagement with LARC users and service providers

Study setting and participant characteristics

LARC users ($n = 243$) were recruited via a multipoint online recruitment strategy involving advertisements in online spaces, including boosted advertisements on Facebook, Twitter and the Netmums forum, a call for participants via Cardiff Online Surveys and distribution to potentially

eligible participants via Healthwise Wales.[96] Although it is an approximation, when correlating timings of advertisements and completion of online surveys, it appears probable that the majority of participants were recruited via Healthwise Wales and Facebook (*Table 11*).

Table 12 describes the characteristics of LARC users at the time of survey completion. All respondents had experience of using LARC: 52.7% at the time of survey completion and 47.3% in the past. The majority of LARC users self-classified as having overweight currently, while 14.8% reported having had overweight at some point in the past; 41.6% of LARC users either were pregnant currently or had been in the past and 58.4% of LARC users were planning to conceive in the future.

Health-care practitioners ($n = 100$) were recruited at seven professional events by the study team (*Table 13*).

Table 14 shows the characteristics of health-care practitioners at the time of survey completion. Most health-care practitioners were medical practitioners (79%), 18% were nursing practitioners and 3% classified their job role as 'other'. Job role settings were split fairly evenly between primary care (46%) and SHCs (43%), with 5% at both settings and 5% at 'other'. Most health-care practitioners had been in their job role for more than 6 years (92%), and most roles involved both LARC insertion and LARC removal (94%).

Weight loss practitioners (i.e. people who support women to lose weight as part of their role) were recruited via existing contacts or boosted Facebook advertisements. Only four weight loss practitioners completed the online surveys: two personal/fitness trainers, one dietitian/nutritionist and one life/health coach working across NHS, local authority and private organisations. All of them received referrals from the NHS, and two worked with pregnant women. In describing their clientele, all reported that they worked, on average, with one or two women per month who aimed to lose weight to experience a healthier pregnancy, and three of them (75%) also had one or two female clients per month who were trying to lose weight to increase their chances of conceiving.

TABLE 11 Estimated LARC user recruitment channels

Recruitment method	Estimated number of LARC users
Twitter advertisements	0
Boosted Facebook advertisements	78
Targeted Facebook 'shares'	15
Netmums forum	0
Call for participants via Cardiff Online Surveys	0
Healthwise Wales	150
Total	243

TABLE 12 The LARC users' characteristics

Characteristic	Currently, *n*/%	In the past, *n*/%	Planning in the future, *n*/%
Use of LARC	128/52.7	115/47.3	N/A
Overweight	207/85.2	36/14.8	N/A
Pregnant	12/4.9	89/36.6	142/58.4

N/A, not applicable.

TABLE 13 Health-care practitioner recruitment rates at professional events

Details of professional event		Number of responses	
Event	Date	Paper completion	Electronic completion
FSRH/British Association for Sexual Health and HIV (BASHH) joint event (Cardiff)	3 July 2019	5	0
Mediconf event (Birmingham)	21 September 2019	6	0
Welsh Association of Sexual and Contraceptive Health	16 November 2019	1	2
Welsh Obstetrics and Gynaecology Society (Cardiff)	11 October 2019	4	0
Primary Care Women's Health Forum (London)	6 November 2019	2	10
Faculty of Sexual and Reproductive Healthcare of the RCOG event (London)	21–22 November 2019	9	33
Totals		27	45
Electronic (post event, e-mails, etc.)			28
Total		100	

TABLE 14 Health-care practitioner characteristics

Characteristic	Response
Job role	
Medical practitioner	79/79%
Nursing practitioner	18/18%
Other	3/3%
Job role setting	
Primary care	46/46%
Sexual health	43/43%
Both	5/5%
Other	6/6%
Length of time in role (years)	
< 1	0/0%
Between 1 and 5	8/8%
Between 6 and 10	26/26%
≥ 11	66/66%
Role in relation to LARC practice	
Both insertion and removal	94/94%
Removal only	3/3%
Did not respond	3/3%
Number of women seen in relation to LARC per month	
< 5	38/38%
Between 6 and 10	23/23%
≥ 11	38/38%
No response	1/1%

Aim C: assess current practice of how health-care practitioners approach discussions of weight loss with women with overweight or obesity and the inter-relationship between discussions about overweight/obesity and family planning

Health-care practitioners and LARC users reported that weight was discussed at both general appointments and appointments related to family planning.

Conversations with health-care practitioners regarding weight at general health appointments

A total of 119 (49.2%) of LARC users reported that weight had been discussed at general health-care appointments (i.e. not specifically related to LARC removal). Weight-related discussions were more likely if the woman had a BMI of > 30 kg/m^2 (61.0% compared with 32.6% for those with a BMI of < 30 kg/m^2). LARC users described conversations regarding weight in many different appointment contexts with numerous health-care practitioners across primary and secondary care ('every health-care professional'). Some health-care practitioners described introducing weight opportunistically at any health-care appointment, whereas others would be more selective, for example discussing weight only if it was relevant to the appointment.

Information provided to patients

The type of weight-related information provided in general appointments included (1) healthy lifestyle advice, (2) advice related to existing health conditions, (3) referrals for specialist weight loss support and (4) medication information.

Overall, there seemed to be little practical or psychological support available, with often very brief, unhelpful comments on weight being made; for example, 'I was told I was overweight and to lose it. There was no help offered at all'. A few examples of positive experiences were reported, when health-care practitioners had been supportive and non-judgemental and had offered practical, long-term help.

Weight was discussed in the context of health conditions (e.g. PCOS, diabetes), but this did not seem to improve LARC users' experiences of weight-related support. Referral to specialist support for weight loss was not commonplace, and LARC users described having to fight for the support, receiving a referral that was unsuitable for their needs or experiencing long waiting lists. Some LARC users had been prescribed medication (e.g. Orlistat) to help with weight loss.

The weight loss practitioners who completed the survey ($n = 4$) described the importance in preparation for pregnancy of following NHS guidelines and having a healthy lifestyle but not focusing on weight loss.

Conversations with health-care practitioners regarding weight at family planning appointments

The nature of family planning/preconception weight-related guidance and discussions varied depending on the type of health-care appointment and the health-care practitioner involved.

Information provided to patients Information provided to LARC users included advice related to conception/fertility and contraception.

The majority of health-care practitioners (72%) said that they discussed weight during preconception discussions as part of preconception advice or when discussing fertility issues with patients. However, some health-care practitioners said that they felt that weight was not a priority in preconception advice or that this was not an appropriate time to address weight.

i. Fertility issues or increasing conception chances LARC users reported that they had received general recommendations from health-care practitioners to lose weight to increase their likelihood of

conceiving but had not been given practical advice or support to do so. Infertility issues were attributed to obesity, and a reduction in BMI was a requirement for access to IVF treatment:

> *I have been told that I will not get any support in relation to my fertility until I have lost a considerable amount of weight to be eligible.*
>
> *LU21*

ii. Associated with contraception Discussions about weight at contraception appointments were initiated either by the health-care practitioner due to limitations on contraceptive options in women with a raised BMI or by LARC users who had concerns about weight gain resulting from the use of contraceptives (contraceptive pill or LARC).

Barriers to and facilitators of discussing weight in general health-care appointments

LARC users and health-care practitioners reported several barriers to and facilitators of discussing weight in general health-care appointments. There was a substantial overlap between these themes and those identified in relation to the discussion of weight during LARC removal. To reduce repetition, the themes are summarised in *Table 15* and presented in detail in the following section in relation to the LARC removal appointment.

Aim D: assess the barriers and facilitators, including practical and ethical considerations, to introducing weight and the option of delaying LARC removal from the perspective of LARC users and health-care practitioners

The surveys for both groups of stakeholders included specific questions about the introduction of weight as a topic during a LARC removal and the acceptability of asking/being asked to delay the LARC removal in order to take part in a WLI before pregnancy.

Many LARC users (46.8%) described feeling uncomfortable at the prospect of discussing weight at LARC removal appointments; 38.4% said that they would be comfortable and 14.8% said that they would be neither comfortable nor uncomfortable with the conversation. However, the majority of health-care practitioners said that they would feel comfortable introducing the subject of weight with patients attending for LARC removal (65%), whereas 12% reported that they would feel uncomfortable and 23% would feel neither comfortable nor uncomfortable.

TABLE 15 Barriers to and facilitators of discussing weight in general health appointments

Barriers	Facilitators
Sensitivity of the subject	Part of role as health-care practitioner
Potential vulnerability of patient (e.g. mental health)	Health-care practitioner approaching the subject sensitively
Lack of skills/training	Existing health-care practitioner–patient relationship
Risk of complaint	Patient's right to choose and knowledge (to have the discussion/to know health risk)
Lack of services	
Lack of evidence base of risk available to share	
Weight not seen as relevant to the consultation agenda (including contraception)	
Woman not weighed in clinic so discussion based on appearance	
Patient's prior experience of weight loss discussions	
Pragmatics of short appointment times	

In answer to the specific question about whether it would be acceptable to ask LARC users with overweight or obesity to delay LARC removal to attend a WLI prior to trying to conceive (*Figure 9*), 39.9% of LARC users stated that they felt it would be acceptable, compared with 29.6% of LARC users who felt that it was unacceptable and 30.5% of LARC users who were unsure. The majority of health-care practitioners (63.6%) reported that they felt that women would be willing to postpone LARC removal to take part in a preconception WLI, whereas only 17.2% of health-care practitioners felt that women would be unwilling to postpone LARC removal and 19.2% were unsure.

The themes that emerged from responses to these questions are described below in the broad categories of barriers to and facilitators of introducing preconception weight and delaying LARC removal at LARC removal appointments. Many of these themes repeated or resonated with those that emerged from the LARC user and health-care practitioner responses to the questions surrounding the discussion of weight in health consultations generally.

Barriers to the introduction of preconception weight and LARC removal delay at LARC removal appointments

Barriers are detailed according to the following themes: (1) the sensitivity of weight as a topic area, (2) LARC user engagement and past experiences, (3) knowledge and beliefs of the LARC user, (4) the context of the consultation and service setting, (5) health-care practitioners' skills, (6) the information/interventions provided and (7) ethical implications of requesting a delay in LARC removal.

Sensitivity of the topic Both stakeholder groups considered weight a sensitive topic and felt that conversations regarding weight at LARC removal appointments would be difficult. LARC users described that they would feel ashamed, attacked and judged for having a raised BMI if weight was discussed at LARC removal appointments; health-care practitioners were aware of the potential to upset patients and were concerned about possible repercussions:

> *I gained a good amount of weight on the implant, and I don't like talking about it. I feel judged.*
>
> *LU234*

> *Following a recent complaint when I discussed weight with a patient at a contraceptive review, it has made me wary about initiating discussions.*
>
> *HCP64*

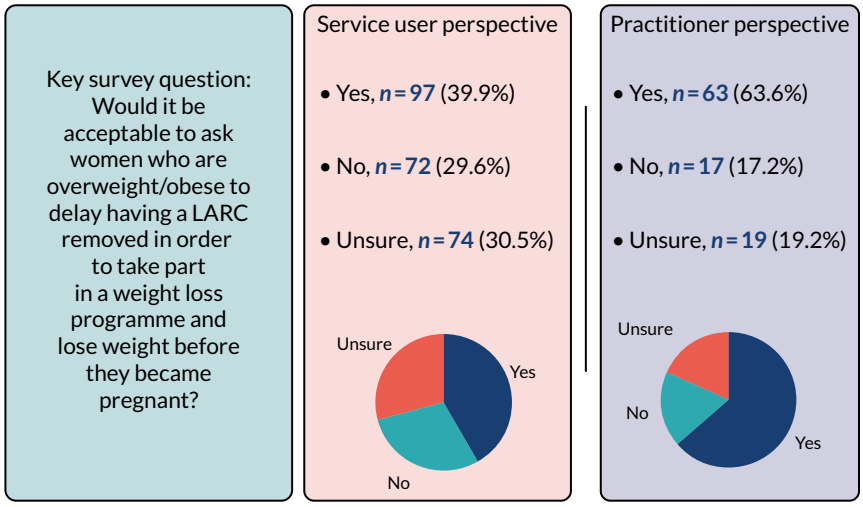

FIGURE 9 Stakeholder responses to the acceptability of delaying LARC removal to lose weight.

However, some in both groups were ambivalent, acknowledging both the discomfort with the conversation and the belief that the conversation was needed. Some LARC users appreciated the importance of the conversation and health-care practitioners' good intentions; similarly, health-care practitioners described the necessity of discussing weight as a health risk with patients despite the potential outcomes:

> *Because weight is a very personal thing and it sometimes feels like an attack even though with a health professional I know it is in my best interest.*
>
> *LU44*

> *I am uncomfortable about it because it upsets women but think I it is my medical duty to mention it so try and do it as tactfully as possible.*
>
> *HCP87*

LARC user engagement and previous experiences LARC users reported being reluctant to engage in discussions about weight loss during LARC removal appointments. Barriers included being content with their weight but also the complexity of weight loss that requires more support than a simple mention during a health-care appointment, which is ineffectual:

> *If there was a point. What are your aims to ask about weight? Weight isn't as cut and dry as smoking or drinking alcohol. It's not like you can ask 'are you currently thinking about quitting food?'*
>
> *LU5*

Past experiences of weight discussions in health-care consultations could be a significant barrier to introducing the topic of weight during a LARC removal appointment. LARC users reported frustration that weight was so frequently a focus in consultations, often, in their view, inappropriately. As a result of these types of experiences, LARC users said that they avoided health care if possible, and health-care practitioners acknowledged that patients are unwilling to engage because of their previous experiences. Furthermore, LARC users reported occasions when they had attempted to seek help to lose weight but had been disappointed by the lack of support from the health-care practitioner and the quality of the care/intervention:

> *Almost every medical professional I have ever seen has suggested symptoms of everything from a chest infection to a sprained wrist would be improved if I lost weight.*
>
> *LU4*

> *Almost everything you go to see a health-care professional about has the opportunity for them to bring up the subject of weight. I'm rarely ill, but even if I am, I put off going to see anyone for as long as humanly possible.*
>
> *LU8*

> *I mention it to patients, feel that they are not motivated to change and get 'fed up' with health-care professionals telling them they are overweight when they already know they are overweight.*
>
> *HCP27*

Mental health issues, both related and unrelated to weight, may be a barrier to introducing the topic of weight at LARC removal appointments. Anxiety, experiences of bullying and low self-esteem were all described as barriers to engaging in conversations with health-care practitioners or WLIs. LARC users reported the potential negative impact that discussing weight could have on patients who have a history of disordered eating:

> *Before giving advice or recommendations on weight loss methods get to know the patient and their history better so it feels more like you're being helped rather than being told off.*
>
> *LU215*

> *I have struggled with eating disorders in the past, and I know that any attempt at losing weight quickly turns to me starving myself for quick weight loss.*
>
> *LU235*

Knowledge and beliefs of the LARC user LARC users felt that weight did not map on to health as closely as was suggested by health-care practitioners and mistrusted the emphasis on BMI. Some LARC users questioned the assertions related to risk, deeming the interpretation of statistical risk exaggerated, and they wanted clearer information/statistics to be able to make an informed choice:

> *I know all about the risks but lots are correlation rather than causation. I have not had any complications in my pregnancy despite a high BMI . . . Don't worry about the confounding socioeconomic factors behind those statistics I am fat so I am doomed.*
>
> *LU6*

LARC users believed that the LARC was a causative factor in their weight gain and wanted this to be acknowledged by health-care practitioners. One health-care practitioner reported using patients' perception of LARC and weight gain as a way to introduce weight loss:

> *Sometimes a route in is in their perception of the LARC and their weight, i.e. 'I am taking it out because I've gained weight'.*
>
> *HCP63*

Service setting/context LARC users, and some health-care practitioners, suggested that weight is not relevant to contraception, and that discussion of weight or health matters at a contraception appointment is not appropriate unless raised by the patient:

> *Client is in LARC clinic not in a weight watchers' class or slimming clinic!*
>
> *HCP43*

> *If it was just asked off the cuff with getting contraception removed I'd be a bit taken aback. I'm not there presenting with a health complaint, so why discuss weight?*
>
> *LU5*

Several barriers were suggested by health-care practitioners regarding the logistics of asking women to delay LARC removal when presenting at contraception appointments. Health-care practitioners and LARC users reported long waiting times for appointments and time limits placed on appointments:

> *I had to wait months for an appointment to remove my implant in the first place which was difficult as I was keen to try and get pregnant – I would have been upset if I'd had to consider delaying removal further.*
>
> *LU18*

> *It would be really hard to have this kind of conversation in a very short appointment in a successful and productive way.*
>
> *LU44*

> *In my surgery, patients book in without prior counselling for a 10 min (coil) or 20min (implant) removal so time is limited. We would have to change our system.*
>
> *HCP93*

The reason for a patient requesting LARC removal may determine whether or not weight should be introduced during the LARC removal appointment. Participants suggested that if patients requested

LARC removal for reasons other than wanting to conceive, such as side effects including heavy periods, weight gain and changes in mood, then it may not be appropriate to raise the topic of weight:

> *I had a coil removed for mood swings, I couldn't have spent any longer on it. God help if a stranger had told me to leave it in and lose weight!*
>
> *LU75*

> *The majority of women for whom I remove LARC state they want removal for side effects (perceived or actual) and it is not often that I see someone that wants removal purely for pregnancy.*
>
> *HCP42*

Finally, LARC users reported feeling vulnerable during intimate LARC removal appointments and felt that it would be inappropriate for practitioners to instigate discussions regarding weight:

> *For some females it can be incredibly nerve wrecking going to have a discussion with a total stranger about birth control. Especially if it's the coil where they are at the most intimate part of a female's body then they start talking about the person's weight!*
>
> *LU75*

Health-care practitioners Many LARC users thought that health-care practitioners lacked the required skills to deal with the sensitive topic of weight management. Similarly, health-care practitioners acknowledged that they could feel uncomfortable discussing weight with patients, particularly when providing preconception advice. Health-care practitioners wanted to be provided with guidance or accurate information regarding the risks of raised BMI in pregnancy or effective weight loss advice to enable them to have successful discussions with patients:

> *Making us feel crap about our choices and our bodies, is not a way to motivate anyone. Look up motivational counselling techniques. Look up life coaching techniques. How the healthcare service treats overweight and obese people is literally the opposite, with the effect that we feel crap and we get fatter.*
>
> *LU8*

> *If this HCP was someone I was only seeing as a one off. There was no follow up with the same person or I'd never met the person. No rapport or trust. I would be fairly insulted if they offered unsolicited advice.*
>
> *LU5*

> *Staff will feel uncomfortable unless they have some guidance on how and when to phrase things.*
>
> *HCP87*

> *I'd be willing to try it – but would like to have some training about how to raise weight loss anyway . . . would there be any supporting patient resources – then the patient might feel the suggestion is not coming personally from me.*
>
> *HCP67*

The weight status of the health-care practitioner also appeared to be a barrier to successful discussions regarding weight at LARC removal appointments. Health-care practitioners with overweight may appear hypocritical, whereas health-care practitioners with a healthy weight may appear unsympathetic and patronising:

> *It would be nice if the healthcare professional followed their own advice. Being out of puff and smelling of bacon is an example that rather frustrates the patient.*
>
> *LU161*

> *Some clinicians may not be keen particularly if obese themselves – practice what you preach!*
>
> *HCP64*

Health-care practitioners spoke about the requirement for referral pathways to effective interventions, and both stakeholder groups reported their frustration at the lack of efficacious interventions or at unsuitable interventions:

> *. . . unhelpful advice relating to solutions that are financially inaccessible and not accessible to single parents with limited support.*
>
> *LU137*

Ethical implications of requesting LARC removal delay In many of the responses to the idea of delaying LARC removal to lose weight, respondents reported what can broadly be described as ethical barriers relating to personal choice, conception decision-making, impact on the care pathway and exclusion of non-LARC users.

Individual freedom to choose LARC users and health-care practitioners highlighted the ethical implications of what could be interpreted as an imposition of a contraceptive decision on patients, suggesting that this should, ultimately, be the choice of the individual. Some LARC users referred to discrimination against people with overweight/obesity and said that the inference would be that 'fat people shouldn't breed' (LU4). LARC users felt that state involvement in personal reproductive decisions was unacceptable. They were also concerned that people may feel pressured into agreeing to delay LARC, acknowledging that health-care practitioners, despite acting with best intentions, may be unaware of this consequence. However, health-care practitioners also acknowledged the potential to pressure patients in a 'doctor-led approach':

> *I understand that you are concerned about fat people having babies and the implications for the healthcare system but if a woman wants her coil taken out at any time for any reason that is her choice.*
>
> *LU117*

> *I would find it ethically complex to suggest to women that their freedom of choice to have their contraception removed may be compromised by their weight. I would however feel happy to discuss the options with them and share evidence about the pregnancy-outcomes in obese women.*
>
> *HCP57*

> *Because you're denying someone the right to get pregnant due to their weight. That is a breach of their human rights.*
>
> *LU180*

> *People who are overweight are already treated like second class citizens by some professionals, this would feel like a form of eugenics unless treated very carefully.*
>
> *LU23*

> *. . . this is already happening in places, with women are reporting having been 'refused' to have their implant/coil removed, conditional on losing weight. That may not be what the healthcare professional thought they were saying, but that is the message women are hearing.*
>
> *LU8*

Complexity of timing in conception decisions The complexity of decision-making surrounding trying to conceive may be a barrier to asking patients to delay LARC removal to lose weight; LARC users said that the decision to have a baby is a complex one, which may be informed by their relationship, their studies, their career choices, sibling age gaps, financial implications, etc.:

> *People do not lightly decide the time is right to try for a baby!?!? They will have thought long and hard about it, and undoubtedly already have concerns about weight.*
>
> *LU8*

Both LARC users and health-care practitioners commented on the risk of delay in older women, saying that a long delay may have implications for their chances of conceiving or lead to complications in pregnancy due to age. Additionally, women who have fertility issues may not want to delay LARC removal:

> *. . . may not achieve anything other than delaying pregnancy and LARC removal – so you end up with older overweight people getting pregnant.*
>
> *HCP42*

Impact on care pathway It was suggested that, if patients were aware that they would be asked to delay LARC removal due to their weight, this may discourage patients from having a LARC fitted in the first place, or they may go elsewhere for removal. LARC users also questioned whether a process would be in place if patients declined to attend a WLI or if they were unsuccessful at losing weight and whether this would have implications on the care they received or if they were 'allowed' to have a baby. Furthermore, there was an expectation that, if the risks are greater in women with overweight/obesity, then supplementary screening/care should be offered to pregnant women:

> *It also carries the connotation that if they do undergo a weight loss programme but don't succeed – what happens then? . . . I feel this kind of protocol carries a lot of weight and as such needs to be undertaken very carefully and sensitively.*
>
> *LU63*

> *Being asked if I would like to discuss potential risks/additional screening in the event of falling pregnant.*
>
> *LU2*

Exclusive intervention Finally, it was highlighted that people may feel excluded from an intervention targeting women trying to conceive, suggesting that an effective WLI should be offered at a population level.

Facilitators of the introduction of preconception weight and LARC removal delay at LARC removal appointments

The facilitators are a mirror image of the barriers across the following themes: LARC user engagement and previous experiences, knowledge and beliefs of the LARC user, service setting/context, health-care professional and information provided/available interventions.

LARC user engagement and previous experiences LARC users stated that they are accustomed to discussing weight at health-care appointments and appreciated the importance of the conversation and, therefore, despite the innate sensitivity of the topic, they would be co-operative and unlikely to be offended. Some LARC users described the prospect of delaying LARC removal as a reasonable proposal, and potentially would welcome the discussion as a motivating factor and any offers of support. Health-care practitioners also referred to patients' attitude, wishes and motivation as facilitators of successful discussions regarding weight; if the patient has a positive attitude to weight loss, initiates the conversation or has a desire to improve their health, it allows for beneficial discussions. LARC users and health-care practitioners suggested that whether or not women find the conversation acceptable would depend on their circumstances, age, history and weight status; participants suggested that asking people to delay removal would be acceptable only if the individual had obesity and was not just 'slightly overweight':

> *I would be happy being asked to take part in a weight loss programme before trying to become pregnant. I would see it as a way to become more healthy before conceiving, which could also increase the chance of becoming pregnant if I lost weight.*
>
> *LU9*

Knowledge and beliefs of the LARC user Nearly two-thirds of LARC users (64.2%) said that they were aware of risks of overweight/obesity in pregnancy, and each described between 1 and 10 risks, including conception risks (difficultly conceiving), pregnancy risks (miscarriage, pre-eclampsia, failed intubations, pelvic symphysis disorder, severe pregnancy symptoms, etc.), delivery risks (shoulder dystocia, stillbirth, cesaerean section, post-partum haemorrhage, instrumental delivery) and risks to the baby (cerebral palsy, spina bifida, large or small birthweight, premature birth). A total of 15.2% of LARC users stated that they did not know any risks, 2.9% were unsure of the risks and 17.7% did not respond. LARC users thought that knowledge about or being informed of the health benefits of being a healthy weight could be a motivator to engage in a WLI. They stated that communication of the risks of obesity in pregnancy was essential to allow patients to make an informed choice and maintain autonomy. However, as discussed previously, some LARC users were sceptical about the risks of overweight/obesity in pregnancy, saying that these are exaggerated by the health-care profession:

> *Personally, with the current weight I am, I would be less keen to become pregnant now. I would prefer to lose some weight and get fitter – but that's because I know how pregnancy has an impact on my body and I would want to be as prepared as possible before hand to help support my back and hips (previous pgp).*
>
> *LU5*

> *It's in their interests, they are free to decline . . . they may be unaware of the risks. Few service user participants these days mind not smoking and not drinking alcohol in pregnancy, weight loss may simply not be on their radar.*
>
> *HCP20*

Service setting/context LARC users suggested that preconception and pregnancy may provide a window of opportunity to introduce weight loss in order to maximise fertility and improve health in pregnancy. In addition, the potential benefits to the unborn child may be a facilitator of healthy behaviours. Others described this opportunity in pragmatic terms, that is a time of increased contact with health-care practitioners and a potential willingness to discuss weight when it is considered as part of a broader preconception/healthy pregnancy package of health recommendations:

> *Because the healthier you are the better chance you have of getting pregnant and having a problem free pregnancy. Wouldn't any mother want that?*
>
> *LU150*

Health-care professional LARC users believed that it was the medical professional's role to discuss health issues such as weight with patients and expressed confidence that health-care practitioners prioritise patients' health. They valued an ongoing relationship with health-care practitioners and continuity of care, including the practitioner's knowledge of the patient's existing medical conditions, as vital for successful discussions.

LARC users highlighted the importance of good communication skills; they indicated that the health-care practitioner should be sensitive, compassionate, non-judgemental and not patronising and be aware of their tone and body language to ensure that the patient is at ease during the consultation. Having adequate time was seen as a facilitator of ensuring effective communication, as was not treating the conversation like a 'tick-box' exercise. An open, honest discussion was important to LARC users, as was practitioners having an awareness of terminology likely to cause offence, such as 'obese' or 'fat', and an understanding of the difficulties of losing weight. LARC users suggested ways of broaching the topic, rather than giving abrupt unsolicited advice. Health-care practitioners also considered themselves potential facilitators if they approached the discussion sensitively and had a

good rapport with the patient, but they also requested additional training, guidance and potentially a script to ensure that they took the right approach:

> *If this HCP was someone I was only seeing as a one off. There was no follow up with the same person or I'd never met the person. No rapport or trust. I would be fairly insulted if they offered unsolicited advice.*
>
> *LU5*

Information provided/available interventions LARC users said that, instead of simply instructing the patient to lose weight, health-care practitioners should provide support for and/or practical advice about losing weight or signpost to a choice of options for effective support. Practical solutions were recommended, such as diet tips, meal planning, free gym membership, WLIs and support networks. Similarly, health-care practitioners said that they could justify initiating such conversations if they were able to offer an effective intervention. Support that had a positive focus was important to LARC users, with the discussion being in the context of supporting health goals and highlighting the benefits of weight loss, rather than just focusing on the risks. Both LARC users and health-care practitioners suggested that, to increase acceptability and reduce stigma or risking patients feeling judged or singled out, weight and healthy lifestyle should be a standard part of preconception and contraceptive discussions:

> *If we could provide support/refer service user participants for intervention then I think service user participants would see that and find it acceptable/understand why they have been asked.*
>
> *HCP44*

> *It will be more acceptable if offered to everyone in this scenario.*
>
> *HCP8*

Both LARC users and health-care practitioners thought that referring to evidence-based guidance was a facilitator of acceptable discussions and enrolment in a potential intervention:

> *. . . information-giving discussion including introducing some of the evidence behind the issues to help it feel objective.*
>
> *LU33*

Aim E: identify feasible opportunities to intervene with a potential preconception weight loss intervention

To assess the acceptability of using the LARC pathway to propose a potential preconception WLI, health-care practitioners were asked: 'When you do think would be the best opportunity to introduce a preconception WLI to women with overweight/obesity attending for LARC removal?'. In addition, responses from LARC users regarding potentially introducing the subject of weight at LARC removal appointments mapped on to this theme. Responses from both health-care practitioners and LARC users are detailed collectively.

Prior to LARC removal

Health-care practitioners suggested that LARC removal appointments take place too late, as by that time patients have resolved to try to conceive, and that patients should be engaged in discussions regarding weight at the earliest opportunity, including at the insertion of the LARC, at smear appointments or during general contraceptive consultations, to allow optimum time for consideration of the topic.

Arranging the LARC removal appointment

LARC users suggested that advance notice that weight may be part of the discussion at LARC removal appointments would allow them to prepare. This could take the form of a discussion at the time of

booking with the receptionist or service provider, a pre-assessment appointment with a nurse, or a leaflet:

> *Needs to be done BEFORE they attend. i.e. in pre-removal text/email/website link. When service user participants get to clinic, they want to receive treatment not delay.*
>
> *HCP42*

At LARC removal appointment

Although some health-care practitioners stated that the LARC removal appointment was, realistically, the only opportunity to introduce a potential preconception WLI because of logistical issues in the clinical setting, LARC users stated that this would be acceptable only if done sensitively and appropriately. Some LARC users thought that the discussion about the intervention should happen only subsequent to LARC removal in the context of optimising health for conception and pregnancy:

> *. . . at pre removal chat although these patients are often put into one stop clinics (chat and removal at same time).*
>
> *HCP88*

> *If you like, after you've done the procedure I came in for, offer me a leaflet or a follow-up telephone call about optimising my body for pregnancy.*
>
> *LU8*

> *Discussion only if wanting to get pregnant was already discussed.*
>
> *LU173*

At a separate appointment

LARC users suggested having a general, preconception appointment at which the benefits of weight loss would be discussed in the context of 'preparation for pregnancy' or a fertility preparation appointment:

> *If it was offered as part of a separate appointment – a holistic 'preparation for pregnancy' type appt.*
>
> *LU18*

Not at all

Some LARC users and health-care practitioners said that there would be no appropriate time to engage women in discussions about preconception weight loss because there was a lack of effective interventions:

> *Not at all – until we have a highly effective weight loss intervention!*
>
> *HCP42*

Aim E: assess the desired characteristics of a potential preconception weight loss intervention from the perspective of LARC users and health-care practitioners

Both LARC users and health-care practitioners were asked what they considered to be the most effective characteristics of a potential preconception intervention. The responses are summarised in *Table 16*.

The majority of LARC users (87.1%) stated that a potential intervention should contain a diet/healthy eating aspect. However, the specifics of the suggested diet components varied significantly. Whereas some LARC users suggested that diet plans and dietary advice should be provided, others argued that 'diets don't work' and that advice should be couched in terms of healthy eating and healthy lifestyle. Additionally, whereas some LARC users had had positive experience of commercial weight loss groups, such as Slimming World (Alfreton, UK) or Weight Watchers (WW International, New York, NY, USA), and were in favour of the inclusion of commercial weight groups in a potential intervention, some LARC users stated that commercial weight loss groups were condescending and not appropriate for

TABLE 16 Stakeholders' views of key characteristics of a preconception WLI

Characteristics of the intervention	Description
Accessibility	Free/low-cost, easy/immediate access
Duration	Defined
Dietary advice	Not a diet – defined as healthy eating/healthy lifestyle
Physical activity	Important component but unspecified
Psychological support	Coping mechanisms, dealing with habits, vicious cycle of overeating and dieting
Group-based peer support	Optional element
Multifaceted lifestyle advice	Broader than weight – positive frame of a healthy preparation for pregnancy
Signposting	To support services locally
Individualised	Different options to choose from (e.g. group support and physical activity)

an NHS setting. Very low-calorie diets were also favoured by some LARC users (27.5%) as a time-limited and goal-oriented weight loss regime; however, others described these as 'dangerous', especially for women with a history of disordered eating, and said that they were not appropriate for an NHS setting. LARC users also suggested referrals to dietitians as a method for receiving reliable, appropriate support.

A high proportion of LARC users (80.3%) considered physical activity advice an important component of a potential preconception WLI, with 75.1% favouring a physical activity component to the programme, including access to free community fitness centres/classes. This was also reflected in the surveys of health-care practitioners, who emphasised the importance of a combined diet and physical activity programme.

A high proportion of LARC users (71.7%) and health-care practitioners favoured the inclusion of a psychological component in the potential intervention, and referred to support to address unhealthy habits, coping mechanisms, comfort eating, societal conditioning to view unhealthy foods as treats and rewards and the vicious cycle of overeating and dieting.

Although group-based interventions were valued by 61.4% of LARC users, because of the encouragement and motivation received from other group members in a similar position and accountability to the group instructor, some LARC users were concerned about the lack of confidentiality in group settings and reflected that, for some women, the social aspect of group interventions would be intimidating and overwhelming.

LARC users suggested that the intervention should be multifaceted and bespoke, with optional components targeted to individuals. Others suggested a broad and holistic intervention related to health preconception and in pregnancy. This was echoed by health-care practitioners, who suggested the inclusion of information about other lifestyle factors, such as smoking, alcohol, drug use, immunisations and folic acid. Health-care practitioners said that any intervention would need to be culturally appropriate.

Health-care practitioners emphasised the need to fully inform patients about the risks of overweight/obesity in pregnancy. Whereas some LARC users suggested developing an intervention focused on 'preparing for pregnancy', others were concerned about the risk to attendees' mental health if they attended a group intervention but were unsuccessful in conceiving:

> *A pregnancy related group could well cause depression in those unsuccessful service user participants so instinct says to avoid.*
>
> *LU161*

LARC users and health-care practitioners were questioned about the facilitators of and barriers to implementation of the intervention. The overwhelming concern from both LARC users and health-care practitioners was that the intervention should be free (whether this included a free app or free membership to a gymnasium/fitness classes) and widely accessible. Attendance at intervention sessions may also be optimised by financial incentives. Although LARC users suggested that in-person support would be most beneficial, some suggested that virtual/remote support may complement an intervention if used in addition to face-to-face contact. Barriers to the implementation of a potential preconception WLI included logistics such as timings of classes for working patients/parents and location of classes and if the patient had any medical conditions that may prevent them participating in physical activity or certain diets. The majority of health-care practitioners said that the intervention could be introduced by any health-care practitioner involved in the person's care, including GPs, nurses and health visitors.

Conclusions

The purpose of the surveys was to develop an understanding of key stakeholders' experiences of the interface between the LARC care pathway and weight-related discussions between health-care practitioners and LARC users. The methods were appropriate for the purpose. Data collection techniques were revised after initial attempts to conduct qualitative interviews at professional events proved to be difficult in the setting. However, the online survey responses were full and detailed and recruitment of health-care practitioners at professional events was successful.

The generalisability of the data is a limitation of this component of the study. The vast majority of health-care practitioners were medical, rather than nursing, practitioners, due to the nature of attendance at the professional events attended. However, there was balanced representation of health-care practitioners from primary care and sexual health settings and in terms of years of experience. The majority of LARC users were recruited either via boosted advertisement on Facebook or via Healthwise Wales, which may have resulted in the recruitment of highly motivated, like-minded (i.e. sharing within special interest groups) or research-knowledgeable participants. The inclusion criteria for LARC user recruitment were very specific, which was also a potential barrier; however, being mindful of these limitations, responses were highly relevant and full. The low recruitment of weight loss consultants was disappointing; only four were recruited because of limited recruitment pathways. The use of a shared coding framework across LARC users and health-care practitioners was considered appropriate, as emerging themes were very similar across LARC user and health-care practitioner groups. In addition, it allowed easy identification of when themes converged and diverged and allowed the consideration of themes during the phase 2 interviews and intervention design.

The policy review produced several findings. Encounters where PCC and/or contraception are discussed (including LARC removal appointments) are regarded by policy-makers as key opportunities for discussions of maternal weight. LARC use by women with overweight/obesity is safe, with no evidence of a link with weight gain. Training requirements for UK practitioners in relation to LARC insertion/removal are specified, but guidance on how and when LARC removal should be discussed with women is minimal.

LARC users gave a strong sense of the generic nature of weight discussions with health-care practitioners, with many reporting that weight is always discussed regardless of the context of the consultation, and also that the discussions were often based on appearance rather than arising after being weighed. The discussions about weight in health consultations, including those in relation to family planning and pregnancy, were often unhelpful and had a negative focus. In the worst cases, they were experienced as psychologically harmful and put people off going to any form of health-care consultation.

One of the key examples of the generic approach, which LARC users felt allowed no recognition of the individual, was allocation to consultant-led maternity care because of raised BMI. This caused frustration as it seemed to be an unjustified, automatic decision made without any reference to the woman's health. This process has now been changed in the care pathway, with more personalised discussions taking place for women with a BMI of < 35 kg/m^2.[101] However, given the quality of the communication described by women in this survey, it remains to be seen whether this will have reduced the sense of stigma, or potentially made it worse if there are no improvements in health-care practitioners' communication skills around weight.

The barriers to talking about weight for both parties encompassed a full range of practical, cognitive and emotional factors, from time in clinic to beliefs about the relative unimportance of weight and the sensitivity of the topic. Few facilitators were identified apart from beliefs about the nature of the roles of the people in the dialogue (i.e. the woman's right to knowledge and choice and the practitioners' duty to inform). These themes were replicated in the responses to the questions about discussing weight in LARC removal appointments and the acceptability of proposing a delay in removal in order to lose weight before pregnancy. The sensitivity of the topic of weight was universally acknowledged; raising it during an intimate process such as LARC removal was seen to result in an uncomfortable combination by nearly half of the LARC users. Some health-care practitioners and LARC users were ambivalent. They recognised the importance of weight in relation to pregnancy while also being reluctant to engage in those discussions for many reasons: the sensitivity of the topic; the sense of lacking the necessary communication skills on the part of the health-care practitioners; and the futility of it, given the complexity of weight loss, the lack of support available and the lack of robust evidence (as the health-care practitioners viewed it) to support the discussion of risk and benefits. Others responded positively to the idea; they felt that many people would welcome the support to lose weight as they know that having a raised BMI presents risks to the pregnancy, and this could be a window of opportunity to introduce weight loss with a focus on the health of the baby. This would need to be introduced sensitively by a health-care practitioner with good communication skills, and, most importantly, if it were coupled with a potential programme of support, the conversation could be a positive step.

The views on the key components of a preconception WLI were many and varied, with many participants opting for a multifaceted and bespoke intervention as part of a healthy preparation for pregnancy programme.

The survey responses raised many practicalities that would need to be considered were the topic of weight to be introduced routinely as part of the LARC removal appointment, for example appointment length and health-care practitioner skills, which hypothetically could be addressed through training, the consideration of appointment schedules and so on. However, there were some more fundamental principles underlying the barriers to both the discussion of weight and to the delay of the removal that require essential changes to the potential design of any intervention at this point in the LARC pathway. These were as follows.

Timing in the context of the decision process

The decision to have a baby is often complex, thought through (also with partner), and timing is part of an emotional, social, cultural and financial web of circumstances. Although many have LARC removal for reasons other than wanting to become pregnant straight away, for example because of side effects, they would still not want to delay removal, and for those where it is a deliberate step to pregnancy, the removal appointment is considered too late.

Woman's right to choose

The proposed intervention interweaves two complex sociopolitical issues in weight and conception, which can be captured by the concept of a 'woman's right to choose', a phrase that has become synonymous with women's reproductive rights. While there was never any intention that the intervention would remove a woman's choices, the underlying message that some stakeholders

identified was discriminatory, suggesting that women with a raised BMI should not become pregnant, and there was perceived to be a risk that women would feel pressured to participate, however unintentionally, by the health-care practitioners' description of the option to delay the LARC removal.

Is weight part of health/family planning?

Throughout the themes is a thread of whether weight is regarded as a health/family planning issue.

In summary, several factors were important to consider when designing a potential preconception WLI and were to be explored further through the SAGs and phase 2:

- In the discussion of the intervention, it should be clear that the woman retains the right to choose to delay or not delay the removal of the LARC. This could be achieved by timing the discussion better so that it takes place well in advance of a LARC removal appointment, or ensuring that the delay of the removal is not one of the eligibility criteria for taking part in the intervention.
- The intervention could be offered to the general population, so that the LARC removal appointment is simply an opportunity to engage.
- Information that is clear for all about risk should be included in referral and intervention information.
- Health-care practitioners should be provided with training in communication skills and information regarding risks.
- Women's experiences with weight loss should be taken into account, as these encounters set the stage for their likelihood of engaging with any future intervention.
- The referral and intervention should have a positive approach, focusing on the benefits of weight loss, rather than the risk of current weight.
- The intervention should be free and available to all.
- The intervention should be part of a healthy pregnancy approach.

Chapter 5 Realist review

Introduction

Although there is consensus that, for women with overweight or obesity, a 10% lower preconception BMI is associated with a clinically meaningful risk reduction in pregnancy outcomes, and that achieving a healthy weight prior to pregnancy is a health priority, there is little information about how best to deliver a preconception WLI for women with raised BMI. This review, following a realist approach,[84] will bring together information from a range of sources to begin to develop theories about how and when health behaviour interventions in the preconception phase might work, in order to design a preconception WLI for women with raised BMI.

Overall research questions for the review

- Preconception WLIs: what works, for whom and in what contexts?
- What are the barriers to and facilitators of engagement in preconception health behaviour change interventions?
- Is anything additional to be learned from WLIs during pregnancy and postnatally that could contribute to the development of a preconception WLI?

Aims of the realist review

To answer the research questions and consider any potential intervention designs, the aims were to develop an understanding of and potential theories about:

1. intervention characteristics and approaches to recruitment
2. contextual influences on the intervention
3. potential CMO configurations.

Methods

The review is guided by the principles of Pawson and Tilley's scientific realism.[84] This approach was designed for the evaluation of complex social interventions based on a realist understanding of causation that recognises that social interventions lead to outcomes by triggering a reaction in individuals. The way in which individuals respond to interventions is understood to relate to characteristics of both the interventions themselves and the context in which the intervention is delivered. Realist research focuses on the development of explanatory theories that describe the interactions of these factors using CMO configurations. Programme theories can be developed from these CMO configurations to offer possible explanations about how the intervention works or could work and highlight facilitators of and barriers to interventions working, with a focus on theory generation (rather than testing).

Search strategies methods

In realist methodology, concept mining describes the search process across a wide range of published evidence to explore potentially relevant mechanisms and how those might be affected by context in order to help build theories. This could include reviews, intervention studies, protocols and qualitative research.

Several systematic reviews and meta-analyses related to obesity and the perinatal period have been published in recent years (see *Appendix 8*). The conclusions drawn in those reviews and the studies they cite were examined to identify (1) possible intervention designs and (2) relevant information on

contexts, mechanisms and outcomes. Supplementary searches, based on the review research questions, were performed to ensure that more current publications were included, and to bring together additional relevant evidence to support the theory development (see *Appendices 4–6*).

For each search, a search strategy was developed and run, and relevant papers were identified through purposive and snowball sampling (see *Appendix 6* for details of the search strategies and the papers identified).

Analysis and synthesis

A realist approach to evaluation was followed, as described by Pawson[86] and implemented by other researchers as part of intervention development.[102,103] In an area of limited existing research such as preconception, a wide range of sources are used to generate theories. Following an iterative database search strategy, sources were not assessed in a traditional review approach of using a quality appraisal tool, but instead were included if they offered information that was 'good and relevant enough'[103] to maximise diversity of information. The data from the sources were transferred to data extraction spreadsheets, including a core set of descriptors such as identifiers, nature of study, setting and country, and inclusion criteria.

The relevant information from the identified sources was captured in the form of explanatory accounts (see *Appendix 12*). These accounts summarised the lessons that could be drawn from the source on how best to approach the problem being tackled, in this instance the design of a preconception WLI. These accounts covered a broad spectrum of approaches to allow for a comprehensive overview; some explanatory accounts were articulated in the if . . . then structure familiar from developing CMOs, but also included information from, for example, commentaries or more conceptual work from experts in the field, if those added to the depth of understanding of the contextual factors to be considered in the programme theory.

Once explanatory accounts from individual sources had been documented, they were grouped into consolidated explanatory accounts, with the original source identifier retained to ensure transparency. The first step in this process of data reduction was to identify the outcome of interest; then, we considered any information in the account that enabled us to generate dyadic links, namely mechanism–outcome or context–outcome statements, a process used by Byng *et al.*[104] and Pearson *et al.*[105] (see *Appendix 13*). The descriptions of interventions in academic papers were often not detailed enough to provide the depth of information to form detailed CMO configurations from just one paper but were of sufficient interest to merit inclusion, at least in the first round of grouped explanatory accounts. Once the explanatory accounts were clustered by outcome and any dyadic links were noted, the accounts could be consolidated (see *Appendix 14*). This was done (following Pearson's[105] method) by first looking at whether or not the account was novel. If it was, then it was entered intact into the consolidated accounts. If it was not, then it was examined to see if it challenged or refined other accounts (i.e. it added to our understanding of contexts, mechanisms or outcomes). Through this process, the consolidated explanatory accounts generated comprised both the single source explanatory accounts that offer a unique perspective and those where the initial explanatory accounts could be integrated.

The use of middle-range theories

As part of the development of programme theories to guide the intervention development, existing middle-range theories that could relate to preconception weight loss and identified barriers and facilitators were explored, as were theories that may be considered central to weight loss in pregnancy and may generalise to the preconception period. Middle-range theories are those that, on the continuum of theory development, would fall between working hypotheses (as can be generated within individual projects, often described as programme theories) and the grand theories that aim to present a unified theory of the social world.[106] They operate at a more abstract level than the programme theories, specify mechanisms by which change may occur and, therefore, enable the development of more generalisable hypotheses.

Theories were identified in three ways. First, a list of relevant theories familiar to the research team from their work in studies relating to weight loss, GWG and behaviour change was generated. Second, theories that were stated as underpinning the interventions were identified through the searches. Third, a Google Scholar (Google, Mountain View, CA, USA) search specifically focused on theory[107] was conducted to identify any texts that had not been identified in relation to preconception interventions (see *Appendix 6* for the search strategy).

The consolidated explanatory accounts that were developed from the research literature were then considered alongside the formal theories identified through the searches. The next step was to integrate all of the data sources to produce a theory to take forward to the next stage of development. This process is outlined in the sections below.

Results

The review results are described in two sections. First, the relevant middle-range theories are identified, with an accompanying description of each theory, and, second, the CMO configurations are identified, which, together, form the basis of a hypothesised programme theory according to which a preconception WLI could work in the general population.

Identified middle-range theories

The Google Scholar search identified two papers that described theoretical models relevant to preconception and obesity. The B'More Fit programme[108] described the work of a coalition tackling obesity in a preconception population and used the social-ecological model, emphasising the multilayered nature of influence and the relationship between behaviours and the social environment. The second source included from this search was Liang *et al.*,[109] a review of theoretical components of guidelines for physicians. Although not specifically related to obesity, this source was thought to be relevant given the importance of obesity guidelines. In this review the theory of planned behaviour (TPB) and theoretical domains framework were most frequently used (in 16/42 and 10/42), with NPT also used (2/42).

The theories identified as of potential relevance and the source(s) used to identify these are listed in *Table 17*.

TABLE 17 Theories identified as potentially relevant to the review

Theory	Familiar to research team?	Cited by studies included in the literature review?	Theory search
COM-B/behaviour change wheel: Michie *et al.* 2011[110]	Yes	Vesco *et al.* 2014,[111] Hanson *et al.* 2017[112]	No
NPT: May and Finch 2009[113]	Yes	Liang *et al.* 2017[109]	Yes
Self-determination theory: Ryan and Deci 2000[114]	Yes		
Self-efficacy: Bandura 1986[115]	Yes	Barker *et al.* 2018,[29] Hussein *et al.* 2016[36]	No
Social cognitive learning theory: Bandura 1986[115]	Yes	Harrison *et al.* 2016,[117] Liang *et al.* 2017,[109] Poston *et al.* 2015,[118] Hillemeier *et al.* 2008[71]	No
Social ecological model: Bronfenbrenner 1979[119]	Yes	Truiett-Theodorson *et al.* 2015,[108] Hanson *et al.* 2017,[112] Hill 2021[120]	Yes
Social practice theory: Shove *et al.* 2012[121]	No	Barker *et al.* 2018[29]	No
Theoretical domains framework: Michie *et al.* 2005[122]	Yes	Liang *et al.* 2017[109]	Yes
TPB: Ajzen 1991[69]	Yes	Liang *et al.* 2017[109]	Yes
Transtheoretical model of change: Prochaska and DiClemente 1983[123]	Yes	Ockhuijsen *et al.* 2012,[124] Hanson *et al.* 2017[112]	No

COM-B, Capability, Opportunity and Motivation to Behaviour.

The lack of theory underpinning preconception interventions was identified in a review of preconception health behaviour research.[38] Many of the papers in this review either refer to interventions in broad terms, such as modifying behaviour, lifestyle modification and increasing motivation, but without references or pinpointing specific underpinning theory, or refer to constructs such as knowledge and attitudes, but often lack a definition of the construct. As a consequence, to include them would require interpretation and assumptions about potential theoretical mechanisms of action [e.g. impact of knowledge could be classified as Capability, Opportunity and Motivation to Behaviour (COM-B) self-efficacy], introducing bias and inaccuracies at this stage.

Each of the theories identified could potentially have a bearing on the review and were considered by two qualitative researchers. The four theories selected as of particular relevance and also encompassing many elements of the remaining theories were the TPB, COM-B, NPT and the social ecological model. Although areas of overlap exist between these four theories, each provides a unique structure that enables clear consideration of three central aspects of PCC programmes, namely individual behaviour change, practitioner behaviour change/embedding changes in professional practice, and relationships between individual behaviours and the social/societal contexts in which they occur.

These theories are briefly described, and their role in relation to the hypothesised programme theories is then considered in more depth.

Theory of planned behaviour[69]

The TPB states that whether or not a person engages in a behaviour is determined by both intention (motivation) and perceived behavioural control (PBC). The strength of a person's intention is determined by attitudes, subjective norms and PBC.

The key constructs of the TPB are:

- Intention – drives a person to engage in a particular behaviour; the stronger the intent (motivation), the more likely it is that the behaviour will be performed.
- PBC – perception of how easy or difficult the behaviour is (which will often vary depending on context).
- Attitudes – the person's positive or negative evaluation of the behavioural beliefs, which relate to the behaviour itself and the outcomes of the behaviour.
- Subjective norms – whether the person believes that their peers, other significant people or wider culture approve or disapprove of the behaviour (normative beliefs), combined with the individual's motivation to comply with these groups.
- Control beliefs – the perceived presence of facilitators or barriers that might affect a person's ability to engage in the behaviour.

COM-B model[110]

The COM-B model, incorporating the behaviour change wheel, links determinants of behaviour, drawn from the theoretical domains framework, to behaviour change techniques (BCTs). The theoretical domains framework, which has 14 domains of potential determinants of behaviour,[125] was originally designed to support health-care practitioners in intervention development, but its use has been extended to the health behaviour change domain, and it can, therefore, also be used to explore individual behaviour change.[126]

At the centre of the wheel are the key constructs proposed in the model as at the heart of behaviour change: capability (including knowledge and skills), opportunity (including social influences and environmental context/resources) and motivation (including beliefs about capabilities and emotion). Surrounding this inner hub of the sources of behaviour are the nine intervention functions (e.g. education, incentivisation, environmental restructuring), which are encircled by the policy categories, such as guidelines, fiscal measures and service provision.

Normalisation process theory[113]

Normalisation process theory (NPT) focuses on how work is socially organised, and how new practices become embedded and sustained, with an emphasis on the importance of context in this normalisation process.[113] NPT describes normalisation as occurring via four generative mechanisms: coherence, cognitive participation, collective action and reflexive monitoring.[113] Each mechanism has four subprocesses (indicated in brackets):

- Coherence relates to the process of making sense of the work involved in implementing a new intervention (differentiation, communal specification, individual specification and internalisation).
- Cognitive participation relates to the process of working out who will be involved in the new work required (initiation, enrolment, legitimation and activation).
- Collective action relates to understanding the process through which the new intervention is enacted, and possible constraints (interactional workability, relational integration, skill-set workability and contextual integration).
- Reflexive monitoring refers to how people make judgments about the new intervention (systematisation, communal appraisal, individual appraisal and reconfiguration).

The social ecological theory[119]

Brofenbrenner's social ecological theory (SET) is a systems model that recognises that behaviour affects and is affected by social environments and that changes that occur within social environments have the potential to influence an individual's behaviour. The influences on behaviour are divided into levels:

- microsystem – includes the closest relationship settings such as immediate family and social networks
- mesosystem – includes inter-relationships in the broader personal context (e.g. school, wider peer groups)
- exosystem – refers to influences within the larger social system, such as employment
- macrosystem – refers to cultural beliefs and values that influence both the microsystem and the exosystem.

CMO configurations

The review process, taking information from the searches through into explanatory accounts and consolidated accounts, resulted in seven CMO configurations that together form the basis of a hypothesised programme theory by which a preconception WLI could work in the general population. Each configuration is described, citing the evidence from the literature that underpins it, followed by the fit with the middle-range theories and the stakeholder survey results. Configurations 1–6 integrate findings from these three types of sources; configuration 7 did not emerge from the literature but has been developed from the stakeholder feedback and is considered in the light of the theories.

CMO configurations:

1. Reaching out to people.
2. Recognising the diversity and wealth of the individual's experience.
3. Build the health-care practitioners' confidence and commitment to weight management in their practice of PCC.
4. This is something for me.
5. An intervention that is fit for purpose.
6. Building confidence and motivation.
7. Weight loss discussions should be founded on the principles of informed choice and a client-centred approach.

CMO configuration 1: reaching out to people

To achieve the widest reach of engagement (outcome), any preconception intervention with recruitment across the general population, where women have limited knowledge of the role of raised BMI in the

preconception period (context), will need to be co-produced with service users with a positive health message and include a multimedia approach that is accessible in the community and on social media (mechanisms). It needs to be clear who it is for and have a range of culturally sensitive tailored messages, so that women who would be eligible to take part feel that it is relevant to them (outcomes).

Evidence from the literature

One of the central issues in addressing obesity prior to pregnancy, and PCC generally, is that there is little recognition in the wider population of its importance or personal relevance. Women without fertility issues or an existing health condition are unlikely to see PCC as relevant to them[127] and do not identify with the term 'preconception'.[128] In addition, those with a raised BMI often do not identify as overweight (70% with BMI of 25–30 kg/m^2 and 18.4% with BMI of > 30 kg/m^2).[129] Approximately 70% of pregnancies are planned,[30,130] and a high percentage of those women (83%)[131] will make at least one preconception health behaviour change. However, the least common changes will be to their dietary intake or weight.[131,132]

The coproduction of the intervention and engagement strategy with service users will help to ensure that it is relevant to and resonates with potential recipients.[133] Overcoming the lack of awareness of the importance of weight in pregnancy goes well beyond educating individuals; preconception health messages need to be more widely promoted, for example in community spaces and using social media and across the age ranges so that children and young adults are aware of the messages ahead of childbearing.[29] Those broader health promotion messages about preconception health also need to resonate with different groups of people with protected characteristics to ensure that individuals at risk of marginalisation are not further excluded from health care.[134] Ideally the intervention should be delivered in both health-care locations and other settings in the community.[127] It may also be the case that an e-health intervention delivered predominantly remotely might be more engaging for many.[53,116,135] An emphasis on positive health rather than weight/risk would increase the likelihood of people expressing an interest in the intervention.[128]

Fit with middle-range theories

Motivation (COM-B) is key to engagement with any behaviour change. Currently the lack of awareness of consequences of obesity (TPB) in pregnancy at an individual level and the normative beliefs and attitudes at a social level (SET) related to PCC generally but weight management in particular are all significant barriers to the success of any preconception weight management intervention. Increasing awareness of the issues at a societal and social level (SET) requires information about risk to underpin the relevance of losing weight in the preconception phase, which in turn creates a change in attitudes and societal norms (TPB). However, at an individual level, the messages need to be focused on health gain to maximise women's sense of competence and confidence (COM-B) in order that they develop an intention to change without fearing that they are unable to make the changes necessary (TPB).

Fit with stakeholder survey

LARC users stated that they would want the discussion with the health-care practitioner to have a positive focus. The discussion should be part of supporting health goals, rather than focusing on weight alone. Participants suggested that the tone should be pleasant and not 'lecturing', using open questions and supportive language and highlighting the benefits rather than dwelling on risks. There was a range of knowledge and beliefs about the risks of having overweight or obesity during pregnancy. LARC users clearly understood that having obesity poses a risk to both the pregnant person and their future baby. They expressed the wish to lose weight to improve their fertility, to be in better health so their body could cope with the pregnancy and birth, and to have better outcomes for the baby with a better start in life.

CMO configuration 2: recognising the diversity and wealth of the individual's experience

If the intervention is widely advertised, acknowledges and responds to the different individual experiences of and cultural beliefs about weight loss and health in pregnancy (context), and adopts a tailored, positive-

focused approach, then it would reduce the sense of shame that women often experience when talking about weight and would maximise a sense of competence and autonomy (mechanism), thereby enhancing recruitment, engagement and retention (outcome).

Women with a raised BMI in the preconception phase will bring a vast array of experiences and beliefs that are relevant to their engagement with a potential programme. These could be about weight (loss and gain, relevance to pregnancy), diet, physical activity and other health behaviours in preconception. The intervention must include some element of tailoring at an individual level (e.g. to cultural beliefs[64]) and take life experiences (of weight loss and previous pregnancy in particular) into account.[29,117,134,136,137] One example of tailoring information is the mHealth intervention Smarter Pregnancy,[138] which offers tailored mobile health coaching to improve awareness of the importance of nutrition and lifestyle as a part of PCC and supports women and men to make changes in these areas prior to conception.

Knowledge is unlikely to be enough to create change in itself.[38] For example, Barker *et al.*[29] cited the lack of impact of the social marketing campaign change4life, suggesting that individuals and communities require not only knowledge but also resources to enact change, and a purpose or meaning to provide motivation to engage with the message. There will inevitably be different levels of engagement or interest in PCC and weight loss.[41] For some, pregnancy health starts with a positive pregnancy test and there is a lack of awareness of preconception health;[132] others may engage in some change in health behaviours as part of their pregnancy planning, but this is unlikely to include weight loss.[131,139] There may be some elements of a programme that could put people off. For example, physical activity needs to be carefully described and not be too onerous, as some women with a raised BMI may have little experience of formal exercise, and a lack of time for scheduled activity may also be a barrier.[140] Some programmes have been designed to target specific groups; for example, the SHW programme was offered to women in low-income communities.[49] Rather than offering a generic programme, where possible the programme should be designed with flexibility to be responsive to people's expertise in their own life circumstances and lessons they have learned about themselves along the way.

Fit with middle-range theories

People's experience of weight management over the course of their life, and particularly during any previous pregnancy, will have a powerful influence on their PBC and attitudes to the behaviour (TPB). Their existing knowledge and understanding of their behavioural regulation around diet and exercise (COM-B capability) as well as their social influences, such as partner/family support (COM-B opportunity; SET micro and mesosystem), will be important in the tailoring of the programme. Understanding individuals' narratives of their experiences of weight loss and their intentions related to pregnancy weight management will be critical to retention in any preconception WLI. This would be considered part of their reflective motivation in the COM-B model, exploring their goals, beliefs about their capabilities and beliefs about consequences.

Fit with stakeholder surveys' findings

The powerful narratives from the women who completed the survey about their experience of weight really underlined the importance of this aspect of the programme theory. Women often have considerable experience of different weight loss programmes, and they will be the expert in what has and has not worked for them in the past. Each new effort to lose weight can, in some ways, be described as a new start, but the approach needs to be tailored to factor in the woman's knowledge, social circumstances, general health and cultural beliefs. A preconception WLI, particularly for an individual's first pregnancy, is a unique opportunity to develop a very different frame of reference for the intervention: around their health and well-being at that particular time, but also around their baby's health and well-being.

As well as recognising women's experiences of weight management, this intervention will also have to overcome their experiences of sometimes very distressing interactions with health-care staff. One of the themes that came through in the survey was that discussions about weight seem to come

out of the blue and lead nowhere, leaving the woman feeling punished and shamed. Although a new intervention cannot undo that experience, by making sure that there is adequate publicity, advance notice of discussions, invitations to discuss the topic rather than oversimplistic declarations about risk, and a programme on offer as part of that discussion, hopefully a more positive experience can be provided.

CMO configuration 3: build the health-care practitioners' confidence and commitment to weight management in their practice of preconception care

Health-care practitioners identify multiple barriers to delivering PCC and discussing weight with women during consultations (context). The intervention therefore needs to include training to build practitioners' skills and confidence in discussing weight, evidence-based guidance and an effective WLI they can refer to (mechanisms) if they are going to be willing and able to recruit women to the intervention (outcome).

It is not just the general population who do not consider weight to be a central part of PCC: weight is often not included in PCC interventions.[36,139,141] In studies exploring barriers to PCC, health-care practitioners cite time, sensitivity of topic, access to women in the preconception phase, lack of access to clinical guidance and treatments, a questionable fit with their role and perceived value.[116,124,134,135] In designing and delivering a PCC package, multiple barriers can be encountered at the individual, practitioner and organisational levels.[131,142,143] Less evidence is available related to the facilitators of delivering PCC, but training such as Healthy Conversation Skills[29] has helped practitioners engage and motivate patients about nutrition and physical activity. If national evidence-based guidance and preconception checklists were developed, practitioners would feel more able to give appropriate advice.[144]

Fit with middle-range theories

On an individual level, many of the aspects of CMO configuration 2 apply to the health-care practitioner as well as to the programme participants (e.g. PBC, attitudes, capability and motivation). An additional factor for the health-care practitioner is the complexity of the inter-relationship between their personal history of weight management and their professional practice. At the mesosystem level (SET), delivery of the intervention by health-care practitioners will include education (COM-B opportunity), enablement, training and modelling (COM-B motivation and capability).

All of the mechanisms specified in NPT are relevant to this intervention.

Mechanism 1: coherence The types of considerations that will need to be taken into account in the design of the intervention are:

- how the health-care practitioner's role in the potential preconception WLI differs from (differentiation) or fits with (individual specification) the current PCC practice
- how the rest of the health-care team see the potential preconception WLI and whether they have a shared understanding of it (communal specification)
- how the health-care practitioner's role in the potential preconception WLI relates to their previous experience of PCC or weight-related conversations (internalisation).

As has been considered for the participants, the development of the intervention and its integration into practice needs to take into account the health-care team's current PCC and weight management approaches with regard to pregnancy. Most of the practitioners work in small teams (in sexual health or primary care), so a shared understanding of the intervention among the team will be important for its uptake. Given the evidence that this type of work has an uncertain fit with their role, this would need to be a significant part of the engagement work and, ideally, the intervention would be co-produced with a cohort of practitioners to address this adequately. It may be that a lack of engagement with the intervention from a practitioner perspective underpins many of the barriers identified to PCC implementation.

Mechanism 2: cognitive participation Most of the implementation of PCC will happen in individual consultations so that practitioners can reach their own decision about whether or not to implement the potential preconception WLI (initiation), but team members can play a significant role in encouraging others in the team to take part (enrolment). Understanding what they might value about a PCC programme will be important in the design (legitimisation), as will, crucially, their having the resources to deliver it (activation).

Mechanism 3: collective action Time and workload are barriers to PCC, so a WLI would need to take place outside front-line consultations in sexual health and primary care. However, the introduction of the programme and the initial engagement of the patients will be the role of those health-care practitioners. The information about the programme, respective roles and so on would need to be clearly operationalised (interactional and skill-set workability), and the delivery of the information to patients would need to be managed with an appropriate balance of standardisation and responsiveness (relational and contextual integration).

Mechanism 4: reflective monitoring With any new intervention, practitioners make their own decisions about its effectiveness at both an individual and a practice level (individual and communal appraisal). As part of this, there may be changes in practice over time as practitioners make judgements about and potentially reshape the intervention (reconfiguration). In an initial evaluation as part of a feasibility trial, monitoring of this would be part of the trial design in a process evaluation to try to capture both the formal and the informal appraisals of the intervention.

Fit with stakeholder survey

Many of the health-care practitioners viewed themselves as potential facilitators of a preconception WLI. They suggested that if they had the right approach, good training and a good relationship with the patient, then this would facilitate the discussion and make it more acceptable. They also referred to patients' attitudes, wishes and levels of motivation as facilitators; if the patient is positive about losing weight, or brings it up themselves, discussing the topic is seen as more acceptable to both parties.

Barriers to engagement in a preconception WLI identified in the published literature also came through in the responses to the health-care practitioner survey: time, sensitivity of topic, access to women in the preconception phase, lack of access to clinical guidance and treatments, a questionable fit with their role and perceived value. Some practitioners referred to the fact that, although they might refer to other preconception health behaviours, such as taking folic acid, they do not include weight in those conversations. Their beliefs about the importance of weight in pregnancy, the efficacy and availability of any intervention and their low confidence in their ability to have conversations about weight may be the barriers that underpin their reluctance to engage in discussions of weight with their patients. If these barriers were addressed in the programme training with clear information about risk and a programme to refer to, then implementation might be more successful.

CMO configuration 4: this is something for me

To recruit women from the general population with a BMI of ≥ 25 kg/m^2 and engage them in a WLI in the preconception phase (context), practitioners who are introducing the intervention and the patient to whom they are introducing it would need to acknowledge the principle of a preconception phase and know the patient's weight (mechanisms) to be able to identify the intervention as relevant (outcome).

With only 29% of women whose weight falls in the BMI category of 25–30 kg/m^2 identifying themselves as overweight and 18% of women with a BMI of > 30 kg/m^2 not knowing that their weight would be classified as overweight/obese,[129] a process would be required by which women would understand that this intervention is relevant to them. The weight of those seeking assistance with fertility would be known and highlighted as an area for change (often before they receive fertility treatment, for those with a BMI of > 30 or > 35 kg/m^2, depending on the context). However, women in the general population will usually be weighed only if this is indicated by their type of contraceptive (e.g. combined

oral contraceptive pill), not with all LARC. In addition to knowing their BMI, they would need to perceive preconception health as relevant, and that weight is a part of that health, if they are to engage in an intervention.

Fit with middle-range theories

In the UK, > 50% of women have overweight or obesity; therefore, in terms of social comparison across their peer groups and the wider social system (SET), women who have overweight are likely to see themselves as 'normal' weight. Although there are guidelines, regulations and environmental initiatives in the macrosystem (SET) that focus on reducing obesity (COM-B), currently these seem to have little impact, possibly in part because societal norms and attitudes (TPB) do not highlight the relevance of these to individuals.

Fit with stakeholder survey

LARC users reported having some knowledge about the risks of preconception obesity in relation to fertility and risks of obesity during pregnancy, which included some familiarity with the risks to the baby (size at birth and future health). However, it was not part of the survey to delineate the level of overweight to which these risks referred. The amount of weight that would trigger an invitation to delay LARC removal and take part in a preconception WLI was an important consideration to service users; an invitation to take part in a preconception WLI was considered acceptable for individuals with obesity, but not for individuals 'slightly overweight'. Women described being upset at being engaged in a conversation about weight based purely on their appearance, but if weight measurement was seen as a standard part of a consultation about contraception, then conversations about weight could be initiated without people feeling they were being singled out.

CMO configuration 5: an intervention that is fit for purpose

Interventions that helped women identified as having a BMI in the overweight/obese range in the preconception period (context) to achieve a clinically significant weight loss of 5–10% (outcome) had multiple components including both nutritional (tailored hypocaloric diet) and psychosocial (e.g. lifestyle counselling, motivational interviewing) support over a period of several months, which allowed women to develop effective weight management techniques (mechanisms).

The majority of preconception WLIs are in the context of preparation for fertility treatment, so it could be expected that motivation would be very high among people in this group and that the findings may not be fully generalisable to our population. However, this does provide some information on the range of weight loss that women of similar age and BMI could achieve in the context of preconception. Many of these programmes incorporated some degree of meal replacement to reduce calorie intake; among those using total meal replacement, the range of average weight loss in 12–16 weeks was between 6.9% in 12 weeks[145] and 13% in 16 weeks.[146] In a programme with partial meal replacement, women lost an average of 6% in 16 weeks,[147] and in a tailored hypocaloric WLI without meal replacement over 12 weeks, women lost an average of 5%[148] to 6.97% of their body weight.[149] When women take part in a longer intervention (e.g. 6 months), the greatest effect of the intervention takes place in the first 3 months.[150] For adults with obesity in the general population, a weight loss goal of 5–10% of body weight over a 6-month period is viewed as realistic.[151] Measuring waist circumference as well as weight was recommended, as the former is an important health indicator.

The term 'tailored' in relation to a WLI often appears to refer to adjusting the calorie intake to the person's weight or pre-study calorie intake.[145,148] This was found to be an important aspect of weight management approaches in pregnancy, when moderate energy targets adjusted by weight (18–24 kcal/kg) were associated with the greatest reduction in GWG,[131] possibly avoiding unrealistic targets for women with raised BMI.

Some studies include 'lifestyle counselling' as an intervention component, but this is insufficiently described for any potential mechanisms to be extracted. In one study, women who received motivational

interviewing without a dietary or physical activity component lost an average of 7 lb in 12 weeks, suggesting that motivational interviewing is not enough on its own. Many women of reproductive age will not be prepared nutritionally for pregnancy,[27] and their usual diet will be insufficient in terms of nutritional guidelines.[141] However, this can change as a result of a preconception lifestyle intervention,[152] so this would contribute to the health education element of a preconception WLI.

When women agreed to delay having LARC removed for 24 weeks and completed a full meal replacement for the duration, they lost an average of 14.2% of their body weight.[80] However, this programme had a very low take-up rate and high attrition, suggesting that this approach might be too aversive for a general population. If women are offered a preconception intervention but do not delay becoming pregnant, then weight loss might not be significant in the preconception period, as some will have only very limited exposure to the intervention.[137] In the Prepare trial,[53] women were recruited prior to conception and the intervention continued for up to 24 months or until the end of pregnancy, whichever was earlier. Those who received the behavioural WLI lost 3.5% of their body weight prior to conception, a significantly greater amount than those in the usual-care group. However, by the end of pregnancy there was no difference between the groups because of the significantly higher GWG in the intervention group. The authors suggest that a more intensive weight loss support needs to continue throughout pregnancy if any benefits from the preconception period are to be maintained.

It is rare that studies describing preconception WLIs explicitly identify BCTs that underpin the interventions. Two reviews[153,154] of the pregnancy literature identify key BCTs ('goals and planning' and 'feedback and monitoring') as significant in reducing GWG. Clearly, in pregnancy the approach to behaviour change may differ for safety reasons (e.g. a gestational weight management intervention may not focus on weight loss) or because of barriers associated with pregnancy, such as morning sickness or physical issues, so care needs to be taken when transposing these to preconception weight loss. However, the design of a preconception WLI may utilise BCTs that may provide women with the skills to adapt these techniques at their different life stages, allowing effective weight management at the preconception, gestational and post-partum stages. We also need to consider that BCTs might operate differently for people with BMIs in different categories; in pregnancy, we know this to be the case in physical activity interventions,[140] but potentially it may also be the case for other BCTs. For example, 'feedback' via self-weighing, which increases the effectiveness of behavioural weight programmes in the general population[155] and is acceptable to women in pregnancy,[156] might be experienced differently by those with a BMI of 25–30 kg/m^2 compared to those with a BMI of > 35 kg/m^2.

Fit with middle-range theories

Without existing evidence of a new programme's effectiveness, it may be difficult to motivate people to engage as they will be unsure whether or not the outcomes will justify their effort (COM-B motivation). It is difficult to address this catch-22 of evidence building and engagement, but, potentially, providing information on what others have achieved on similar programmes will enhance people's behavioural and control beliefs (TPB), and being clear about the health gains achieved with 5–10% weight loss, and the nature of the support offered, will enhance their knowledge, motivation and sense of opportunity (COM-B). This links closely with CMO configuration 6.

Fit with stakeholder survey

The surveys showed that both health-care practitioners and their patients were mindful of the lack of effective interventions available and that this acts as a limiter to their conversations. Both LARC users and health-care practitioners suggested that information about the risks of having overweight or obesity during pregnancy should be backed up by evidence. Although the research evidence may be robust, currently the risks are not presented in ways that are understandable or usable by stakeholders. If the statistics were presented in a more accessible way to highlight the importance of the healthy body during pregnancy and postnatally, then this would facilitate these discussions.

There was a high level of agreement about the key aspects of any preconception WLI across the two stakeholder groups when they were asked to describe the type of service they would like to see. This service would be an accessible preconception health programme, incorporating a combination of dietary advice, physical activity and psychological support that could be tailored using optional elements (e.g. peer support) and signposting to other accessible resources.

CMO configuration 6: building confidence and motivation

Many women's previous experiences of weight loss efforts will have been negative, and they will know of women with a raised BMI (including themselves) who have had a healthy pregnancy and birth (context). The recruitment and approach to the intervention must build women's (1) belief that a 5–10% weight loss can be beneficial for their quality of life, clinically significant and achievable; (2) belief that the WLI can be effective; and (3) confidence in their own ability to follow the WLI (mechanisms) if they are going to agree to take part in the intervention (outcome).

This configuration is driven largely by trying to counter the potential barriers to preconception weight loss. There is limited evidence from the general population, but, in the context of fertility treatment, where the evidence of clinical importance will have been explained and motivation will be high (e.g. with the minimum BMI eligibility criterion for accessing IVF services), the take-up of WLIs ranges widely, from 17%[44] to 100%.[148] It is not possible to hypothesise the reasons for this from the methods reported, as very few studies included any process-focused evaluation. However, in one study,[146] the reasons for non-participation were captured, and these included the time needed to achieve weight loss, concerns about limited success and a belief that the risks of pregnancy associated with obesity are small and manageable.

Fit with middle-range theories

Given the shortage of information on the potential mechanisms of action in preconception interventions, our initial hypotheses will need to draw on evidence from the wider population.

A systematic review of systematic reviews[153] identified that the key behaviour change clusters in the efficacy of WLIs are 'goals and planning' and 'feedback and monitoring'. Using the work completed by Carey *et al.*[157] on synthesising published data on BCTs and their mechanisms of action, the key components of an intervention cut across all of the elements of COM-B and should include (within goals and planning) self-monitoring, planning, goal-setting, a behavioural contract and a review of outcomes. In terms of feedback and monitoring, the key components would include individual feedback on outcomes, social comparison, information about health consequences and how to perform the required behaviours. A sensitive balance would be required between building beliefs in the need for weight loss (TPB attitudes and norms) and instilling confidence in the person that they have the ability to make the changes (TPB PBC).

Fit with stakeholder survey

One of the themes that came through strongly from the LARC user survey was ambivalence, which is known to be a key factor to be addressed in any behaviour change intervention and relates to the perceived importance of the change and one's confidence in their ability to make the change.[158] Women reported knowing that they needed to talk about their weight because it was important in terms of their health but being reluctant to do so because it is a sensitive topic. Some women clearly did not want to discuss weight with health-care practitioners, whereas others reported wishing that it had been introduced and that they would have welcomed the discussion. Women gave many reasons why they did not want to have discussions about weight, but common ones were that they did not regard weight as particularly relevant in terms of their overall preconception health, that discussions were shaming without being productive (i.e. no support was offered), and that discussions were based on appearance rather than actual weight or BMI, which was experienced as judgemental and unjustified.

CMO configuration 7: weight loss discussions should be founded on the principles of informed choice and a client-centred approach

For many LARC users and health-care practitioners, discussions about weight are difficult and potentially aversive (context). A key ingredient at all stages of the discussion and any subsequent intervention is the principle of the patient's personal choice, including information provided to make sure they can make an informed choice; all discussions need to be sensitively handled and client-led (mechanisms) so that the intervention is ethical and acceptable to both LARC user and health-care practitioner (outcome).

This configuration is driven by the findings from the LARC user survey, and so this will be described first. These components of sensitive communication, client-led conversations and informed choice were central to stakeholder responses to the proposal of delaying LARC removal in order to lose weight before conception. The woman being well informed and made aware of the risks but also maintaining a level of autonomy was important to both LARC users and health-care practitioners. LARC users identified that knowing the risks of obesity in pregnancy would enable them to make an informed choice, and both groups of stakeholders said that this information could be part of the discussion that would lead to the LARC user deciding whether to follow the advice or take part in the intervention.

Communication was important to LARC users; the manner in which the subject was introduced and discussed was key. LARC users indicated that the health-care practitioner should be sensitive, tactful, courteous, compassionate, non-judgemental and not patronising, be aware of their tone and body language and make an effort to ensure that the patient is at ease during the conversation. The discussion should also not be rushed, so that adequate time is taken to ensure that the patient is at ease and does not feel judged or blamed. Several participants mentioned honesty from the health-care practitioner, and that the practitioner should have empathy with and understanding of the difficulties in losing weight. Care should be taken in the choice of words, with some stakeholders believing that 'obesity' was a stigmatised word that should be avoided.

Fit with published evidence

These themes did not emerge from the published papers. For example, a scoping review of preconception health interventions[139] mentions the narrowness of measured behaviours and outcomes but does not mention exploring the participants' experiences of the communication. The evidence is obviously also limited, as only one small study[80] addresses the idea of delaying LARC removal in order to lose weight before conception. This study describes the initial discussion focusing on risk but does not identify the number of women who received the information about the study, only those who expressed an interest in taking part, so the effectiveness of the recruitment strategy is unclear. It would seem that this research field is dominated by outcomes rather than process of engagement (or, at least, that is what dominates the publications), and so this is an area in which more research is needed.

Fit with middle-range theories

Informed choice can be understood in the context of both TPB and COM-B. The experience of having information sensitively provided will increase a person's knowledge and help them consider their beliefs about the consequences of their actions and decisions (COM-B capability, TPB attitudes). Crucially, if the practitioner is genuinely in equipoise, allowing the patient to make an informed decision whether to lose weight or delay removal of a LARC, the patient will experience an enhanced sense of PBC (TPB). Whatever their decision, the patient will have stronger reflective motivation to proceed as the decision has been theirs to make.

Conclusions

This review brought together information from a range of sources to begin to develop a programme theory about how and when health behaviour interventions in the preconception phase might work, in order to design a preconception WLI for women with raised BMI. Information from published

research in preconception and pregnancy was integrated, along with wider relevant health behaviour change literature, and included studies using a range of methodologies as well as expert commentaries. Four middle-range theories were selected as being of particular relevance, enabling consideration of individual behaviour change, making changes in professional practice and also the relationships between individual behaviours and the societal contexts in which they occur. From these resources, six CMO configurations were generated and explored in the context of relevant middle-range theories and the survey responses from women with lived experience and from health-care practitioners. A seventh CMO configuration was developed from the stakeholder feedback on the proposed model of intervention. These seven configurations were combined to form a potential programme theory that formed the basis of the proposed intervention to be explored in depth in the stakeholder interviews in phase 2.

Chapter 6 Work package 2: phase 1 stakeholder advisory groups

Introduction

Aim of the chapter

Work package 2 identified potentially suitable preconception/pregnancy-related WLIs and the theories underpinning them using realist methods, in addition to assessing the feasibility and acceptability of a preconception WLI to stakeholders (LARC users and health-care practitioners). The aim of this chapter is to describe the work with the SAGs, refining the intervention components and associated theory, and to consider the key questions to ask participants in phase 2.

Stakeholder Advisory Groups

Methods

The findings from the phase 1 work were synthesised to describe the core and optional components of an intervention. These findings from phase 1 were presented at two SAG meetings: a LARC user SAG and a health-care practitioner SAG. Questions to be addressed at each SAG were agreed by the study team (see *Report Supplementary Material 5* and *6*). The health-care practitioner SAG was held at a British Association of Sexual Health and HIV (BASHH) audit event, and the LARC user SAG was held remotely via Zoom (due to COVID-19 restrictions).

Participant identification/selection

Members of the LARC user SAG were recruited from a pool of participants who had previously consented to be contacted in the WP2 phase 1 online surveys. At the time of the invitation, this was planned as a 3-hour, face-to-face, daytime, weekend meeting, but it was changed to a meeting via Zoom due to COVID-19 restrictions. Up to 12 participants were purposively sampled to ensure diversity of representation, with attendees having a range of BMI values and reproductive histories/plans.

Members of the health-care practitioner SAG were recruited at a BASHH audit event, as a high percentage of attendees remove LARCs in their current practice.

Participant informed consent

Participants in the LARC user SAG were e-mailed the PIS (see *Report Supplementary Material 7*) and consent statements (see *Report Supplementary Material 8*) and were given sufficient time to consider the information prior to attending the SAG meeting. At the meeting, participants were given the opportunity to ask any questions and the consent statement was read aloud by a member of the research team. All participants were asked to consent verbally, and this was recorded.

The health-care practitioner SAG was included on the event agenda, and PISs (see *Report Supplementary Material 9*) were circulated ahead of the event by the event organisers so that practitioners could decide in advance whether or not to take part. The attending health-care practitioners were invited to attend the SAG discussion if appropriate to their professional role. The study was explained in detail to all attending health-care practitioners, and participants were asked to sign an attendance sheet providing consent for the session to be recorded.

Withdrawal

Participants in both SAGs were able to withdraw at any time by leaving the SAG meeting. However, the nature of the focus group meant that any contribution made up to that point was unable to be withdrawn.

Procedure

In both SAGs, the research team summarised the LARC users' and health-care practitioners' responses to the core question concerning the acceptability of asking women to delay LARC removal in order to take part in a preconception WLI and presented the potential core and optional components of the intervention developed from the phase 1 synthesis (*Table 18*).

Questions to be addressed at each SAG were agreed by the study team and used as a foundation for discussions, but prompts were used based on participant responses.

Stakeholder Advisory Group information and question guide

In the LARC user SAG, the research team described three potential preconception WLI design options, including the pros and cons of each and how each option mapped onto responses from LARC user surveys, to stimulate discussion: (1) delay LARC removal, (2) offer delay but include those who choose not to delay and (3) develop a population-based intervention for women who want to conceive in the next 1–2 years (see *Report Supplementary Material 5*). This was followed by an exploration of LARC users' views on the proposed components of the programme and ideas for relevant interview questions for phase 2.

In the health-care practitioner SAG, the team focused on questions relating to the participants' views of the proposed components of an intervention and their role in engaging women with the programme (see *Report Supplementary Material 6*).

TABLE 18 Synthesised core and optional components of the proposed Plan-it intervention (phase 1)

Core components	Optional components
12- to 16-week intervention	Broader description as a preconception health programme for weight loss for pregnancy including information on folic acid, alcohol, nutrition and exercise
Training for practitioners on sensitive communication and introduction of the intervention	Include tailoring to fit for all – the individual session at start to identify needs/goals
Aims: • to reduce by 5–10% body weight • to increase confidence in ability to manage weight pre, during and post pregnancy	Include partners
First contact via the GP surgery or SHC to offer women access to the intervention	Psychological support, for example monthly individual sessions of 'health coaching' focusing on confidence and goals
Include some online materials specific to health preconception	Face-to-face peer support group
Include resources already available, potentially with 'referral' (e.g. 12-week NHS weight loss online programme/ NHS online dietetic provision, online exercise classes/ national exercise referral scheme)	Virtual peer support (e.g. Facebook group)
Scales provided if none at home	Include people with BMI of 25–30 kg/m^2 ('overweight')
	All done face to face (i.e. no online information)
	All done virtually/telephone
	Include an exercise component

Analysis

Both SAGs were recorded, anonymously transcribed and analysed thematically. Themes related to the study objectives (refinement of the intervention components and associated theories, and development of questions to ask in phase 2 participant interviews) were described.

Results of the Stakeholder Advisory Groups

Three LARC users attended the LARC user SAG meeting and 34 health-care practitioners attended the health-care practitioner SAG. The feedback from the two SAGs is summarised in four domains: (1) general response to the model of the intervention, (2) specific components of the programme, (3) barriers in practice and (4) questions to include in phase 2 interviews.

General response to the model of the intervention

In considering the general principles of the preconception WLI, the LARC user SAG results reiterated some of the ethical and practical difficulties of requiring delayed removal that had come through from the surveys. The importance of offering opportunities, rather than taking away choices, was evident. In terms of eligibility and recruitment, the option of providing information to LARC users, including the potential benefits of delayed LARC removal, but without LARC removal as a prerequisite for attendance, was favoured. Similarly, the potential for offering a preconception WLI more widely was suggested to prevent LARC users feeling singled out or penalised for making sensible choices:

> *I'm in that small percentage and we almost get penalised (a) for being overweight and (b) for choosing to have, to not have an unplanned pregnancy because the actual percentage of women who have babies, who have had a LARC is very small I'd imagine.*
>
> *LARC user SAG P1*

The health-care practitioners were generally positive about the idea of an intervention to lose weight pre conception, but there were concerns that a discussion of a delay in LARC removal could result in some women disengaging with the service and missing out on preconception advice. Both of these observations reinforced the importance of putting the principles of informed choice at the heart of the programme design (programme theory CMO 7).

The health-care practitioners reflected that their own practice around preconception advice commonly did not involve weight. This confirmed the theme from the survey that weight is a neglected area in preconception health care (CMO 3). However, the discussion also highlighted that the lack of effective interventions to refer to and the absence of a referral pathway make it much less likely that practitioners will open a discussion about weight.

Specific components of the programme

In terms of specific programme content, LARC users raised important considerations about the complexity of group support in the context of trying to conceive:

> *Trying for a child is very sort of sensitive in a way, you know, people are very nervous about will I get pregnant, am I able to have a baby, all those things as well, so to be put in a position that you're sort of announcing that to a group of people that maybe you don't know.*
>
> *LARC user SAG P1*

Potential difficulties with 'remote' weighing were highlighted; LARC users felt that accountability (to a programme facilitator) would be an important component of a WLI:

> *. . . if I had to just type it into a screen once a week I maybe inclined [laughs] to . . not put your numbers in or, put them in and lie, or something like that . . .*
>
> *LARC user SAG P3*

There were mixed views on involving partners, having a 5–10% weight reduction goal, the inclusion of people with a BMI of 25–30 kg/m^2 and low-calorie meal replacements.

Barriers in practice

The ambivalence and discomfort about discussing weight that came through from the survey was reflected in the health-care practitioner SAG. Health-care practitioners recognised the potential importance of weight as a topic, but there were multiple barriers to raising it, ranging across different levels of the system from practitioners' knowledge and beliefs about its importance in preconception health, to their sense of competence and confidence in their own abilities to have the conversation, the legitimacy of weight as a topic in their service context, their fear of patient response and the availability of resources.

Questions to be included in phase 2 interviews

The LARC users felt that it would be useful to ask the interviewees about (1) what had been helpful for them in the past, (2) details of good conversations about weight, (3) what weight loss methods had worked and (4) whether or not particular language used during recruitment could cause distress. This would enable the study team to build on people's positive experiences. This information could then be used to inform health-care practitioners of the most effective ways to introduce the subject of weight during health-care appointments:

> *But I think getting people's experience of what are the words and the language and the conversations they would want to have that . . . are there words that would be more or less triggering in a way.*
>
> *LARC user SAG P1*

The need for positive conversations about weight fitted with CMO 1 (incorporating co-construction and a positive focus) and CMO 2 (recognising the diversity and value of people's lived experiences of weight management). The health-care practitioners identified the need for health-care practitioner training and discussed the impact of their own weight on their practice.

Preparation for phase 2 interviews

The discussions enriched and expanded on the themes that had been raised in the survey. Both SAGs proposed a number of questions to take forward to phase 2 interviews with LARC users and health-care practitioners.

Both SAGs reinforced ethical concerns about the delay of LARC removal being the route to accessing an intervention. As a result, it was decided that the interviews about the proposed intervention would include a discussion of delaying removal as an opportunity for patients to lose weight prior to conception, in other words as part of the informed choice that women would make at that point, with the information about BMI and risk having been provided. The need to broaden beyond the delay of LARC removal, as well as the feedback from the LARC user SAG that it would be preferable not to 'single out' LARC users, suggested that this could be an intervention open to many people. This was a question to take to the interviews with health-care practitioners and LARC users about the acceptability of a preconception WLI that would not have health-care practitioners as gatekeepers but would include them as one part of the pathway. There were also mixed responses to the inclusion of people with a BMI of 25–30 kg/m^2, and so this was to be explored further in phase 2 interviews.

Some themes in the health-care practitioner SAG about current practice resonated with the review and led to the identification of areas for interview questions. Many of these related to the barriers at different levels of the system, including (1) the general lack of inclusion of weight loss in practitioners' preconception thinking; (2) the lack of available WLIs to refer to; (3) the impact of their own weight on the introduction of the topic of weight into the consultation; (4) their need for training on weight, BMI and risk; and (5) the practicalities of weighing women to facilitate the discussion.

The themes specific to the LARC user SAG that required more detailed exploration in the interviews were (1) the acceptability of group support in the context of preconception weight loss and how this could be managed, (2) the best approach to self-monitoring of weight as part of the intervention and (3) the eliciting of good experiences of weight-related consultations. This last suggestion, although made by LARC users, was felt by the research team to be an important question to explore with both the LARC user and the health-care practitioner interviewees to maximise the understanding of positive conversations from both perspectives.

The feedback from the SAGs and areas highlighted for further discussion were considered in relation to the CMO configurations that emerged from the realist review and formed the basis of the topics for the phase 2 interviews to refine the intervention (*Table 19*).

TABLE 19 Topics for the phase 2 interviews in relation to CMO configurations

CMO configuration	Topics for phase 2 stakeholder interviews
1. Reaching out to people	General response to the proposed programme, strategies for engagement, how to maximise diverse appeal, population based rather than just LARC users/health service referral (linking with theory 7)
2. Recognising the diversity and wealth of the individual's experience	Successful experiences of weight loss (link with 6), language of risk and benefit, what might attract you to a particular programme
3. Build health-care practitioners' confidence and commitment to weight management in their practice of preconception care	What training has helped, what would help, personal barriers regarding weight (health-care provider interviews)
4. This is something for me	Inclusion of people with BMI 25–30 kg/m^2, views about weighing in clinic, preferred modes of intervention delivery (peer support)
5. An intervention that is fit for purpose	Inclusion of goal-setting of 5–10% weight loss, meal replacement, feedback weight, resources they use and value, potential obstacles
6. Building confidence and motivation	Successful experiences of conversations and weight loss
7. Weight loss discussions should be founded on the principles of informed choice and a client-centred approach	Views on the idea of including both those who delay LARC removal and those who do not. Should it be a programme offered out to the general population, with LARC removal as just one opportunity to advertise the programme?

Chapter 7 Phase 2: acceptability and feasibility of proposed intervention

Introduction

Aim of the chapter

The aim of the chapter was to further refine outputs from the phase 1 survey and the SAGs. The potential intervention design and associated CMO configurations informed by phase 1 findings were tested with targeted qualitative interviews with LARC users and health-care practitioners.

The aims of the qualitative interviews were to assess:

- LARC users' views regarding the acceptability and feasibility of the potential WLI
- health-care practitioners' views regarding the type of intervention and their willingness to recruit women to such an intervention.

The findings from the interviews were then presented to the two SAGs for discussion to refine a final version of a proposed intervention.

Methods

LARC user and health-care practitioner qualitative interviews were conducted over the telephone or via Zoom; the LARC user SAG was held remotely via Zoom (due to COVID-19 restrictions) and the health-care practitioner SAG was conducted as a group discussion via a Padlet discussion board. Padlet was chosen primarily as it enabled asynchronous, anonymous feedback from the health-care practitioners, but it also offered flexibility of format.

Participant identification/selection

Participants in all qualitative interviews and SAGs were identified from the pool of participants who had previously consented to be contacted in the WP2 phase 1 online surveys.

Potential participants in the LARC user and health-care practitioner qualitative interviews and the LARC user SAG were contacted by a member of the study team using the person's preferred method (e-mail/telephone) with information about the phase 2 interviews/SAG. Participants were purposively sampled to ensure a range of BMI and reproductive histories/plans (LARC users) and professional backgrounds and genders (health-care practitioner interviews). All potential participants in the health-care practitioner SAG were invited by e-mail to take part in the SAG.

Participant informed consent

Participants in the qualitative interviews and the LARC user SAG were e-mailed the PIS (see *Report Supplementary Material 10–12*) and consent statements (see *Report Supplementary Material 13* and *14*) and were given sufficient time to consider the information prior to the interview/SAG. At each interview/SAG, participants were given the opportunity to ask any questions, and consent statements were read aloud by a member of the research team. All participants were asked to consent verbally, and this was recorded.

All potential participants in the health-care practitioner SAG were e-mailed an information sheet (see *Report Supplementary Material 15*) and link to the Padlet discussion forum. Participants were informed that participation in the discussion was considered consent to participate.

Withdrawal

Participants were able to withdraw at any time by leaving the interview/SAG, but their contributions up to that point were unable to be withdrawn.

Procedure

Topic guides for interviews were based on the synthesis of phase 1 results, described in *Table 12* (see *Chapter 6*; and see *Report Supplementary Material 16* and *17*). For the LARC user SAG, the study team presented study progress, which was followed by a discussion based on the synthesis of phase 1 results (see *Report Supplementary Material 18*). For the health-care practitioner SAG, a study update was provided using a combination of written text, a PowerPoint summary and a video of the chief investigator presenting the main findings. Participants were asked to respond to three questions, each focusing on a service-related topic: (1) how to contact women who use their service who might be interested in a preconception WLI, (2) how to advertise it more broadly in the community and (3) what training practitioners would want in talking about weight.

Questions to be addressed in interviews and with SAGs were agreed by the study team and used as a foundation for discussions, but prompts were used based on participant responses.

Analysis

Both SAGs were recorded, anonymously transcribed and analysed thematically. The results were further grouped and are reported according to the CMO with which they most closely align. Any repetition of the findings in phase 1 (see *Chapter 6*) has not been reported in detail.

Results

The results are presented in themes, according to the seven CMO configurations generated from the realist review. A summary of the themes and associated CMOs is provided in *Table 20*. This is followed by the refinement of the potential programme theory, a summary of the stakeholder SAGs and a description of the final potential intervention. The quotations taken from the interviews are identified as LUI or HCPI for LARC user and health-care practitioner interviews, respectively, and each is followed by an ID number.

CMO 1: reaching out to people – maximising engagement

Qualitative feedback relating to CMO 1 included interviewees' general impression of the proposed intervention and their views on the recruitment route and the approach to discussing risk.

General appeal of proposed intervention

Overall, there was a positive response to the intervention design from both LARC users and health-care practitioners. The LARC users particularly liked the free provision and the flexibility of having options that meant that the intervention would be tailored to the individual. Although the timescale of the intervention itself was generally acceptable, there was concern that it might be too short, giving less opportunity for support and conveying a 'quick fix' rather than a message of a lifetime commitment:

> *I think the danger is if you only have three meetings, from 12 to 16 weeks, then you might have people stray or it might not be enough guidance for some people. But you also don't want to give too many appointments . . . So I think it's a balance. Compliance might be an issue if you only do the three face to face.*
>
> *LUI04*

TABLE 20 Themes from the stakeholder interviews grouped by CMO configuration

CMO configuration	Theme
1: Maximising engagement	Appeal
	Recruitment
	Discussion of risk
2: Recognising individuals experience	Key dimensions of previous weight loss success
3: Health-care practitioners	Communication skills
	Knowledge of risk
	Script
4: This is something for me	BMI eligibility
	Weighing in clinic
	Mode of delivery
5: An intervention that is fit for purpose	Target weight loss
	Weight feedback
	Meal replacements
	NHS resources
	Group support
	Challenges
6: Building confidence and motivation	Successful conversations about weight
	Practitioners' readiness to refer
7: Informed choice	Options and facts

LARC users supported the idea that the intervention should have a positive, broad health focus, rather than simply focusing on weight per se, and suggested that this should be an important underlying ethos of and emphasis in the advertising:

> *I just think the emphasis just on weight sends out the wrong message . . . It should be more . . . a programme to help you have a healthy pregnancy when you're trying to conceive.*
>
> *LUI10*

> *If it's sold and marketed as an exciting, cool, forward-thinking thing to do, to plan for your pregnancy, and to plan for your life after . . . I think that could be helpful.*
>
> *LUI07*

Recruitment route: via the general population or health-care practitioners?

A clear majority of interviewees stated that it would be preferable to offer the intervention for self-referral (e.g. advertising on social media), rather than gatekeeping the invitation to the intervention through health-care practitioners, as this would increase reach to the target group, especially for some women with overweight/obesity who avoid appointments with health-care practitioners, as well as increasing inclusivity for all women, not just those using LARC. General promotion, such as via leaflets, may allow women to digest information prior to attending for LARC removal, allow them to discuss with partners and prevent them feeling targeted because of their appearance. The stakeholders also thought that, by allowing self-referral, participants might be more motivated because they would have

more control over the process, and that the entry to the programme could be quicker and more straightforward and reduce the likelihood of an individual feeling shame:

> *I would do social media because not everybody goes to the doctor's . . . you try and avoid it to be honest.*
>
> *LUI13*

> *If you're planning that, then you would discuss that with your partner first . . . I would discuss it with him first . . .*
>
> *LUI01*

> *So it would be really good to have it out more widely wouldn't it? . . . feel like that takes away some of the, 'oh, the doctor had a go at me for being fat'. You come home and eat a cake [laughs] . . . Empowering people to do something about it for themselves. And having that information out there . . .*
>
> *HCPI03*

However, LARC users acknowledged that a health-care practitioner introducing the intervention had the advantage that health services are a more trusted source of information. In addition, existing relationships with health-care practitioners, who may know any relevant background issues/conditions, may increase engagement and reduce the risk of harm. It was suggested that combining the two recruitment methods could maximise reach in terms of people's circumstances but also across a wider demographic:

> *I think because there's so many things out there, unless it's kind of got a bit of the professional backing, or it being delivered by somebody, you know, like that, it might not be considered as seriously . . .*
>
> *LUI15*

> *It has to be a practitioner that knows that woman and her medical history because I also suffered from postnatal depression, and around my miscarriage I had depression as well and so if you approach a woman that's had those types of issues on top of disordered eating, weight management problems, I think you're opening it up to a real difficult situation not just for the practitioner but also for the women.*
>
> *LUI10*

Discussion of risk

One of the key factors in making the decision about whether to engage with this intervention is the discussion of risk and how that message is conveyed. There were six broad themes in people's reflections on how risk needs to be integrated into the conversation about the intervention: (1) simplify/make personal, (2) RR as part of holistic preconception approach, (3) positive health promotion, (4) facts not fear, (5) baby health and (6) fertility.

Simplify

Some practitioners talked about discussing risk in simple terms or personalising it so that the patient can understand what is being said:

> *We talk about risk in one in a hundred and one in a thousand, but a lot of the time people don't seem to grasp that, they prefer percentage. It's talking about it in normal terms and not overcomplicating things.*
>
> *HCPI07*

Relative risk as part of preconception health

Both groups of stakeholders said that a discussion of risk should be undertaken in relation to other risk factors (e.g. alcohol and smoking) as a way of seeing the bigger picture and also suggested easing into the discussion about weight via topics that might be more acceptable (e.g. folic acid):

> *If any expectant mother is serious about getting pregnant, I think you're going to need to know the pros and cons of everything, to do with weight, smoking, alcohol, you know it's all under the same thing.*
>
> *LUI03*

Positive health promotion

Some participants said that risk should not be mentioned, but that the focus should be on positive messages, offering support, and optimising health and the health of the baby, as negative messages put people off and potentially add stress:

> *I think it's got to be the positive way hasn't it? . . . You don't want to be scaring people to death and adding to the stress. It's a stressful time anyway.*
>
> *LUI20*

Facts not fear

Stakeholders suggested that couples be provided with information on risks as part of their decision-making; however, they said that this should be framed factually as medical information rather than delivered in the form of 'shock tactics':

> *I think if you sat people down and said, 'These are the facts and these are the figures and this is the percent of actually you have a greater chance of miscarriage', or whatever, then it might be harder hitting and hit home to people, and sometimes I think people almost shy away from that and actually it's the truth, so maybe it needs to be said.*
>
> *LUI06*

Baby-focused

Many interviewees said that the health of the baby was a prime motivator, so risk factors associated with the baby might engage people more than risks to themselves:

> *. . . every decision I made while I was pregnant, including like the drugs during the birth were, 'if it harms me, I don't mind; if it harms him, it's not happening'.*
>
> *LUI17*

Fertility

Participants suggested talking about the difference the target weight loss could make in terms of fertility, but said that this was a conversation to be had with a health-care practitioner.

CMO 2: recognising the diversity and wealth of individuals' experience

All of the LARC users interviewed had experiences of weight loss attempts and had tried various approaches or programmes, which would inform their approach to any new weight loss programme. The aspects of previous weight loss plans that they found useful included (1) weekly weigh-ins (increased motivation due to accountability); (2) group support elements, including apps (although not suitable for all); (3) different apps to track progress; and (4) flexibility in order to fit in with people's lives:

> *I just think physically going somewhere and knowing in a week, that actually you're going down and step on those scales on Tuesday in front of Joe Bloggs keeps you motivated.*
>
> *LUI01*

> *So if, if you're having a bad day and you, you know, you'd have a day when you'd eaten far more than you should have, they were very supportive and, you know, with all being there and, you know, just get back on it tomorrow.*
>
> *LUI03*

CMO 3: building health-care practitioners' confidence and commitment to weight management in their practice of preconception care

Practitioners were asked about how they and their colleagues could be best supported to have discussions about preconception weight with patients in order to introduce the intervention. They felt that the communication skills required should already be integral to their role, but some suggested

that training in motivational interviewing[158] may be beneficial. Additional information via fact sheets or existing guidance documents and training would help overcome their lack of knowledge about some of the risks. Some thought that a script could potentially be useful for introducing the topic, and training videos and role playing using the script were suggested as ways to help practitioners become confident. Furthermore, a thorough understanding of the intervention itself would be essential for engaging patients:

> *I mean certainly as a GP my understanding of risk, I know it is desperately poor and my ability to articulate that and explain that in most circumstances could be better.*
>
> *HCPI01*

> *A lot of staff don't feel confident about asking any number of things about alcohol, substance abuse . . . but what we found is that if they can be given some key strategies or phrases, they're often happy to run with it.*
>
> *HCPI10*

> *Where it's an awkward conversation [it] needs to be scripted. You need to have practised it.*
>
> *HCPI03*

> *I think they need to have a good idea of what the intervention was, in terms of how long it lasted, and the kind of steps that people would go through . . . when they could withdraw from it if they wanted to or not. If they became pregnant early on, what they would then do after that. And the safety of those things.*
>
> *HCPI06*

Practitioner weight

In the online surveys of LARC users, the issue, and potential barrier, of the practitioner's weight was raised, and so this was explored in the stakeholder interviews. Some LARC users said that a practitioner's weight would not make a difference to them; some, while acknowledging that it should not matter, suggested that, in reality, whether a health-care practitioner appears overweight (experienced as hypocrisy) or slim (lack of empathy) can have an impact on people's level of engagement in discussions about weight. For health-care practitioners, the quality of the interaction was considered most important, and the weight of the health-care practitioner was irrelevant. However, some health-care practitioners described 'uneasy' conversations with patients because of their own weight or personal issues. The LARC users' and practitioners' feedback shows that the value of self-disclosure clearly varies by consultation and may be something that the practitioner has to decide on a patient-by-patient basis:

> *It shouldn't because we're not talking about their health, we're talking about my health, but I think it does, yeah. If you've got somebody incredibly overweight telling you to lose weight then that's going to be difficult, or, if you've got someone very underweight or, you know, very slim . . . you'd almost, I'd almost feel resentful towards them.*
>
> *LUI10*

> *You have to gauge it patient by patient. There are quite a few scenarios where it can be useful and can really get them on board with something. I think they feel like, 'yeah, well that doctor really knows what she's talking about, she understands, she's been there', type thing.*
>
> *HCPI03*

CMO 4: this is something for me

Three key topics in this CMO related to eligibility for and engagement with the programme where we needed feedback from stakeholders to progress the design: (1) the lower threshold of BMI for the programme, (2) the acceptability and feasibility of weighing women in clinic and (3) the preferred mode of delivery of the intervention.

Body mass index category

There were mixed views about including people with a BMI classified as overweight but not obese (25–30 kg/m^2) in the intervention. The main argument in favour was prevention, to potentially reduce GWG and give a positive start to a healthy pregnancy. However, the majority of views tended towards not including women with weight in this category in the programme, with the arguments falling broadly into three overarching themes: (1) RR, (2) limited resources and (3) coherence.

Relative risk and body mass index

The use of BMI as the key eligibility criterion raised questions for some about its sensitivity as a measure of health and also the quality of differentiation between the risks at different BMI categories:

> *Obviously to do with muscle mass and things like that, you know. I don't entirely agree with BMI to be honest.*
>
> *LUI03*

> *I would imagine the evidence is that if you have a BMI of 27, it probably isn't that different in terms of pregnancy outcome to a BMI of 23. I think my instinct would be 30 and above.*
>
> *HCPI08*

Limited resource to be targeted

It was suggested that people with a higher BMI are the ones most in need of an intervention, and including those with a BMI of 25–30 kg/m^2 would run the risk of the programme being overwhelmed. In addition, stakeholders argued that including the lower BMI group might not provide the best test of the intervention, with views differing on whether those with a higher BMI would be more or less likely to succeed.

Coherence

It was suggested that a focus on those with a BMI of $\geq$ 30 kg/m^2 would fit better with other services (which use BMI 30 kg/m^2 as a threshold) but would also make more sense to service users, creating a stronger sense of group identity. In addition, health-care practitioners would not be required to initiate much more difficult conversations with people whose weight is in the overweight BMI category but may not regard themselves as overweight, and, therefore, the potential to cause upset would be reduced.

Being weighed in clinic

The phase 1 online surveys with LARC users highlighted that LARC users found it distressing to be judged overweight and told to lose weight simply on appearance. It was, therefore, important to explore the acceptability to women of being weighed when they came to the clinic for LARC removal. Most women said that they would expect to be weighed in a clinical environment, and that measuring weight is part of routine care, but, given the negative feelings that this can evoke, it should be done privately, discreetly and with no judgement:

> *I think lots of procedures when you go to the GPs, you get weighed and measured for lots of standard things, and, and I think if it was just done routinely.*
>
> *LUI08*

> *I'd hate it, I hate being weighed, it's embarrassing, especially if you've got a young slim nurse at the side of you . . . It's the fear of judgement.*
>
> *LUI20*

When health-care practitioners were questioned about weighing patients in clinic, they also said that this can provide a good opportunity to raise the topic of weight, particularly as part of a preconception discussion, in a way that would not necessitate judging weight on appearance. However, barriers to this include time restraints and the fact that the topic may not be essential for clinical decision-making.

Health-care practitioners suggested a self-weighing system, such as a machine in the waiting room, but acknowledged the need to be really sensitive to how public this would be:

> *It's just such a grotesquely uncomfortable conversation for both the practitioner and the patient, that probably we do it very obliquely.*
>
> *HCPI04*

> *So I don't weigh people unless I have to, because that's an extra, you know, minute and a half that you don't want to waste.*
>
> *HCPI08*

> *We just had the machine in the waiting room that they could stand on it and it just gives them a little ticket. So it does their blood pressure, their height and their weight that they can bring that in . . . Most women were happy they have to do that, yeah.*
>
> *HCPI05*

Mode of delivery

In designing the programme it would be important to strike the right balance of online- and face-to-face-delivered content, so the differences between modes were discussed. Positive aspects of online experiences included ease of access, no travel, the possibility of anonymity, the ability to keep track of progress and the availability of large amounts of information and ideas. However, participants described some negative aspects of online delivery, including the possibility of getting too engrossed/obsessive about one's weight in apps without anyone else there to check. In addition, participants talked about having difficulty building relationships with people they had not met in person and missing the social aspects of in-person contact. Participants said that face-to-face delivery is easier for receiving complex information, asking questions and being given tailored explanations, and they equated this with being motivated.

Participants pointed out that there are certain things that must be done in physical meet-ups, such as being weighed by someone else or sharing food. In addition, having this in-person contact meant that there was a level of accountability that would encourage the individual to work harder between meetings. However, negative aspects of in-person groups were reported, such as the feelings that can sometimes arise from feeling judged, hearing someone else's stories or comparing oneself with others:

> *You know they say these places are non-judgemental but you're always comparing yourself against the others. Oh Sandra's had six takeaways this week and she's lost weight. How come I haven't? It's just human nature. So those weeks the app works better for me so I can have that conversation privately.*
>
> *LUI09*

Participants tended to appreciate having a combination of options for contact, and that there is an aspect of individual choice in this, but the key thing is to maintain the contact with the group or health coach in whatever way suits you.

COVID-19 also appeared to have had an impact on the acceptability of online/remote contact. People talked about how the months of lockdown had changed their opinions about using online groups, for example fitness classes on Zoom. They felt that this was more acceptable than it had been prior to lockdown, because more things are done virtually and people have got used to it.

CMO 5: an intervention that is fit for purpose

The questions for stakeholders that arose from this CMO concerned the acceptability of explicitly describing the 5–10% weight loss and the inclusion of meal replacements as an option. We also explored the practicalities of weight loss feedback, which resources interviewees had found useful in their weight loss experience and any obstacles they could see that had not been brought to the fore by other interview topics.

Target weight loss

There were mixed responses to the idea of a 5–10% target weight loss. The majority of the interviewees said that goals for weight loss are generally helpful because they are something to work towards, and that personalising the goal, by making it a number, would also help. Participants said that the key factor with the goal is that people perceive it as achievable, and the 5–10% proposed goal seemed to satisfy stakeholders in this regard. Some said that this goal might be low enough to encourage service users to believe that they could lose enough weight to make a difference to their health, but it could also encourage practitioners, who might feel more able to initiate the conversation with this goal in mind:

> *I think that would be really helpful because it breaks it down and it seems more manageable. Because if a woman knows they're four stone overweight, that seems a massive hill to climb, doesn't it?*
>
> *HCPI09*

Some participants felt that, for them, goals can be counterproductive and that the upper limit of 10% might feel too daunting for those with a very high BMI. This could potentially put people off joining the programme or result in feelings of anxiety or failure if the level of weight loss is not achieved:

> *It might put some people off, having a target weight, 'cos they might feel like more of a Slimming World-type of environment. Or you might feel that you failed and that you can't become pregnant if you don't reach that goal.*
>
> *LUI04*

Participants suggested that having a goal was an individual preference, as it would work for some people but not for others. Where possible, goal-setting should be part of the individualisation of the programme; the clinical benefits of 5–10% weight loss could be given as information, but it would be the individual's choice whether or not that would be helpful. In addition, a target could be set based on the individual's experience of weight loss in the past rather than on theoretically achievable goals:

> *People are one of two aren't they: they like goals or they don't . . . So, I suppose it's probably that trying to find the in between, because it's not one-size-fits-all, is it?*
>
> *HCPI02*

In addition to the concern about delay of LARC removal previously discussed, LARC users talked about the need to manage expectations, for example if someone could not lose weight and felt like a failure, or if, following the delay and losing weight, the patient still had difficulty conceiving and felt let down:

> *[The] challenge is that expectation management of, 'what happens if I do lose this weight but I still don't conceive?' Or, 'I signed up and I didn't manage to lose the weight and now I'm a failure', so it's that management of the expectations.*
>
> *LUI08*

How to feedback weight

The weekly weight feedback received mixed responses from LARC users. Some participants stated that they would be happy to self-report as it gives a greater sense of control over when the information is sent. However, others felt that self-reporting might lead to people not being completely honest with themselves or the person they were feeding back to, and could risk creating a situation in which people weighed themselves multiple times. Therefore, most felt that having clear evidence of time and date, via a video call, Bluetooth scales or a photograph, was the best option. Participants said that

people would be committed to the programme and therefore should be expected to be honest about the weight that they send in if they self-reported:

> *If it was too flexible as to when you send your weight in, then at least I know I would be tempted to . . . [weigh] myself several times a day. Seven days a week and trying to find the best figure.*
>
> *LUI19*

On the contrary, others saying that being asked to send a photograph of the scales would be insulting as it would make them feel not trusted:

> *You could take photos, but then I suppose if you say, 'oh can you submit a photo?', it's almost like saying I don't trust you just to write it down . . . I think you should be able to trust a person . . . I wouldn't have a problem with it.*
>
> *LUI06*

Some participants were positive about the photograph idea, as they said that they would not have to think about it or they could ask someone else to take the photograph so that they would not have to look and potentially get upset. The potential use of Bluetooth scales was popular as a way of reporting with ease and ensuring accuracy. However, some participants questioned the expense involved in these and the possibility that someone could join the intervention to receive the scales and then withdraw. Concern was expressed about the calibration of the scales if weighing was carried out at home, but interim weighing at home was seen as acceptable, given that weight would be taken at the beginning and end of the intervention. LARC users also stressed the importance of receiving a response to the weight report in order to encourage people to continue with the intervention.

Meal replacements

The discussion about meal replacements also elicited mixed responses, with many interviewees talking about both positive and negative aspects of these. Meal replacements were very much framed as a matter of personal choice. The positive aspects of meal replacements were that they offer a kick-start to weight loss, and one does not have to think about food. Reasons given for meal replacements not being included are that they are not sustainable, they do not fit well with family or social life and, once a normal pattern of eating is resumed, the person will gain weight again. A significant concern was that they did not teach people to eat healthily, for long-term health. Participants were worried that meal replacements would not be good for mental health or preparation for health in pregnancy:

> *. . . it's the simplicity of it. Like, if you just do this one thing for 8 weeks, it's almost a guarantee that at the end of it you'll have had a little early win. And once you've got that under your belt, it might be a bit easier from then on. That sounds appealing.*
>
> *LUI02*

> *I guess you do risk it moving forwards into pregnancy. People thinking, 'oh, I can just have a shake'. I don't know what that would do to a developing baby but I mean they say they've got everything in them they need, which I guess is where the danger is, isn't it?*
>
> *LUI09*

The consensus among LARC users was that as long as meal replacements were one option, and managed, then it would be the individual's choice. Meal replacements should not be compulsory, and care would need to be taken to ensure that they were not the only aspect of the programme.

NHS and other resources

Participants had varying levels of experience with the resources available for losing weight. Whereas some had used resources such as Exercise on Prescription or NHS-provided Slimming World vouchers, or knew people who had, others had not heard of these NHS-supported schemes. The NHS 10-week

plan was mentioned by one woman who found it helpful. There seemed to be disparities between localities, with some areas having local schemes, from weight management in the practice to motivational interviewing services, bariatric referrals, self-help schemes and so on, and other areas having very little. The health-care practitioners working in sexual health services did not have these referral options, and instead suggested that women return to their GP.

Other apps mentioned included MyFitnessPal (MyFitnessPal Inc., San Francisco, CA, USA), Strava (Strava, San Francisco, CA, USA), Couch to 5K and Mind Matters. The benefits of apps included the ability to track and keep a record of food, exercise, ideas and motivation. Exercise options included parkrun and, more unusually, Zombies, Run! (Six to Start and Naomi Alderman, London, UK).

In general, participants favoured including existing resources in the intervention, as they understood the reasoning behind not wanting to 'reinvent the wheel', that the existing resources are expert-led, and that using existing resources to create a bespoke programme would be flexible enough for everyone.

Group support

LARC users tended to see peer support as an important and valued aspect of weight loss. Most agreed that peer support has value in the camaraderie of knowing you are not alone. LARC users favoured different formats for the peer support: online for flexibility, text based for anonymity or distance for sensitive discussions that could be digested in one's own time. However, some participants raised concerns around accountability and honesty in using an anonymous forum and the need for the forum to be moderated for safety:

> *I guess if you were doing it virtually you could choose which kind of group you wanted to be in. As obviously you don't have to be physically nearby so I guess that would give that flexibility potentially.*
>
> *LUI12*

> *[In an online forum] anything that's deemed to be in anyway aggressive to others or shaming or anything or belittling is, is taken down straight away. I think it's got to be like a safe place. And, and be managed and monitored though by admins.*
>
> *LUI05*

Whereas some participants favoured group support, other stated that they found in-person groups, such as Slimming World, very difficult because they did not have anything in common with other members of the group and group rapport was lacking. Some participants stated that they preferred one-to-one sessions rather than group support.

Obstacles

Participants were asked if they could foresee any obstacles or challenges that we might encounter in this programme, over and above those already identified in the content-specific questions. One participant commented on the growth of distrust of medical experts and disbelief of medical advice, which might influence people's willingness to engage with the programme:

> *I don't like the emerging trend about ignoring medical experts . . . The growing, kind of body positivity movement. I am seeing a growing anti-medical thing about obesity. Cancer Research I think did a campaign either at the end of last year, the beginning of this year about obesity kind of reinforcing the link between obesity and cancer. There was a real big backlash to that. That kind of thing makes me a bit worried.*
>
> *LUI02*

Practitioners said that patients might not be able to fit an intervention that involved exercise classes into their work and life, and they also mentioned the differences in, for example, food and exercise facilities available in rural areas and cities.

Health-care practitioners suggested that people who are not in their first pregnancy are less likely to engage with this intervention, as they will already have had the experience and know what they are doing. They might question the evidence on risk if their previous pregnancies had resulted in healthy children, or they might just not have the time to engage with the intervention because of their busy lives as parents.

CMO 6: building confidence and motivation

Participants were asked about their experiences of successful consultations about weight to try to elicit the key ingredients for establishing strategies to build confidence and motivation.

Some LARC users said that they had never had a good conversation about weight with health-care practitioners. However, those who had done identified various aspects that had made a difference, including the attitude of the practitioner, for instance if they were non-judgemental and matter-of-fact. Some participants talked about having a good relationship with their health-care practitioner, and participants said that the experience is improved when health-care practitioners take the time to listen to the patient. One health-care practitioner said that this might be easier for nurses, who are allocated more time for consultations. Health-care practitioners felt that factual starts to the conversation might also help:

> *I appreciated what she said actually, she didn't really pussy foot around . . . she didn't shame me . . . she just said, 'keep walking, what you're doing, but just control maybe your portions and don't eat as much' [laughs]. And she was right, she was right [laughs], what can I say?*
>
> *LUI05*

Both groups of stakeholders felt that the conversation needed to be led by the patient, either that they introduced the topic or that it was given as an option and left to the patient to decide whether they wanted to explore it. The practitioners said that it was important to ensure that they took the position that the patient was an expert in their own condition, tailoring the discussion and acknowledging their knowledge:

> *At the point where you go in and say, 'I would like some help with my weight', that's the point where it should be a positive experience. They should be like, 'That's really great you've come in. These are your options'.*
>
> *LUI11*

Happy to refer to the intervention

Health-care practitioners were also asked if, hypothetically, they would be happy to refer their patients to the programme if it was on offer. The key factors identified were having more information about the actual programme to inform patients and, in particular, that it was evidence based.

Health-care practitioners wanted to know what their role would be in the follow-up of patients who attended the WLI. Some practitioners wanted reassurance that the participant could still have their LARC removed if they decided to withdraw from the study or were unsuccessful at losing weight. Furthermore, health-care practitioners said that staying in contact with the patient, and receiving feedback regarding the outcomes so that they could continue to support the patient, would be important:

> *I suppose from the legalities view, you want to make all the governance is there in place, the safety. What happens after 12 to 16 weeks if they haven't succeeded, or totally failed at it? Gone the other way even. Do we then say, 'we're not removing your LARC'?*
>
> *HCPI02*

CMO 7: weight loss discussions should be founded on the principles of informed choice and a client-centred approach

The theme of ensuring that women were given information and able to make their own choices came through several of the areas of discussion in the interview. As with the survey responses, when discussing the design, LARC users wanted it to be really clear that delay was just one option, that it was not a prerequisite for attendance and that the idea of informed choice was front and centre of the discussion. This includes presenting the risks and advantages of different decisions so that the woman can fully understand the choices being presented and is fully aware of her options. Health-care practitioners linked the discussion of risk and options with their professional responsibility and the discussions they have in relation to other procedures. The aim is to make sure that the woman can make an informed choice, fully aware of the risks and benefits:

> *So yes, I think, but I do think that informed choice is important and you can't make an informed decision if you haven't been presented with all the facts around weight and pregnancy and if you haven't been given an option to delay with support to lose weight.*
>
> *LUI04*

Refinement of potential programme theory

From the results of the interviews, the programme theory for a potential preconception WLI was further refined (*Figure 10*).

Phase 2 Stakeholder Advisory Groups

The LARC user SAG was attended by three members of the research team and five women, two with children and pregnant/planning to be pregnant, two planning to be pregnant in the next year and one planning to be pregnant within the next 5 years. The results are presented under the three main themes of the discussion: (1) engagement, (2) outcomes and (3) support and improving practitioner skills.

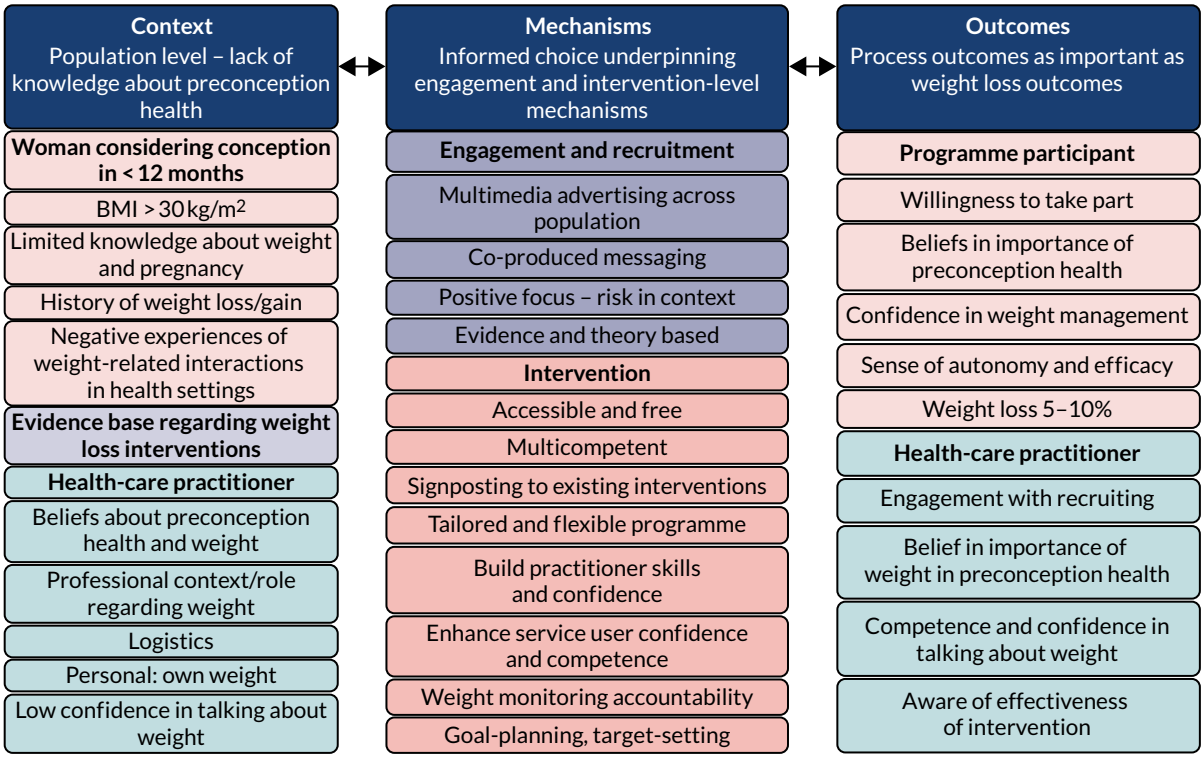

FIGURE 10 Refinement of a potential preconception WLI.

Three main points were made by the SAG with regard to maximising engagement with the programme. The advertisement of the programme would need to be wide reaching, involving physical spaces such as community pharmacies (not just online), and also be clearly identified as NHS-endorsed to be seen as trustworthy. The emerging evidence of the potential effectiveness of the intervention would need to be widely disseminated, and not just shared with clinicians, to enable women to make decisions about the suitability of the programme for them. The health coach was seen as key to retention as they would offer continuity, being the person with whom participants felt safe and connected.

In terms of engagement with the WLI, the stakeholders stressed that it would be important to consider what outcomes (not just weight loss) would be valued by service users, which could therefore be included as outcomes of any research but also reflected in the advertising. The SAG members identified the following potential benefits of importance: (1) increasing energy, (2) confidence, (3) feeling proud of yourself, (4) feeling healthier, (5) able to exercise, (6) posture and (7) less weight on joints. They also said that the critical shift, the thing that makes the difference between this and other times in a person's life, is that preparing for family life and doing the best for your baby's health were seen as powerful psychological motivators, far more so than thinking of one's own health and well-being alone.

The peer support element of the proposed intervention divided opinion. Some felt that it was really important to be 'trying to achieve something together', whereas others felt that this was something that needed to be approached with caution, not just because they found group work unhelpful, but also because non-experts may start offering advice regarding pregnancy. In terms of training practitioners, the group reflected that it is very difficult to train people in fundamental communication skills if they do not have them already; therefore, it is important to advertise the programme so that women know to ask for it, and also to design a script for health-care practitioners to ensure that, as a minimum, the opening of the conversation is done well.

The time frame of the programme was discussed, reflecting on the recent findings from the Prepare trial in the USA,[53] and it was suggested that a preconception WLI may need to support women until the end of pregnancy to counteract a rebound of preconception weight loss with greater GWG.

In summary, the LARC user SAG identified important considerations in engagement and recruitment, the centrality of the continuity of care provided by the health coach and the value of ensuring that advertising was widely disseminated not just to let people know about the programme but also to provide knowledge so that service users would be empowered to initiate the conversation with their health-care provider and suggest attending the WLI. The individuality of women's needs around weight management means that, if possible, tailoring elements of the programme, such as the nature of provision, intensity of support and goals, would be beneficial. The programme would need to offer 'light-touch' support after the initial preconception programme.

Nine responses were received across the three questions in the health-care practitioner SAG. The ideas suggested for contacting women in their service included wall posters, waiting room QR codes, a link on the pre-procedure questionnaire sent for all LARC attendances, taking permission for health promotion text messages at registration, a link on the clinic website on the page for pre-pregnancy planning and also on the sexual health website. The general advertising followed similar approaches, with QR codes in toilets, gyms, and so on, but it also involved a social media campaign, including developing community champions. The themes in the responses to the training question echoed those from the interviews, of really working on improving the motivational interviewing training for practitioners and also the central importance of having an effective intervention to refer to. The biggest barrier to opening up the conversation about weight is if nowhere is offering support.

Potential intervention

The outline of a potential WLI for women in the preconception phase and the principles underlying it based on evidence and stakeholder feedback are shown in *Figure 11*. The WLI is framed as a healthy

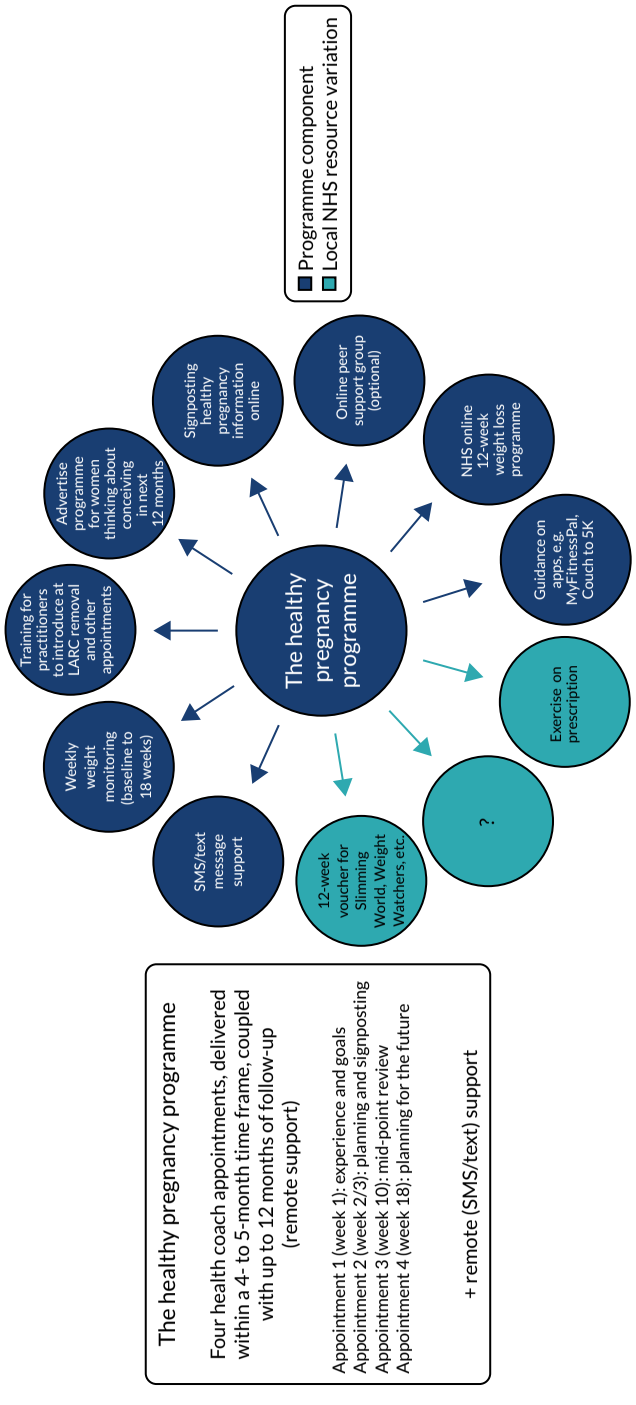

FIGURE 11 Outline of a potential preconception WLI.

pregnancy programme for women with BMI of ≥ 30 kg/m^2, advertised widely in the community for self-referral but also discussed by practitioners involved in family planning services when working with women of reproductive age who are considering conception in the next 12 months, including those presenting for LARC removal. For women still using contraception, the discussion with the practitioner will include the potential benefits of continuing with contraception for the next 4 months to maximise their chances of losing a clinically significant amount of weight prior to conception. Practitioners would receive clear evidence-based guidance on the benefits of reduced BMI that they could share with their patients, and would also receive training in how to introduce the topic using a loose script co-produced with service users and the research team.

The intervention itself is a signposting intervention, delivered by a health coach who has been trained in motivational interviewing and has an understanding of the evidence-based principles of behaviour change, incorporating planning and goal-setting. With knowledge of the resources available locally and online, the health coach will support the woman to identify her own goals and understand the key components of her experience of successful and unsuccessful weight loss attempts. The information provided will focus on preparation for a healthy pregnancy and will be provided initially via an online platform and then in discussion with the health coach. Signposting to a range of interventions inherently maximises a sense of autonomy, and this will be partnered with support from the health-coach, in person and via text, introducing accountability with weight monitoring. Additional support via a group peer-support network will be offered if requested by the service user. The exact nature of the full programme will be tailored to the individual but also to the resources available locally (e.g. NHS-provided support).

Chapter 8 Discussion

The aim of the Plan-it study was to establish if it would be acceptable and feasible to conduct a study in the future that asked women with overweight/obesity to delay the removal of LARC to participate in a targeted pre-pregnancy WLI.

The main findings of the study will be summarised in relation to the study objectives; these will be followed by a broader discussion, including recommendations for further research.

Main findings

Objective 1: to identify the annual number of women of reproductive age in the UK who request LARC removal and subsequently have a pregnancy

The pathway from LARC removal to pregnancy is not easily captured. The stakeholder narratives and the CPRD routine data show that the reasons for removal are many and varied, of which planning a pregnancy is just one. The current structure of routine data collected through CPRD and SHCs does not enable the sequential relationship between removal of LARC and subsequent pregnancy to be reliably determined. The main barriers include the quality of the routine data, in particular the multiple Read codes relating to LARC use in CPRD and the very limited coding in the Sexual Health data; and the lack of connectivity between SHC and CPRD data, which, given women's freedom to choose the service they wish to access to remove the LARC (which may well be different from the setting where it was inserted), means that it is not possible to generate a reliable timeline of LARC-related events. Having a 'clear' pathway in the data between removal and a pregnancy within 15 months (our assumed definition of 'subsequent') may well relate to a minority of the women for whom that is indeed their lived experience.

In conclusion, the relationship between LARC removal and subsequent pregnancy is not clear enough to be able to reliably answer this objective with a number. It would not be feasible, using the current routine data sets relating to LARC use and pregnancy, to reliably identify women who request a LARC removal with the intention of becoming pregnant.

Objective 2: means of identifying women at study sites who are overweight/obese and plan to have LARC removal for the purpose of planning a pregnancy and opportunities to intervene

The barriers identified in objective 1 would also hold true in relation to objective 2. In terms of BMI information, there was an overall average of 62% of women having a BMI recorded within 3 years of a LARC event. Of those, 51–54% had a BMI of ≥ 25 kg/m^2, which is in line with the National Maternity and Perinatal Audit 2019,[1] in which 50.4% of women giving birth had a BMI in the overweight/obese category, suggesting that there is no particular skew towards higher rates of recording of higher BMI. This rate of recording could be considered adequate for identifying women at study sites with overweight/obesity. However, the routine data barriers would impede this route in the current circumstances.

The quality of the routine data, in particular the identification of the exact purpose of the consultation, would also preclude using them to identify opportunities to intervene and introduce the topic of weight. Even if the data were more reliable, it is questionable whether using LARC-related events would be acceptable as an opportunity to intervene. When the idea of opportunities to talk about weight was explored with stakeholders, opinions ranged from feeling that weight should only ever be raised by the woman to feeling that any consultation was potentially an opportunity. Insertion was the most commonly identified LARC-related opportunity in which it felt appropriate for weight to be discussed. However, many others felt that any LARC event was a situation in which women were physically and emotionally vulnerable, and, therefore, introducing the topic of weight was not appropriate.

To conclude, from the routine data it is not possible to reliably identify women with overweight/obesity and who plan to have LARC removed for the purpose of planning a pregnancy. The acceptability of the intervention to stakeholders (described under objectives 3–5 in the following sections) would also preclude this approach to identifying opportunities to intervene.

Objective 3: suitable and acceptable interventions that can be incorporated into a pre-pregnancy weight loss intervention

The published research on preconception weight loss is dominated by studies relating to IVF that focus most commonly on hypocaloric deficit with pregnancy as the primary outcome. IVF as the context of the studies puts the emphasis on the relationship between BMI and conception, in relation to either the BMI threshold for eligibility for IVF or exploring the relationship between BMI and fertility. There is rarely any detail of support on offer or theoretical underpinning of any intervention other than the biological mechanisms relating to calorie deficit or fertility. These studies provide useful information on the level of weight loss possible with this very motivated group. However, the issue of fertility is the dominant narrative and so the studies may not offer direct guidance on the suitability of particular interventions for a broader population.

The literature on interventions in managing GWG is significantly more developed in terms of details, models, theoretical underpinning and so on. The key crossover with the preconception context is in terms of motivation for change, with our stakeholders citing the health of the baby and their own health in caring for their child as prime motivators for behaviour change at this particular point in their lives. It is useful to incorporate the evidence of the effective mechanisms underpinning intervention design in pregnancy-focused studies into a preconception WLI, with planning and feedback/monitoring being key to success.[153] Some of the barriers to WLI in pregnancy, in particular the reduction in effectiveness of physical activity interventions,[117,159] would need to be considered, that is to say whether or not a preconception WLI should follow protocols closer to those of general adult or pregnancy WLIs.

The review of the literature and relevant middle-range theories using realist principles, combined with the stakeholder experiences, generated seven CMO configurations that together create a potential programme theory. A model of a signposting intervention is proposed, with focused preconception content delivered via online modules and individual sessions with a health coach. The use of a signposting model seeks to address the question of whether the intervention should be a specialist preconception WLI or essentially add bespoke content to a more generic adult WLI. The stakeholders were really supportive of the idea of not reinventing the weight loss programme wheel; there are many generic interventions available that women have used, are using or would be happy to explore. However, preconception is a special context, so the intervention requires tailoring to the preconception/pregnancy context with elements of individualised support via a health coach. This would include nutritional and physical activity information about preparation for pregnancy, motivation for change, understanding the goals in terms of clinical impact of the weight loss on perinatal health, time frames and so on. These elements came through several of the CMO configurations in the review, identifying the importance of sensitive messaging during the recruitment process so that women know that the intervention is for them (CMOs 1 and 4), that their experience (positive and negative) of weight management will be recognised (CMO 2) and that it is fit for purpose in a preconception context (CMO 5).

Objective 4: willingness of clinicians to raise weight loss in consultations with eligible women and recruit them to the intervention

The majority of clinicians reported that they were willing to raise the topic of weight in consultations, seeing discussing this as part of their role either in relation to contraceptive choices (in SHCs) or as part of general health (in primary care roles). However, practitioners reported many barriers to these discussions (in line with the published literature[160,161]), which ranged from the practical, in terms of time, to the sensitivity of the topic, their skills and also broader ethical concerns. These concerns

included whether it was their role to discuss weight if this was not directly related to contraceptive options (e.g. if a woman's BMI prohibited certain choices) and whether weight may be such a complex issue that a woman needed to raise the topic herself.

Over 60% of practitioners would have considered recruiting to a WLI that focused on delaying LARC removal. This would have been facilitated by information on the programme, skills training in the recruitment approach and evidence of potential effectiveness of the intervention. However, practitioners identified significant barriers that resonated with LARC users' views, which included those to discussing weight in general (described under objective 3) but also the critical issue that the discussion was inappropriate during the LARC removal appointment. They had concerns about the impact on the woman, their professional relationship, the feasibility of recruiting in their service context with their skills/role and, generally, that weight discussions ought to be patient-initiated.

Objective 5: views of eligible women as to the acceptability and feasibility of the intervention

The views of the women who completed the survey, all of whom had experience of having a raised BMI and using LARC, were divided fairly evenly on the question of the acceptability of this WLI in its basic form, of delayed LARC removal. The argument could be made that, with nearly 40% of the respondents thinking that this would be an acceptable model of intervention, it might be worth pursuing as an option, as it may suit some people. The themes that emerged from the free-text comments, the phase 1 SAG and the interviews help to clarify the context of that 'acceptability'. The core conditions for the intervention's acceptability included the need for it to be approached sensitively, using a person-centred approach that respectfully acknowledged their history and difficulties with weight, their ambivalence and so on, and also in a way that puts them in control of the decision-making with a positive focus. Delaying LARC removal is not something that would be embraced enthusiastically; it is something that could potentially be tolerated with the importance of the end goal in mind. However, as well as the barriers relating to communication, there were also practical and ethical considerations, ranging from concerns about the practicalities of getting another appointment to a view that this was an unethical intervention that damaged the woman's right to choose when she could conceive.

Across the two phases of the study, the stakeholder responses led to the conclusion that, in its basic form, an intervention comprising the delay of LARC removal in order to take part in a weight loss programme prior to conception would not be acceptable or feasible. However, including this as one option in a preconception health and weight loss programme that is designed with the key principle of informed choice at its heart would be acceptable and potentially feasible if it also followed the other aspects of the proposed programme theory. This is discussed in objective 6.

Objective 6: future potential intervention based on feasibility and acceptability to stakeholders

A potential preconception WLI has been proposed, designed as part of a healthy pregnancy programme based on feasibility and acceptability to stakeholders and informed by the hypothesised programme theory. It is based on a broad population-based recruitment approach, with individual meetings with a health coach, whose work would be founded on the principles of the COM-B model.[110] Their role would be supporting women to feel competent and confident in relation to their weight across the preconception period and pregnancy and signposting to existing programmes, supplemented by tailored online information. The proposed WLI recruitment incorporates the opportunity for discussion of options presented by LARC removal, but, in recognition of all of the ethical and pragmatic complexities of making that the sole focus, the idea of delaying removal is one potential choice and the eligibility criteria would be much wider. Short-term interventions that simply focus on a relatively brief preconception period have recently been shown[53] to be unlikely to work if the aim is to impact on health and weight management throughout the pregnancy rather than, at best, in the first trimester. Therefore, although the focus of the intervention is on introducing change in a 12- to 16-week preconception period, a form of support needs to be incorporated to support women to consolidate the changes over a longer time frame.

Weight management and weight in relation to health are very complex contexts. Ranging from the highly personal to the wider population system, there are layers of meaning to weight that go well beyond the simple 'calories in, calories out' model that is often reflected in the interventions delivered. Similarly, LARC removal is not a straightforward procedural opportunity; it is an appointment that has been made in response to an intricate web of life choices and decisions, some of which may relate to pregnancy. Individuals' beliefs about the health impact of weight and how it fits with other health issues is critical to their engagement with any weight intervention, and this is true for both the service user and the practitioner. One of the messages that came through from the stakeholder work was the current conceptual separation of weight from other components of a healthy pregnancy (e.g. smoking, folic acid). Similarly, there was representation in both groups of stakeholders of the view that contraception is not part of wider health and that somehow it is a separate issue. To improve preconception health, programmes need to reflect this complexity and, as with the potential programme theory described here, draw on middle-range theories that incorporate individual- and systems-level change. As identified by Bull and Willumsen[162] in their review of evidence to prevent childhood obesity via the continuum of preconception, pregnancy and postnatal interventions, no single intervention will suffice; action is needed at multiple levels and a life course approach needs to be taken. Preconception programmes must incorporate both individual and societal components, underpinned by socioecological as well as individual behaviour change theories, if we are not simply going to continue making minor changes and exacerbate the social inequities that already exist in nutritional and behavioural aspects of preconception health.[27,29]

The ethical considerations in delaying LARC removal as part of the original proposed intervention interlaced two complex sociopolitical issues in weight and conception, which can be captured by the concept of a woman's right to choose. Although there was never any intention that the intervention would remove women's choices, the underlying message that some stakeholders identified was discriminatory, suggesting that women with a raised BMI should not become pregnant, and there was perceived to be a risk that women would feel pressured to participate, however unintentionally, by the practitioner's description of the option to delay LARC removal.

In many ways, preconception does not need a dedicated WLI. Most, if not all, general population WLIs would be suitable or could be adapted. The key differences include the unique primary motivation to succeed; the intervention can also be wrapped in preconception health provision that offers advice on a wider range of important health issues. The stakeholders seemed to feel that this would be more acceptable. However, the reason for this must be considered, along with whether it is a positive step to, in some ways, disguise the focus on weight to make it acceptable. One of the barriers to any new programme, as identified by our stakeholders, is difficulty engaging people, as they need to know that their effort will be rewarded. Being clear about the evidence (e.g. relating to health gains from a 5–10% weight loss) and also about what support will be provided would be positive steps to improving engagement.

Both groups of stakeholders recognised the need for greater awareness of the importance of weight and preconception health at a population level. It may be that investment in a public health campaign (e.g. as suggested by Barker *et al.*[29] and Stephenson *et al.*[27]) has more of a lasting impact, changing the attitudes and awareness of future generations, as well as those of people who are currently of reproductive age. As identified by Hemsing *et al.*[37] in a review of preconception interventions, taking a more population-based approach, using gender transformative principles, would also benefit everyone (given the general health benefits of the suggested behaviour changes) and reduce the stigma experienced by women who feel solely responsible for the health of their baby.

Strengths

The main strengths of this study are the use of routine data to consider feasibility, the central involvement of key stakeholders in exploring the acceptability of the idea without incurring the expense of a feasibility pilot study, and the use of a realist-informed approach to reviewing the literature.

The work on the routine data revealed just how difficult it is to use these data to answer some questions that, on the face of it, could seem quite simple. The combination of the multiple and duplicate codes and the way in which practitioners use the codes made for a very dense data set that necessitated a lot of work to decipher. The lack of crossover between the data sets of primary care and sexual health services adds another layer of complexity, and individuals' movements between providers of contraceptive services makes it impossible to draw firm conclusions. This was a very thorough exploration, which has established that the data sets as they currently stand could not be used as a way of identifying particular populations for this type of intervention.

The stakeholders were involved and engaged at each step of the study. The research questions were predetermined in the commission call, but our PPI partners were part of the study development, the study management and study steering groups. We had substantial engagement from women with lived experience of LARC use and raised BMI, initially from 243 women in their responses to the survey, 173 (71.2%) of whom agreed to be contacted for further involvement in the project. The survey consisted largely of open questions and open text, which meant that women could give us detailed accounts of their experiences. These informed the design of the phase 2 interviews, with input from the SAGs. The power of the women's testimony informed all of the components of the programme theory, but, in particular, it ensured that the concept of informed choice, which did not come through in the published literature, was put at the heart of the proposed intervention.

Similarly, the project was also informed and the outcomes shaped by the engagement with practitioners. Meeting with practitioners at professional events and asking for their time in that setting was a successful and pragmatic way to engage with a large number of health-care staff. Their responses to the survey and during the interviews really brought to life the experiences of working in this area and, in particular, the barriers to any weight-related intervention. The findings resonated with and extended the research literature in the field and highlighted several areas that merit exploration in future research.

Most of the weight-related preconception interventions lacked a theoretical rationale or any form of process evaluation. The review of the literature informed by realist principles allowed the team to capture relevant work using a much more exploratory lens that highlighted these gaps and started the process of theory building alongside the stakeholder work. These components of the study will be of use in any intervention development work that follows.

Limitations

Given that COVID-19 struck half-way through the study, it was fortunate that much of the second half of the study had been designed to be delivered remotely and so the protocol did not require substantial revision. However, the pandemic did have a significant impact on the range of feedback that was available in both of the LARC user SAGs and the phase 2 practitioner SAG. Had these events been face to face as planned, the engagement and feedback would undoubtedly have been more extensive.

We designed the study to use routine data as this was thought to be the best way to answer the research questions about the size of the potential population, but unfortunately the quality of the data set was not good enough to generate the answers with any degree of reliability. The rationale for using non-NHS-based recruitment was to maximise the extent and reach of recruitment within the tight timescale of the study. However, despite our best efforts at advertising and use of social media, including costing in the advice of a communications officer from a public health organisation, the response rate to the survey from LARC users was not as high as we had hoped. This may have been because the specificity of our target group made the message difficult to convey succinctly. Those who did respond were knowledgeable about the risks related to weight and pregnancy, which suggests that they were not typical of the general population, so it may be that including recruitment via the NHS contraception and weight management clinics would have added a different perspective.

We did not collect demographics in the survey because we did not want this to be a barrier to participation, but it would have been valuable information. We know that a significant proportion of the stakeholder responses came in following advertisements on Facebook and Healthwise Wales, so the cultural diversity of our group is likely to have been limited, which in turn limits the generalisability of the findings.

The engagement with practitioners also had its limitations. Despite dialogues with several commercial weight loss organisations, they were unwilling to circulate the survey to their weight loss consultants, and so our response from practitioners for whom weight loss support was part of their role was very restricted. Approaching health-care practitioners at professional events was a very successful way of engaging with them, but this could have been further enhanced by asking participants if they were willing to take part in an interview at a later date (rather than at the event, as originally planned). Recruiting through professional events also meant that the contributors tended to be those who had a lot of experience and also were from a medical background. The views of nurses and those newer to the profession were therefore less well represented. This could potentially have been mitigated by recruiting via the NHS or through the FSRH.

The search for suitable interventions focused on the research directly relevant to preconception, which we have identified as lacking in terms of theoretical principles and process evaluation. This aspect of the study could potentially have been enhanced by exploring the more population-based weight loss research, extracting key mechanisms of action and considering how these might operate in the context of preconception.

Further research

It would seem that, until very recently, this area of research was dominated by physical outcomes (i.e. weight loss, GWG, conception, etc.) rather than the woman's experience of the intervention and the practitioner's role in implementation. More mixed-methods studies are required with a much greater level of service user involvement. If a preconception WLI is to be successful, we need to have a much more nuanced understanding of people's perceptions of the relationship between weight and health in pregnancy. This includes practitioners, who in their responses acknowledged that their knowledge was limited, and it is known [e.g. from the work of the Winton Centre (Cambridge, UK; URL: https://wintoncentre.maths.cam.ac.uk)] that medical practitioners' risk communication is generally very poor. There is also the conceptual separation for stakeholders between contraception and health, which would need to be understood if SHCs were to be used for recruitment to a preconception intervention. There is clearly a need to explore not simply the practical barriers, but also how to address the attitudinal, knowledge and communication barriers that prevent these discussions taking place successfully. This needs to be a priority as, unless these barriers are reduced or removed and the quality of the communication is improved, no population-based preconception WLI based in the NHS will be feasible.

Therefore, the research priorities would be:

- How do people of reproductive age and health-care practitioners delivering family planning and preconception services understand the role of weight in a healthy pregnancy and labour?
- What are the best ways to discuss weight (including issues of risk) in relation to pregnancy in the preconception phase as part of routine health-care practice in order to meet the health and well-being needs of the woman and her family?

Given the low recruitment rates and extremely high attrition rates in many of the studies, the woman's experience of preconception interventions seems to be a crucial missing piece of the evidence. Assuming that there is often extremely high motivation, for example in the studies that

would enable access to fertility treatment, the low recruitment and retention rates are a surprise, but with no clear explanations, as the woman's experience is not included in published research. Every trial should include a process evaluation to understand the barriers to and facilitators of engagement.

Conclusions

At the present time, developing an intervention that asks women with a raised BMI to delay removal of LARC to participate in a targeted preconception WLI would be neither feasible nor acceptable. However, contraception-related appointments, including those for LARC removal, do offer an opportunity to engage in discussions about preparation for pregnancy. They could be incorporated into a broader, population-based preconception programme, and one potential model of this type of programme is described. However, more development work is needed before it would be possible to progress to the feasibility and evaluation phases of the Medical Research Council framework of complex intervention development; in particular, some of the barriers to communication about weight in pregnancy must be overcome and significant improvement in the routine data sets brought about, including streamlined coding and links between services. The design of preconception WLIs needs to be informed by theories of change, reflecting the complexity of weight management at this life stage, and the profile of preconception health needs to be raised in the general population for the benefit of all.

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Contributions of authors

Susan Channon (https://orcid.org/0000-0002-5394-1483) (Senior Research Fellow) was the chief investigator, with overall responsibility for the design, co-ordination and delivery of the study. With the co-investigators, she conceived, designed and led the original grant application. She co-facilitated the SAGs and interviews. She led on drafting report chapters and made substantial contributions to synthesis and write-up of chapters in the report, commented on drafts and outputs of the study and facilitated stakeholder activities.

Elinor Coulman (https://orcid.org/0000-0002-8854-2140) (Research Associate – Study Management) was responsible for study co-ordination, governance and team management. She led on the development and dissemination of the survey; recruited to and co-facilitated the SAGs; co-analysed the qualitative data from the surveys and interviews; co-wrote chapters in the report; and collated, reviewed and commented on the final report.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review. The full trial protocol can be obtained by contacting the corresponding author.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

References

1. National Maternity and Perinatal Audit Project Team. *National Maternity and Perinatal Audit: Clinical Report 2019*. London: Royal College of Obstetricians and Gynaecologists; 2019.
2. Government Office for Science. *Foresight Report*. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/287937/07-1184x-tackling-obesities-future-choices-report.pdf (accessed 13 September 2021).
3. Agha M, Agha RA, Sandell J. Interventions to reduce and prevent obesity in pre-conceptual and pregnant women: a systematic review and meta-analysis. *PLOS ONE* 2014;**9**:e95132. https://doi.org/10.1371/journal.pone.0095132
4. Marchi J, Berg M, Dencker A, Olander EK, Begley C. Risks associated with obesity in pregnancy, for the mother and baby: a systematic review of reviews. *Obes Rev* 2015;**16**:621–38. https://doi.org/10.1111/obr.12288
5. Boney CM, Verma A, Tucker R, Vohr BR. Metabolic syndrome in childhood: association with birth weight, maternal obesity, and gestational diabetes mellitus. *Pediatrics* 2005;**115**:e290–6. https://doi.org/10.1542/peds.2004-1808
6. Valgeirsdottir H, Vanky E, Sundström-Poromaa I, Roos N, Løvvik TS, Stephansson O, Wikström AK. Prenatal exposures and birth indices, and subsequent risk of polycystic ovary syndrome: a national registry-based cohort study. *BJOG* 2019;**126**:244–51. https://doi.org/10.1111/1471-0528.15236
7. Jacob CM, Newell ML, Hanson M. Narrative review of reviews of preconception interventions to prevent an increased risk of obesity and non-communicable diseases in children. *Obes Rev* 2019;**20**(Suppl. 1):5–17. https://doi.org/10.1111/obr.12769
8. Crozier SR, Inskip HM, Godfrey KM, Cooper C, Harvey NC, Cole ZA, *et al.* Weight gain in pregnancy and childhood body composition: findings from the Southampton Women's Survey. *Am J Clin Nutr* 2010;**91**:1745–51. https://doi.org/10.3945/ajcn.2009.29128
9. Olander EK. Weight management in pregnancy. *Nursing in Practice*, September/October 2015, pp. 19–24.
10. Cheney K, Berkemeier S, Sim KA, Gordon A, Black K. Prevalence and predictors of early gestational weight gain associated with obesity risk in a diverse Australian antenatal population: a cross-sectional study. *BMC Pregnancy Childbirth* 2017;**17**:296. https://doi.org/10.1186/s12884-017-1482-6
11. Schummers L, Hutcheon JA, Bodnar LM, Lieberman E, Himes KP. Risk of adverse pregnancy outcomes by prepregnancy body mass index: a population-based study to inform prepregnancy weight loss counseling. *Obstet Gynecol* 2015;**125**:133–43. https://doi.org/10.1097/AOG.0000000000000591
12. Amorim AR, Rössner S, Neovius M, Lourenço PM, Linné Y. Does excess pregnancy weight gain constitute a major risk for increasing long-term BMI? *Obesity* 2007;**15**:1278–86. https://doi.org/10.1038/oby.2007.149
13. Christenson A, Johansson E, Reynisdottir S, Torgerson J, Hemmingsson E. Women's perceived reasons for their excessive postpartum weight retention: a qualitative interview study. *PLOS ONE* 2016;**11**:e0167731. https://doi.org/10.1371/journal.pone.0167731
14. Amorim Adegboye AR, Linne YM. Diet or exercise, or both, for weight reduction in women after childbirth. *Cochrane Database Syst Rev* 2013;**7**:CD005627. https://doi.org/10.1002/14651858.CD005627.pub3

15. Christiansen PK, Skjøth MM, Rothmann MJ, Vinter CA, Lamont RF, Draborg E. Lifestyle interventions to maternal weight loss after birth: a systematic review. *Syst Rev* 2019;**8**:327. https://doi.org/10.1186/s13643-019-1186-2

16. National Institute for Health and Care Excellence (NICE). *Weight Management Before, During and After Pregnancy*. Public Health Guideline [PH27]. London: NICE; 2010. URL: www.nice.org.uk/guidance/ph27/resources/weight-management-before-during-and-after-pregnancy-pdf-1996242046405 (accessed 13 September 2021).

17. Centre for Maternal and Child Enquiries, Royal College of Obstetricians and Gynaecologists. *CMACE/RCOG Joint Guideline: Management of Women with Obesity in Pregnancy*. 2010. URL: www.rcog.org.uk/globalassets/documents/guidelines/cmacercogjointguidelinemanagementwomenobesitypregnancya.pdf (accessed 13 September 2021).

18. Royal College of Obstetricians and Gynaecologists. *Care of Women with Obesity in Pregnancy (Green-top Guidelines No. 72)*. 2018. URL: www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg72/ (accessed 13 September 2021).

19. American College of Obstetricians and Gynecologists. *Weight Gain During Pregnancy*. URL: www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/01/weight-gain-during-pregnancy (accessed 11 May 2021).

20. McAuliffe FM, Killeen SL, Jacob CM, Hanson MA, Hadar E, McIntyre HD, *et al.* Management of prepregnancy, pregnancy, and postpartum obesity from the FIGO Pregnancy and Non-Communicable Diseases Committee: a FIGO (International Federation of Gynecology and Obstetrics) guideline. *Int J Gynaecol Obstet* 2020;**151**(Suppl. 1):16–36. https://doi.org/10.1002/ijgo.13334

21. International Weight Management in Pregnancy Collaborative Group. Effect of diet and physical activity based interventions in pregnancy on gestational weight gain and pregnancy outcomes: meta-analysis of individual participant data from randomised trials. *BMJ* 2017;**358**:j3119. https://doi.org/10.1136/bmj.j3119

22. Farpour-Lambert NJ, Ells LJ, Martinez de Tejada B, Scott C. Obesity and weight gain in pregnancy and postpartum: an evidence review of lifestyle interventions to inform maternal and child health policies. *Front Endocrinol* 2018;**9**:546. https://doi.org/10.3389/fendo.2018.00546

23. Walker R, Bennett C, Blumfield M, Gwini S, Ma J, Wang F, *et al.* Attenuating pregnancy weight gain – what works and why: a systematic review and meta-analysis. *Nutrients* 2018;**10**:E944. https://doi.org/10.3390/nu10070944

24. Tomedi LE, Simhan HN, Chang CC, McTigue KM, Bodnar LM. Gestational weight gain, early pregnancy maternal adiposity distribution, and maternal hyperglycemia. *Matern Child Health J* 2014;**18**:1265–70. https://doi.org/10.1007/s10995-013-1361-3

25. Brunner S, Stecher L, Ziebarth S, Nehring I, Rifas-Shiman SL, Sommer C, *et al.* Excessive gestational weight gain prior to glucose screening and the risk of gestational diabetes: a meta-analysis. *Diabetologia* 2015;**58**:2229–37. https://doi.org/10.1007/s00125-015-3686-5

26. World Health Organization. *Maximising the Gains for Maternal and Child Health*. URL: www.who.int/publications/i/item/WHO-FWC-MCA-13.02 (accessed 13 September 2021).

27. Stephenson J, Heslehurst N, Hall J, Schoenaker DAJM, Hutchinson J, Cade JE, *et al.* Before the beginning: nutrition and lifestyle in the preconception period and its importance for future health. *Lancet* 2018;**391**:1830–41. https://doi.org/10.1016/S0140-6736(18)30311-8

28. Fleming TP, Watkins AJ, Velazquez MA, Mathers JC, Prentice AM, Stephenson J, *et al.* Origins of lifetime health around the time of conception: causes and consequences. *Lancet* 2018;**391**:1842–52. https://doi.org/10.1016/S0140-6736(18)30312-X

29. Barker M, Dombrowski SU, Colbourn T, Fall CHD, Kriznik NM, Lawrence WT, *et al.* Intervention strategies to improve nutrition and health behaviours before conception. *Lancet* 2018;**391**:1853–64. https://doi.org/10.1016/S0140-6736(18)30313-1

30. Stephenson J, Vogel C, Hall J, Hutchinson J, Mann S, Duncan H, *et al.* Preconception health in England: a proposal for annual reporting with core metrics. *Lancet* 2019;**393**:2262–71. https://doi.org/10.1016/S0140-6736(19)30954-7

31. Hill B, Hall J, Skouteris H, Currie S. Defining preconception: exploring the concept of a preconception population. *BMC Pregnancy Childbirth* 2020;**20**:280. https://doi.org/10.1186/s12884-020-02973-1

32. Hill B, Skouteris H, Boyle JA, Bailey C, Walker R, Thangaratinam S, *et al.* Health in Preconception, Pregnancy and Postpartum Global Alliance: international network pregnancy priorities for the prevention of maternal obesity and related pregnancy and long-term complications. *J Clin Med* 2020;**9**:E822. https://doi.org/10.3390/jcm9030822

33. Caut C, Leach M, Steel A. Dietary guideline adherence during preconception and pregnancy: a systematic review. *Matern Child Nutr* 2020;**16**:e12916. https://doi.org/10.1111/mcn.12916

34. Inskip HM, Crozier SR, Godfrey KM, Borland SE, Cooper C, Robinson SM, *et al.* Women's compliance with nutrition and lifestyle recommendations before pregnancy: general population cohort study. *BMJ* 2009;**338**:b481. https://doi.org/10.1136/bmj.b481

35. Stephenson J, Patel D, Barrett G, Howden B, Copas A, Ojukwu O, *et al.* How do women prepare for pregnancy? Preconception experiences of women attending antenatal services and views of health professionals. *PLOS ONE* 2014;**9**:e103085. https://doi.org/10.1371/journal.pone.0103085

36. Hussein N, Kai J, Qureshi N. The effects of preconception interventions on improving reproductive health and pregnancy outcomes in primary care: a systematic review. *Eur J Gen Pract* 2016;**22**:42–52. https://doi.org/10.3109/13814788.2015.1099039

37. Hemsing N, Greaves L, Poole N. Preconception health care interventions: a scoping review. *Sex Reprod Healthc* 2017;**14**:24–32. https://doi.org/10.1016/j.srhc.2017.08.004

38. Delissaint D, McKyer EL. A systematic review of factors utilized in preconception health behavior research. *Health Educ Behav* 2011;**38**:603–16. https://doi.org/10.1177/1090198110389709

39. Ezegwui HU, Dim C, Dim N, Ikeme AC. Preconception care in South Eastern Nigeria. *J Obstet Gynaecol* 2008;**28**:765–8. https://doi.org/10.1080/01443610802462647

40. Wallace M, Hurwitz B. Preconception care: who needs it, who wants it, and how should it be provided? *Br J Gen Pract* 1998;**48**:963–6.

41. Barrett G, Shawe J, Howden B, Patel D, Ojukwu O, Pandya P, Stephenson J. Why do women invest in pre-pregnancy health and care? A qualitative investigation with women attending maternity services. *BMC Pregnancy Childbirth* 2015;**15**:236. https://doi.org/10.1186/s12884-015-0672-3

42. Adams TD, Gress RE, Smith SC, Halverson RC, Simper SC, Rosamond WD, *et al.* Long-term mortality after gastric bypass surgery. *N Engl J Med* 2007;**357**:753–61. https://doi.org/10.1056/NEJMoa066603

43. Cunningham J, Endacott R, Gibbons D. Communication with health professionals: the views of pregnant women with a raised BMI. *Br J Midwifery* 2018;**26**:598–604. https://doi.org/10.12968/bjom.2018.26.9.598

44. Legro RS, Dodson WC, Kris-Etherton PM, Kunselman AR, Stetter CM, Williams NI, *et al.* Randomized controlled trial of preconception interventions in infertile women with polycystic ovary syndrome. *J Clin Endocrinol Metab* 2015;**100**:4048–58. https://doi.org/10.1210/jc.2015-2778

45. Harden SM, Ramalingam NS, Wilson KE, Evans-Hoeker E. Informing the development and uptake of a weight management intervention for preconception: a mixed-methods investigation of patient and provider perceptions. *BMC Obes* 2017;**4**:8. https://doi.org/10.1186/s40608-017-0144-6

46. Opray N, Grivell RM, Deussen AR, Dodd JM. Directed preconception health programs and interventions for improving pregnancy outcomes for women who are overweight or obese. *Cochrane Database Syst Rev* 2015;**7**:CD010932. https://doi.org/10.1002/14651858.CD010932.pub2

47. Furber CM, McGowan L, Bower P, Kontopantelis E, Quenby S, Lavender T. Antenatal interventions for reducing weight in obese women for improving pregnancy outcome. *Cochrane Database Syst Rev* 2013;**1**:CD009334. https://doi.org/10.1002/14651858.CD009334.pub2

48. Lan L, Harrison CL, Misso M, Hill B, Teede HJ, Mol BW, Moran LJ. Systematic review and meta-analysis of the impact of preconception lifestyle interventions on fertility, obstetric, fetal, anthropometric and metabolic outcomes in men and women. *Hum Reprod* 2017;**32**:1925–40. https://doi.org/10.1093/humrep/dex241

49. Weisman CS, Hillemeier MM, Downs DS, Feinberg ME, Chuang CH, Botti JJ, Dyer AM. Improving women's preconceptional health: long-term effects of the Strong Healthy Women behavior change intervention in the central Pennsylvania Women's Health Study. *Womens Health Issues* 2011;**21**:265–71. https://doi.org/10.1016/j.whi.2011.03.007

50. Bandura A. Social cognitive theory. In Vasta R, editor. *Annals of Child Development: Volume 6*. Greenwich, CT: JAI Press; 1989. pp. 1–60.

51. Hutchesson MJ, de Jonge Mulock Houwer M, Brown HM, Lim S, Moran LJ, Vincze L, *et al*. Supporting women of childbearing age in the prevention and treatment of overweight and obesity: a scoping review of randomized control trials of behavioral interventions. *BMC Womens Health* 2020;**20**:14. https://doi.org/10.1186/s12905-020-0882-3

52. LeBlanc ES, Vesco KK, Funk KL, Karanja N, Smith N, Stevens VJ. Prepare, a randomized trial to promote and evaluate weight loss among overweight and obese women planning pregnancy: study design and rationale. *Contemp Clin Trials* 2016;**49**:174–80. https://doi.org/10.1016/j.cct.2016.07.002

53. LeBlanc ES, Smith N, Vesco KK, Paul IM Stevens VJ. Weight loss prior to pregnancy and subsequent gestation weight gain: Prepare, a randomised clinical trial. *Am J Obstet Gynaecol* 2021;**224**:99. https://doi.org/10.1016/j.ajog.2020.07.027

54. Maas VYF, Koster MPH, Ista E, Vanden Auweele KLH, de Bie RWA, de Smit DJ, *et al*. Study design of a stepped wedge cluster randomized controlled trial to evaluate the effect of a locally tailored approach for preconception care – the APROPOS-II study. *BMC Public Health* 2020;**20**:235. https://doi.org/10.1186/s12889-020-8329-1

55. NHS Digital. *Statistics on Obesity, Physical Activity and Diet, England, 2020*. URL: https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-obesity-physical-activity-and-diet/england-2020/part-3-adult-obesity-copy (accessed 11 May 2021).

56. Phelan S. Pregnancy: a 'teachable moment' for weight control and obesity prevention. *Am J Obstet Gynecol* 2010;**202**:135.e1–8. https://doi.org/10.1016/j.ajog.2009.06.008

57. Poels M, Koster MPH, Franx A, van Stel HF. Parental perspectives on the awareness and delivery of preconception care. *BMC Pregnancy Childbirth* 2017;**17**:324. https://doi.org/10.1186/s12884-017-1531-1

58. Callaway LK, O'Callaghan MJ, McIntyre HD. Barriers to addressing overweight and obesity before conception. *Med J Aust* 2009;**191**:425–8.

59. NHS Digital. *Health Survey for England 2019*. URL: https://files.digital.nhs.uk/EF/AB0F0C/HSE17-Adult-Child-BMI-rep-v2.pdf (accessed 11 May 2021).

60. NHS Information Centre. *Health Survey for England 2004: Health of Minority Ethnic Groups*. London: NHS Information Centre, 2006.

61. Gatineau M, Mathrani S. Ethnicity and obesity in the UK. *Perspect Public Health* 2011;**131**:159–60. https://doi.org/10.1177/1757913911412478

62. National Institute for Health and Care Excellence (NICE). *BMI: Preventing Ill Health and Premature Death in Black, Asian and Other Minority Ethnic Groups*. Public Health Guideline [PH46]. London: NICE; 2013. URL: https://www.nice.org.uk/guidance/PH46 (accessed 11 May 2021).

63. Taylor C, Bhavnani V, Zasada M, Ussher M, Bick D, SWAN trial team. Barriers and facilitators to uptake and retention of inner-city ethnically diverse women in a postnatal weight management intervention: a mixed-methods process evaluation within a feasibility trial in England. *BMJ Open* 2020;**10**:e034747. https://doi.org/10.1136/bmjopen-2019-034747

64. Tuomainen H, Cross-Bardell L, Bhoday M, Qureshi N, Kai J. Opportunities and challenges for enhancing preconception health in primary care: qualitative study with women from ethnically diverse communities. *BMJ Open* 2013;**3**:e002977. https://doi.org/10.1136/bmjopen-2013-002977

65. Stotland NE, Gilbert P, Bogetz A, Harper CC, Abrams B, Gerbert B. Preventing excessive weight gain in pregnancy: how do prenatal care providers approach counseling? *J Womens Health* 2010;**19**:807–14. https://doi.org/10.1089/jwh.2009.1462

66. Blackburn M, Stathi A, Keogh E, Eccleston C. Raising the topic of weight in general practice: perspectives of GPs and primary care nurses. *BMJ Open* 2015;**5**:e008546. https://doi.org/10.1136/bmjopen-2015-008546

67. Steel A, Lucke J, Reid R, Adams J. A systematic review of women's and health professional's attitudes and experience of preconception care service delivery. *Fam Pract* 2016;**33**:588–95. https://doi.org/10.1093/fampra/cmw094

68. Keyworth C, Hart J, Armitage CJ, Tully MP. What maximizes the effectiveness and implementation of technology-based interventions to support healthcare professional practice? A systematic literature review. *BMC Med Inform Decis Mak* 2018;**18**:93. https://doi.org/10.1186/s12911-018-0661-3

69. Ajzen I. The theory of planned behaviour. *Organ Behav Hum Decision Proc* 1991;**50**:179–211. https://doi.org/10.1016/0749-5978(91)90020-T

70. Downs DS, Feinberg M, Hillemeier MM, Weisman CS, Chase GA, Chuang CH, *et al.* Design of the Central Pennsylvania Women's Health Study (CePAWHS) strong healthy women intervention: improving preconceptional health. *Matern Child Health J* 2009;**13**:18–28. https://doi.org/10.1007/s10995-008-0323-7

71. Hillemeier MM, Downs DS, Feinberg ME, Weisman CS, Chuang CH, Parrott R, *et al.* Improving women's preconceptional health: findings from a randomized trial of the Strong Healthy Women intervention in the Central Pennsylvania women's health study. *Womens Health Issues* 2008;**18**(Suppl. 6):87–96. https://doi.org/10.1016/j.whi.2008.07.008

72. Materia FT, Smyth JM, Heron KE, Hillemeier M, Feinberg ME, Fonzi P, Symons Downs D. Preconceptional health behavior change in women with overweight and obesity: prototype for SMART strong healthy women intervention. *Mhealth* 2018;**4**:24. https://doi.org/10.21037/mhealth.2018.06.06

73. Bogaerts A, Bijlholt M, Mertens L, Braeken M, Jacobs B, Vandenberghe B, *et al.* Development and field evaluation of the INTER-ACT App, a pregnancy and interpregnancy coaching app to reduce maternal overweight and obesity: mixed methods design. *JMIR Form Res* 2020;**4**:e16090. https://doi.org/10.2196/16090

74. Skau JK, Nordin AB, Cheah JC, Ali R, Zainal R, Aris T, *et al.* A complex behavioural change intervention to reduce the risk of diabetes and prediabetes in the pre-conception period in Malaysia: study protocol for a randomised controlled trial. *Trials* 2016;**17**:215. https://doi.org/10.1186/s13063-016-1345-x

75. Timmermans YEG, van de Kant KDG, Krumeich JSM, Zimmermann LJI, Dompeling E, Kramer BW, *et al.* Socio-ecological determinants of lifestyle behavior of women with overweight or obesity before, during and after pregnancy: qualitative interview analysis in the Netherlands. *BMC Pregnancy Childbirth* 2020;**20**:105. https://doi.org/10.1186/s12884-020-2786-5

76. ClinicalTrials.gov. *Healthy for My Baby – RCT of a Lifestyle Intervention for Overweight Women in Preconception*. URL: https://clinicaltrials.gov/ct2/show/NCT04242069 (accessed 1 May 2021).

77. Gould Rothberg BE, Magriples U, Kershaw TS, Rising SS, Ickovics JR. Gestational weight gain and subsequent postpartum weight loss among young, low-income, ethnic minority women. *Am J Obstet Gynecol* 2011;**204**:52.e1 –11. https://doi.org/10.1016/j.ajog.2010.08.028

78. ClinicalTrials.gov. *Preconception and Pregnancy Obesity Treatment and Prevention Among Women With a History of Depression*. 2017. URL: https://clinicaltrials.gov/ct2/show/NCT03053323 (accessed 9 May 2021).

79. Phelan S, Jelalian E, Coustan D, Caughey AB, Castorino K, Hagobian T, *et al.* Protocol for a randomized controlled trial of pre-pregnancy lifestyle intervention to reduce recurrence of gestational diabetes: Gestational Diabetes Prevention/Prevención de la Diabetes Gestacional. *Trials* 2021;**22**:256. https://doi.org/10.1186/s13063-021-05204-w

80. Brackenridge L, Finer N, Batterham RL, Pedram K, Ding T, Stephenson J, *et al.* Pre-pregnancy weight loss in women with obesity requesting removal of their intra-uterine contraceptive device in order to conceive: a pilot study of full meal replacement. *Clin Obes* 2018;**8**:244–9. https://doi.org/10.1111/cob.12252

81. Arrowsmith ME, Majeed A, Lee JT, Saxena S Impact of pay for performance on prescribing of long-acting reversible contraception in primary care: an interrupted time series study. *PLOS ONE* 2014;**9**:e92205. https://doi.org/10.1371/journal.pone.0092205

82. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655. https://doi.org/10.1136/bmj.a1655

83. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, *et al.* Guidance on how to develop complex interventions to improve health and healthcare. *BMJ Open* 2019;**9**:e029954. https://doi.org/10.1136/bmjopen-2019-029954

84. Pawson R, Tilley N. *Realistic Evaluation*. London: SAGE Publications Ltd; 1997.

85. *General Data Protection Regulation*. URL: https://gdpr-info.eu/ (accessed 11 May 2021).

86. Pawson R. *The Science of Evaluation: A Realist Manifesto*. London: SAGE Publications Ltd; 2013. https://doi.org/10.4135/9781473913820

87. Herrett E, Gallagher AM, Bhaskaran K, Forbes H, Mathur R, van Staa T, Smeeth L. Data Resource Profile: Clinical Practice Research Datalink (CPRD). *Int J Epidemiol* 2015;**44**:827–36. https://doi.org/10.1093/ije/dyv098

88. Minassian C, Williams R, Meeraus WH, Smeeth L, Campbell OMR, Thomas SL. Methods to generate and validate a Pregnancy Register in the UK Clinical Practice Research Datalink primary care database. *Pharmacoepidemiol Drug Saf* 2019;**28**:923–33. https://doi.org/10.1002/pds.4811

89. NES Digital Service. URL: www.nationaldigitalplatform.scot (accessed May 2021).

90. NHS Digital. *Sexual and Reproductive Health Services, England (Contraception) 2019/20*. URL: https://digital.nhs.uk/data-and-information/publications/statistical/sexual-and-reproductive-health-services/2019-20 (accessed 9 May 2021).

91. Channon S, Coulman E, Cannings-John R, Henley J, Lau M, Lugg-Widger F, *et al.* The acceptability of asking women to delay removal of a long-acting reversible contraceptive to take part in a preconception weight loss programme: a mixed methods study using qualitative and routine data (Plan-it). *BMC Pregnancy Childbirth* 2022;**22**:778.

92. Bhaskaran K, Forbes HJ, Douglas I, Leon DA, Smeeth L. Representativeness and optimal use of body mass index (BMI) in the UK Clinical Practice Research Datalink (CPRD). *BMJ Open* 2013;**3**:e003389. https://doi.org/10.1136/bmjopen-2013-003389

93. Cea Soriano L, Wallander MA, Andersson S, Filonenko A, García Rodríguez LA. The continuation rates of long-acting reversible contraceptives in UK general practice using data from The Health Improvement Network. *Pharmacoepidemiol Drug Saf* 2015;**24**:52–8. https://doi.org/10.1002/pds.3710

94. RECORD. *What is RECORD?* URL: www.record-statement.org/ (accessed 9 April 2021).

95. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. *Qual Health Res* 2016;**26**:1753–60. https://doi.org/10.1177/1049732315617444

96. Healthwise Wales. URL www.healthwisewales.gov.wales (accessed 9 April 2021).

97. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101. https://doi.org/10.1191/1478088706qp063oa

98. Denison FC, Aedla NR, Keag O, Hor K, Reynolds RM, Milne A, *et al.* Care of Women with Obesity in Pregnancy: Green-top Guideline No. 72. *BJOG* 2019;**126**:e62–e106. https://doi.org/10.1111/1471-0528.15386

99. Faculty of Sexual and Reproductive Healthcare (FSRH). *FSRH Clinical Guideline: Intrauterine Contraception*. London: FSRH; 2015 (amended 2019).

100. Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Unit. *Provision of LARC Methods to Young Women in the UK: CEU Statement*. London: FSRH; 2015.

101. Royal College of Obstetrician and Gyneacologists. *RCOG Co-launches New Digital Tool to Help Prepare Women for Pregnancy*. URL: www.rcog.org.uk/en/news/rcog-co-launches-new-digital-tool-to-help-prepare-women-for-pregnancy/ (accessed 28 April 2021).

102. Jackson SF, Kolla G. A new realistic evaluation analysis method: linked coding of context, mechanism, and outcome relationships. *Am J Eval* 2012;**33**:339–49. https://doi.org/10.1177/1098214012440030

103. Pawson R. *Evidence-based Policy: A Realist Perspective*. London: SAGE Publications Ltd; 2006. https://doi.org/10.4135/9781849209120

104. Byng R, Norman I, Redfern S. Using realistic evaluation to evaluate a practice-level intervention to improve primary healthcare for patients with long-term mental illness. *Evaluation* 2005;**11**:69–93. https://doi.org/10.1177/1356389005053198

105. Pearson M, Brand SL, Quinn C, Shaw J, Maguire M, Michie S, *et al.* Using realist review to inform intervention development: methodological illustration and conceptual platform for collaborative care in offender mental health. *Implement Sci* 2015;**10**:134. https://doi.org/10.1186/s13012-015-0321-2

106. Kislov R, Pope C, Martin GP, Wilson PM. Harnessing the power of theorising in implementation science. *Implement Sci* 2019;**14**:103. https://doi.org/10.1186/s13012-019-0957-4

107. Booth A, Carroll C. Systematic searching for theory to inform systematic reviews: is it feasible? Is it desirable? *Health Info Libr J* 2015;**32**:220–35. https://doi.org/10.1111/hir.12108

108. Truiett-Theodorson R, Tuck S, Bowie JV, Summers AC, Kelber-Kaye J. Building effective partnerships to improve birth outcomes by reducing obesity: the B'more Fit for healthy babies coalition of Baltimore. *Eval Program Plann* 2015;**51**:53–8. https://doi.org/10.1016/j.evalprogplan.2014.12.007

109. Liang L, Bernhardsson S, Vernooij RW, Armstrong MJ, Bussières A, Brouwers MC, *et al.* Use of theory to plan or evaluate guideline implementation among physicians: a scoping review. *Implement Sci* 2017;**12**:26. https://doi.org/10.1186/s13012-017-0557-0

110. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;**6**:42. https://doi.org/10.1186/1748-5908-6-42

111. Vesco KK, Karanja N, King JC, Gillman MW, Leo MC, Perrin N, *et al.* Efficacy of a group-based dietary intervention for limiting gestational weight gain among obese women: a randomized trial. *Obesity* 2014;**22**:1989–96. https://doi.org/10.1002/oby.20831

112. Hanson M, Barker M, Dodd JM, Kumanyika S, Norris S, Steegers E, *et al.* Interventions to prevent maternal obesity before conception, during pregnancy, and post partum. *Lancet Diabetes Endocrinol* 2017;**5**:65–76. https://doi.org/10.1016/S2213-8587(16)30108-5

113. May C, Finch T. Implementing, embedding, and integrating practices: an outline of normalization process theory. *Sociology* 2009;**43**:535–54. https://doi.org/10.1177/0038038509103208

114. Ryan RM, Deci EL. Intrinsic and extrinsic motivations: classic definitions and new directions. *Contemp Educ Psychol* 2000;**25**:54–67. https://doi.org/10.1006/ceps.1999.1020

115. Bandura A, National Institute of Mental Health. *Prentice-Hall Series in Social Learning Theory. Social Foundations of Thought and Action: A Social Cognitive Theory*. Hoboken, NJ: Prentice-Hall; 1986.

116. Redman LM, Gilmore LA, Breaux J, Thomas DM, Elkind-Hirsch K, Stewart T, *et al.* Effectiveness of SmartMoms, a novel eHealth intervention for management of gestational weight gain: randomized controlled pilot trial. *JMIR Mhealth Uhealth* 2017;**5**:e133. https://doi.org/10.2196/mhealth.8228

117. Harrison CL, Brown WJ, Hayman M, Moran LJ, Redman LM. The role of physical activity in preconception, pregnancy and postpartum health. *Semin Reprod Med* 2016;**34**:e28–37. https://doi.org/10.1055/s-0036-1583530

118. Poston L, Bell R, Croker H, Flynn AC, Godfrey KM, Goff L, *et al.* Effect of a behavioural intervention in obese pregnant women (the UPBEAT study): a multicentre, randomised controlled trial. *Lancet Diabetes Endocrinol* 2015;**3**:767–77. https://doi.org/10.1016/S2213-8587(15)00227-2

119. Brofenbrenner U. *The Ecology of Human Development*. Cambridge, MA: Harvard University Press; 1979.

120. Hill B. Expanding our understanding and use of the ecological systems theory model for the prevention of maternal obesity: a new socioecological framework. *Obes Rev* 2021;**22**:e13147. https://doi.org/10.1111/obr.13147

121. Shove E, Pantzar M, Watson M. *The Dynamics of Social Practice: Everyday Life and How it Changes*. London: SAGE Publications Ltd; 2012. https://doi.org/10.4135/9781446250655

122. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A, on behalf of the 'Psychological Theory' Group. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Qual Saf Health Care* 2005;**14**:26–33. https://doi.org/10.1136/qshc.2004.011155

123. Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983;**51**:390–5. https://doi.org/10.1037/0022-006x.51.3.390

124. Ockhuijsen HD, Gamel CJ, van den Hoogen A, Macklon NS. Integrating preconceptional care into an IVF programme. *J Adv Nurs* 2012;**68**:1156–65. https://doi.org/10.1111/j.1365-2648.2011.05829.x

125. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* 2012;**7**:37. https://doi.org/10.1186/1748-5908-7-37

126. Cowdell F, Dyson J. How is the theoretical domains framework applied to developing health behaviour interventions? A systematic search and narrative synthesis. *BMC Public Health* 2019;**19**:1180. https://doi.org/10.1186/s12889-019-7442-5

127. van der Zee B, de Beaufort ID, Steegers EA, Denktas S. Perceptions of preconception counselling among women planning a pregnancy: a qualitative study. *Fam Pract* 2013;**30**:341–6. https://doi.org/10.1093/fampra/cms074

128. Squiers L, Mitchell EW, Levis DM, Lynch M, Dolina S, Margolis M, *et al.* Consumers' perceptions of preconception health. *Am J Health Promot* 2013;**27**(Suppl. 3):10–19. https://doi.org/10.4278/ajhp.120217-QUAL-95

129. Lang AY, Hall JA, Boyle JA, Harrison CL, Teede H, Moran LJ, Barrett G. Validation of the London Measure of Unplanned Pregnancy among pregnant Australian women. *PLOS ONE* 2019;**14**:e0220774. https://doi.org/10.1371/journal.pone.0220774

130. Shawe J, Patel D, Joy M, Howden B, Barrett G, Stephenson J. Preparation for fatherhood: a survey of men's preconception health knowledge and behaviour in England. *PLOS ONE* 2019;**14**:e0213897. https://doi.org/10.1371/journal.pone.0213897

131. Goossens J, De Roose M, Van Hecke A, Goemaes R, Verhaeghe S, Beeckman D. Barriers and facilitators to the provision of preconception care by healthcare providers: a systematic review. *Int J Nurs Stud* 2018;**87**:113–30. https://doi.org/10.1016/j.ijnurstu.2018.06.009

132. Bortolus R, Oprandi NC, Morassutti FR, Marchetto L, Filippini F, Tozzi AE, *et al.* Why women do not ask for information on preconception health? A qualitative study. *BMC Pregnancy Childbirth* 2017;**17**. https://doi.org/10.1186/s12884-016-1198-z

133. Norris SA, Ho JC, Rashed AA, Vinding V, Skau JK, Biesma R, *et al.* Pre-pregnancy community-based intervention for couples in Malaysia: application of intervention mapping. *BMC Public Health* 2016;**16**:1167. https://doi.org/10.1186/s12889-016-3827-x

134. Greenhalgh T, Clinch M, Afsar N, Choudhury Y, Sudra R, Campbell-Richards D, *et al.* Socio-cultural influences on the behaviour of South Asian women with diabetes in pregnancy: qualitative study using a multi-level theoretical approach. *BMC Med* 2015;**13**:120. https://doi.org/10.1186/s12916-015-0360-1

135. Willcox JC, van der Pligt P, Ball K, Wilkinson SA, Lappas M, McCarthy EA, Campbell KJ. Views of women and health professionals on mHealth lifestyle interventions in pregnancy: a qualitative investigation. *JMIR Mhealth Uhealth* 2015;**3**:e99. https://doi.org/10.2196/mhealth.4869

136. McBride N, Carruthers S, Hutchinson D. Reducing alcohol use during pregnancy: listening to women who drink as an intervention starting point. *Glob Health Promot* 2012;**19**:6–18. https://doi.org/10.1177/1757975912441225

137. Rönö K, Stach-Lempinen B, Eriksson JG, Pöyhönen-Alho M, Klemetti MM, Roine RP, *et al.* Prevention of gestational diabetes with a prepregnancy lifestyle intervention – findings from a randomized controlled trial. *Int J Womens Health* 2018;**10**:493–501. https://doi.org/10.2147/IJWH.S162061

138. Van Dijk MR, Koster MP, Rosman AN, Steegers-Theunissen RP. Opportunities of mHealth in preconception care: preferences and experiences of patients and health care providers and other involved professionals. *JMIR Mhealth Uhealth* 2017;**5**:e123. https://doi.org/10.2196/mhealth.7834

139. Toivonen KI, Oinonen KA, Duchene KM. Preconception health behaviours: a scoping review. *Prev Med* 2017;**96**:1–15. https://doi.org/10.1016/j.ypmed.2016.11.022

140. Flannery C, Fredrix M, Olander EK, McAuliffe FM, Byrne M, Kearney PM. Effectiveness of physical activity interventions for overweight and obesity during pregnancy: a systematic review of the content of behaviour change interventions. *Int J Behav Nutr Phys Act* 2019;**16**:97. https://doi.org/10.1186/s12966-019-0859-5

141. Harelick L, Viola D, Tahara D. Preconception health of low socioeconomic status women: assessing knowledge and behaviors. *Womens Health Issues* 2011;**21**:272–6. https://doi.org/10.1016/j.whi.2011.03.006

142. Heslehurst N, Newham J, Maniatopoulos G, Fleetwood C, Robalino S, Rankin J. Implementation of pregnancy weight management and obesity guidelines: a meta-synthesis of healthcare professionals' barriers and facilitators using the Theoretical Domains Framework. *Obes Rev* 2014;**15**:462–86. https://doi.org/10.1111/obr.12160

143. Keyworth C, Epton T, Goldthorpe J, Calam R, Armitage CJ. Delivering opportunistic behaviour change interventions: a systematic review of systematic reviews. *Prev Sci* 2020;**21**:319–31. https://doi.org/10.1007/s11121-020-01087-6

144. Khan NN, Boyle JA, Lang AY, Harrison CL. Preconception health attitudes and behaviours of women: a qualitative investigation. *Nutrients* 2019;**11**:E1490. https://doi.org/10.3390/nu11071490

145. Sim KA, Dezarnaulds GM, Denyer GS, Skilton MR, Caterson ID. Weight loss improves reproductive outcomes in obese women undergoing fertility treatment: a randomized controlled trial. *Clin Obes* 2014;**4**:61–8. https://doi.org/10.1111/cob.12048

146. Rothberg A, Lanham M, Randolph J, Fowler C, Miller N, Smith Y. Feasibility of a brief, intensive weight loss intervention to improve reproductive outcomes in obese, subfertile women: a pilot study. *Fertil Steril* 2016;**106**:1212–20. https://doi.org/10.1016/j.fertnstert.2016.06.004

147. Legro RS, Dodson WC, Kunselman AR, Stetter CM, Kris-Etherton PM, Williams NI, *et al.* Benefit of delayed fertility therapy with preconception weight loss over immediate therapy in obese women with PCOS. *J Clin Endocrinol Metab* 2016;**101**:2658–66. https://doi.org/10.1210/jc.2016-1659

148. Becker GF, Passos EP, Moulin CC. Short-term effects of a hypocaloric diet with low glycemic index and low glycemic load on body adiposity, metabolic variables, ghrelin, leptin, and pregnancy rate in overweight and obese infertile women: a randomized controlled trial. *Am J Clin Nutr* 2015;**102**:1365–72. https://doi.org/10.3945/ajcn.115.117200

149. Espinós JJ, Polo A, Sánchez-Hernández J, Bordas R, Pares P, Martínez O, Calaf J. Weight decrease improves live birth rates in obese women undergoing IVF: a pilot study. *Reprod Biomed Online* 2017;**35**:417–24. https://doi.org/10.1016/j.rbmo.2017.06.019

150. Mutsaerts MA, van Oers AM, Groen H, Burggraaff JM, Kuchenbecker WK, Perquin DA, *et al.* Randomized trial of a lifestyle program in obese infertile women. *N Engl J Med* 2016;**374**:1942–53. https://doi.org/10.1056/NEJMoa1505297

151. Yumuk V, Tsigos C, Fried M, Schindler K, Busetto L, Micic D, Toplak H. European guidelines for obesity management in adults. *Obes Facts* 2015;**8**:402–24. https://doi.org/10.1159/000442721

152. van Dammen L, Wekker V, van Oers AM, Mutsaerts MAQ, Painter RC, Zwinderman AH, *et al.* Effect of a lifestyle intervention in obese infertile women on cardiometabolic health and quality of life: a randomized controlled trial. *PLOS ONE* 2018;**13**:e0190662. https://doi.org/10.1371/journal.pone.0190662

153. McGirr C, Dombrowski S, Holmes V, McKinley M. What behaviour change techniques are associated with effectiveness of weight management interventions? A systematic review of systematic reviews. *Proc Nutr Soc* 2017;**76**(OCE3):E92. https://doi.org/10.1017/S0029665117001653

154. Hill B, Skouteris H, Fuller-Tyszkiewicz M. Interventions designed to limit gestational weight gain: a systematic review of theory and meta-analysis of intervention components. *Obes Rev* 2013;**14**:435–50. https://doi.org/10.1111/obr.12022

155. Madigan CD, Daley AJ, Kabir E, Aveyard P, Brown W. Cluster analysis of behavioural weight management strategies and associations with weight change in young women: a longitudinal analysis. *Int J Obes* 2015;**39**:1601–6. https://doi.org/10.1038/ijo.2015.116

156. Sanders J, Channon S, Cannings-John R, Coulman E, Hunter B, Paranjothy S, *et al.* Pregnancy and weight monitoring: a feasibility study of weight charts and midwife support. *Matern Child Nutr* 2020;**16**:e12996. https://doi.org/10.1111/mcn.12996

157. Carey RN, Connell LE, Johnston M, Rothman AJ, de Bruin M, Kelly MP, Michie S. Behavior change techniques and their mechanisms of action: a synthesis of links described in published intervention literature. *Ann Behav Med* 2019;**53**:693–707. https://doi.org/10.1111/mcn.12996https://doi.org/10.1093/abm/kay078

158. Miller W, Rollnick S. *Motivational Interviewing. Helping People Change*. 3rd edn. New York, NY: Guildford Press; 2013.

159. Muktabhant B, Lawrie TA, Lumbiganon P, Laopaiboon M. Diet or exercise, or both, for preventing excessive weight gain in pregnancy. *Cochrane Database Syst Rev* 2015;**6**:CD007145. https://doi.org/10.1002/14651858.CD007145.pub3

160. M'hamdi HI, van Voorst SF, Pinxten W, Hilhorst MT, Steegers EA. Barriers in the uptake and delivery of preconception care: exploring the views of care providers. *Matern Child Health J* 2017;**21**:21–8. https://doi.org/10.1007/s10995-016-2089-7

161. Mazza D, Chapman A, Michie S. Barriers to the implementation of preconception care guidelines as perceived by general practitioners: a qualitative study. *BMC Health Serv Res* 2013;**13**:36. https://doi.org/10.1186/1472-6963-13-36

162. Bull F, Willumsen J. Evidence to prevent childhood obesity: the continuum of preconception, pregnancy, and postnatal interventions. *Obes Rev* 2019;**20**(Suppl. 1):3–4. https://doi.org/10.1111/obr.12844

163. Joint Formulary Committee. *British National Formulary*. 76 ed. London: BMJ Group and Pharmaceutical Press; 2008.

164. NHS Digital. *Sexual and Reproductive Health Services – England, 2014/15 to 2018/19*. URL: https://digital.nhs.uk/data-and-information/publications/statistical/sexual-and-reproductive-health-services (accessed 2 August 2022).

165. Public Health Scotland. *Data Tables: Long Acting Reversible Methods of Contraception (LARC) in Scotland*. URL: www.isdscotland.org/Health-Topics/Sexual-Health/Publications/data-tables2017.asp?id=2488#2488 (accessed 12 May 2021).

166. Office for National Statistics. *Population by Index of Multiple Deprivation Decile, England, 2001 to 2016*. 2018. URL: www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/adhocs/008868populationbyindexofmultipledeprivationdecileengland2001to2016 (accessed 13 July 2022).

167. Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Unit. *FSRH CEU Statement: Contraception and Weight Gain*. London: FSRH; 2019.

168. Faculty of Sexual and Reproductive Healthcare (FSRH). *FSRH Clinical Guideline: Contraception for Women Aged over 40 Years*. London: FSRH; 2017 (updated 2019).

169. Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Unit. *Contraception for Women with Eating Disorders: CEU Statement*. London: FSRH; 2018.

170. Faculty of Sexual and Reproductive Healthcare (FSRH). *FSRH Clinical Guideline: Contraception After Pregnancy*. London: FSRH; 2017 (updated 2020).

171. Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Unit. *FSRH Clinical Guideline: Progestogen-only Implant*. London: FSRH, 2014.

172. Faculty of Sexual and Reproductive Healthcare (FSRH). *FSRH Clinical Guideline: Overweight, Obesity and Contraception*. London: FSRH; 2019.

173. National Institute for Health and Care Excellence (NICE). *Long-acting Reversible Contraception*. Clinical Guideline [CG30]. London: NICE; 2005 (updated 2019).

174. British Pregnancy Advisory Service. *Women Cannot Control Fertility Through Contraception Alone*. URL: www.bpas.org/about-our-charity/press-office/press-releases/women-cannot-control-fertility-through-contraception-alone-bpas-data-shows-1-in-4-women-having-an-abortion-were-using-most-effective-contraception/ (accessed 28 April 2021).

175. Shawe J, Delbaere I, Ekstrand M, Hegaard HK, Larsson M, Mastroiacovo P, *et al.* Preconception care policy, guidelines, recommendations and services across six European countries: Belgium (Flanders), Denmark, Italy, the Netherlands, Sweden and the United Kingdom. *Eur J Contracept Reprod Health Care* 2015;**20**:77–87. https://doi.org/10.3109/13625187.2014.990088

176. Kothe E, Bailey C, Weiner C, Nagle C, Nowson C, Hill B, *et al.* An investigation of Australian midwifery curricula for obesity management and health behaviour change training. *Nurse Educ Pract* 2019;**36**:54–7. https://doi.org/10.1016/j.nepr.2019.03.003

177. Musgrave LM, Homer CSE, Kizirian NV, Gordon A. Addressing preconception behaviour change through mobile phone apps: a protocol for a systematic review and meta-analysis. *Syst Rev* 2019;**8**:86. https://doi.org/10.1186/s13643-019-0996-6

178. Brown HK, Mueller M, Edwards S, Mill C, Enders J, Graves L, *et al.* Preconception health interventions delivered in public health and community settings: a systematic review. *Can J Public Health* 2017;**108**:e388–e397. https://doi.org/10.17269/cjph.108.6029

179. Agricola E, Pandolfi E, Gonfiantini MV, Gesualdo F, Romano M, Carloni E, *et al.* A cohort study of a tailored web intervention for preconception care. *BMC Med Inform Decis Mak* 2014;**14**:33. https://doi.org/10.1186/1472-6947-14-33

180. Schwarz EB, Sobota M, Gonzales R, Gerbert B. Computerized counseling for folate knowledge and use: a randomized controlled trial. *Am J Prev Med* 2008;**35**:568–71. https://doi.org/10.1016/j.amepre.2008.06.034

181. Chan A, Pickering J, Haan E, Netting M, Burford A, Johnson A, Keane RJ. 'Folate before pregnancy': the impact on women and health professionals of a population-based health promotion campaign in South Australia. *Med J Aust* 2001;**174**:631–6. https://doi.org/10.5694/j.1326-5377.2001.tb143471.x

182. DeJoy SB. Pilot test of a preconception and midwifery care promotion program for college women. *J Midwifery Womens Health* 2014;**59**:523–7. https://doi.org/10.1111/jmwh.12106

183. Hussaini KS, Hamm E, Means T. Using community-based participatory mixed methods research to understand preconception health in African American communities of Arizona. *Matern Child Health J* 2013;**17**:1862–71. https://doi.org/10.1007/s10995-012-1206-5

184. Whitehill King K, Freimuth V, Lee M, Johnson-Turbes CA. The effectiveness of bundled health messages on recall. *Am J Health Promot* 2013;**27**(Suppl. 3):28–35. https://doi.org/10.4278/ajhp.120113-QUAN-27

185. Mackert M, Kim E, Guadagmo M, Donovan-Kicken E. Using Twitter for prenatal health promotion: encouraging a multivitamin habit among college-aged females. *Stud Health Technol Inform* 2012;**182**:93–103.

186. Milan JE, White AA. Impact of a stage-tailored, web-based intervention on folic acid-containing multivitamin use by college women. *Am J Health Promot* 2010;**24**:388–95. https://doi.org/10.4278/ajhp.071231143

187. Wade GH, Herrman J, McBeth-Snyder L. A preconception care program for women in a college setting. *MCN Am J Matern Child Nurs* 2012;**37**:164–70. https://doi.org/10.1097/NMC.0b013e31824b59c7

188. Watson M, Watson L, Bell R, Halliday J. The increasing knowledge of the role of periconceptional folate in Victorian women of child-bearing age: follow-up of a randomized community intervention trial. *Aust N Z J Public Health* 2001;**25**:389–95. https://doi.org/10.1111/j.1467-842X.2001.tb00280.x

189. Williams P, McHenery J, McMahon A, Anderson H. Impact evaluation of a folate education campaign with and without the use of a health claim. *Aust N Z J Public Health* 2001;**25**:396–404. https://doi.org/10.1111/j.1467-842X.2001.tb00281.x

190. Beckmann MM, Widmer T, Bolton E. Does preconception care work? *Aus N Z J Obstetrics Gynaecol* 2014;**54**:510–14. https://doi.org/10.1111/ajo.12224

191. Mutsaerts MA, Groen H, ter Bogt NC, Bolster JH, Land JA, Bemelmans WJ, *et al.* The LIFESTYLE study: costs and effects of a structured lifestyle program in overweight and obese subfertile women to reduce the need for fertility treatment and improve reproductive outcome. A randomised controlled trial. *BMC Womens Health* 2010;**10**:22. https://doi.org/10.1186/1472-6874-10-22

192. Moran L, Tsagareli V, Norman R, Noakes M. Diet and IVF pilot study: short-term weight loss improves pregnancy rates in overweight/obese women undertaking IVF. *Aust N Z J Obstet Gynaecol* 2011;**51**:455–9. https://doi.org/10.1111/j.1479-828X.2011.01343.x

193. Barker M, Baird J, Lawrence W, Jarman M, Black C, Barnard K, *et al.* The Southampton Initiative for Health: a complex intervention to improve the diets and increase the physical activity levels of women from disadvantaged communities. *J Health Psychol* 2011;**16**:178–91. https://doi.org/10.1177/1359105310371397

194. Brofenbrenner U. *The Ecology of Human Development*. Cambridge, MA: Harvard University Press; 1979.

195. Hill B, McPhie S, Fuller-Tyszkiewicz M, Gillman MW, Skouteris H. Psychological health and lifestyle management preconception and in pregnancy. *Semin Reprod Med* 2016;**34**:121–8. https://doi.org/10.1055/s-0036-1571352

196. Hillemeier MM, Domino ME, Wells R, Goyal RK, Kum HC, Cilenti D, *et al.* Effects of maternity care coordination on pregnancy outcomes: propensity-weighted analyses. *Matern Child Health J* 2015;**19**:121–7. https://doi.org/10.1007/s10995-014-1502-3

197. Forsum E, Brantsæter AL, Olafsdottir A, Olsen S, Thorsdottir I. Weight loss before conception: a systematic literature review. *Food Nutrition Res* 2013;**57**:1. https://doi.org/10.3402/fnr.v57i0.20522

198. Bogaerts AF, Devlieger R, Nuyts E, Witters I, Gyselaers W, Van den Bergh BR. Effects of lifestyle intervention in obese pregnant women on gestational weight gain and mental health: a randomized controlled trial. *Int J Obes* 2013;**37**:814–21. https://doi.org/10.1038/ijo.2012.162

199. Dodd JM, McPhee AJ, Turnbull D, Yelland LN, Deussen AR, Grivell RM, *et al.* The effects of antenatal dietary and lifestyle advice for women who are overweight or obese on neonatal health outcomes: the LIMIT randomised trial. *BMC Med* 2014;**12**:163. https://doi.org/10.1186/s12916-014-0163-9

200. Dodd JM, Cramp C, Sui Z, Yelland LN, Deussen AR, Grivell RM, *et al.* The effects of antenatal dietary and lifestyle advice for women who are overweight or obese on maternal diet and physical activity: the LIMIT randomised trial. *BMC Med* 2014;**12**:161. https://doi.org/10.1186/s12916-014-0161-y

201. Dodd JM, Turnbull DA, McPhee AJ, Wittert G, Crowther CA, Robinson JS. Limiting weight gain in overweight and obese women during pregnancy to improve health outcomes: the LIMIT randomised controlled trial. *BMC Pregnancy Childbirth* 2011;**11**:79. https://doi.org/10.1186/1471-2393-11-79

202. Grivell RM, Yelland LN, Deussen A, Crowther CA, Dodd JM. Antenatal dietary and lifestyle advice for women who are overweight or obese and the effect on fetal growth and adiposity: the LIMIT randomised trial. *BJOG* 2016;**123**:233–43. https://doi.org/10.1111/1471-0528.13777

203. Szmeja MA, Cramp C, Grivell RM, Deussen AR, Yelland LN, Dodd JM. Use of a DVD to provide dietary and lifestyle information to pregnant women who are overweight or obese: a nested randomised trial. *BMC Pregnancy Childbirth* 2014;**14**:409. https://doi.org/10.1186/s12884-014-0409-8

204. Dodd JM, Ahmed S, Karnon J, Umberger W, Deussen AR, Tran T, *et al.* The cost-effectiveness of providing antenatal lifestyle advice for women who are overweight or obese: the LIMIT randomised trial. *BMC Obes* 2015;**2**:14. https://doi.org/10.1186/s40608-015-0046-4

205. Dodd JM, Newman A, Moran LJ, Deussen AR, Grivell RM, Yelland LN, *et al.* The effect of antenatal dietary and lifestyle advice for women who are overweight or obese on emotional well-being: the LIMIT randomized trial. *Acta Obstet Gynecol Scand* 2016;**95**:309–18. https://doi.org/10.1111/aogs.12832

206. Harrison CL, Lombard CB, Strauss BJ, Teede HJ. Optimizing healthy gestational weight gain in women at high risk of gestational diabetes: a randomized controlled trial. *Obesity* 2013;**21**:904–9. https://doi.org/10.1002/oby.20163

207. Hawkins M, Hosker M, Marcus BH, Rosal MC, Braun B, Stanek EJ, *et al.* A pregnancy lifestyle intervention to prevent gestational diabetes risk factors in overweight Hispanic women: a feasibility randomized controlled trial. *Diabet Med* 2015;**32**:108–15. https://doi.org/10.1111/dme.12601

208. Petrella E, Malavolti M, Bertarini V, Pignatti L, Neri I, Battistini NC, Facchinetti F. Gestational weight gain in overweight and obese women enrolled in a healthy lifestyle and eating habits program. *J Matern Fetal Neonatal Med* 2014;**27**:1348–52. https://doi.org/10.3109/14767058.2013.858318

209. Briley AL, Barr S, Badger S, Bell R, Croker H, Godfrey KM, *et al.* A complex intervention to improve pregnancy outcome in obese women; the UPBEAT randomised controlled trial. *BMC Pregnancy Childbirth* 2014;**14**:74. https://doi.org/10.1186/1471-2393-14-74

210. Flynn AC, Schneeberger C, Seed PT, Barr S, Poston L, Goff LM, *et al.* The Effects of the UK Pregnancies Better Eating and Activity Trial Intervention on dietary patterns in obese pregnant women participating in a pilot randomized controlled trial. *Nutr Metabol Insights* 2015;**8**(Suppl. 1):79–86. https://doi.org/10.4137/NMI.S29529

211. Poston L, Briley AL, Barr S, Bell R, Croker H, Coxon K, *et al.* Developing a complex intervention for diet and activity behaviour change in obese pregnant women (the UPBEAT trial); assessment of behavioural change and process evaluation in a pilot randomised controlled trial. *BMC Pregnancy Childbirth* 2013;**13**:148. https://doi.org/10.1186/1471-2393-13-148

212. Gardner B, Croker H, Barr S, Briley A, Poston L, Wardle J, on behalf of the UPBEAT Trial. Psychological predictors of dietary intentions in pregnancy. *J Hum Nutr Diet* 2012;**25**:345–53. https://doi.org/10.1111/j.1365-277X.2012.01239.x

213. Maitland RA, Seed PT, Briley AL, Homsy M, Thomas S, Pasupathy D, *et al.* Prediction of gestational diabetes in obese pregnant women from the UK Pregnancies Better Eating and Activity (UPBEAT) pilot trial. *Diabet Med* 2014;**31**:963–70. https://doi.org/10.1111/dme.12482

214. Flynn AC, Seed PT, Patel N, Barr S, Bell R, Briley AL, *et al.* Dietary patterns in obese pregnant women; influence of a behavioral intervention of diet and physical activity in the UPBEAT randomized controlled trial. *Int J Behav Nutr Phys Act* 2016;**13**:124. https://doi.org/10.1186/s12966-016-0450-2

215. Patel N, Godfrey KM, Pasupathy D, Levin J, Flynn AC, Hayes L, *et al.* Infant adiposity following a randomised controlled trial of a behavioural intervention in obese pregnancy. *Int J Obes* 2017;**41**:1018–26. https://doi.org/10.1038/ijo.2017.44

216. Quinlivan JA, Lam LT, Fisher J. A randomised trial of a four-step multidisciplinary approach to the antenatal care of obese pregnant women. *Aust N Z J Obstet Gynaecol* 2011;**51**:141–6. https://doi.org/10.1111/j.1479-828X.2010.01268.x

217. Renault KM, Nørgaard K, Nilas L, Carlsen EM, Cortes D, Pryds O, Secher NJ. The Treatment of Obese Pregnant Women (TOP) study: a randomized controlled trial of the effect of physical activity intervention assessed by pedometer with or without dietary intervention in obese pregnant women. *Am J Obstet Gynecol* 2014;**210**:134.e1–9. https://doi.org/10.1016/j.ajog.2013.09.029

218. Vesco KK, Karanja N, King JC, Gillman MW, Perrin N, McEvoy C, *et al.* Healthy Moms, a randomized trial to promote and evaluate weight maintenance among obese pregnant women: study design and rationale. *Contemp Clin Trials* 2012;**33**:777–85. https://doi.org/10.1016/j.cct.2012.03.006

219. Vinter CA, Jensen DM, Ovesen P, Beck-Nielsen H, Jørgensen JS. The LiP (Lifestyle in Pregnancy) study: a randomized controlled trial of lifestyle intervention in 360 obese pregnant women. *Diabetes Care* 2011;**34**:2502–7. https://doi.org/10.2337/dc11-1150

220. Vinter CA, Jensen DM, Ovesen P, Beck-Nielsen H, Tanvig M, Lamont RF, Jørgensen JS. Postpartum weight retention and breastfeeding among obese women from the randomized controlled Lifestyle in Pregnancy (LiP) trial. *Acta Obstet Gynecol Scand* 2014;**93**:794–801. https://doi.org/10.1111/aogs.12429

221. Walsh J, Mahony R, Foley M, Mc Auliffe F. A randomised control trial of low glycaemic index carbohydrate diet versus no dietary intervention in the prevention of recurrence of macrosomia. *BMC Pregnancy Childbirth* 2010;**10**:16. https://doi.org/10.1186/1471-2393-10-16

222. Walsh JM, McAuliffe FM. Impact of maternal nutrition on pregnancy outcome: does it matter what pregnant women eat? *Best Prac Res Clin Obstet Gynaecol* 2015;**29**:63–78. https://doi.org/10.1016/j.bpobgyn.2014.08.003

223. Walsh JM, McGowan CA, Mahony R, Foley ME, McAuliffe FM. Low glycaemic index diet in pregnancy to prevent macrosomia (ROLO study): randomised control trial. *BMJ* 2012;**345**:e5605. https://doi.org/10.1136/bmj.e5605

224. McGowan CA, McAuliffe FM. The influence of maternal glycaemia and dietary glycaemic index on pregnancy outcome in healthy mothers. *Br J Nutr* 2010;**104**:153–9. https://doi.org/10.1017/S0007114510000425

225. McGowan CA, Walsh JM, Byrne J, Curran S, McAuliffe FM. The influence of a low glycemic index dietary intervention on maternal dietary intake, glycemic index and gestational weight gain during pregnancy: a randomized controlled trial. *Nutr J* 2013;**12**:140. https://doi.org/10.1186/1475-2891-12-140

226. Walsh JM, Mahony RM, Culliton M, Foley ME, McAuliffe FM. Impact of a low glycemic index diet in pregnancy on markers of maternal and fetal metabolism and inflammation. *Reprod Sci* 2014;**21**:1378–81. https://doi.org/10.1177/1933719114525275

227. Horan MK, Donnelly JM, McGowan CA, Gibney ER, McAuliffe FM. The association between maternal nutrition and lifestyle during pregnancy and 2-year-old offspring adiposity: analysis from the ROLO study. *Z Gesundh Wiss* 2016;**24**:427–36. https://doi.org/10.1007/s10389-016-0740-9

228. Dodd JM, Deussen AR, Louise J. Optimising gestational weight gain and improving maternal and infant health outcomes through antenatal dietary, lifestyle and physical activity advice: the OPTIMISE randomised controlled trial protocol. *BMJ Open* 2018;**8**:e019583. https://doi.org/10.1136/bmjopen-2017-019583

229. Kunath J, Günther J, Rauh K, Hoffmann J, Stecher L, Rosenfeld E, *et al.* Effects of a lifestyle intervention during pregnancy to prevent excessive gestational weight gain in routine care – the cluster-randomised GeliS trial. *BMC Med* 2019;**17**:5. https://doi.org/10.1186/s12916-018-1235-z

230. Simmons D, Devlieger R, van Assche A, Jans G, Galjaard S, Corcoy R, *et al.* Effect of physical activity and/or healthy eating on GDM Risk: the DALI Lifestyle Study. *J Clin Endocrinol Metab* 2017;**102**:903–13. https://doi.org/10.1210/jc.2016-3455

231. van Poppel MNM, Simmons D, Devlieger R, van Assche FA, Jans G, Galjaard S, *et al.* A reduction in sedentary behaviour in obese women during pregnancy reduces neonatal adiposity: the DALI randomised controlled trial. *Diabetologia* 2019;**62**:915–25. https://doi.org/10.1007/s00125-019-4842-0

232. van Poppel MN, Jelsma JGM, Simmons D, Devlieger R, Jans G, Galjaard S, *et al.* Mediators of lifestyle behaviour changes in obese pregnant women. secondary analyses from the DALI Lifestyle Randomised Controlled Trial. *Nutrients* 2019;**11**:E311. https://doi.org/10.3390/nu11020311

233. Jelsma JGM, Simmons D, Gobat N, Rollnick S, Blumska K, Jans G, *et al.* Is a motivational interviewing based lifestyle intervention for obese pregnant women across Europe implemented as planned? Process evaluation of the DALI study. *BMC Pregnancy Childbirth* 2017;**17**:293. https://doi.org/10.1186/s12884-017-1471-9

234. Lifestyle Interventions for Expectant Moms. *LIFE-Moms Consortium*. URL: https://lifemoms.bsc.gwu.edu/ (accessed 12 May 2021).

235. Poels M, van Stel HF, Franx A, Koster MPH. Actively preparing for pregnancy is associated with healthier lifestyle of women during the preconception period. *Midwifery* 2017;**50**:228–34. https://doi.org/10.1016/j.midw.2017.04.015

236. McPhie S, Skouteris H, Millar L, Olsson C, Campbell K, van der Pligt P, *et al.* Preconception weight management: an untapped area of women's health. *Aust J Prim Health* 2017;**23**:61–5. https://doi.org/10.1071/PY16004

237. Duthie EA, Drew EM, Flynn KE. Patient-provider communication about gestational weight gain among nulliparous women: a qualitative study of the views of obstetricians and first-time pregnant women. *BMC Pregnancy Childbirth* 2013;**13**:231. https://doi.org/10.1186/1471-2393-13-231

238. Ojukwu O, Patel D, Stephenson J, Howden B, Shawe J. General practitioners' knowledge, attitudes and views of providing preconception care: a qualitative investigation. *Ups J Med Sci* 2016;**121**:256–63. https://doi.org/10.1080/03009734.2016.1215853

239. Bombard JM, Robbins CL, Dietz PM, Valderrama AL. Preconception care: the perfect opportunity for health care providers to advise lifestyle changes for hypertensive women. *Am J Health Promot* 2013;**27**(Suppl. 3):43–9. https://doi.org/10.4278/ajhp.120109-QUAN-6

240. Cohen A, Gilman SE, Houck PR, Szanto K, Reynolds CF. Socioeconomic status and anxiety as predictors of antidepressant treatment response and suicidal ideation in older adults. *Soc Psychiatry Psychiatr Epidemiol* 2009;**44**:272–7. https://doi.org/10.1007/s00127-008-0436-8

241. Goossens J, Beeckman D, Van Hecke A, Delbaere I, Verhaeghe S. Preconception lifestyle changes in women with planned pregnancies. *Midwifery* 2018;**56**:112–20. https://doi.org/10.1016/j.midw.2017.10.004

242. Campbell F, Johnson M, Messina J, Guillaume L, Goyder E. Behavioural interventions for weight management in pregnancy: a systematic review of quantitative and qualitative data. *BMC Public Health* 2011;**11**:491. https://doi.org/10.1186/1471-2458-11-491

243. Einarsson S, Bergh C, Friberg B, Pinborg A, Klajnbard A, Karlström PO, *et al.* Weight reduction intervention for obese infertile women prior to IVF: a randomized controlled trial. *Hum Reprod* 2017;**32**:1621–30. https://doi.org/10.1093/humrep/dex235

244. Homan G, Litt J, Norman RJ. The FAST study: Fertility ASsessment and advice Targeting lifestyle choices and behaviours: a pilot study. *Hum Reprod* 2012;**27**:2396–404. https://doi.org/10.1093/humrep/des176

245. Mahoney D. Lifestyle modification intervention among infertile overweight and obese women with polycystic ovary syndrome. *J Am Assoc Nurse Pract* 2014;**26**:301–8. https://doi.org/10.1002/2327-6924.12073

246. Montanaro C, Lacey L, Robson L, Estill A, Vukovic S. Preconception care: a technology-based model for delivery in the primary care setting supported by public health. *Matern Child Health J* 2019;**23**:1581–6. https://doi.org/10.1007/s10995-019-02806-4

247. van Dammen L, Wekker V, de Rooij SR, Mol BWJ, Groen H, Hoek A, Roseboom TJ. The effects of a pre-conception lifestyle intervention in women with obesity and infertility on perceived stress, mood symptoms, sleep and quality of life. *PLOS ONE* 2019;**14**:e0212914. https://doi.org/10.1371/journal.pone.0212914

248. van Elten TM, Karsten MDA, Geelen A, Gemke RJBJ, Groen H, Hoek A, *et al.* Preconception lifestyle intervention reduces long term energy intake in women with obesity and infertility: a randomised controlled trial. *Int J Behav Nutr Phys Act* 2019;**16**:3. https://doi.org/10.1186/s12966-018-0761-6

249. Wekker V, Huvinen E, van Dammen L, Rono K, Painter RC, Zwinderman AH, *et al.* Long-term effects of a preconception lifestyle intervention on cardiometabolic health of overweight and obese women. *Eur J Public Health* 2019;**29**:308–14. https://doi.org/10.1093/eurpub/cky222

250. Kim LP, Koleilat M, Whaley SE. A qualitative study to examine perceptions and barriers to appropriate gestational weight gain among participants in the Special Supplemental Nutrition Program for Women Infants and Children Program. *J Pregnancy* 2016;**2016**:4569742. https://doi.org/10.1155/2016/4569742

251. Shieh C, Cullen DL, Pike C, Pressler SJ. Intervention strategies for preventing excessive gestational weight gain: systematic review and meta-analysis. *Obes Rev* 2018;**19**:1093–109. https://doi.org/10.1111/obr.12691

252. Thangaratinam S, Rogozińska E, Jolly K, Glinkowski S, Duda W, Borowiack E, *et al.* Interventions to reduce or prevent obesity in pregnant women: a systematic review. *Health Technol Assess* 2012;**16**(31). https://doi.org/10.3310/hta16310

253. Willcox JC, Wilkinson SA, Lappas M, Ball K, Crawford D, McCarthy EA, *et al.* A mobile health intervention promoting healthy gestational weight gain for women entering pregnancy at a high body mass index: the txt4two pilot randomised controlled trial. *BJOG* 2017;**124**:1718–28. https://doi.org/10.1111/1471-0528.14552

Appendix 1 Defining LARC events using Read codes and *British National Formulary* prescription codes

Inclusion criteria: women of reproductive age (16–48 years old) who had a LARC-related event (insertion, in situ or removal) between 1 January 2009 and 31 December 2018.

TABLE 21 Read codes

MedCode	Label	LARC consultation type	Type of LARC
8354	[V]Coil in situ	In situ	IUD
10957	[V]Coil check	In situ	IUD
45339	[V]Coil maintenance	In situ	IUD
20658	[V]Coil check	In situ	IUD
107776	Retained intrauterine contraceptive device	In situ	IUD
12029	[V]Intrauterine contraceptive device present	In situ	IUD
6306	[V]Intrauterine contraceptive device present	In situ	IUD
2145	[V]Intrauterine contraceptive device present	In situ	IUD
47908	Intrauterine contraceptive device 6 week check	In situ	IUD
22914	Intrauterine contraceptive device annual review	In situ	IUD
6265	[V]Intrauterine contraceptive device check	In situ	IUD
20557	[V]Intrauterine contraceptive device check	In situ	IUD
21515	[V]Intrauterine contraceptive device check	In situ	IUD
5917	IUD checked – no problems	In situ	IUD
225	IUD in situ	In situ	IUD
20392	Coil follow-up administration	In situ	IUD
107433	Uterine perforation by intrauterine contraceptive device	In situ	IUD
54183	[V]Surveillance of (intrauterine) contraceptive device	In situ	IUD
51242	IUD follow-up admininstration. NOS	In situ	IUD
21421	IUD follow-up administration	In situ	IUD
63924	FP1002 due next with new IUD	In situ	IUD
44917	IUD check – 2nd call	In situ	IUD
40783	IUD check – 1st call	In situ	IUD
45820	IUD check – 3rd call	In situ	IUD
13004	IUD change due	In situ	IUD
37020	IUD – defaulted from check	In situ	IUD
19950	IUD check due	In situ	IUD
445	IUD check	In situ	IUD

continued

TABLE 21 Read codes (*continued*)

MedCode	Label	LARC consultation type	Type of LARC
20538	Mechanical complication of coil	In situ	IUD
112311	Infection associated with intrauterine contraceptive device	In situ	IUD
29106	Mechanical complication intrauterine contracep.device (IUCD)	In situ	IUD
23439	Bleeding due to intrauterine contraceptive device	In situ	IUD
17735	Mechanical complication of intrauterine contraceptive device	In situ	IUD
104471	Intrauterine contraceptive device threads seen	In situ	IUD
108636	Bleeding due to intrauterine contraceptive device	In situ	IUD
30765	IUD partially expelled	In situ	IUD
7888	IUD checked – problems	In situ	IUD
5564	IUD threads lost	In situ	IUD
52230	Intrauterine contraceptive device annual review by telephone	In situ	IUD
6050	Change of intrauterine contraceptive device	In situ	IUD
88224	Intrauterine contraceptive device fit by another GP practice	In situ	IUD
22652	Replacement of intrauterine contraceptive device	In situ	IUD
95906	Intrauterine contracep device checked by other hlth provider	In situ	IUD
2738	IUD in situ from other agency	In situ	IUD
93404	Subcutaneous contraceptive in situ	In situ	Implant
26477	Check of subcutaneous contraceptive	In situ	Implant
96963	Subcutaneous contraceptive implant palpable	In situ	Implant
106241	Contraceptive implant removal invitation	In situ	Implant
98121	Mirena coil check	In situ	IU system
21114	Coil intrauterine contraceptive device procedure	Insertion	IUD
10614	Coil contraception	Insertion	IUD
24497	[V]Reinsertion of coil	Insertion	IUD
6064	[V]Coil insertion	Insertion	IUD
21365	[V]Reinsertion of coil	Insertion	IUD
17573	IUD contraception	Insertion	IUD
10754	[V]Reinsertion of intrauterine contraceptive device	Insertion	IUD
9226	Fitting of intrauterine contraceptive device	Insertion	IUD
6772	Intrauterine contraceptive device procedure	Insertion	IUD
4401	[V]Reinsertion of intrauterine contraceptive device	Insertion	IUD
31602	[V]Reinsertion of intrauterine contraceptive device	Insertion	IUD
6941	Introduction of intrauterine contraceptive device	Insertion	IUD
2144	[V]Intrauterine contraceptive device insertion	Insertion	IUD
3882	[V]Intrauterine contraceptive device insertion	Insertion	IUD
26317	Intrauterine contraceptive device procedure NOS	Insertion	IUD
17980	[V]Intrauterine contraceptive device insertion	Insertion	IUD

TABLE 21 Read codes (*continued*)

MedCode	Label	LARC consultation type	Type of LARC
53523	Other specified intrauterine contraceptive device	Insertion	IUD
182	IUD fitted	Insertion	IUD
42310	Post-coital IUD fitted	Insertion	IUD
38544	'Morning after' IUD fitted	Insertion	IUD
485	IUD re-fitted	Insertion	IUD
17440	Intrauterine device procedure	Insertion	IUD
40402	Coil contraceptive claim	Insertion	IUD
99571	IUD contraceptive claim	Insertion	IUD
27859	IUD contraceptive claim	Insertion	IUD
27872	IUCD contraceptive claim	Insertion	IUD
55297	FP1002 – IUD insertion claim	Insertion	IUD
103642	Insertion of etonogestrel radio-opaque contraceptive implant	Insertion	Implant
104317	Insertion of subcutaneous contraceptive claim	Insertion	Implant
22950	Insertion of subcutaneous contraceptive	Insertion	Implant
101819	Reinsertion of subcutaneous contraceptive	Insertion	Implant
70535	Insertion of hormone into subcutaneous tissue	Insertion	Implant
90157	Replacement of hormone in subcutaneous tissue	Insertion	Implant
17183	Insertion of hormone implant	Insertion	Implant
103004	Subdermal etonogestrel implant insertion ESA	Insertion	Implant
100958	Insert subcutaneous contraceptive implnt othr healthcre prov	Insertion	Implant
7255	Introduction of Mirena coil	Insertion	IU system
102368	Intrauterine system contraception	Insertion	IU system
2795	IUD – NOS	Insertion/in situ	IUD
22951	Subcutaneous contraceptive NOS	Insertion/in situ	Implant
26092	Subcutaneous contraceptive	Insertion/in situ	Implant
20424	[V]Removal of coil	Removal	IUD
18341	[V]Removal of coil	Removal	IUD
7379	Removal of intrauterine contraceptive device NEC	Removal	IUD
11561	[V]Removal of intrauterine contraceptive device	Removal	IUD
5252	[V]Removal of intrauterine contraceptive device	Removal	IUD
27929	[V]Removal of intrauterine contraceptive device	Removal	IUD
446	IUD removed	Removal	IUD
106270	Intrauterine contraceptive device removal invitation	Removal	IUD
107556	Expulsion of intrauterine contraceptive device	Removal	IUD
26476	IUD removal awaited	Removal	IUD
25680	Removal of contraceptive coil from pouch of Douglas	Removal	IUD
6225	Removal intrauterine contracept device from pouch of Douglas	Removal	IUD

continued

TABLE 21 Read codes (*continued*)

MedCode	Label	LARC consultation type	Type of LARC
32611	Removal of displaced intrauterine contraceptive device	Removal	IUD
22945	IUD fallen out	Removal	IUD
22946	IUD expelled	Removal	IUD
95476	Intrauterine contracep device removed by other hlth provider	Removal	IUD
107048	Removal of subcut contraceptive implant using US guidance	Removal	Implant
26260	Removal of subcutaneous contraceptive	Removal	Implant
104861	Removal of subcutaneous contraceptive claim	Removal	Implant
22875	Removal of hormone implant from subcutaneous tissue	Removal	Implant
71272	Removal of hormone implant from subcutaneous tissue	Removal	Implant
103620	Removal of etonogestrel radio-opaque contraceptive implant	Removal	Implant
101010	Remov subcutaneous contraceptive implant othr healthcre prov	Removal	Implant
18745	Removal of Mirena coil	Removal	IU system
109722	Removal of intrauterine system	Removal	IU system

British National Formulary[163] chapters have been identified for inclusion (rather than specific prodcodes): chapters 7.3.2.2, 7.3.2.3 and 7.3.4.1.

TABLE 22 Prescription codes

Prodcode	Product name	*British National Formulary*	*British National Formulary* chapter	Type of LARC
66331	Ancora 375 Ag intrauterine contraceptive device (RF Medical Supplies Ltd, Saint Helens, UK)	07030400/ 07030450	Contraceptive Devices/ Intrauterine Contraceptive Devices	IUD
66341	Ancora 375 Cu intrauterine contraceptive device (RF Medical Supplies Ltd)			IUD
1196	Novagard type 6 intrauterine device (Pharmacia Ltd, Sandwich, UK)	7030450	Intrauterine Contraceptive Devices	IUD
4904	Gyne-T 380S intrauterine device (Janssen UK, High Wycombe, UK)			IUD
5265	Multiload Cu375 intrauterine contraceptive device (Organon UK, London, UK)			IUD
5405	Nova-T 380 intrauterine contraceptive device (Bayer plc, Reading, UK)			IUD
5647	T-Safe 380A QL® intrauterine contraceptive device (Williams Medical Supplies Ltd, Rhymney, UK)			IUD
12146	Ortho Gyne type 4a intrauterine device (Janssen UK)			IUD
13678	Ortho Gyne type 4b Intrauterine device T380S (Janssen UK)			IUD

TABLE 22 Prescription codes (*continued*)

Prodcode	Product name	*British National Formulary*	*British National Formulary* chapter	Type of LARC
14038	Flexi-T 300 intrauterine contraceptive device (Durbin plc, Hayes, UK)			IUD
14295	Flexi-T+ 380 intrauterine contraceptive device (Durbin plc)			IUD
14959	TT380 Slimline intrauterine contraceptive device (Durbin plc)			IUD
18826	Multi-Safe 375 intrauterine contraceptive device (Williams Medical Supplies Ltd)			IUD
19143	GyneFix intrauterine contraceptive device (Williams Medical Supplies Ltd)			IUD
26488	Neo-Safe T380 intrauterine contraceptive device (Williams Medical Supplies Ltd)			IUD
33367	Load 375 intrauterine contraceptive device (Durbin plc)			IUD
36984	Mini TT380 Slimline intrauterine contraceptive device (Durbin plc)			IUD
36995	UT380 Short intrauterine contraceptive device (Durbin plc)			IUD
38015	UT380 Standard intrauterine contraceptive device (Durbin plc)			IUD
43404	Steriload intrauterine contraceptive device (Farla Medical Ltd, London, UK)			IUD
45739	Optima TCu380A intrauterine contraceptive device (Farla Medical Ltd)			IUD
49127	Copper T380A intrauterine contraceptive device (RF Medical Supplies Ltd)			IUD
50899	Novaplus T 380 Ag intrauterine contraceptive device normal (RF Medical Supplies Ltd)			IUD
51443	Novaplus T 380 Cu intrauterine contraceptive device normal (RF Medical Supplies Ltd)			IUD
55209	Novaplus T 380 Cu intrauterine contraceptive device mini (RF Medical Supplies Ltd)			IUD
56568	Novaplus T 380 Ag intrauterine contraceptive device maxi (RF Medical Supplies Ltd)			IUD
58198	Novaplus T 380 Ag intrauterine contraceptive device mini (RF Medical Supplies Ltd)			IUD
66415	Intrauterine contraceptive device			IUD
67254	Mirena 20 µg/24 hours intrauterine device (Dowelhurst Ltd, Warwick, UK)			IU system
2819	Norplant 228 mg implant (Hoechst Marion Roussel, Kansas City, MO, USA)	7030202	Parenteral Progestogen-Only Contraceptives	Implant
9592	Implanon 68 mg implant (Organon UK)			Implant

continued

TABLE 22 Prescription codes (*continued*)

Prodcode	Product name	*British National Formulary*	*British National Formulary* chapter	Type of LARC
16624	Levonorgestrel 228 mg implant			Implant
2748	Mirena 20 µg/24 hours intrauterine device (Bayer plc)	06040103/ 07030203	Progestogen Products Doubling (In House Use)/ Intra-Uterine Progestogen-Only Device	IU system
6906	Levonorgestrel 20 µg/24 hours intrauterine device			IUD
57359	Mirena 20 µg/24 hours intrauterine device (Mawdsley-Brooks & Company Ltd, Salford, UK)			IU system
60564	Levonorgestrel 13.5 mg intrauterine device			IUD
60632	Jaydess 13.5 mg intrauterine device (Bayer plc)			IUD
66047	Levosert 20 µg/24 hours intrauterine device (Gedeon Richter UK Ltd, London, UK)			IUD
72106	Kyleena 19.5 mg intrauterine device (Bayer plc)			IUD
73046	Levonorgestrel 19.5 mg intrauterine device			IUD
13209	Etonogestrel 68 mg implant			Implant
44196	Nexplanon 68 mg implant (Merck Sharp & Dohme Ltd, London, UK)			Implant
938	NovaT	Other		IUD
2747	multiload			IUD
4904	gyne-t			IUD
5265	multiload			IUD
5405	NovaT			IUD
5647	t-safe			IUD
14038	flexi-t			IUD
14158	multiload			IUD
14295	flexi-t			IUD
14959	tt380			IUD
18826	multisafe			IUD
19143	gynefix			IUD
21686	gynefix			IUD
26488	neosafe			IUD
33367	load 375			IUD
36984	mini tt380			IUD
36995	ut380			IUD
38015	ut380			IUD
43404	steriload			IUD
45739	optima			IUD

Appendix 2 Clinical codes

TABLE 23 Read codes for contraception

Med code	Label
11507	Depot contraception
29297	Oral contracept. check administration
29030	Depot contraceptive – problem
71415	GMS3 claim – temporary contraceptive (non-IUCD) signed
19267	Oral contraceptive poisoning
19496	Withdrawal contraception
56806	[X]Other contraceptive management
98936	GMS3 claim – temporary contraceptive (non-IUCD) paid
4688	Sheath contraception
25857	GMS4 claim – contraception (non-IUCD) sent to HA
96592	Contraceptive check first letter
98363	Contraceptive check third letter
103973	Migraine induced by oestrogen contraceptive
41407	Sympto-thermal contraceptn NOS
105984	Uses contraceptive sponge
91670	Adv to GP to change patient oral contraceptive from progestog only
19501	Oral contraception NOS
19500	Contraceptive sheath NOS
29034	Transdermal contraceptive
29958	[X] Adverse reaction to unspecified oral contraceptive
46842	GMS4 claim – contraception (non-IUCD) due next visit
94002	Contraceptive registration
16887	Oral contraceptive claim
100878	Stopped using contraceptive sponge
29035	Uses sympto-thermal contracepn
32976	Hypertension induced by oral contraceptive pill
5836	Pill-oral contraceptive claim
22936	Contraceptive diaphragm
60409	[V]Contraceptive cream prescription
72028	[V]Contraceptive foam fitting
6413	[V]Contraceptive cap fitting
3940	Adverse reaction to unspecified oral contraceptive
20716	[V]Repeat prescription of oral contraceptive
15806	Post-coital contraception NOS

continued

TABLE 23 Read codes for contraception (*continued*)

Med code	Label
22947	Depot contraception stopped
22940	Depot contraceptive-no problem
12989	Contraception from other agency
14830	Contraceptive sheath
19499	Oral contraceptive started
29033	Sympto-thermal contraception
106646	Emergency contraception indicated
97329	GMS4 claim – contraception (IUCD) due with new IUCD
57146	Contraceptive sponge
90951	Advice to GP to change pt oral contraceptive from combined
27523	Headache caused by oral contraceptive pill
69159	Contraceptive sponge failure
180	Oral contraceptive prescribed
22935	Post-coital contraception NOS
19508	Oral contraceptive re-started
13005	Diaphragm contraception
6255	CAP contraception
22941	Spermicide alone contraception
13003	Depot contraceptive NOS
11810	FP1001 – contraception claim
8387	[V]Oral contraceptive prescription
72078	GMS3 claim – temporary contraceptive (IUCD) sent to HA
12993	Oral contraceptive repeat
20581	Oral contraception – problem
106129	Contraceptive sponge NOS
22938	Depot contraceptive repeated
90120	GMS4 claim – contraception (non-IUCD) paid
103361	Contraceptive sheath problem
30766	Contraceptive usage NOS
17879	[V]Repeat prescription of oral contraceptive
102867	Problem with contraception
29032	Spermicidal contraceptive
6759	Post-coital contraception
41	Contraception
19506	Depot contraceptive given
110589	Barrier contraception method
6586	Contraceptive claims
71434	GMS3 claim – temporary contraceptive (IUCD) signed

TABLE 23 Read codes for contraception (*continued*)

Med code	Label
13007	Oral contraception – no problem
20354	Combined oral contraceptive
61591	GMS4 claim – contraception (IUCD) signed
102367	Uses contraception
47020	Contraceptive sheath issued
69241	GMS4 claim – contraception (non-IUCD) due
113582	GMS4 claim – contraception (IUCD) paid
5666	Oral contraception
12995	Oral contraceptive
100565	GMS4 claim – contraception (non-IUCD) forgot to claim
8538	Emergency contraception
5839	Contraceptive administration
13006	Contracep. NOS – other agency
12992	Depot contraceptive
19507	Uses contraceptive sheath
41761	GMS3 claim – temporary contraceptive (non-IUCD) sent to HA
18538	Pill contraceptive administration
17291	Oral contraceptive administration
104174	Progestogen only oral contraceptive
19505	Mini-pill: oral contraceptive
37428	[V]Repeat prescription of oral contraceptive (OC)
9252	Missed contraceptive pill
20360	Oral contraceptive changed
25858	GMS4 claim – contraception (non-IUCD) signed
96063	GMS4 claim – contraception (non-IUCD) up to date
98074	Contraceptive check second letter
100069	GMS4 claim – contraception (non-IUCD) returned unpaid
68735	GMS4 claim – contraception (IUCD) sent to HA
6358	Pill – oral contraception
22944	Spermicide + sheath contraception
39563	Stopped using sheath
22943	Uses sheath + spermicide
100655	Uses contraceptive sponge & spermicide
2438	Progestagen-only oral contraception
94215	Neuroleptic depot injection
12994	Progestagen-only pill
20388	Adverse reaction to combined oestrogens and progestogens

continued

TABLE 23 Read codes for contraception (*continued*)

Med code	Label
715	'Morning after' pills given
15255	Oral contraceptive stopped
102608	UK medical eligibility criteria for contraceptive use 2009 cat 2
1848	Contraception counselling
2446	Contraception contraindicated
102610	UK medical eligibility criteria for contraceptive use 2009 cat 3
96591	Contraceptive check invitation
109059	Combined oral contraceptive pill contraindicated
107774	Emergency contraception declined
102678	Education for contraceptive sheath
63613	Contraceptive scheme card issued
102676	Education for postcoital contraceptive
3618	General contraceptive advice
103240	Education for contraceptive diaphragm
6477	Emergency contraception advice
102957	UK medical eligibility criteria for contraceptive use 2009 cat 4
95989	Discussion about contraception injection
47069	[V]Unspecified contraceptive management
12711	[V]Contraceptive management
102604	Planned contraception method
52109	[V]Surveillance previously prescribed contraceptive methods
102609	UK medical eligibility criteria for contraceptive use 2009 cat 1
107837	GMS4 claim – contraception (non-IUCD) cancelled
102521	Education for transdermal contraceptive patch
108120	Referral to contraception and sexual health service
109280	Progestogen only oral contraceptive contraindicated
100652	Contraceptive advice for patients with epilepsy
19497	Rhythm method contraception
104432	Education about missed dose of oral contraceptive
26212	Advice about progestogen only oral contraceptive
101143	Contraceptiv advice for patients with epilepsy not indicated
105422	Discussion about risks of combined oral contraception
110889	Natural contraception
108552	Education for spermicidal contraceptive
2282	Oral contraceptive advice
102190	Contraceptive advice for patients with epilepsy declined
100549	Parental consent for contraceptive treatment
26039	[V]Other specified contraceptive management

TABLE 23 Read codes for contraception (*continued*)

Med code	Label
102876	UK medical eligibility criteria for contraceptive use 2009 risk
269	Total abdominal hysterectomy NEC
813	Abdominal hysterectomy and bilateral salpingoophorectomy
873	Vaginal hysterectomy
1729	Subtotal abdominal hysterectomy
1830	Abdominal hysterectomy and right salpingoopherectomy
2058	Abdominal hysterectomy and left salpingoopherectomy
2448	Abdominal hysterectomy
3064	Wertheim hysterectomy
3433	TAH – Tot abdom hysterectomy and BSO – bilat salpingophorect
3666	Hysterectomy NEC
6231	H/O: hysterectomy
7411	Vaginal hysterectomy NEC
7798	TAH – total abdom hysterectomy & bilateral salpingoophorect
7949	Abdominal hysterectomy and left salpingoophorectomy
10888	Post hysterectomy vaginal vault prolapse
11662	Abdominal hysterectomy with conservation of ovaries
12910	No smear – hysterectomy
12920	No smear – benign hysterectomy
18980	Laparoscopic hysterectomy
19088	Laparoscopic vaginal hysterectomy
19182	Radical hysterectomy
23863	Abdominal hysterectomy & bilateral salpingoophorectomy (BSO)
31312	Abdominal hysterectomy & excision of periuterine tissue NEC
42949	Vaginal hysterectomy with conservation of ovaries
47215	Ward vaginal hysterectomy
49408	Cervical smear to continue post hysterectomy
52057	Schauta radical vaginal hysterectomy
54109	Vaginal hysterectomy and excision of periuterine tissue NEC
69607	Bonney abdominal hysterectomy
94490	Total abdominal hysterectomy with conservation of ovaries
94549	Laparoscopic subtotal hysterectomy
94934	Subtotal abdominal hysterectomy with conservation of ovaries
97020	Lap assist vag hysterectomy with bilat salpingo-oophorectomy
100097	Heaney vaginal hysterectomy
109060	Subtotl abdominal hysterectomy & bilat salpingo-oophorectomy
109193	Vaginal hysterectomy and right salpingo-oophorectomy

continued

TABLE 23 Read codes for contraception (*continued*)

Med code	Label
109229	Subtotal abdominal hysterectomy & left salpingo-oophorectomy
109286	Radical hysterectomy with bilateral salpingo-oophorectomy
109351	Vaginal hysterectomy and left salpingo-oophorectomy
109686	Subtotl abdominal hysterectomy & right salpingo-oophorectomy
111335	Radical hysterectomy with conservation of ovaries
168	[V]Sterilisation
2932	[V]Post-sterilisation vasoplasty or tuboplasty
3532	H/O: sterilisation – female
4178	Laparoscopic bilateral female sterilisation
6338	[V]Admission for sterilisation
6841	Open bilateral female sterilisation
6847	Endoscopic bilateral female sterilisation
7163	Other open female sterilisation
7903	Other endoscopic female sterilisation
8231	[V]Other sterilisation
12998	Contraception: female sterilis
18751	Other laparoscopic female sterilisation
43832	Sterilising procedure
48256	[V]Reattempted sterilisation
60089	[V]Post-sterilisation tuboplasty
5210	H/O: tubal ligation
9724	[V]Admission for tubal ligation
14653	Open bilateral ligation of fallopian tubes
35984	Pomeroy open bilateral ligation of fallopian tubes
55932	Open ligation of remaining solitary fallopian tube

TABLE 24 Read codes for menopause

Med code	Label
38792	Hormone replacement therapy bleed pattern – normal
62292	Hormone replacement therapy bleed pattern – not relevant
26606	Hormone replacement therapy ongoing treatment
49111	Hormone replacement therapy bleed pattern – abnormal
59447	Hormone replacement therapy bleed pattern – no bleeding
13054	Health education – hormone replacement therapy
1671	Hormone replacement therapy
337	Hormone replacement therapy
12611	Hormone replacement therapy requested
11923	Hormone replacement therapy review
50119	Years on hormone replacement therapy
52904	[X]Other specified menopausal and perimenopausal disorders
38395	Postmenopausal osteoporosis with pathological fracture
2087	Premature menopause NOS
45409	Menopausal and postmenopausal disorder NOS
9171	Menopausal and postmenopausal disorders
19954	Artificial menopause state
1583	Postmenopausal bleeding
36514	Menopause: LH, FSH checked
67495	Post menopausal urethritis
25549	Menopausal concentration lack
22074	Menopause follow-up assessment
86026	Menopausal profile
21464	Menopause monitoring NOS
17628	Postmenopausal disorders
707	Postmenopausal atrophic vaginitis
30359	Perimenopausal atrophic vaginitis
20628	Menopause initial assessment
17442	Menopause symptoms present
2702	Menopause: bone density check
4462	H/O: post-menopausal bleeding
93526	Perimenopausal menorrhagia
15436	Post menopausal atrophic urethritis
828	Menopausal symptoms NOS
94499	Early menopause
9700	Postmenopausal osteoporosis
15283	Menopausal sleeplessness

continued

TABLE 24 Read codes for menopause (*continued*)

Med code	Label
4043	Menopausal or female climacteric state
30590	Postmenopausal state
4383	Menopause
9313	Menopause monitoring
9547	Menopausal flushing
62797	Menopause: dietary advice
17051	Menopausal arthritis
46997	Postmenopausal postcoital bleeding
814	Hot flushes – menopausal
15022	Premenopausal menorrhagia
28046	Other menopausal and postmenopausal states
58681	Menopause: sexual advice
18730	Menopausal headache
21534	Menopause: gen counselling
52129	H/O: hormone replacement (HRT)
38723	HRT: combined oestrog/progest
34489	HRT contraindicated
33436	HRT: unopposed oestrogen
29275	HRT changed
26608	HRT side-effects
26607	HRT started
25078	HRT stopped
13199	Hormone implant – HRT
13198	HRT prophylaxis
73849	[X] Adverse reaction to clonidine
67676	Clonidine poisoning
26107	Adverse reaction to clonidine
11438	Hot flushes

TABLE 25 Read codes for planning, trying and difficult to get pregnancy

Med code	Label
102359	Pregnancy advice for patients with epilepsy
5778	Pregnancy advice
36903	Pregnancy advice NOS
12996	Trying to conceive
10205	Advice relating to pregnancy and fertility
2949	Seen in fertility clinic
4571	Seen in fertility clinic
26088	[V]Infertility investigation and testing
9036	Fertility counselling
9983	Treatment for infertility NOS
5239	Referral to fertility clinic
33458	Female infertility therapy
1810	Treatment for infertility
9133	Fertility investigation of female NEC
2548	Procreat/fertility counselling
39295	[V]Infertility general advice and counselling
1154	Infertility investigations NOS
36458	Other female infertility
102589	Infertility care
16131	Infertility investigation – fem
41692	Female infertility test abnormal
53018	Other female infertility NOS
17756	Female infertility test normal
7246	Subfertility
25361	Fertility counselling
10445	Advice on fertility and infertility
7351	Fertility problem
33510	[V]Procreative management
100920	Pre-conception advice for patients with epilepsy
41319	Preconception care
41033	EDC – estimated date of conception
63344	Estimated date of conception
25307	Reproductive counselling
20847	[V]IVF
93810	Other specified in vitro fertilisation (IVF)
10238	IVF
52626	In vitro fertilisation (IVF)

continued

TABLE 25 Read codes for planning, trying and difficult to get pregnancy (*continued*)

Med code	Label
102280	IVF with pre-implantation for genetic diagnosis
90936	In vitro fertilisation (IVF) NOS
89966	IVF with donor sperm
57000	IVF with intracytoplasmic sperm injection (ICSI)
21532	Folic acid advice – pre pregnancy
49884	Diabetic pre-pregnancy counselling
4609	Pre-pregnancy counselling
50937	Referral to diabetes preconception counselling clinic
102767	Pre-conception advice for diabetes mellitus
10761	Pre-conception advice
69751	[V]Unspecified infertility management
2957	Infertility problem
1808	Infertility – female
37047	A/N care: H/O infertility
40072	Infertility studies
30392	Female infertility NOS
26150	[V]Other specified infertility management
9938	[V]Infertility management
64063	IVF with donor eggs
97981	IVF intracytoplasmic sperm injection (ICSI) and donor egg
89716	IVF with surrogacy
20977	Adverse reaction to clomiphene
73091	Maternity grant advice
459	Endoscopic bilateral occlusion of fallopian tubes NOS
1891	Endoscopic bilateral occlusion of fallopian tubes
4935	Open bilateral occlusion of fallopian tubes NOS
17760	Other endoscopic occlusion of fallopian tube
23346	Occlusion of vagina
28161	Endoscopic occlusion of left fallopian tube
32187	Open bilateral occlusion of fallopian tubes
42543	Unilateral occlusion of fallopian tube
45721	Other open occlusion of fallopian tube
50204	Endoscopic occlusion of right fallopian tube
50773	Other specified open bilateral occlusion of fallopian tubes
55972	Other open occlusion of fallopian tube NOS
58048	Endoscopic occlusion of remaining solitary fallopian tube
59338	Other specified endoscopic occlusion of fallopian tube
61157	Endoscopic bilateral occlusion of fallopian tubes OS
64187	Endoscopic occlusion of fallopian tube NOS

TABLE 25 Read codes for planning, trying and difficult to get pregnancy (*continued*)

Med code	Label
68272	Endoscopic unilateral occlusion of fallopian tubes
68614	Occlusion of cervix
69724	Other specified other open occlusion of fallopian tube
95677	In vitro fertilisation with pre-implantation for genetic diagnosis
97196	Antenatal screen shows homozygote/compound heterozygote of genetic sign
97802	Antenatal screen shows homozygote/compound heterozygote no genetic sign
100785	Antenatal screen, partner tested and no genetic risk identified
102280	IVF with pre-implantation for genetic diagnosis

TABLE 26 Read codes for planned and unplanned pregnancy

Med code	Label	Planned/unplanned
14877	Pregnant –? planned	Planned
20240	Pregnant – planned	Planned
30365	Wanted pregnancy	Planned
8767	Open reversal of female sterilisation	Planned
8844	Open reversal of female sterilisation	Planned
24538	Endoscopic reversal of female sterilisation	Planned
24657	[V]Reversal of sterilisation	Planned
40709	Open reversal of female sterilisation NOS	Planned
41343	Laparoscopic reversal of female sterilisation	Planned
56297	Other specified endoscopic reversal of female sterilisation	Planned
66719	Endoscopic reversal of female sterilisation NOS	Planned
97970	Other specified open reversal of female sterilisation	Planned
29915	Open reversal of tubal ligation	Planned
6197	[V]Failed sterilisation NOS	Unplanned
37019	Female sterilisation failure	Unplanned
15338	Pregnancy unplanned? wanted	Unplanned
7517	Unplanned pregnancy	Unplanned
30618	Unplanned pregnancy	Unplanned
14842	Pregnant – unplanned – wanted	Unplanned
15567	Pregnant – unplanned – not wanted	Unplanned
23421	IUD failure – pregnant	Unplanned
29692	Pregnant, IUD failure	Unplanned
20623	[V]Problems related to unwanted pregnancy	Unplanned

continued

TABLE 26 Read codes for planned and unplanned pregnancy (*continued*)

Med code	Label	Planned/unplanned
5044	Unwanted pregnancy	Unplanned
15033	[V]Other unwanted pregnancy	Unplanned
50421	Unwanted pregnancy	Unplanned
32975	Pregnant, diaphragm failure	Unplanned
14994	Pregnant, sheath failure	Unplanned
40851	Depot contraceptive failure	Unplanned
19503	Progestogen-only pill failure	Unplanned

Appendix 3 Routine data results

Codes to refute or confirm that the pregnancy was planned

To determine whether or not the LARC was removed for the purpose of conception, events between the two were examined to either confirm or refute (to the best of our abilities) that the pregnancy had been planned. The following clinical events were identified to confirm an intended pregnancy: trying or difficult to get pregnancy, and planning a pregnancy. The following were identified to refute a pregnancy: alternative contraception, and unplanned pregnancy and menopause (*Table 27*).

LARC use over time

LARC insertions are most frequently performed in general practice (*Figure 12*). An examination of LARC prescription type over time in general practice shows that insertions for IUDs fell over time, whereas insertions for IU systems and implants increased (*Figure 13*). Contrast this with Scotland SHC data, which show that implants were favoured but decreased over time, with IU systems increasing (*Figure 14*). Similarly, in Wales, implants are most popular, with IUDs and IU systems accounting for around one-quarter of all LARC contacts (*Figure 15*). A higher proportion of women in the 25–44 years age group consulted

TABLE 27 Number of clinical codes we used as indicator of contraceptive/pregnancy status for grouping women

Events	Unique number of events	Number of women with at least one event
Confirming an intended pregnancy		
Trying or difficult to get pregnancy	7494	6494
Planning a pregnancy	69	68
Refuting a pregnancy		
Alternative contraception	96,134	78,898
Unplanned pregnancy	1232	1211
Menopause	5628	4917

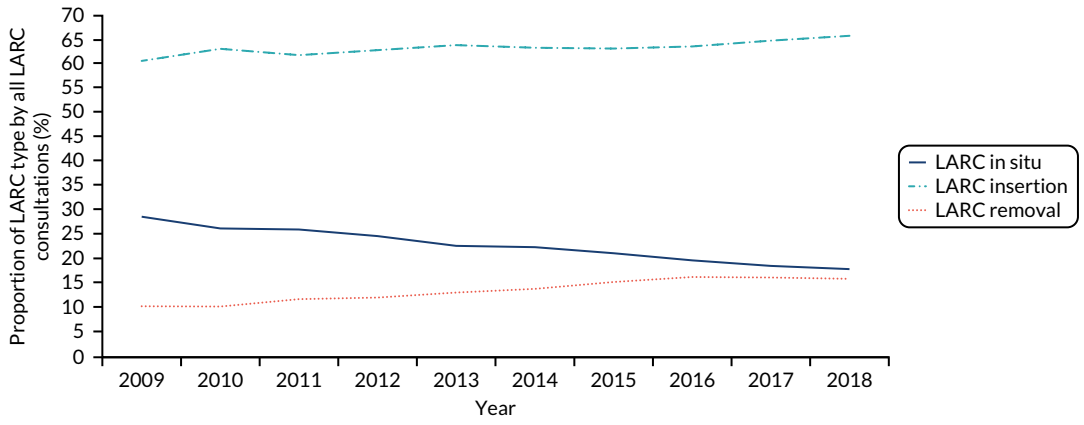

FIGURE 12 LARC users over time by LARC consultation type: CPRD (2009–18).

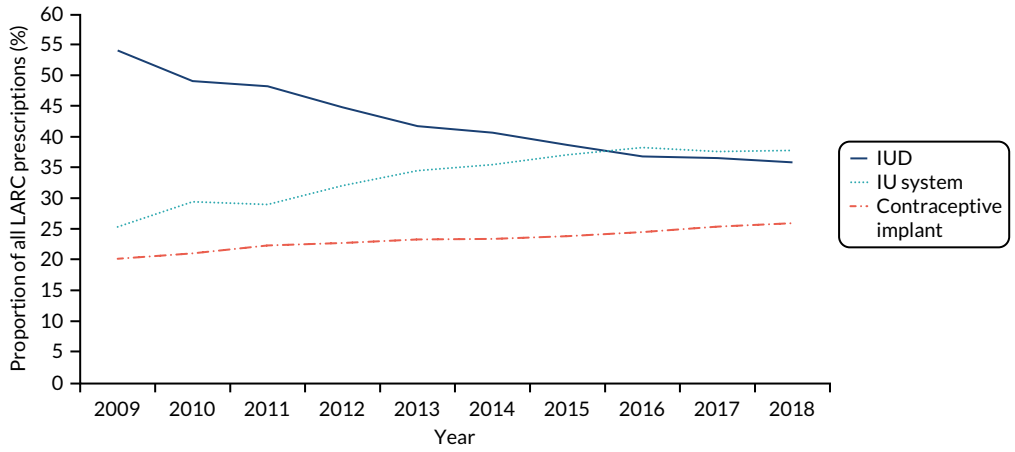

FIGURE 13 LARC users over time by LARC prescription type. (A person contacting a service for the same contraception multiple times during the year will be counted only once. The first attendance for that contraceptive is counted.) CPRD (2009–18). IU, intrauterine.

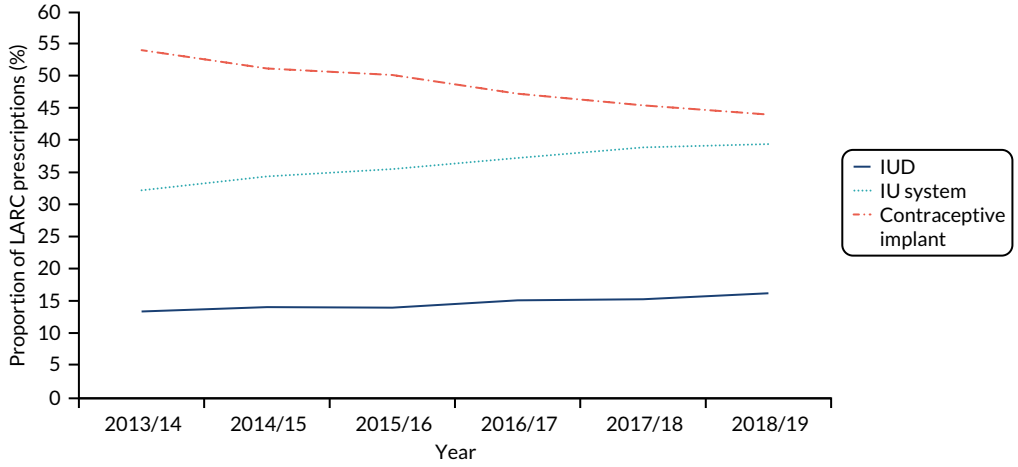

FIGURE 14 LARC users over time by LARC prescription type. (A person contacting a service for the same contraception multiple times during the year will be counted only once. The first attendance for that contraceptive is counted.) Scotland SHC data (2009–18).

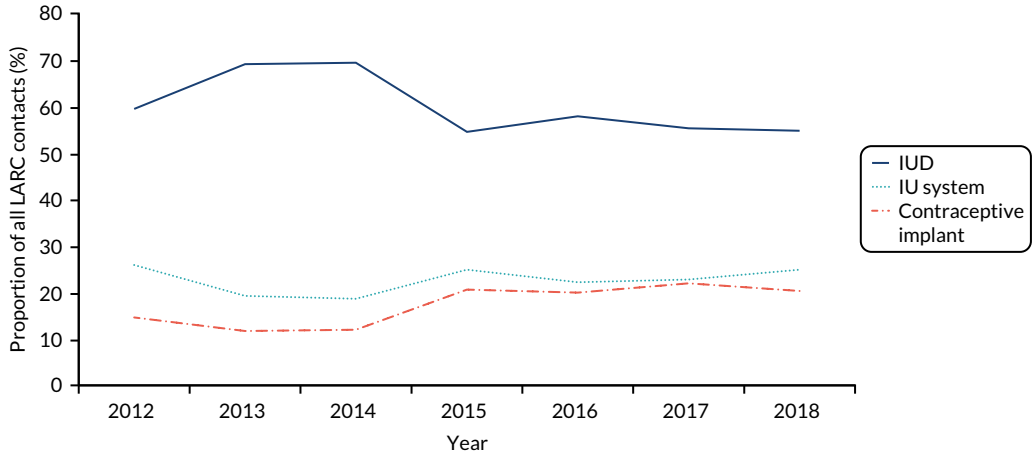

FIGURE 15 LARC users over time by LARC prescription type. (A person contacting a service for the same contraception multiple times during the year will be counted only once. The first attendance for that contraceptive is counted.) Wales SHC data (2012–18). Note that data from 2012 to 2015 are unreliable owing to under-reporting by some health boards.

their GP regarding LARC use, whereas younger age groups (under 20s and 20–24 years) were more likely to consult SHCs (*Figures 16* and *17*). Across both settings, consultations for LARC were lowest in the ≥ 45 years age group.

Time to conception for women in different age and body mass index categories

We are interested in how time to conception may differ by BMI and age categories. In total, 7469 pregnancy events (within 7224 women) have both BMI data and conception time data available. The time to conception by BMI category can be seen in *Table 28*. We are interested in how time to conception may differ between age category. We have split the study population by the following age categories: ≤ 28 versus ≥ 29 years and ≤ 34 versus ≥ 35 years. Age 28 years was the median age of first LARC for women with a pregnancy event, and age 34 years was the median age of first LARC for women in our study population. Additionally, we split the population according to England Sexual and Reproductive Health Services age categories (16–17, 18–19, 20–24, 25–34, 35–44 and 45–54 years). The time to conception by age category can be seen in *Table 28* and *Figure 18*.

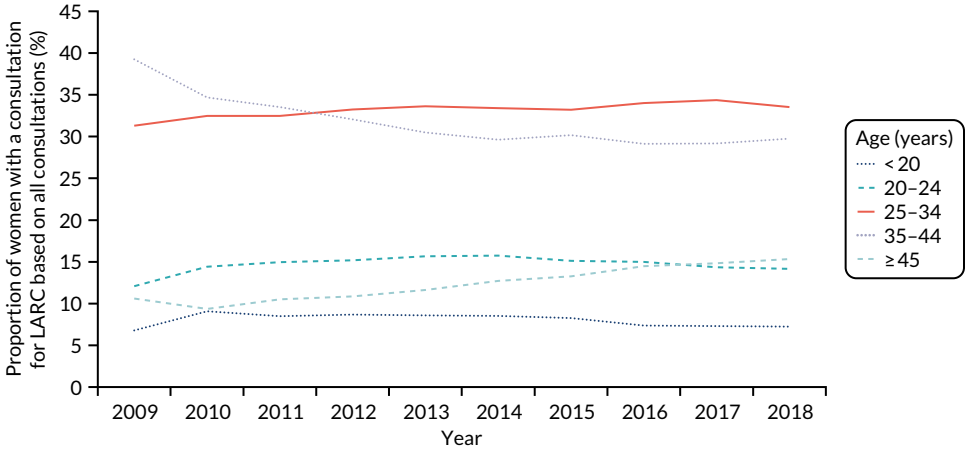

FIGURE 16 LARC users over time by age group: CPRD (2009–18).

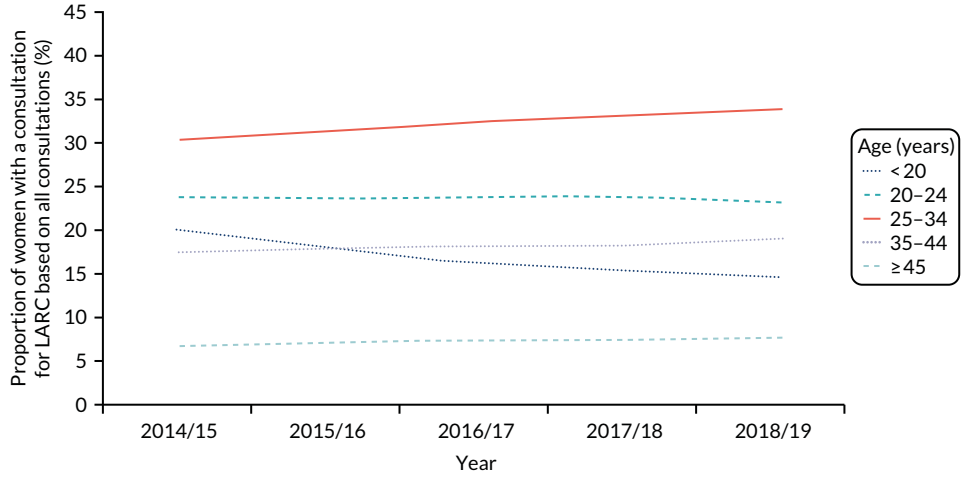

FIGURE 17 LARC users over time by age group: England SHC (2014/15 to 2018/19).[164]

TABLE 28 Time to conception by BMI and age categories

	Pregnancy events, *n*	Conception time (days), median (25th, 75th centiles)
BMI category (kg/m²)		
≤ 24.99 (underweight/healthy)	3731	106 (44, 218)
≥ 25 (overweight)	3738	113 (50, 227)
≤ 29.99 (underweight/healthy/overweight)	5699	107 (46, 220)
≥ 30 (obesity)	1770	118 (54, 231)
≤ 39.99 (underweight/healthy/overweight)	7264	109.5 (47, 222)
≥ 40 (morbid obesity)	205	130 (62, 242)
Age category (years)		
≤ 28[a]	5911	112 (48, 223)
≥ 29	5430	108 (47, 218)
≤ 34[b]	9580	109 (46, 217)
≥ 34	1761	114 (52, 240)
16–17[c]	247	169 (75.5, 301.5)
18–19	555	138 (61.5, 258.5)
20–24	2412	111 (47, 220)
25–34	6335	105 (44, 208.5)
35–44	1747	114 (53, 240)
45–54	17	154 (36, 311)

a Cut-off value based on median age of first LARC for women with a pregnancy event.
b Cut-off value based on median age of first LARC for women in our study population.
c Based on England Sexual and Reproductive Health Services categories.

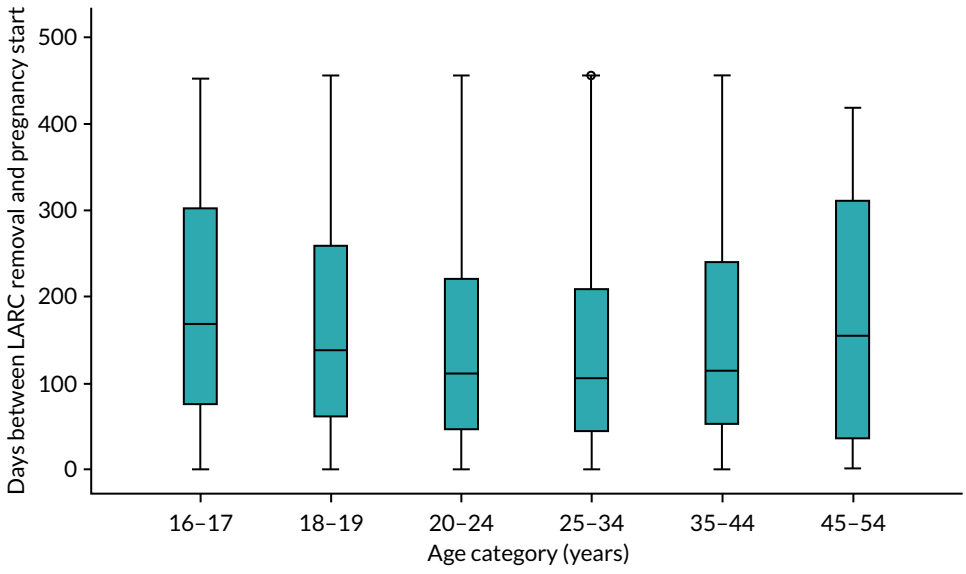

FIGURE 18 Time to conception by age category.

Other analysis: further contraception patterns

We are interested in further contraception patterns for women who had a LARC removed for the purpose of conception and subsequently became pregnant. After pregnancy ended, of the 16,455 pregnancy events, 1365 events (8.3%) had an alternative conception, and 956 events (5.8%) had a LARC in situ or insertion code. The median days between pregnancy end and an alternative conception was 233 days (interquartile range 7–886 days) (*Figure 19*), and the median days between pregnancy end and next LARC in situ or insertion event was 325 days (interquartile range 26.5–502 days) (*Figure 20*).

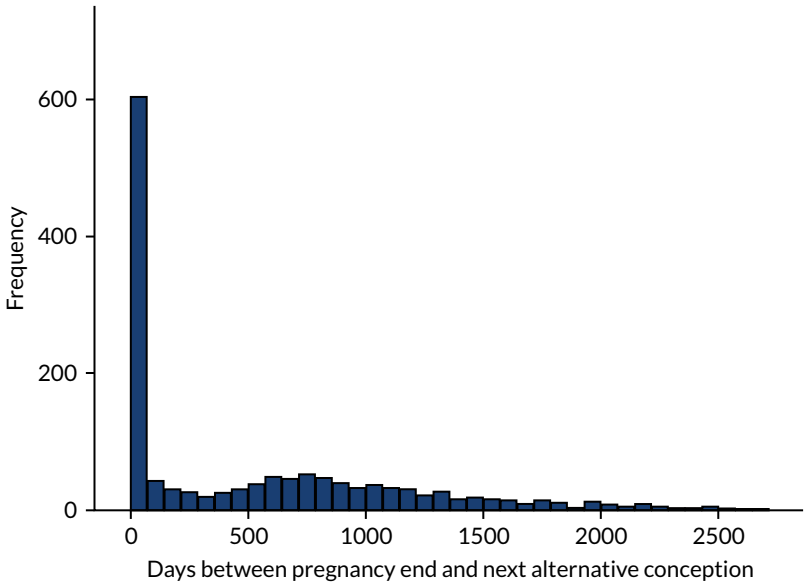

FIGURE 19 Time between pregnancy end and an alternative conception (days) ($n = 1365$).

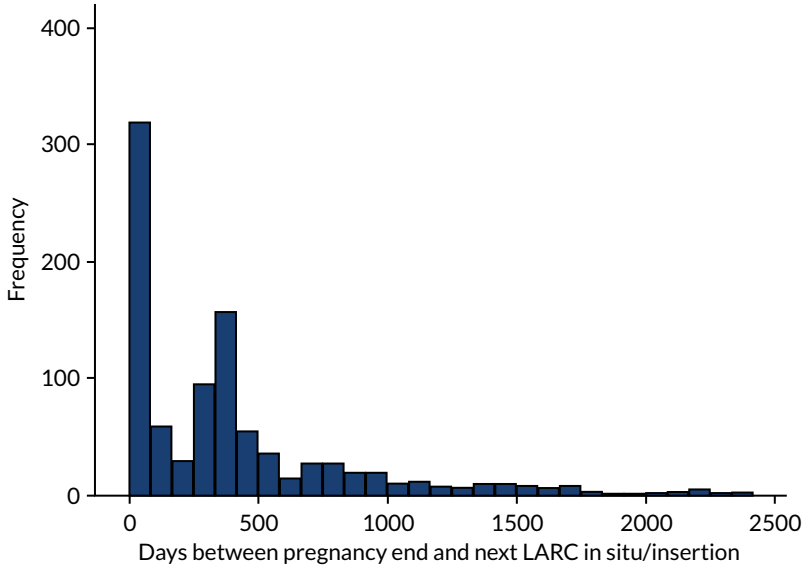

FIGURE 20 Time between pregnancy end and next LARC in situ or insertion event (days) ($n = 956$). Mean 397.76 (standard deviation 459.005); $n = 956$.

TABLE 29 Summary of CPRD outcomes by year

Population	Outcome	Year									
		2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
All women	Number of women aged 16–48 years	1,413,791	1,408,118	1,380,332	1,355,832	1,330,823	1,244,434	1,108,991	914,755	812,739	741,453
	Number of GPs	738	728	713	699	680	645	580	491	437	397
	Average number of women per GP	1915	1934	1935	1939	1957	1929	1912	1863	1859	1867
	Number of BMI records	135,526	131,017	127,482	121,836	116,660	102,977	87,948	71,334	59,858	52,326
	Within how many women	91,764	91,103	89,443	87,622	83,568	74,473	64,503	52,591	44,583	39,007
	% of women with at least one BMI	6.49	6.47	6.48	6.46	6.28	5.98	5.82	5.75	5.49	5.26
Women in study population	Women with at least one LARC event	61,440	67,947	66,987	66,988	65,313	59,668	51,357	40,468	35,100	31,765
	Number of LARC in situ	31,074	31,479	30,540	28,768	25,384	22,996	18,558	13,258	10,972	9526
	Number of LARC insertions	65,523	75,430	72,290	72,904	71,152	64,713	55,091	42,554	38,001	34,744
	Number of LARC removals	11,293	12,402	13,891	14,150	14,735	14,283	13,410	10,985	9585	8470
	Age category (years)										
	16–17	1846	2290	2084	2077	2011	1754	1523	1072	969	846
	18–19	2370	2820	2556	2780	2740	2571	2130	1534	1290	1191
	20–24	7509	8115	8188	8496	8650	7993	6701	5299	4438	3985
	25–34	19,457	18,283	17,763	18,617	18,580	16,964	14,706	12,015	10,632	9442
	35–44	24,399	19,534	18,346	17,942	16,851	15,046	13,356	10,289	9026	8377
	45–54	6583	5269	5754	6075	6430	6454	5866	5116	4585	4317
	LARC type										
	IUD	58,253	58,610	56,388	51,899	46,535	41,568	33,694	24,586	21,448	19,019
	IU system	28,266	36,417	35,150	38,208	39,396	37,106	33,053	25,907	22,243	20,095
	Implant	21,821	25,235	26,217	26,400	26,072	23,959	20,789	16,386	14,920	13,747

Population	Outcome	Year									
		2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
	LARC removal without replacing with an alternative contraception within 4 months	10,024	11,029	12,299	12,532	13,042	12,563	11,872	9697	8412	7366
	Number of pregnancy event (start year)	1302	2378	2582	2453	2292	1969	1542	989	705	182
	Number of LARC removal with pregnancy for the purpose of conception (groups 1 and 2 plus pregnancy)	1721	1775	2016	1813	1689	1387	1016	631	456	33
	Number of LARC use for the purpose of conception (groups 1 and 2)	2039	2203	2691	2543	2497	2007	1540	980	726	182
	For the purpose of conception, *n* (%)										
	Without BMI	666 (32.7)	774 (35.1)	877 (32.6)	867 (34.1)	831 (33.3)	693 (34.5)	557 (36.2)	408 (41.5)	293 (40.4)	80 (44.0)
	With BMI										
	BMI $< 24.99\ kg/m^2$	725 (52.8)	739 (51.7)	868 (47.9)	782 (46.7)	797 (47.8)	648 (49.3)	442 (45.0)	268 (46.9)	187 (43.2)	38 (37.3)
	BMI $\geq 25\ kg/m^2$	648 (47.2)	690 (48.3)	946 (52.1)	894 (53.3)	869 (52.2)	666 (50.7)	541 (55.0)	304 (53.1)	246 (56.8)	64 (62.7)
	No LARC removal code before conception – remove elsewhere	337	784	884	730	642	532	395	242	167	40
	Rate of women who request LARC removal and subsequently have a pregnancy (groups 1 and 2/women at reproductive age)	0.0014	0.0016	0.0019	0.0019	0.0019	0.0016	0.0014	0.0011	0.0009	0.0002

Appendix 4 Sexual health clinic data: open access

Scotland sexual health clinic summary table

TABLE 30 Summary of LARC use in Scotland between 2013 and 2018

	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19
Number of prescriptions						
IUDs	3698	3942	3893	4345	4502	4985
Contraceptive implant	14,823	14,268	13,899	13,510	13,297	13,465
IU systems	8856	9601	9859	10,655	11,392	12,064
LARC by NHS board						
Scotland[a]	27,377	27,811	27,651	28,510	29,191	30,514
Ayrshire & Arran	1754	1813	1820	2000	2046	2069
Borders	589	516	595	592	612	710
Dumfries & Galloway	440	474	467	592	645	737
Fife	1831	1849	1890	1915	1871	1819
Forth Valley	867	782	958	1025	1027	1013
Grampian	1500	1648	1532	1666	2071	2109
Greater Glasgow & Clyde	10,763	10,488	9828	9790	10,035	10,190
Highland	808	840	961	1088	1146	1218
Lanarkshire	3040	3374	3545	3723	3637	3874
Lothian	4031	4263	4467	4498	4550	5277
Orkney	NA	NA	NA	NA	NA	NA
Shetland	NA	NA	NA	NA	NA	NA
Tayside	1754	1764	1588	1615	1551	1489
Western Isles	NA	NA	NA	NA	NA	NA
LARC use by age group (years)						
< 20	8327	7936	7375	6460	6318	6749
20–24	10,636	10,481	10,267	10,476	10,401	10,571
25–29	9295	9342	9242	9619	9654	9679
30–34	7986	8009	8015	8153	7942	8208
35–39	6346	6459	6543	6954	7017	7304
40–44	6179	5970	5767	5901	5555	5852
≥ 45	5316	5512	5863	6211	6508	6792
Not known	12,261	12,464	11,943	11,075	9947	10,445

continued

TABLE 30 Summary of LARC use in Scotland between 2013 and 2018 (*continued*)

	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19
LARC use by deprivation area[b]						
1 (most deprived)	NA	NA	7473	7650	7342	6734
2	NA	NA	5444	5753	5599	5306
3	NA	NA	4385	4783	4670	4513
4	NA	NA	4281	4305	4212	4248
5 (least deprived)	NA	NA	4289	4470	4433	4608
Not known	NA	NA	1779	1549	2935	5105
Total	NA	NA	27,651	28,510	29,191	30,514

NA, not available.
a Scotland totals can include prescriptions where the NHS board is unknown.
b Scottish Index of Multiple Deprivation (SIMD) 2016 configuration at Scotland level has been used.
Source: ISD Scotland.[165] Contains public sector information licensed under the Open Government Licence v3.0.

England Sexual and Reproductive Health Services summary table

TABLE 31 Summary of LARC use in England between 2013 and 2018

		2014/15	2015/16	2016/17	2017/18	2018/19
Number of prescriptions (all ages)	IUDs	54,216	52,855	54,198	56,593	60,921
	Contraceptive implant	67,666	70,621	72,229	74,931	83,369
	IU systems	138,937	140,019	134,623	129,760	136,584
Contraception-related services (excluding those aged under 16 years)	New main method[a]	244,459	218,291	211,352	192,441	189,119
	Change of main method	280,508	280,460	272,779	265,102	267,074
	Maintain existing main method	930,092	889,076	825,248	743,033	711,743
	Pre-contraception advice[b]	194,872	177,573	155,585	129,020	127,978
LARC by local authority (excluding those aged under 16 years between 2014/15 and 2017/18, all age at 2018/19)	England	253,604	257,322	256,210	256,657	263,000
	North East region	16,070	15,450	13,685	13,075	32,000
	North West region	45,750	43,675	40,630	40,950	30,000
	Yorkshire & the Humber region	22,140	19,245	20,845	23,440	37,000
	East Midlands region	19,165	17,705	17,830	18,875	44,000
	West Midlands region	22,900	22,285	20,420	22,100	35,000
	East of England region	17,510	19,060	16,635	19,150	37,000
	London region	51,080	54,055	54,765	53,130	36,000
	South East region	30,895	31,900	33,325	33,260	34,000
	South West region	21,915	22,530	24,300	22,520	40,000

TABLE 31 Summary of LARC use in England between 2013 and 2018 (*continued*)

		2014/15	2015/16	2016/17	2017/18	2018/19
Women using sexual and reproductive health services by age group (years)	16–17	105,997	90,127	77,917	71,238	66,153
	18–19	132,982	125,396	115,392	109,143	103,807
	20–24	305,978	298,185	286,336	276,326	271,202
	25–34	334,089	333,866	327,927	326,036	334,406
	35–44	154,734	154,166	147,769	144,958	153,579
	45–54	69,249	67,749	63,879	61,148	64,376
	≥ 55	11,778	11,582	10,182	9,574	11,238
LARC (IUD, IU system and implant) by age group[c] (all local authorities between 2014 and 2015 and England only at 2017/18)	16–17	34,177	30,489	24,404	24,596	12,733
	18–19	43,397	41,119	36,570	37,047	19,191
	20–24	111,989	111,975	107,591	112,836	60,758
	25–34	164,616	168,857	171,967	178,347	98,643
	34–44	102,451	104,219	107,156	103,723	58,296
	≥ 45	44,399	46,568	48,787	46,608	25,871
IMD decile (women aged 13–54 years using services – percentage of population)[d] (all ages and including injectable contraceptive)	1 (most deprived)	11.46	10.56	7.73	8.00	7.89
	2	10.61	8.64	6.75	6.51	5.99
	3	9.07	7.41	6.13	6.00	5.22
	4	7.84	6.26	5.45	5.16	4.89
	5	6.82	5.87	4.34	4.57	4.17
	6	5.99	5.28	4.66	4.62	4.17
	7	5.61	5.09	4.28	4.09	3.94
	8	5.06	5.33	4.16	3.93	3.45
	9	4.93	3.87	3.67	3.59	2.41
	10 (least deprived)	4.23	2.95	2.56	2.40	2.35
	Total	7.59	6.50	5.58	5.04	–

a New is where a patient receives contraceptives for the first time, or where a contraceptive had not been in use for at least 1 month.
b Where no main method was provided.
c A person contacting a service multiple times during the year will be counted only once. Age is based on a person's first contact in the year.
d IMD deciles based on deprivation scores for 2001 English lower super output areas produced by the Office for National Statistics.[166]
Source: NHS Digital.[55] Contains public sector information licensed under the Open Government Licence v3.0.

Appendix 5 Data cleaning flow chart for body mass index

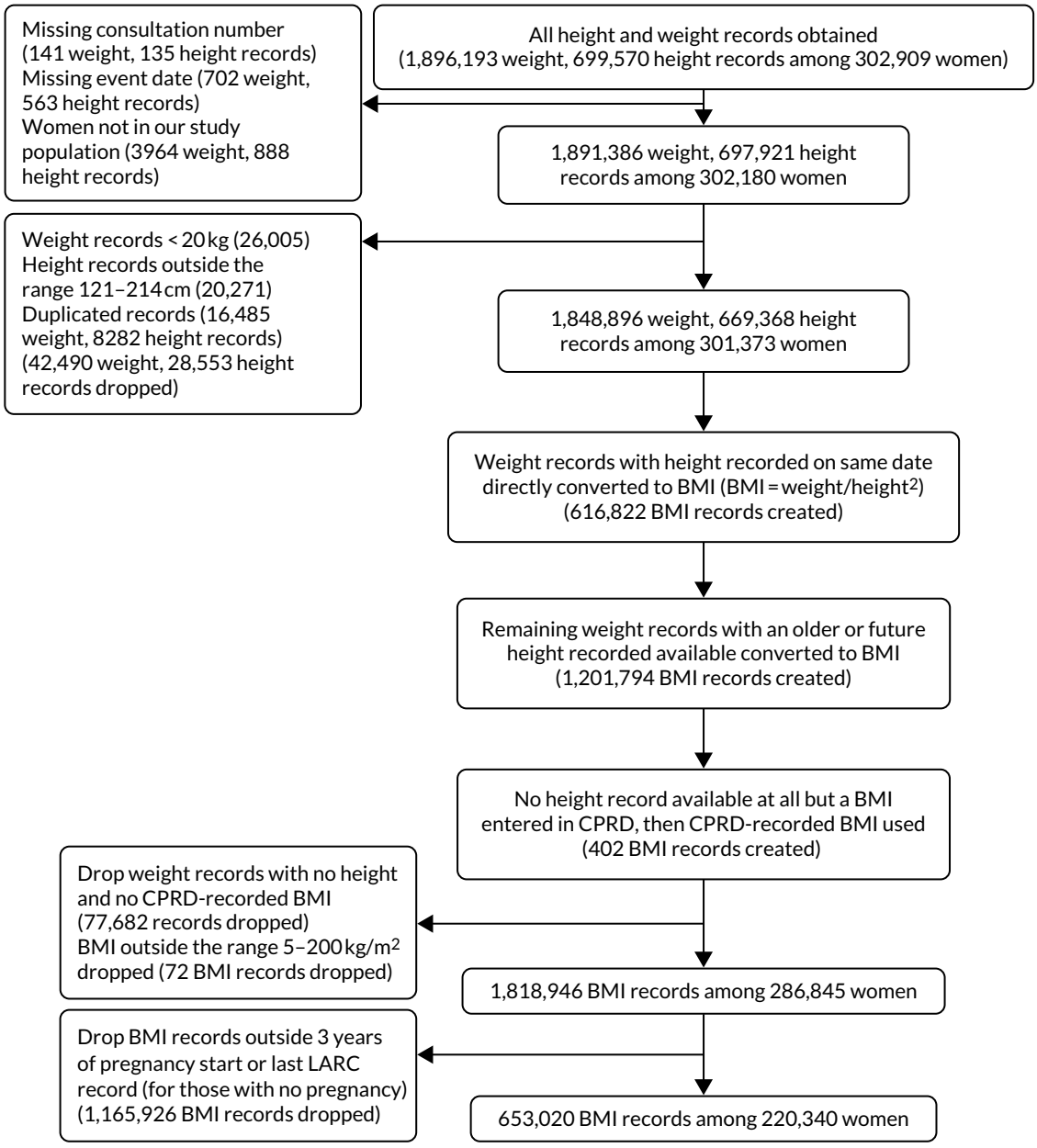

FIGURE 21 Data cleaning flow chart for BMI.

Appendix 6 Search strategies and results

Policy review

Review aims and search strategies

Aim
To identify advice, guidance and/or policy documents pertaining to use of LARCs in the UK.

Website searches targeted towards: LARC removal, management of women with obesity/overweight, diet, exercise. Specific search terms utilised: 'LARC', 'removal', 'coil', 'implant', 'obese', 'obesity', 'overweight', 'weight', 'diet', 'exercise'.

Key organisations to search (websites and/or online repositories): FSRH, RCOG, NICE and BPAS.

Additional materials were identified by the study team and/or advisory group members.

Results
A total of 15 documents were identified for inclusion in the review.

TABLE 32 Policy review: included documents

Data source: organisational website/repository or study team	Document type	Year of publication	Document title
FSRH	CEU statement[167]	2019	'Contraception and weight gain'
	Guideline[168]	2019	'Contraception for women aged over 40 years'
	Clinical guidance[99]	2019	'Intrauterine contraception'
	CEU statement[169]	2018	'Contraception for women with eating disorders'
	Clinical guideline[170]	2017	'Contraception after pregnancy'
	CEU statement[100]	2015	'Provision of LARC methods to young women in the UK'
	Clinical guidance[171]	2014	'Progestogen-only implant'
	Guideline[172]	2019	'Overweight, obesity and contraception'
RCOG	Press release[101]	2018	'RCOG co-launches new digital tool to help prepare women for pregnancy' (Tommy's Planning for Pregnancy tool)
	Green-top Guideline[98]	2018	'Care of women with obesity in pregnancy'
NICE	Public health guideline[16]	2010	'Weight management before, during and after pregnancy'
	Clinical guideline[173]	2005	'Long-acting reversible contraception'
BPAS	Press release[174]	2017	'Women cannot control fertility through contraception alone'
Identified by study team	Review[175]	2014	'Preconception care policy, guidelines, recommendations and services across six European countries: Belgium (Flanders), Denmark, Italy, the Netherlands, Sweden and the United Kingdom'
	FIGO guideline[20]	2020	'Management of prepregnancy, pregnancy, and postpartum obesity from the FIGO Pregnancy and Non-Communicable Diseases Committee: a FIGO (International Federation of Gynecology and Obstetrics) guideline'

CEU, Clinical Effectiveness Unit.

Barriers to and facilitators of engagement in pre-conception health behaviour change interventions and research

Review aims and search strategies

Aim

To identify studies focused on preconception health and behaviour change, including, but not specific to, diet and weight loss, and to identify key barriers to and facilitators of successful engagement in behaviour change.

A series of search strategies were designed to identify studies that addressed the following target behaviours:

- diet
- alcohol
- smoking
- folic acid
- eating/dietary restrictions.

Date range

2008–19.

Databases searched

EMBASE™ (Elsevier, Amsterdam, the Netherlands) (via Ovid), Web of Science™ (Clarivate Analytics, Philadelphia, PA, USA).

Results

A total of eight studies were identified for inclusion in the review.

Review of key qualitative and survey-based literature (preconception and prenatal)

A total of 18 qualitative and survey-based studies, reporting on service user and provider experiences, behaviours and perspectives on prenatal and preconception weight, were identified via the main study searches.

TABLE 33 Barriers and facilitators: included documents

Search strategy	EMBASE	Web of Science	Duplicates	Inclusions	Running total
"behaviour change" AND "diet" AND ("preconception" or "pre-conception")	6	4	2	8	8
"behaviour change" AND "alcohol" AND ("preconception" or "pre-conception")	9	4	4	9	17
"behaviour change" AND "smoking" AND ("preconception" or "pre-conception")	4	2	2	4	21
"behaviour change" AND "folic acid" AND ("preconception" or "pre-conception")	3	2	1	4	25
"behaviour change" AND "eating restrictions" AND ("preconception" or "pre-conception")	0	0			25
"behaviour change" AND "dietary restrictions" AND ("preconception" or "pre-conception")	0	0			25
Duplicates (between searches)	8				17
Studies excluded at full-text review (conference abstracts, protocols, duplicates between study searches)	9				8
Final total					$n = 8$

Review of review papers and intervention strategies

TABLE 34 Review aims and search strategies: summaries

Search aim	Search strategy	Setting	Databases searched	Inclusion criteria	Data to be extracted	Results
Recent preconception and obesity reviews and meta-analyses	Preconception AND obes* filter for meta-analysis/review	English-language only. High- and middle-income countries	MEDLINE, PubMed, ScienceDirect	Meta-analysis, review, date range: 2010–20	Methods, participants, intervention characteristics, results, information relevant to CMO configurations	8 papers included in final review Total hits, $N = 139$ Excluded, $n = 131$ Not a review, $n = 20$ Unavailable, $n = 3$ Child-focused outcomes, $n = 18$ Nutrition focus, $n = 11$ Postpartum and pregnancy $n = 7$ Anima/lab based $n = 5$ LMIC $n = 8$ Specific condition, $n = 59$ A further 13 identified via snowballing using references of papers and via other searches

continued

TABLE 34 Review aims and search strategies: summaries (*continued*)

Search aim	Search strategy	Setting	Databases searched	Inclusion criteria	Data to be extracted	Results
Theories of interventions	("logic model" OR "theory of change" OR "theory of action" OR "outcomes chain" OR "program * theory" OR "program * logic" OR "logical framework") AND ("preconception care" OR "preconception health")	English language only High- and middle-income countries	Google Scholar	Publications 2015–20	Theory identified underpinning intervention	**14 papers included in the final review** 65 identified Screen abstracts 49 not relevant/lacked adequate explanatory power to contribute to theory 11 LMIC 1 duplicate 4 read in full and 2 excluded as no theoretical component

Review of pregnancy and weight management studies

Review aims and search strategies

Aim
To identify key effective weight management interventions in pregnancy and to summarise content and context to be considered in a preconception weight management intervention. A simple search of systematic reviews, and subsequent snowballing, was carried out to identify relevant interventions.

Date range
2010–19.

Specific search strategy
"Systematic review" AND ("intervention" OR "programme") AND ("obesity" OR "overweight" OR "obese") AND (("diet" OR "physical activity" OR "exercise" OR "healthy eating" OR "lifestyle" OR "weight loss" OR "weight management" OR "healthy lifestyle" OR "weight gain") AND ("pregnant" OR "pregnancy" OR "gestation" OR "obstetrics")

Databases searched
PubMed.

Results
A total of 35 systematic reviews were reviewed for relevant information and key weight management in pregnancy interventions.

TABLE 35 Search strategy results: pregnancy and weight management studies

Search terms	PubMed	Total hits	Excluded	Final total
Intervention AND ("Weight loss" OR "Weight management" OR "diet counselling" OR overweight OR obese OR obesity) AND ("Physical activity" OR exercise OR diet OR "healthy eating") AND (pregnancy OR postnatal* Or post-natal*) AND ("Randomised controlled trail" OR "Randomized controlled trail" OR trial OR study)	109	109	74	35

Appendix 7 Policy review results

TABLE 36 Policy review

	Organisation and website/ repository searched	Document title	Document type	Year	Topic(s) of discussion
1	FSRH (www.fsrh.org)	Contraception for women with eating disorders[169]	CEU statement	2018	Weight gain associated with LARC
2	FSRH (www.fsrh.org)	Provision of LARC methods to young women in the UK[100]	CEU statement	2015	n/a
3	FSRH (www.fsrh.org)	Intrauterine contraception[99]	Clinical guidance	2019	LARC removal as an opportunity to provide preconception health advice
					LARC removal
					Weight gain and LARCs
4	FSRH (www.fsrh.org)	Progestogen-only implants[171]	Clinical guidance	2014	Weight gain and contraception
					Drug interactions; LARCs and weight
5	FSRH (www.fsrh.org)	Contraception after pregnancy[170]	Clinical guideline	2017	Obesity as a medical consideration
6	FSRH (www.fsrh.org)	Overweight, obesity and contraception[172]	Guideline	2019	Progesterone-only implants
					Anti-obesity medication and contraception
					Benefits and risks of combined hormonal contraception (oral, patch, transvaginal ring)
					Effectiveness of IUDs/LARC in women with overweight or obesity
					Progesterone-only injectables and weight/BMI
7	FSRH (www.fsrh.org)	Contraception for women aged over 40 years[168]	Guideline	2019	Weight gain
8	FSRH (www.fsrh.org)	Contraception and weight gain[167]	CEU statement	2019	Weight gain
9	Denison *et al.*, on behalf of RCOG (www.rcog.org.uk)[18]	Care of Women with Obesity in Pregnancy	Green-top Guideline (No. 72)	2019	PCC and maternal weight
10	RCOG (www.rcog.org.uk)	RCOG co-launches new digital tool to help prepare women for pregnancy (Tommy's Planning for Pregnancy tool)[101]	Press release	2018	Promotion of preconception health/healthy pregnancy advice

	Organisation and website/ repository searched	Document title	Document type	Year	Topic(s) of discussion
11	NICE (www.nice.org.uk)	Long-acting reversible contraception[173]	Clinical guideline	2005	LARC removal
12	NICE (www.nice.org.uk)	Weight management before, during and after pregnancy[16]	Public health guideline	2010	Pre-pregnancy planning for women with high BMI
13	BPAS (www.bpas.org)	Women cannot control fertility through contraception alone[174]	Press release	2017	LARC failure
14	Shawe *et al.* 2015[175] Identified by study team/advisory group	Preconception care policy, guidelines, recommendations and services across six European countries: Belgium (Flanders), Denmark, Italy, the Netherlands, Sweden and the UK	Review	2014	Scope and content of current PCC guidance in Europe
15	McAuliffe *et al.*, on behalf of the International Federation of Gynaecology and Obstetrics (FIGO) Pregnancy and Non-Communicable Diseases Committee[20] Identified by study team/advisory group	Management of prepregnancy, pregnancy, and postpartum obesity	FIGO guideline	2020	Impact of obesity on preconception, pregnancy and post-pregnancy care Effectiveness and applicability of interventions

Appendix 8 Review paper results

TABLE 37 Review papers

	Authors and year	Source type	Title	Key preconception papers identified/research notes	Findings
1	Hill *et al.* 2021[120]	CR	Expanding our understanding and use of ecological systems theory model for the prevention of maternal obesity: a new socioecological framework	Theoretical model with potential to underpin intervention development (Kothe *et al.*[176])	Considers the ecological systems theory model for maternal obesity prevention, including in the preconception phase, and the importance of moving away from an oversimplistic focus on the woman's behaviour and responsibility for change; instead, intervention design and understanding of obesity needs to take the wider system into account
2	Hutchesson *et al.* 2020[51]	ScR	Supporting women of childbearing age in the prevention and treatment of overweight and obesity: a scoping review of randomised control trials of behavioural interventions	Only one preconception paper: the Prepare trial protocol (LeBlanc *et al.*[52])	This scoping review identified an increasing volume of research over time undertaken to support women of childbearing age to prevent and treat overweight and obesity. Only preconception study is LeBlanc *et al.* protocol. Of the 87 included RCTs, 52.9% ($n = 46$) focused on preventing excessive GWG, 20.7% ($n = 18$) focused on weight loss or preventing weight retention in the post-partum period, and 16.1% ($n = 14$) focused on both, with the remaining studies in the general population, not related to pregnancy
3	Caut *et al.* 2020[33]	SR	Dietary guideline adherence during preconception and pregnancy: a systematic review	Importance of diet	Review of observational studies of dietary intake of men and women in preconception and pregnancy. Main findings are that usual diet is insufficient in terms of nutritional guidelines. Preconceptual and pregnant women may not be consuming enough vegetables, cereal grains, folate, iron and calcium, and may be consuming excess fat
4	Farpour-Lambert *et al.* 2018[22]	SR MA	Obesity and weight gain in pregnancy and postpartum: an evidence review of lifestyle interventions to inform maternal and child health policies	Focus on pregnancy but identifies need for preconception intervention and also some key parameters	Weight loss prior pregnancy is probably needed to achieve both GWG goals and optimal pregnancy outcomes. Weight loss objectives should be realistic (5–10% over a period of 6 months) and individualised. Structured intensive programs using cognitive–behavioural techniques in individual or group setting are effective in achieving realistic goals in an adequate time frame

	Authors and year	Source type	Title	Key preconception papers identified/research notes	Findings
5	Musgrave *et al.* 2019[177]	SR MA	Addressing preconception behaviour change through mobile phone apps: a protocol for a systematic review and meta-analysis	When findings available they can be used to inform any app-based aspect of future intervention	This review will include trials that assess any mobile phone application that assist women of reproductive age to optimise health behaviours
6	Barker *et al.* 2018[29]	CR	Intervention strategies to improve nutrition and health behaviours before conception	Community engagement with preconception	Preconception interventions often require engagement from individuals who are unlikely to be using maternal health services. Interventions to improve health behaviours in adolescents and young adults might, therefore, need to appeal to motivations unrelated to health
7	Stephenson *et al.* 2018[27]	CR	Before the beginning: nutrition and lifestyle in the preconception period and its importance for future health	Help to think about the stage of 'planning' women are at and how that relates to potential target behaviours/ population-based intervention	Discussion of the concept of planning in pregnancy and whether it is linked to preconception health behaviours. Planning is more common than previously recognised and associated with a mixed pattern of health behaviours before conception. Paper proposes three definitions of the preconception period relating to embryo development and actions at individual or population level
8	Goossens *et al.* 2018[131]	SR	Barriers and facilitators to the provision of preconception care by healthcare providers: a systematic review	Key elements to consider at provider level for any preconception intervention	Mixed-methods SR including 31 papers. Barriers were more reported than facilitators, including attitude and knowledge of provider and client. Limited resources (lack of time, tools, guidelines and reimbursement) were frequently reported at the organisational and societal levels. Conclusions: need for multilevel interventions
9	Toivonen *et al.* 2017[139]	ScR	Preconception health behaviours: a scoping review	Identifies narrow definition of relevant preconception health behaviours	This paper briefly reviews evidence of the importance of various preconception health behaviours and examines the extent to which specific preconception health behaviours have been included in recent studies of such knowledge, behaviours and intentions. Over 40% of studies examining preconception health behaviour focused exclusively on folic acid; only 11% of all studies included male participants. Recommends including men in future research, assessing a wider variety of behaviours and consideration of intention, knowledge and behaviour

continued

TABLE 37 Review papers (*continued*)

	Authors and year	Source type	Title	Key preconception papers identified/research notes	Findings
10	Brown *et al.* 2017[178]	SR	Preconception health interventions delivered in public health and community settings: a systematic review	Agricola *et al.* 2014;[179] Schwarz *et al.* 2008;[180] Chan *et al.* 2001;[181] DeJoy 2014;[182] Hillemeier *et al.* 2008;[71] Hussaini *et al.* 2013;[183] Whitehill King *et al.* 2013;[184] Mackert *et al.* 2012;[185] Milan and White 2010;[186] Wade *et al.* 2012;[187] Watson *et al.* 2001;[188] Williams *et al.* 2001[189]	PCC interventions typically focus on medical and lifestyle determinants of preconception health and are aimed at the individual. Methodological quality of research is poor, and there is a lack of information on interventions appropriate for men and LGBTQ populations. No studies targeted broader determinants of preconception health, including mental health and environment
11	Hemsing *et al.* 2017[37]	ScR	Preconception health care interventions: a scoping review	Beckmann *et al.* 2014[190] reporting change in BMI in 6 months prior to conception	Interventions are mostly education regarding risk and measured alcohol, caffeine and dietary changes and change in knowledge/attitudes. Only one study reports BMI change[190]
12	i-WIP review of pregnancy interventions: International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017[21]	MA	Effect of diet and physical activity based interventions in pregnancy on gestational weight gain and pregnancy outcomes: meta-analysis of individual participant data from randomised trials	Lessons from pregnancy	Diet- and physical activity-based interventions during pregnancy reduce GWG and lower the odds of caesarean section. There is no evidence that this differs across different subgroups of women
13	Lan *et al.* 2017[48]	SR MA	Systematic review and meta-analysis of the impact of preconception lifestyle interventions on fertility, obstetric, fetal, anthropometric and metabolic outcomes in men and women	Mutsaerts *et al.* 2010;[191] Mutsaerts *et al.* 2016;[150] Moran *et al.* 2011;[192] Sim *et al.* 2014;[145] Legro *et al.* 2015[44] Identified lack of weight preconception research outside fertility treatment context	Impact of preconception lifestyle interventions on live birth, birthweight and pregnancy rate. The search returned 1802 articles and eight studies were included for analysis. Populations targeted were primarily overweight or obese subfertile women seeking reproductive assistance, with few community-based studies and none including men. MA showed greater reduction in weight and BMI with intervention
14	Hanson *et al.* 2017[112]	CR	Interventions to prevent maternal obesity before conception, during pregnancy and post-partum	Barker *et al.* (Southampton initiative) 2011;[193] Van Dijk 2017.[138] Key theoretical models, e.g. Bronfenbrenner 1979[194]	Identifies the need for an integrated approach that involves more that just primary care, taking a much wider perspective than the individual – an ecological approach to risk reduction. Much wider societal understanding on preconception health is needed. Discussion of theoretical models of behaviour change

	Authors and year	Source type	Title	Key preconception papers identified/research notes	Findings
15	Hill 2016[195]	NR	Psychological health and lifestyle management preconception and in pregnancy	Importance of psychological factors	Positive role of healthful lifestyles before and during pregnancy. Factors such as psychological well-being, individual motivation for behaviour change and broader social influences are key modifiable aspects to consider in relation to changes in diet and activity. Also require system-wide changes to impact on barriers to healthful lifestyles
16	Hussein *et al.* 2016[36]	SR	The effects of preconception interventions on improving reproductive health and pregnancy outcomes in primary care: a systematic review	SHW[196] intervention (includes BMI and anthropometric measures). Change to folic acid and activity but not anthropometrics	This review identified encouraging benefits of preconception education and counselling on maternal knowledge, self-efficacy and health locus of control, and risk behaviour. The effects on adverse pregnancy outcomes remain unclear
17	Opray *et al.* 2015[46]	SR	Directed preconception health programs and interventions for improving pregnancy outcomes for women who are overweight or obese	Identified lack of preconception weight research. SHW[196] intervention found but excluded as unable to report outcomes by BMI category	Found no randomised controlled trials that assessed the effect of preconception health programmes and interventions in overweight and obese women with the aim of improving pregnancy outcomes
18	Muktabhant *et al.* 2015[159]	SR	Diet or exercise, or both, for preventing excessive weight gain in pregnancy	Value of weight management combining diet and exercise in pregnancy	High-quality evidence indicates that diet or exercise, or both, during pregnancy can reduce the risk of excessive GWG, and also has other health benefits, particularly for high-risk women receiving combined diet and exercise interventions. Exercise appears to be an important part of controlling weight gain in pregnancy and more research is needed to establish safe guideline
19	Heslehurst *et al.* 2014[142]	MS	Implementation of pregnancy weight management and obesity guidelines: a meta-synthesis of healthcare professionals' barriers and facilitators using the theoretical domains framework	Theory-driven review of themes of health-care practitioner boundaries and facilitators with themes resonating from pregnancy	This systematic review aimed to identify the determinants of health-care professionals' behaviours in relation to maternal obesity and weight management. Twenty-five studies were included. The domains most frequently identified included 'knowledge', 'beliefs about consequences' and 'environmental context and resources'. Health-care professionals' weight management practice had the most barriers compared with any other area of maternal obesity practice

continued

TABLE 37 Review papers (*continued*)

	Authors and year	Source type	Title	Key preconception papers identified/research notes	Findings
20	Agha *et al.* 2014[3]	SR MA	Interventions to reduce and prevent obesity in pre-conceptual and pregnant women: a systematic review and meta-analysis	Weisman *et al.* 2011.[49] Long-term effects of the SHW intervention	Behavioural interventions in pregnancy may be effective in reducing GWG in obese women without comorbid conditions, but not in overweight or morbidly obese women. Behavioural interventions had no effect on post-partum weight loss, gestation week of delivery and infant birth weight in overweight, obese and morbidly obese women
21	Forsum *et al.* 2013[197]	SR	Weight loss before conception: a systematic literature review	Highlights lack of evidence; see Caut *et al.* 2020[33]	The objective of this study is to assess the effect of weight loss prior to conception in overweight or obese women on a number of health-related outcomes in mother and offspring. Concludes a lack of evidence on safe weight loss approaches pre conception
22	Dellisaint and McKyer 2011[38]	SR	A systematic review of factors utilised in preconception health behaviour research	Weight does not appear to be included as a risk factor. Lack of association between knowledge and behaviour change	This systematic review critically synthesises the literature focusing on factors related to preconception health behaviours among childbearing-age women. Six factors identified: alcohol, glycaemic control, physical activity, pregnancy planning and screening. Knowledge, awareness and beliefs about PCC do not lead to preconception health practice

CR, conceptual review; MA, meta-analysis; MS, meta-synthesis; NR, narrative review; QR, qualitative review; ScR, scoping review; SR, systematic review.

Appendix 9 Weight management in pregnancy key studies

TABLE 38 Weight management in pregnancy: key studies

	Study/lead author	Methods	Intervention	Results	Key context considerations
1	Bogaerts Antenatal Lifestyle Study[198]	RCT: brochure vs. lifestyle intervention vs. usual care	Antenatal lifestyle intervention based on motivational interviewing principles	Targeted lifestyle intervention programme reduces GWG and levels of anxiety	Pre-pregnancy BMI association with anxiety Group-based intervention
2	LIMIT[199–205]	RCT: diet plus activity vs. usual care	Individualised plans based on Australian recommended dietary standards plus advice on walking/ incidental activity	Improved maternity dietary levels and PA during pregnancy, not sustained at 4 months post partum. No impact on other maternal outcomes or GWG	Theoretical design: informed by stage theories of health decision-making
3	HELP-her Australia[206]	RCT: lifestyle programme vs. control for women at risk of GDM	Individual dietary advice and goals	Significant impact on GWG in women with overweight, not in women with obesity	Health coach delivered intervention at antenatal visits Different impact for different baseline BMI group
4	Pregnancy Lifestyle Intervention[207]	Feasibility RCT: lifestyle programme vs. control for women at risk of GDM	Targeted, culturally sensitive lifestyle intervention for Hispanic women	Improvement in diet but no impact on GWG	Culturally sensitive intervention delivered by health educators
5	Therapeutic Lifestyle Changes[208]	RCT: diet and PA vs. control for women with BMI of > 25 kg/m^2	Change in eating patterns and consumption of high-GI foods	Significant effect on GWG and GDM. Improvements in diet	Intervention described as behavioural but no details; delivered by dietitian
6	UPBEAT UK[118,209–215]	RCT: diet and PA for women with BMI of ≥ 30 kg/m^2	Intervention to lower GI and saturated fats	No significant effect on GWG. Improvements in PA and diet. Sustained reduction in dietary glycaemic load and saturated fat intake at 6 months post partum	Delivered in NHS combined group and individual. Differential impact associated with ethnicity. Theoretical design social cognitive theory
7	Four-step multidisciplinary approach intervention[216]	RCT: four-step multidisciplinary approach vs. usual care	Intervention included dietary advice and assessment of psychological factors in eating habits	Reduced GDM and GWG	Multidisciplinary biopsychosocial intervention
8	TOP study[217]	RCT: dietary advice plus problem-solving with PA vs. PA only vs. control	Intervention based on hypocaloric Mediterranean-style diet delivered by dietitian	Both interventions reduced GWG compared with controls	Dietetics delivery. Use of problem-solving, goal-setting, etc., but no theoretical aspect of design reported. Impact of PA component

	Study/lead author	Methods	Intervention	Results	Key context considerations
9	Healthy Moms US[111,218]	RCT: diet and PA intervention aimed at achieving GWG within 3% of baseline weight, plus standard care	Intervention combining individual and group sessions with dietitian focus on Dietary Approaches to Stop Hypertension, PA, behaviour change	Significant impact on GWG	Use of BCTs, but no specific theory identified. High-intensity intervention
10	Lifestyle in pregnancy (LIP)[219,220]	RCT: diet and PA intervention vs. control	Individualised dietary advice and PA, including pedometer, gym membership, weekly training	Intervention reduced GWG. Increased PA during pregnancy but not sustained post partum	Tailored advice based on energy requirement goals
11	ROLO study[221–227]	RCT: diet-only intervention delivered in small groups vs. routine care	Intervention delivered by dietitians in three small group sessions. Advice on healthy, low-GI diet	Intervention slowed GWG in later pregnancy, reduced overall change in insulin concentrations and improved GI dietary intake	Low intensity intervention. No PA element
12	OPTIMISE[228]	RCT: individualised lifestyle advice vs. routine care on maternal and infant health outcomes for women with BMI of 18.5–24.9 kg/m^2	Intervention combines face-to-face and telephone advice using SMART goals approach	Study ongoing	Women with BMI in normal range. Individualised based on basal metabolic rate and activity level. Informed by stage theories of health decision-making
13	GeliS trial[229]	Cluster RCT: lifestyle intervention vs. routine care	Intervention includes diet, moderate PA, and self-monitoring of weight gain across four sessions with range of health-care providers	No effect on GWG	Greater GWG more frequent among women with overweight and obesity. Implementation within health-care sessions is difficult
14	DALI study[230–233]	Multinational RCT for women with BMI of $\geq$ 29 kg/m^2: lifestyle intervention vs. routine care	Intervention includes tailored diet and PA across nine sessions using principles of motivational interviewing with lifestyle coach	Significantly lower GWG in intervention group but no impact on fasting glucose	Recommendations of limit to GWG. Use of motivational interviewing principles. Intervention delivery did not meet motivational interviewing fidelity
15	LIFE-MOMS[234]	Consortium of seven RCTs testing different lifestyle interventions to reduce excess GWG	Intervention targeting diet, PA and behavioural strategies	Behavioural lifestyle interventions focusing on diet and PA have significant effect on reducing excess GWG	Variety of approaches can be used to support women to change behaviours to control amount of weight gain. Raises the question as to whether maternal weight gain is an appropriate outcome metric. Potentially need to explore body composition/fat mass

GDM, gestational diabetes mellitus; PA, physical activity.

Appendix 10 Barriers and facilitators

TABLE 39 Barriers and facilitators: results

	Reference	Methodology	Study aim; health behaviour(s) addressed; intervention(s)	Results/conclusions	Key contextual influences (barriers/facilitators); limitations and/or recommendations
1	Beckmann *et al.* 2014[190]	**Design:** case–control study of PCC (2010–13); statistical/quantitative study utilising routine data **Participants:** women attending PCC clinics, including those with subfertility and women with pre-existing health conditions that have the potential to impact pregnancy outcomes, as well as low-risk women seeking assessment and advice as to how best to maximise their chance of a healthy pregnancy outcome ($n = 407$). Participant consent not sought **Setting:** PCC services delivered at not-for-profit private tertiary maternity hospital in Brisbane, QLD, Australia **Primary outcome:** likelihood of 'being healthy' at the time of hospital maternity booking. ['Being healthy' defined as (1) early-pregnancy weight in a healthy range (BMI 18.5–24.9 kg/m^2), (2) ceased/reduced smoking and alcohol consumption, (3) folate supplementation for at least 3 months prior to conception and first 3 months of pregnancy, (4) vaccinated against influenza, pertussis, varicella and hepatitis B, and (5) had received specialist consultation with specific aim of optimising a pre-existing health condition prior to conception]	**Aim:** to evaluate whether women who receive PCC through a structured approach will be more likely to be healthy around the time of conception than women who plan their pregnancy but have not been exposed to PCC **Health behaviours addressed:** diet/nutrition, exercise, alcohol and smoking **Intervention:** 45-minute consultation with midwife addressing questions related to participants' reproductive, medical, surgical, social and family histories; lifestyle; nutrition; home; work; and social hazards Participants received specific advice and information regarding folic acid supplementation, vaccinations, healthy eating before and during pregnancy, exercise, smoking cessation, and safe levels of alcohol intake Participants subsequently received consultation from obstetrician; positive responses elicited during midwife consultation were addressed, and examinations, investigations and referrals were completed as required	Women in early pregnancy who attend a preconception consultation are more likely to be healthy across several domains than women who plan their pregnancy but do not attend a preconception consultation. Specifically, they are more likely to: 1. have received adequate periconceptual folate 2. report being vaccinated against influenza and hepatitis B 3. have consulted with a specialist with the specific aim of optimising a pre-existing health condition prior to conception 4. report less weight gain (and a smaller increase in BMI) over the 6 months prior to conception until the booking visit Compared with non-attendees, women who attended a preconception consultation gained less than half as much weight pre pregnancy. Over 80% of women reported taking adequate periconceptual folate	Participants weighed more, were older and experienced more recurrent miscarriages and more difficulties conceiving than the general population Possible selection bias: women who attended PCC may represent a more motivated population than women who did not attend Routinely collected data were entered manually and thus subject to data entry error This service was piloted in a tertiary maternity hospital, but most women planning a pregnancy are not high risk and PCC should be a primary health-care initiative Intervention delivered in setting not routinely accessed by general population (tertiary maternity hospital); more appropriate for use in primary health-care services

	Reference	Methodology	Study aim; health behaviour(s) addressed; intervention(s)	Results/conclusions	Key contextual influences (barriers/facilitators); limitations and/or recommendations
2	Cunningham *et al.* 2018[43]	**Design:** qualitative/observational. Interviews conducted with study participants: standardised interview framework utilised. Interviews audio-recorded, transcribed and analysed thematically **Participants:** pregnant women with BMI of > 30 kg/m^2 ($n = 11$) **Setting:** antenatal services located in a hospital in south-west England (January–June 2016)	**Aim:** to explore the experiences of pregnant women with a raised BMI to investigate if their pregnancies were affected by their interactions with midwives and other health professionals No interventional component	**Results:** Three major themes were identified: 1. 'feeling judged' 2. 'knowledge gap' 3. 'doing your best' While most participants experienced the patient–midwife relationship as supportive, three reported that midwives had been embarrassed to address their weight and found the conversation difficult Pregnant women with raised BMI reported feeling 'judged' about their weight during communications with midwives and other health professionals; feelings of guilt and embarrassment were expressed Women reported a 'knowledge gap' relating to the health implications of weight and raised BMI, and the majority did not remember their midwives talking in any detail about their raised BMI or about why it might be important	Homogeneous sample: all participants were white British and recruited from a single hospital trust Women with raised BMI in this study did not consider themselves 'obese' and found the term rude and offensive; alternative terms such as 'raised BMI' were considered more appropriate/preferable

continued

TABLE 39 Barriers and facilitators: results (*continued*)

	Reference	Methodology	Study aim; health behaviour(s) addressed; intervention(s)	Results/conclusions	Key contextual influences (barriers/facilitators); limitations and/or recommendations
3	Greenhalgh *et al.* 2015[134]	**Design:** qualitative **Methods:** narrative interviews, focus groups/group story-sharing **Participants:** women of Bangladeshi, Indian, Sri Lankan or Pakistani origin, with diabetes, aged 21–45 years, living in London ($n = 45$) **Setting:** diabetes and antenatal services in two deprived London boroughs	**Aim:** to understand multiple influences on behaviour (and risks to metabolic health) of South Asian mothers and their unborn child, theorise how influences interact and build over time, and inform the design of culturally congruent, multilevel interventions No interventional component	**Results:** participants described experiences of diabetic pregnancy as stressful, difficult to control and associated with negative symptoms, especially tiredness Participants reported that exercise and restricted diet worsened diabetes symptoms and conflicted with advice from relatives and peers Participants held beliefs that exercise during pregnancy would cause harm to the fetus and that eating would be strength-giving for mother and fetus Whereas peer advice was familiar, meaningful and morally resonant, health education advice from clinicians was usually unfamiliar and devoid of cultural meaning	Participants cited family and culture as key influences on their understanding of pregnancy-related health Behaviour change interventions aimed at preventing and managing diabetes in South Asian women before and during pregnancy are likely to be ineffective if delivered in a sociocultural vacuum Individual education should be supplemented with community-level interventions to address the sociomaterial constraints and cultural frames within which behavioural 'choices' are made

	Reference	Methodology	Study aim; health behaviour(s) addressed; intervention(s)	Results/conclusions	Key contextual influences (barriers/facilitators); limitations and/or recommendations
4	Khan *et al.* 2019[144]	**Design:** qualitative/ phenomenological. In-depth exploration of women's attitudes and lived experiences achieved via telephone/video semistructured interviews and open-ended questions (data collected March–August 2018). Deductive and inductive thematic analysis was conducted **Participants:** women aged ≥ 18 years who were able to communicate in English and had recently joined or upgraded private health-care insurance cover to include obstetrics, and who were planning a pregnancy in the next 12 months ($n = 7$), were currently pregnant ($n = 7$) or had given birth in the past 12 months ($n = 1$) (total $n = 15$) **Setting:** private health-care services in Australia	**Aim:** to understand women's general attitudes towards preconception health and what health actions they were taking or planning to take in the lead-up to pregnancy No interventional component **Health behaviours discussed:** diet, physical activity, alcohol	Participants identified healthy diet, regular physical activity, reducing alcohol intake and pre-pregnancy vitamin supplementation as important preconception health behaviours Few participants acknowledged the importance of formal preconception health checks and screening with health professionals; awareness of services was low Barriers to achieving health behaviour change included anxiety, stress and challenges obtaining reputable information Participants reported a lack of preconception information about supplementation requirements, safe foods and exercise recommendations Information source preferences included the internet or their GP	Most participants were focused and motivated to engage in healthy preconception behaviour, signalling pregnancy intention to GP, seeking information and adopting positive preconception lifestyle behaviours Although participants were engaged, they had limited awareness of available preconception health checks and screening National preconception health guidance is currently lacking; this could usefully include preconception checklist addressing key health actions and suggested timings

continued

TABLE 39 Barriers and facilitators: results (*continued*)

	Reference	Methodology	Study aim; health behaviour(s) addressed; intervention(s)	Results/conclusions	Key contextual influences (barriers/facilitators); limitations and/or recommendations
5	Kothe *et al.* 2019[176]	**Design:** observational/qualitative; documentary analysis. Midwifery courses were identified ($n = 568$) and course outline material was obtained ($n = 252$) **Setting:** midwifery courses from 20 Australian universities **Methodology:** documentary data coded using Framework Analysis technique against three themes: 1. the effect of weight, diet and physical activity on health outcomes for women who are pregnant or planning a pregnancy 2. weight management advice in any population 3. health BCTs in any context	**Aim:** to identify strengths and deficits in teaching of preconception and antenatal weight management within Australian universities' midwifery curricula **Health behaviours discussed:** weight, diet, physical activity	**Results:** there is a strong focus on health promotion throughout pregnancy in midwifery training in Australia. Teaching methods and skills training addressed risk identification and lifestyle management and emphasised the importance of clinical judgement and autonomous clinical practice, as well as adopting critical enquiry and sourcing reputable evidence Despite these strengths, there is little evidence that weight management advice was taught explicitly to midwifery students	A greater emphasis on skilling midwifery students to address weight gain during pregnancy, and behavioural techniques to achieve this, is required

	Reference	Methodology	Study aim; health behaviour(s) addressed; intervention(s)	Results/conclusions	Key contextual influences (barriers/facilitators); limitations and/or recommendations
6	Stephenson *et al.* 2014[35]	**Design:** cross-sectional questionnaire survey addressing knowledge and uptake of PCC, plus interviews with a range of health-care professionals ($n = 20$) **Participants:** pregnant women attending three maternity services in London ($n = 1173$), and health-care professionals working in general practice, obstetrics and gynaecology, midwifery and sexual and reproductive health	**Aim:** to determine the extent to which women plan and prepare for pregnancy No interventional component **Health behaviours discussed:** folic acid, vitamin supplements, diet, weight, alcohol, smoking, immunisation, recreational drugs, STIs, dental checks, caffeine, stopping contraception/fertility advice	**Results:** 73% had clearly planned their pregnancy, 24% were ambivalent and 3% of pregnancies were unplanned Health professional interviews indicated low awareness of preconception health issues, missed opportunities and confusion about responsibility for delivery of PCC	Despite a high level of pregnancy planning, awareness of preconception health among women and health professionals is low, and responsibility for providing PCC is unclear. Strategies to improve awareness and uptake of pre-pregnancy health care should be identified
7	Weisman *et al.* 2011[49]	**Design:** intervention evaluation utilising statistical analyses of weight-related data and qualitative interviews **Intervention:** SHW, a small-group behavioural intervention for preconceptional and interconceptional women designed to modify key risk factors for adverse pregnancy outcomes **Participants:** women in the original trial of the SHW intervention ($n = 362$) and who had records linked to singleton births during the 12-month follow-up period ($n = 45$) **Setting:** intervention delivered across 12 weeks via six face-to-face sessions held at community locations in low income and rural communities in central Pennsylvania, USA	**Aim:** to investigate long-term (6- and 12-month) effects of SHW intervention on health-related behaviours, weight, BMI and weight gain during pregnancy	**Results:** At 12-month follow-up, SHW participants were significantly more likely than controls to use a daily multivitamin with folic acid and to have lower weight and BMI The intervention's effect on reading food labels for nutritional values dropped off between the 6- and 12-month follow-ups Among those who gave birth to singletons during the follow-up period, women who participated in the intervention had lower average pregnancy weight gain than controls Although the intervention effect was no longer significant when controlling for pre-pregnancy obesity, the adjusted means show a trend towards lower weight gain in the intervention group	Findings strongly suggest that SHW is effective in modifying risk factors for adverse pregnancy outcomes and may help prevent weight gain during pregnancy SHW appears to help women manage weight in the months after the intervention as well as during pregnancy, and may be an effective obesity prevention strategy for women before, during and after the transition to motherhood Delivering all intervention components, activities and content in face-to-face sessions was resource-intensive and expensive, and the time investment required for participation was burdensome for some women

continued

TABLE 39 Barriers and facilitators: results (*continued*)

	Reference	Methodology	Study aim; health behaviour(s) addressed; intervention(s)	Results/conclusions	Key contextual influences (barriers/facilitators); limitations and/or recommendations
8	McBride *et al.* 2012[136]	**Design:** survey **Participants:** pregnant women receiving prenatal health care ($n = 142$) **Setting:** public health-care services in Perth, Western Australia	**Aim:** to identify factors that contribute to alcohol consumption during pregnancy (which may help direct potential intervention strategies)	**Three risk groups identified:** the 'no risk' group discontinued alcohol consumption once pregnant (33.1% of participants), the 'low risk' group consumed one or two drinks per week (45.8% of participants) and the 'risky' group consumed more than two drinks per week (21.1% of participants) **Demographics:** 'low-risk' women were more likely to have a higher education than other participants; 'no-risk' women were significantly more likely to be engaged in full-time home duties than other participants Women who continued to drink more likely to have done so in previous pregnancies and during the preconception period All participants reported that they would be most likely to drink in their own home or in the home of a friend	**Conclusions:** combined prevention efforts may be important to assist women in quitting multiple substances The social determinates that give rise to women's risky use of alcohol (and other drugs) during pregnancy are likely to be complex and will therefore require a complex intervention Participatory research with women who drink while pregnant can assist in identifying potential intervention strategies that have resonance with this group, and therefore more potential for creating behaviour change **Limitations:** participants not representative of population at large (self-selected). Survey limited in scope; additional data collection strategies (e.g. focus groups) could identify additional data/findings

Reference	Methodology	Study aim; health behaviour(s) addressed; intervention(s)	Results/conclusions	Key contextual influences (barriers/facilitators); limitations and/or recommendations
			Participants who continued to drink identified relaxation, social contact and taste as benefits; all groups expressed concern around the potential risk of Fetal Alcohol Syndrome (approximately one-third of women who continued to drink reported this concern) Nearly 40% of 'high-risk' women reported that they had received negative comments from friends, families or partners in response to their drinking, and one-third had been advised by a health professional not to drink alcohol. This group were also more likely to use other drugs, in particular tobacco and cannabis	

Appendix 11 Key qualitative and survey-based literature

TABLE 40 Key qualitative and survey-based literature

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
1	Poels *et al.* 2017[235]	**Observational** **Methods:** retrospective questionnaire (no qualitative component) **Participants:** women who received antenatal care ($n = 283$) **Setting:** primary care community midwifery practice in the Netherlands	**Objective:** to assess whether or not actively preparing for pregnancy is associated with lifestyle changes during the preconception period	A total of 56.5% ($n = 160$) of participants acquired preconception information for themselves in preparation for pregnancy; 24% ($n = 68$) received a PCC consultation from a health-care provider When compared with women who did not prepare for pregnancy, the first group was significantly more likely to make positive lifestyle changes, including ceasing alcohol consumption (adjusted OR 5.46, 95% CI 1.76 to 16.96), improving diet (adjusted OR 7.84, 95% CI 3.03 to 20.30) and using folic acid (adjusted OR 3.90, 95% CI 2.00 to 7.62) Effect sizes were larger for women who also consulted a health-care provider **Key conclusions:** gathering preconception information is associated with women positively changing lifestyles during the preconception period	Self-reported, retrospective data only; study population confined to women who had recently given birth Participant sample was homogeneous and not representative of wider population (Dutch, high education level, high household income)

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
2	Ockhuijsen *et al.* 2012[124]	**Interventional**, with evaluative qualitative questionnaires **Participants:** patients (couples) on the waiting list for an IVF or ICSI treatment ($n = 130$); IVF clinic nurses ($n = 7$) **Setting:** a single IVF preconception clinic in a university medical centre in the Netherlands	To understand outcomes of integrating PCC into an IVF programme by measuring nurses' and patients' attitudes and patients' weight- and smoking-related behaviour	All nurses and 101 patients (77.7%) returned completed questionnaires Patients valued increased attention to adjusting lifestyle factors with the goal to improve fertility outcomes Among participants who smoked or had a BMI of > 30 kg/m^2, 30% quit smoking and 50% lost weight (mean loss: 6.1 kg) Nurses were sceptical of the value of the programme and their ability to perform their new role effectively	Questionnaire validation limited (three expert opinions) Self-reported measurements only Small sample; patient population restricted to those on waiting list for IVF
3	McPhie *et al.* 2017[236]	**Observational** **Methods:** semistructured telephone interviews, thematic analysis **Participants:** health professionals with expertise in maternal health ($n = 20$) **Setting:** maternity services and medical clinics in Melbourne, VIC, Australia	**Aim:** to identify barriers to providing preconception weight management	**Barriers facing women:** lack of awareness regarding importance of preconception weight, not being provided weight management information/interventions **Barriers facing health professionals:** absence of implementation resources, limited access to women of childbearing age who plan to conceive, high percentage of unplanned pregnancies, time constraints in clinic, sensitivity of subject	Participants known to researchers; risk of bias Client base of participants may not be representative of women from a wide range of backgrounds Setting (Australia)

continued

TABLE 40 Key qualitative and survey-based literature (*continued*)

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
4	Shawe *et al.* 2019[130]	**Observational** (no qualitative component) **Methods:** cross-sectional survey **Participants:** men attending antenatal care with their partners ($n = 573$) **Setting:** antenatal care clinics/ maternity units in London, UK	**Research questions:** • What are participants' levels of pregnancy planning? • What are participants' preconception health behaviours? • Had participants sought information and health professional advice before conception?	A total of 46.9% of participants reviewed pregnancy-related information from a variety of sources, including online, before their partner became pregnant 74% of pregnancies were planned Male 'planners' were more likely than other men to reduce smoking, reduce alcohol consumption and eat more healthily in preparation for pregnancy 57% of participants took no action to improve their health	Retrospective, self-reported data only Participant demographics limited diversity; 74% of participants were white, and the majority had a high level of education (67% had a degree) and were in employment or full-time education (87%)
5	Stephenson *et al.* 2014[35]	**Observational** **Methods:** cross-sectional questionnaire survey and telephone interviews **Participants (survey):** women attending maternity services in London ($n = 1173$) **Participants (telephone interviews):** doctors and nurses from a range of health-care professions ($n = 20$) **Setting:** maternity services of three north London hospitals	**Research questions:** • To what extent do women plan pregnancy? • What is women's knowledge and uptake of PCC?	**Women:** 73% had clearly planned pregnancy, 24% were ambivalent, and 3% of pregnancies were unplanned 51% of all women and 63% of those with a planned pregnancy took folic acid before pregnancy 21% of all women reported smoking and 61% reported drinking alcohol in the 3 months before pregnancy 48% of smokers and 41% of drinkers reduced or stopped before pregnancy	Health professionals – particular setting influences ability to provide information (e.g. GPs faced particular barriers)

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
				The 51% of all women who reported advice from a health professional before becoming pregnant were more likely to adopt healthier behaviours before pregnancy **Health professionals:** barriers to providing PCC include unplanned pregnancies, lack of knowledge/ interest, constrained resources, and confusion about responsibility for delivery of PCC	
6	Bortolus *et al.* 2017[132]	**Observational** **Methods:** focus groups **Participants:** nulliparous and multiparous women of childbearing age ($n = 14$); nurses ($n = 3$); midwives ($n = 4$); obstetrics and gynaecology/ paediatric consultants ($n = 5$) **Setting:** obstetrics and gynaecology, paediatrics and assisted reproduction services, Verona University Hospital, Italy	**Aim:** to understand attitudes and behaviours of Italian women of childbearing age and health-care professionals regarding preconception health	Women's knowledge of preconception risk factors, such as pre-existing conditions, overweight/ obesity and infectious disease, is poor Majority of women did not speak to a health professional before trying to become pregnant No clear professional responsibility for addressing preconception health; health-care professionals do not adopt a 'proactive' attitude Poor public health promotion of healthy preconception behaviour	Small sample size Homogeneous cohort (middle class, white, educated)

continued

TABLE 40 Key qualitative and survey-based literature (*continued*)

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
7	Duthie *et al.* 2013[237]	**Observational** **Methods:** semistructured interviews **Participants:** pregnant women (third trimester) ($n = 19$); obstetricians ($n = 7$) **Setting:** obstetrics and gynaecology clinic at a large academic medical centre, midwestern USA	**Aim:** to understand what obstetricians communicate about GWG to pregnant patients and how nulliparous patients perceive weight-related counselling from obstetricians	Four major themes identified, within which there were significant differences between the patient and health-care provider perspective 1. *Discussing GWG.* Obstetricians reported variation in frequency and timing of weight-related discussions with patients. Majority of patients reported that weight was not emphasised by their obstetricians 2. *Discussing nutrition and physical activity.* Obstetricians reported discussing nutrition and physical activity with all patients. Patients reported that their obstetrician either discussed topics in general terms or did not discuss at all 3. *Discussing post-partum weight loss.* Obstetricians reported that they do not typically address post-partum weight loss with patients during prenatal visits. Patients reported having post-partum weight concerns	Limited sample (participants recruited from a single medical centre) Both obstetrician and patient participants self-selected into the study, raising the possibility that those with interest/concern related to gestational weight were more likely to enrol than others

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
				4. *Patient perspective on advice received from obstetricians.* The majority of patients reported that obstetricians do not offer 'unsolicited advice' and do offer information in response to patient questions or concerns. Patients were divided about whether or not they desired more advice from their obstetrician on weight gain, nutrition and activity	
8	Squiers *et al.* 2013[128]	**Observational** **Methods:** focus groups **Participants:** women from a range of demographic backgrounds; 18–44 years old ($n = 65$) **Setting:** Atlanta, GA, USA	**Research questions:** do consumers understand behaviours that fall under the preconception health and health-care umbrella? How do consumers refer to/think about the terms 'preconception health' and 'preconception care'? Is preconception health understood as a set of behaviours or a set of services?	Women planning a pregnancy in the next 2 years had different perspectives on preconception health and health advice from women not currently planning a pregnancy Women who were not planning to get pregnant in the next 2 years reported not wanting to receive preconception health messages from a health-care provider at a routine visit Barriers to preconception health included lack of social support, a medical history of addiction and lack of awareness Participants preferred to think of preconception health behaviours as 'promoting' a healthy baby rather than preventing an unhealthy birth outcome Women preferred to hear preconception health messages from a health-care provider, among other channels	No research recommendations

continued

TABLE 40 Key qualitative and survey-based literature (*continued*)

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
9	Barrett *et al.* 2015[41]	**Observational** **Methods:** in-depth interviews (face to face or telephone), Framework Analysis **Participants:** pregnant and recently pregnant women ($n = 20$). Purposively sampled to include high and low investors in prepregnancy health and care, with variation in age, partnership status, ethnicity and pre-existing medical conditions **Setting:** antenatal clinic attendees, London	**Research question:** why do women invest in prepregnancy health and care?	Relatively few women received advice on healthy diet/healthy weight Three broad groups were identified: 1. The 'prepared' group – had high levels of pregnancy planning and positive attitudes to micronutrient supplementation outside pregnancy, and carried out pre-pregnancy activities such as taking folic acid and making changes to diet and lifestyle 2. The 'poor knowledge' group – had high levels of pregnancy planning, did not carry out prepregnancy activities and described themselves as having poor knowledge. Had a strong dislike of micronutrient supplementation 3. The 'absent pre-pregnancy period' group – had lowest levels of pregnancy planning and also expressed anti-supplement views. Even discussing the pre-pregnancy period with this group was difficult as responses to questions quickly shifted to focus on pregnancy itself 4. Knowledge of folic acid was poor in all groups	Sample bias towards older, well-educated women

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
10	Mazza *et al.* 2013[161]	**Observational** **Methods:** three 90-minute focus groups. Thematic analysis based on the theoretical domain framework, which describes 12 domains related to behaviour change **Participants:** GPs ($n = 22$). Purposive sampling of those working in urban and rural settings, and high and low socioeconomic settings **Setting:** urban and rural GP surgeries in Australia	**Research question:** what are GP-perceived barriers to and enablers of delivery and uptake of PCC guidelines?	**Perceived barriers:** time constraints; lack of women presenting at preconception stage; competing priorities; issues relating to the cost of and access to PCC; and the lack of resources for assisting in the delivery of PCC guidelines **Perceived enablers** identified by GPs included the availability of PCC checklists and patient brochures, handouts, and waiting room posters outlining the benefits and availability of PCC consultations	Australian health-care system (hybrid funding system – some care costs met by patients)
11	Tuomainen *et al.* 2013[64]	**Observational** **Methods:** focus groups ($n = 9$) and follow-up telephone interviews ($n = 19$) **Participants:** women aged 18–45 years, of Pakistani, Indian, Caribbean, African, white and mixed ethnic origin ($n = 41$) **Setting:** ethnically diverse and socially disadvantaged community settings of the UK	**Aim:** to explore perceptions about preconception health and care among women from ethnically diverse communities, and identify opportunities and challenges for intervention development in primary care	Participants had modest/poor awareness of preconception health Participants felt that preconception health could be addressed in primary care if raised within clinically 'relevant' consultations **Challenges highlighted:** little prevailing culture of preparing for pregnancy and/or pregnancies often being unplanned. For those planning pregnancy, sensitivity and maintaining secrecy when trying to conceive Participants expressed a preference for female professionals Participants felt that support was needed to engage men and to enhance access for younger people/women less disposed to general practice	Women under 18 years old were not eligible for participation

continued

TABLE 40 Key qualitative and survey-based literature (*continued*)

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
12	Ojukwu *et al.* 2016[238]	**Observational** **Participants:** GPs ($n = 7$: four male, three female). Five GPs had experience in obstetrics and gynaecology; three had DRCOG qualifications; four were GP trainers **Methods:** interviews **Setting:** London, UK	**Aim:** to examine GPs' knowledge, attitudes and views towards preconception health and care in the general practice setting	GPs agreed on the main issues they would discuss as part of PCC: healthy eating, being a healthy weight, folic acid supplementation, stopping smoking and reducing or abstaining from alcohol consumption Lack of GP knowledge of formal guidelines Some lack of consistency in advice given (e.g. alcohol consumption) Lack of consistency in perceived patient demand for PCC Reaching women before pregnancy was considered important, although not GPs' responsibility (suggested role of educators/nurses) Specialist preconception services were not provided within GP surgeries; PCC was targeted at women clearly planning/with medical conditions GPs described diverse patient groups with very different health needs and significant barriers to providing care [e.g. no preparation for pregnancy, language/culture, lack of time, reluctance to provide unsolicited advice ('nanny state')]	Study was conducted in London borough with disparity of wealth and large ethnic minority population; therefore, may be different from other UK areas

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
13	M'hamdi *et al.* 2017[160]	**Observational** **Participants:** HCPs who regularly provide PCC ($n = 20$: community midwives, $n = 12$; GPs, $n = 3$; obstetricians, $n = 3$; cardiologist, $n = 1$; gastroenterologist, $n = 1$) **Methods**: semistructured interviews **Setting:** the Netherlands	**Aim:** to examine health-care professionals' views of roles and responsibilities in providing PCC and identify barriers that affect delivery and/or uptake	**Multiple barriers identified:** • No comprehensive PCC programme currently exists • Limited patient/parent awareness of PCC benefits • GP hesitance around necessity and effectiveness of PCC • Poor co-ordination and organisation of PCC • Conflicting views of different health-care professionals regarding pregnancy, reproductive autonomy and professional responsibility	Small sample size limits generalisability
14	Van der Zee *et al.* 2013[127]	**Observational** **Participants:** women desiring to conceive, 22–39 years of age (mean 32.8 years). $N = 16$. Recruited online, via 'network of ethnic minority women' and snowball sampling. Educational levels: low ($n = 3$), medium ($n = 3$), high ($n = 10$). Ethnicity/country of birth: Dutch ($n = 12$), Moroccan ($n = 2$), Surinamese ($n = 2$) **Methods**: in-depth, semistructured, face-to-face interviews **Setting**: the Netherlands	**Aim:** to explore women's hesitancy to seek preconception counselling	In some cases, women were disappointed or upset when a GP did not inquire further when they visited to have the coil removed or that a gynaecologist did not mention being overweight as a cause of infertility Women expressed positive attitude towards PCC in general but were hesitant about seeking PCC themselves Women seemed to regard themselves as not being in the target group for PCC Four subthemes identified (subjective norms relating to process of becoming pregnant): planning, publicity, information on fertility and artificiality	Certain participant perceptions (e.g. artificiality) could be culturally specific. The Netherlands has a high rate of planned pregnancy when compared with other nations (85%). Limited user perspective (women only)

continued

TABLE 40 Key qualitative and survey-based literature (*continued*)

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
15	Bombard *et al.* 2013[239]	**Design and methods:** secondary analysis of large national survey (self-reported behavioural and health information) **Participants:** non-pregnant women aged 18–44 years with reported history of hypertension or current antihypertensive medication use ($n = 2063$) **Setting:** USA **Interventional topics discussed:** health-care provider advice on healthy behaviour	**Research questions:** what is the prevalence of receipt of health-care provider advice among women of reproductive age with hypertension, and is receipt of advice associated with behaviour change?	Women who received advice were more likely to report corresponding behaviour change Majority reported that a provider advised them to change eating habits (72.9%), reduce salt intake (74.6%) and exercise (82.1%) Smaller number reported being advised to reduce alcohol use (44.7%) **Behaviour change:** majority reported that they changed eating habits (75.5%), reduced salt intake (80.4%), exercised (70.1%) and reduced alcohol use (67.8%)	Self-reported data only Specific population: women with hypertension history or diagnosis, awareness of health risks
16	Cohen *et al.* 2009[240]	**Design and methods:** secondary analysis of data from the US Government's Centers for Disease Control and Prevention Behavioral Risk Factor Surveillance System telephone survey **Participants:** pregnant women aged 18–44 years who had completed information on attempting to lose weight for the Behavioral Risk Factor Surveillance System survey ($n = 8036$) **Setting:** USA	**Research questions:** what is the prevalence of attempting to lose weight among pregnant women, and to what extent are sociodemographic and health characteristics associated with this behaviour?	The overall proportion of pregnant women who were attempting to lose weight was 8.1% Attempting to lose weight during pregnancy was positively and significantly associated with age (35–44 years), Hispanic ethnicity, obesity, alcohol consumption and mental distress during the previous month	Self-reported data only Data analysed collected 1996, 1998, 2000 and 2003

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
17	Goossens *et al.* 2018[241]	**Design and method:** secondary data analysis of a cross-sectional study about pregnancy planning **Participants:** women with a planned pregnancy ending in birth ($n = 430$) **Setting:** six Flemish hospitals (Belgium)	**Objectives:** (1) to study preconception lifestyle changes and associated factors in women with planned pregnancies; (2) to assess the prevalence of risk factors for adverse pregnancy outcomes in women not reporting any preconception lifestyle changes; and (3) to explore the need for and use of preconception-related advice	Most participants (83%) reported one or more lifestyle change in preparation for pregnancy. The most commonly reported change was consumption of folic acid/multivitamins (76%) and the least common was change focused on diet and/or reducing body weight (12–18%) Nulliparous women and women with a previous miscarriage were more likely to prepare for pregnancy Multiparous women and women of lower socioeconomic status were less likely to change lifestyle before conception Experiencing financial difficulties or having a lower educational level decreased the likelihood of preparing for pregnancy 48% of participants obtained advice about preconception health (and 86% of these participants received advice from a professional caregiver) Three-quarters (77%) of the women who did not improve their lifestyle before conceiving reported one or more risk factors for adverse pregnancy outcomes	Specificity of setting (Belgium)

continued

TABLE 40 Key qualitative and survey-based literature (*continued*)

	Reference	Design (interventional/ observational); methods; participants; setting	Research questions/aims/objectives	Results	Key contextual considerations; study limitations
18	Campbell *et al.* 2011[242]	**Design and method:** systematic review of quantitative and qualitative evidence. Eleven electronic bibliographic databases were searched. Supplementary searching included reference lists of included studies and relevant review articles. A total of five controlled trials and eight qualitative studies were included in the review	**Objectives:** to assess effectiveness of behavioural interventions to prevent excessive weight gain in pregnancy and explore the factors that influence effectiveness	**Controlled trials:** no significant difference in GWG found among participants in intervention groups compared with control groups Study design, participants and interventions varied markedly Subgroup and sensitivity analysis did not identify contextual elements that influenced intervention effectiveness **Qualitative studies:** three major themes emerged relating to women's views of weight management in pregnancy: 1. Pregnancy as a time of transition and change 2. Conflicting and contradictory messages 3. A perceived lack of control Synthesis of qualitative and quantitative results shows that some of the barriers to achieving successful weight management that women identified were not addressed by the interventions evaluated; this may have contributed to the limited effectiveness of the interventions	Small number of studies available met inclusion criteria Many qualitative data conducted in the UK; trial data came from outside the UK: lack of alignment between contexts/cultural settings

Appendix 12 Explanatory accounts

Abbreviations

Nature of source

CC, case–control study; FS, feasibility study; FT, feasibility trial; MA, meta-analysis, ME, methods; NR, narrative review; OC, opinion/conceptual paper; OS, observational study; PT, pilot trial; QR, qualitative review; QS, qualitative study; S, survey; ScR, scoping review; SR, systematic review.

Outcomes

BA, barriers; BC, behaviour change; FE, fertility; HM, health markers; KA, knowledge and attitudes; LT, long-term outcomes; RE, recruitment and engagement; ST, staff related; W16, weight loss in a $\leq$ 16 week programme; W17, weight loss in a $\geq$ 16 week programme.

TABLE 41 Explanatory accounts in preconception-focused studies

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Barker *et al.* 2018[29]	OC	If adults are intending to get pregnant, then the intervention opportunities are to actively support preconception health, for example through text messaging, and provide practical support in an engaging way	RE	Intention	Support
		If adults intending to get pregnant are in a specific subgroup, then they need intense, tailored support	RE	Culture	Tailoring
		If adults intending to get pregnant have previously had a pregnancy, then they will be less receptive to prepregnancy input, and input needs to take previous pregnancy into account	RE	Subsequent pregnancy	Individualised
		If children and young adults are engaged with health behaviour promotions before childbearing capabilities develop, then there is a better chance that they will continue with healthy behaviours in the preconception period	BC	Pre-planning	Habit formation; social movement with preparation for healthy pregnancy becoming more normalised
		If adults with no immediate intention to get pregnant are informed of risk of future loss of ability to have a healthy child, then they may be more motivated by loss aversion	BC	Pre-planning	Loss aversion as motivator in response to public information campaign
		If practitioners are trained in Healthy Conversation Skills, then they will be able to engage and motivate patients and clients about nutrition and PA during brief consultations	ST	Staff skills	Self-efficacy; relationship between competence and confidence of staff
		If supermarkets could convey healthy preconception nutrition messages, for example next to folic acid, then it would be an opportunity to inform a lot of women	RE	Public health messages	Community messages
		If interventions are delivered via digital media, then women experiencing social disadvantage are more likely to engage	RE	Comms strategy	Reach of intervention
		Social marketing (e.g. change4life campaign) did not make an impact because individuals and communities require not only knowledge but also resources to enact change, and a purpose or meaning to provide motivation	BA	Resource	Social practice theory – knowledge, resource and meaning required to enact change

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Becker *et al.* 2015[148]	RCT	If women aged 18–35 years, with BMI of 25–40 kg/m^2, and waiting for their first round of IVF treatment engage in 12 weeks of an individualised low-GI diet plan, then they can achieve a 5.5% weight loss	W16	IVF No-one refused to take part 1/16 could not comply with intervention	Hypocaloric and low-GI individualised plan (20 kcal/kg bodyweight)
		If women on the waiting list for IVF are invited to participate in a WLI, then there is a high take-up rate (100% in this study)	RE	IVF No-one refused to take part 1/16 could not comply with intervention	Motivation
		If women follow too strict a weight loss regimen, then the effect on fertility is uncertain *The exact amount of energy restriction that is safe or deleterious for obese infertile women seeking IVF treatment is not clear*	FE	IVF No-one refused to take part 1/16 could not comply with intervention	Potential risk of too few calories
Beckmann *et al.* 2014[190]	CC	If women are motivated to attend a 90-minute session in a preconception service (including those motivated by subfertility and pre-existing conditions), then they may gain less weight prior to conception	KA	General population attending preconception clinic	Health advice
Brackenridge *et al.* 2018[80]	PS	If women who agree to delay having their coil removed for 24 weeks in order to lose weight are offered intensive meal replacement-based weight loss programme, then one-third of those eligible will agree to take part	RE	BMI > 30 kg/m^2, age 18–40 years Community clinic Delay IUD removal	Hypocaloric, 966–1220 kcal/day
		If women agree to delay having their coil removed for 24 weeks and can follow a low-energy liquid diet weight loss programme, with fortnightly 15-minute motivational support, then they will lose a clinically significant amount of weight (median BMI reduction of 14.2% for completers, 6.6% ITT of all starters)	W17	BMI > 30 kg/m^2, age 18–40 years Community clinic Delay IUD removal	Hypocaloric, 966–1220 kcal/day

continued

TABLE 41 Explanatory accounts in preconception-focused studies (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Caut *et al.* 2020[33]	SR	Usual preconception diet is insufficient in terms of nutritional guidelines	HM	Preconception and pregnancy	Nutrition
Delissaint *et al.* 2011[38]	SR	Knowledge, awareness and beliefs of PCC do not lead to preconception health practice	KA	Preconception health	Need a mechanism for knowledge to be translated into change of behaviour
Einarsson *et al.* 2017[243]	RCT	If participants have a high level of engagement in a 16-week intervention of very low-calorie meal replacement diet plus support every 2–3 weeks, including dietetic input, then they will experience significant weight loss of average 9.44 kg (group mean BMI was 29.8 kg/m^2)	W16	IVF BMI 30–35 kg/m^2 Nordic countries – IVF threshold is BMI of 35 kg/m^2, so all women are already within range	Hypocaloric, 12 weeks at 880 kcal/day
		If women with BMI 30–35 kg/m^2 waiting for IVF are offered 16-week very low calorie meal replacement WLI, then 77% will agree to take part	RE	Nordic countries – IVF threshold is BMI 35 kg/m^2 so all women are already within range	Hypocaloric, 12 weeks at 880 kcal/day
Espinós *et al.* 2017[149]	RCT	If women with BMI 30–40 kg/m^2 waiting for IVF take part in a 12-week diet and exercise programme, then they will lose an average of 6.97% weight	W16	IVF BMI 30–40 kg/m^2, age 18–37 years	Reduction of calories by 500–800 per day plus exercise plus support
Greenhalgh *et al.* 2015[134]	QS	If beliefs about negative effects of diet and exercise during pregnancy are addressed in a culturally relevant way, then participants are more likely to engage with an intervention	RE	South Asian women with GDM	Cultural relevance
		If health promotion messages are not tailored to different groups of people with protected characteristics, then individuals who are understood to be particularly at risk of marginalisation will be further excluded from health care	RE	South Asian women with GDM	Inequity and marginalisation

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Homan *et al.* 2012[244]	PS	If couples undergoing fertility treatment are offered lifestyle advice designed to address lifestyle behaviours potentially influencing fertility and 4 months of weekly support, then 57% will agree to participate and 31% will take part	RE	IVF, all BMI Targeting lifestyle rather than one behaviour such as weight	Engagement/motivation of couples with lifestyle messages is hard to achieve even in motivated population
		If couples undergoing fertility treatment are overweight and are motivated to receive lifestyle intervention using MI principles designed to address lifestyle behaviours potentially influencing fertility and receive weekly follow-up support telephone calls, then 47% of those who take part will lose between 1 and 5 kg in 4 months	W16	IVF all BMI Targeting lifestyle rather than one behaviour such as weight	Motivation – using MI to engage with lifestyle behaviours Couples – mutual support
Hussein *et al.* 2016[36]	SR	If women receive PCC and counselling, then maternal knowledge, self-efficacy and health locus of control, and self-reported risk behaviour will improve	KA	Preconception across BMI	Information increases knowledge and changes attitudes
		If women received preconception care and counselling, then it is unclear whether this has any effect on adverse pregnancy outcomes	KA	Preconception across BMI	The relationship between information, attitude and behaviour change is unclear
		If services have designed and evaluated PCC, then weight is not included in the intervention	BA	SR across BMI	Weight is not regarded as an important aspect of PCC
Khan *et al.* 2019[144]	QS	If the availability of pre-conception screening and advice was promoted to the general public, then anxiety would be reduced and people planning a pregnancy would engage in more healthy behaviours	RE	Australia Preconception, pregnancy and postnatal	Community education
		If national evidence-based guidance and preconception checklists were developed, then clinicians would feel more able to give appropriate advice and people planning pregnancy would feel less anxious about doing the right thing	ST		National guidelines needed

continued

TABLE 41 Explanatory accounts in preconception-focused studies (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
LeBlanc *et al.* 2021[53]	RCT	If women take part in a remotely delivered tailored behavioural WLI, then they can lose 3.5% of their weight before conception	W17	USA Preconception and pregnancy	Behavioural weight loss support
		If women lose a significant amount of weight prior to pregnancy, then there is a risk of weight regain in pregnancy	W17	USA Preconception and pregnancy	Weight loss support needs to continue into pregnancy
		If women lose weight in a preconception intervention, then it is important to continue with support through pregnancy if this loss is to be maintained by the end of the third trimester of pregnancy	W17	USA Preconception and pregnancy	Weight loss support needs to continue into pregnancy
Legro *et al.* 2015[44]	RCT	If women with PCOS undergoing IVF are invited to take part in a 16-week RCT delaying IVF in order to lose a goal of 7% weight, then 17% of eligible women will consent to take part	RE	PCOS and IVF BMI 27–42 kg/m^2; age 18–40 years	Hypocaloric – individualised
		If the intervention is tailored and includes meal replacements and weight loss medication, then participants can experience significant weight loss (between 6.2% and 6.4%) during the 16-week period	W16	PCOS and IVF BMI 27–42 kg/m^2; age 18–40 years	Hypocaloric (between 1200–2000 kcal/day) plus lifestyle modification, including meal replacements, weight loss medication (either sibutramine or orlistat), and increased PA
Mahoney 2014[245]	PS	If women with PCOS are offered a 12-week MI intervention to help with lifestyle change to support fertility, then 22% will participate in the intervention and 16.6% will complete it	RE	PCOS BMI > 27 kg/m^2; age 18–44 years 12 weeks, six MI sessions, daily logs, etc.	MI-based intervention
		If individual tailored motivational interviewing is used, then participants can report behaviour change and lose an average of 7 lb in 12 weeks	BC W16	PCOS BMI > 27 kg/m^2; age 18–44 12 weeks, 6 MI sessions, daily logs	MI, monitoring

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Montanaro *et al.* 2019[246]	FS	If a preconception risk assessment tool is going to be introduced into primary care services then there can be significant challenges in implementation	ST	Primary care services	Organisational challenges
Moran *et al.* 2011[192]	PS	If women follow a reduced-calorie, high-protein diet, there is a meal replacement aspect and they receive lifestyle advice, then participants can lose an average of 3.8 kg in the 5- to 9-week intervention period	W16	IVF BMI 28–45 kg/m^2; age 18–40 years	Hypocaloric, 1200 kcal/day including 1 meal replacement and 3 contacts
		If one-off healthy lifestyle advice is given (to control group), then participants can reduce waist circumference	HM	IVF BMI 28–45 kg/m^2; age 18–40 years	Lifestyle advice
Mutsaerts *et al.* 2016[150]	RCT	If women recruited to take part in a 6-month intervention prior to IVF with goal of 5–10% weight loss, then there will be a 22% discontinuation rate and 37.7% will lose ≥ 5% (43% of the completers)	W17	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric individual – reduced by 600 calories with minimum of 1200 kcal/day Lifestyle motivational counselling Motivation of early IVF if weight loss hit 5–10%
Norris *et al.* 2016[133]	OC	If stakeholders are involved at the development stage of an intervention (Jom Moma) and intervention mapping is used, then the intervention is more likely to be well received by participants	RE	Malaysia population-based intervention	Intervention mapping Co production
Rönö *et al.* 2018[137]	RCT	Recruiting women preconception (in context of GDM) is difficult, but the most effective method is by personal invitation based on risk identified through hospital registers	RE	Gestational diabetes BMI > 30 kg/m^2	Engagement personal
	RCT	If participants do not delay getting pregnant while undergoing the intervention then weight loss will not be significant	BC	Gestational diabetes BMI > 30 kg/m^2	No delay of pregnancy so very limited exposure to intervention before conception

continued

TABLE 41 Explanatory accounts in preconception-focused studies (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Rothberg *et al.* 2016[146]	FT	If women met the strict eligibility criteria for a 16-week intensive weight loss programme, then 56% would agree to be randomised	RE	Anovulatory subfertility BMI 35–45 kg/m^2; age 18–40 years Goal of 15% weight loss	Hypocaloric VLED, 800 kcal/day for up to 12 weeks. 4-week transition to meals. Fortnightly dietetic input. PA advice
	FT	If women were able to complete the 16-week intensive weight loss programme ($n = 6$), then they lost an average of 13% body weight	W16	Subfertility BMI 35–45 kg/m^2; age 18–40 years Goal of 15% weight loss	Hypocaloric VLED, 800 kcal/day for up to 12 weeks. Fortnightly dietetic input. PA advice
Shawe *et al.* 2019[130]	S	Male respondents – 74% pregnancies planned If men are part of a couple planning a pregnancy, then they were more likely than other men (non-planners) to reduce smoking, reduce alcohol consumption and eat more healthily in preparation for pregnancy. However, 57% took no action to improve their health	BC	All antenatal attenders regarding preconception behaviours	Pregnancy planning and partner involvement
Sim *et al.* 2014[145]	RCT	If participants take part in a group programme, the intervention is flexible/tailored and the intervention includes support, then they can lose an average of 6.6 kg in the 12-week period	W16	IVF BMI 30–40 kg/m^2; age 18–37 years	Hypocaloric VLED, 6 weeks at ≈ 650 kcal/day, then 6-week 'refeeding' with ≈ 650 deficit calories described as individually tailored Group process as support mechanism (but not measured)
		If invited to take part in weekly group VLED programme with tailored intervention and support RCT, then 84% agree to participate	RE	IVF BMI 30–40 kg/m^2; age 18–37 years	Tailoring and group support
Stephenson *et al.* 2018[27]	OC	Many women of reproductive age in low-, middle-, and high-income countries will not be prepared nutritionally for pregnancy	HM	International	Nutrition
van Dammen *et al.* 2018[152]	RCT	If women take part in a 6-month intervention prior to IVF with goal of 5–10% weight loss, then their cardiometabolic health and their self-reported physical quality of life improves	HM	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric and lifestyle counselling – authors suggest result mechanism is due to intrinsic motivation (of achieving a healthy pregnancy)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Van Dammen *et al.* 2019[247]	RCT	If women take part in a 6-month intervention prior to IVF with goal of 5–10% weight loss, then there is no significant improvement of stress, mood, sleep quality and mental health QoL 3–8 years following participation	HM	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric and lifestyle counselling
van Elten *et al.* 2019[248]	RCT	If participants lost weight in an intervention, then they will maintain a lower BMI and lower reported energy intake between 3 and 8 years following randomisation	LT	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric and lifestyle counselling Successful weight loss during the intervention predicts longer-term changes
	RCT	If participants take part in an intervention, then their intake of unhealthy foods will be lower 3, 6 and 12 months after randomisation	HM	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric and lifestyle counselling
	RCT	If women take part in a 6-month intervention prior to IVF with goal of 5–10% weight loss, the largest effect of the intervention was within 3 months of randomisation. Therefore, it seems that the higher intensity of guidance in the first 3 months of the intervention programme encouraged healthy changes in diet and PA	W16	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric and lifestyle counselling
Van Dijk *et al.* 2017[138]	QS	MHealth is a useful way of providing information but it needs to be part of an intervention that includes face to face contact and to be tailored/personalised	KA	Preconception population	MHealth Personalised care
		If couples engage with mHealth intervention then they are more likely to achieve positive behaviour changes and pregnancy outcomes	BC	Preconception population	MHealth Personalised care
Weisman *et al.* 2011[49]	RCT	If women in prepregnacy and interpregnacy phase from low-income communities engage with a social cognitive programme to reduce adverse pregnancy outcomes via changing attitudes and behaviours, then their self-efficacy and intention to change health behaviours increases	KA	Non-pregnant women aged 18–35 years in low-income community setting	Social cognitive approach to behaviour change, The group format was intended to motivate women through social support from peers and the lay group facilitators
Wekker *et al.* 2019[249]	RCT	Short-term success predicts long-term success	HM	Preconception obesity	Achieving targets acts as longer-term motivation
		If women reach their target weight during the intervention period, then they will show improved cardiometabolic health 6 years later	LT		

GDM, gestational diabetes mellitus; MI, motivational interviewing; PA, physical activity; VLED, very low energy diet.

TABLE 42 Explanatory accounts from studies in pregnancy

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Agha *et al.* 2014[3]	SR MA	Behavioural interventions in pregnancy may be effective in reducing GWG in obese women without comorbid conditions, but not in overweight or morbidly obese women	GWG	All pregnancy	Tailoring intervention to fit with BMI classification may be critical
Campbell *et al.* 2011[242]	SR	Family advice about diet in pregnancy can be a barrier to healthy eating	BA	Pregnancy	Attitudes to weight and diet in pregnancy
Cunningham *et al.* 2018[43]	QS	If women with BMI > 30 kg/m^2 hear the term obese, then they often do not think that it applies to them	BA	Pregnant, with BMI > 30 kg/m^2	Language and knowledge
		If women have BMI > 30 kg/m^2, then raised BMI is regarded as acceptable term as it is factual	RE	Pregnant, with BMI > 30 kg/m^2	Language
Farpour-Lambert *et al.* 2018[22]	SR/MA	If women take part in an antenatal weight management intervention then there can be a reduction in the likelihood of excessive GWG and a significant reduction in longer-term post-partum weight	GWG	All pregnancy	Potential longer-term impact of antenatal weight management
		Moderate energy targets according to weight (18–24 kcal/kg) was associated with the greatest reduction in GWG	GWG	All pregnancy	Tailor calorie targets according to weight
		If women with overweight/obesity take part in a diet and exercise antenatal weight management intervention, then it reduces risk of pregnancy induced hypertension, macrosomia and neonatal RDS	HM	Pregnancy for women with overweight/obesity	Diet and exercise weight management intervention in pregnancy can reduce risks
		If there are regular scheduled PA sessions, then some women find them difficult to attend	BA	All pregnancy	Barriers to PA in pregnancy
		Early intervention contributes to reduced GWG	GWG	All pregnancy	Timing of intervention is important
Flannery *et al.* 2019[140]		For overweight/obese pregnant women, knowledge about safety of PA and time are two of the barriers to taking part in PA	BA	Women with overweight/obesity in pregnancy	PA in pregnancy WLIs can be a barrier to participation
Furber *et al.* 2013[47]	SR	The safety of weight loss when pregnant and obese is not substantiated	BA	Pregnancy and obesity	Further work needed on safety of weight loss in pregnancy
Heslehurst 2014[142]	SR	If we want to change practice of managing obesity in pregnancy, then we need to address the barriers for staff in dealing with obesity, not just behaviour change for women	ST	Pregnancy and obesity	Staff – individual and organisational-level barriers to management of obesity in pregnancy

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Hill *et al.* 2013[154]	SR MA	Diet interventions more effective than PA interventions at reducing GWG	GWG	All pregnancy	PA interventions not as effective as diet
		Two of the BCTs in weight management, 'provide rewards contingent on successful behaviour' and 'reward and threat', were associated with significantly less weight gain in pregnancy	GWG	All pregnancy	Important to underpin the intervention with the most effective BCTs
Hussein *et al.* 2016[36]	SR	If mobile phone apps are used in an intervention, particularly when part of multimodal intervention (i.e. a text message or app used in conjunction with another form of electronic communications), then GWG can be reduced	GWG	All pregnancy	Consider multimodal components as part of intervention
iWIP 2017[21]	MA	If women take part in weight management interventions, then there will be a modest effect on GWG but it will not improve maternal or child outcomes, except rates of caesarean sections	GWG	All pregnancy	Unclear relationship between weight management, GWG and maternal outcomes
Jelsma *et al.* 2017[233]		If the WLI includes training in motivational interviewing, then only some of the practitioners will be able to deliver the intervention with fidelity	BA ST	Women with overweight/ obesity in pregnancy	Fidelity to the intervention needs to be measured to understand impact of the intervention
Kim *et al.* 2016[250]	QS	Women are not aware of weight goals in pregnancy and receive conflicting advice from health-care practitioners	BA	All pregnancy	Lack of clarity around weight gain in pregnancy across both population and practitioners
		Pregnancy is a time when it is acceptable to gain weight	BA	All pregnancy	Attitudes to pregnancy
McBride *et al.* 2012[136]	S	If women drink during one pregnancy, then they are more likely to drink in subsequent pregnancy	BA	All pregnancy	Importance of engaging with woman's experiences as context
McGirr *et al.* 2017[153]	SR	'Goals and planning' and 'feedback and monitoring' are key BCTs involved in reducing GWG	GWG	All pregnancy	Key BCTs in GWG
Muktabhant *et al.* 2015[159]	MA	If women take part in an antenatal weight management intervention, then there can be a reduction in the likelihood of excessive GWG	GWG	All pregnancy	GWG can be reduced through antenatal weight management intervention
		For overweight/obesity population, exercise interventions may not be as effective at reducing likelihood of GWG as for normal weight population	GWG	Women with overweight/ obesity in pregnancy	Tailoring the intervention for the individual in particular PA

continued

TABLE 42 Explanatory accounts from studies in pregnancy (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Redman *et al.* 2017[116]	RCT	If women take part in an intervention delivered remotely, then they may be more likely to adhere to self monitoring weight than those in the face-to-face group	GWG	Women with overweight/ obesity in pregnancy	Remote delivery of an intervention can have positive impact on outcomes
Shieh *et al.* 2018[251]	SR MA	For overweight/obese pregnant women, healthy eating interventions had a larger effect size than PA or combined interventions	GWG	Women with overweight/ obesity in pregnancy	Healthy eating is key component of a WLI in pregnancy
Sanders *et al.* 2020[156]	PS	If regular weighing in pregnancy is part of an intervention, then women find this acceptable and can welcome it	GWG	All pregnancy	Self-monitoring of weight
Stephenson *et al.* 2014[35]	S	If an intervention is phrased as 'eating a healthy diet' rather than 'being a healthy weight', then double the number of people would be interested and engaged	RE	General population pregnancy	Communication and language
Thangaratinam *et al.* 2012[252]	SR	If women who are overweight/obese take part in any type of weight management intervention, then there is a reduction in GWG	GWG	Women with overweight/ obesity in pregnancy	Dietary interventions in pregnancy help reduce GWG
Willcox *et al.* 2015[135]	QS	If antenatal care includes mHealth components, then women will embrace these, but health-care practitioners experience barriers to including them in the care pathway	BA ST	All pregnancy	MHealth can be important component of engagement and service delivery but barriers to incorporating mHealth into care pathway
Willcox *et al.* 2017[253]	RCT	Interventions delivered remotely can make a significant difference to GWG for pregnant women who are overweight/obese	RE	Women with overweight/ obesity in pregnancy	Remote delivery acceptable

PA, physical activity.

Appendix 13 Consolidated explanatory accounts

Abbreviations

Nature of source

CC, case study; FS, feasibility study; FT, feasibility trial; MA, meta-analysis; ME, methods; NR, narrative review; OC, opinion/conceptual paper; OS, observational study; PT, pilot trial; QR, qualitative review; QS, qualitative study; S, survey; ScR, scoping review; SR, systematic review.

Outcomes

BA, barriers; BC, behaviour change; FE, fertility; HM, health markers; KA, knowledge and attitudes; LT, long-term outcomes; RE, recruitment and engagement; ST, staff related; W16, weight loss in a ≤ 16-week programme; W17, weight loss in a ≥ 16-week programme.

TABLE 43 Consolidated explanatory accounts: barriers

			Outcome (O), context (C), mechanism (M)		
Authors and year	**Source**	**Explanatory account**	**O**	**C**	**M**
Barker *et al.* 2018[29]	OC	Social marketing (e.g. change4life campaign) did not make an impact because individuals and communities require not only knowledge but also resources to enact change, and a purpose or meaning to provide motivation	BA	Resource	Social practice theory – knowledge, resource and meaning required to enact change
Campbell *et al.* 2011[242]	SR	Family advice about diet in pregnancy can be a barrier to healthy eating	BA	Pregnancy	Attitudes to weight and diet in pregnancy
Cunningham *et al.* 2018[43]	QS	If women with BMI > 30 kg/m^2 hear the term obese, then they often do not think it applies to them	BA	Pregnant, with BMI > 30 kg/m^2	Language and knowledge
Farpour-Lambert *et al.* 2018[22]	SR/MA	If there are regular scheduled PA sessions, some women find them difficult to attend	BA	All pregnancy	Barriers to PA in pregnancy
Flannery *et al.* 2019[140]		For overweight/obese pregnant women, knowledge about safety of PA and time are two of the barriers to taking part in PA	BA	Women with overweight/obesity in pregnancy	PA in pregnancy WLIs can be a barrier to participation
Furber *et al.* 2013[47]	SR	The safety of weight loss when pregnant and obese is not substantiated	BA	Pregnancy and obesity	Further work needed on safety of weight loss in pregnancy
Hussein *et al.* 2016[36]	SR	If services have designed and evaluated PCC, then weight is not included in the intervention	BA	SR across BMI	Weight is not regarded as an important aspect of PCC

continued

TABLE 43 Consolidated explanatory accounts: barriers (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Jelsma *et al.* 2017[233]		If the WLI includes training in motivational interviewing, then only some of the practitioners will be able to deliver the intervention with fidelity	BA	Women with overweight/obesity in pregnancy	Fidelity to the intervention needs to be measured to understand impact of the intervention
Kim *et al.* 2016[250]	QS	Women are not aware of weight goals in pregnancy and receive conflicting advice from health-care practitioners	BA	All pregnancy	Lack of clarity around weight gain in pregnancy across both population and practitioners
		Pregnancy is a time when it is acceptable to gain weight	BA	All pregnancy	Attitudes to pregnancy
McBride *et al.* 2012[136]	S	If women drink during one pregnancy, then they are more likely to drink in subsequent pregnancy	BA	All pregnancy	Importance of engaging with women's experiences as context
Willcox *et al.* 2015[135]	QS	If antenatal care includes mHealth components, then women will embrace these, but health-care practitioners experience barriers to including them in the care pathway	BA	All pregnancy	MHealth can be important component of engagement and service delivery but barriers in incorporating mHealth into care pathway

PA, physical activity.

TABLE 44 Consolidated explanatory accounts: behaviour change

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Barker *et al.* 2018[29]	OC	If children and young adults are engaged with health behaviour promotions prior to childbearing capabilities developing, then there is a better chance that they will continue with healthy behaviours in the preconception period	BC	Pre-planning	Habit formation Social movement with preparation for healthy pregnancy becoming more normalised
		If adults with no immediate intention to get pregnant are informed of risk of future loss of ability to have a healthy child, then they may be more motivated by loss aversion	BC	Pre-planning	Loss aversion as motivator in response to public information campaign
Mahoney 2014[245]		If individual tailored motivational interviewing is used, then participants can report behaviour change and lose an average of 7 lb in 12 weeks	BC W16	PCOS BMI > 27 kg/m^2, age 18–44 years 12 weeks, 6 MI sessions, daily logs	MI, monitoring

TABLE 44 Consolidated explanatory accounts: behaviour change (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Rönö *et al.* 2018[137]	RCT	If participants do not delay getting pregnant while undergoing the intervention, then weight loss will not be significant	BC	Gestational diabetes BMI > 30 kg/m^2	No delay of pregnancy so very limited exposure to intervention before conception
Shawe *et al.* 2019[130]	S	Male respondents – 74% pregnancies planned If men are part of a couple planning a pregnancy, then they were more likely than other men (non planners) to reduce smoking, reduce alcohol consumption and to eat more healthily in preparation for pregnancy. However, 57% took no action to improve their health	BC	All antenatal attenders regarding preconception behaviours	Pregnancy planning and partner involvement
Van Dijk *et al.* 2017[138]	QS	If couples engage with mHealth intervention, then they are more likely to achieve positive behaviour changes and pregnancy outcomes	BC	Preconception population	MHealth Personalised care

MI, motivational interviewing.

TABLE 45 Consolidated explanatory accounts: fertility

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Becker *et al.* 2015[148]	RCT	If women follow too strict a weight loss regimen, then the effect on fertility is uncertain *The exact amount of energy restriction that is safe or deleterious for obese infertile women seeking IVF treatment is not clear*	FE	IVF No one refused to take part 1 out of 16 could not comply with intervention	Potential risk of too few calories

TABLE 46 Consolidated explanatory accounts: GWG

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Agha *et al.* 2014[3]	SR MA	Behavioural interventions in pregnancy may be effective in reducing GWG in obese women without comorbid conditions, but not in overweight or morbidly obese women	GWG	All pregnancy	Tailoring intervention to fit with BMI classification may be critical
Farpour-Lambert *et al.* 2018[22]	SR/MA	If women take part in an antenatal weight management intervention, then there can be a reduction in the likelihood of excessive GWG and a significant reduction in longer-term post-partum weight	GWG	All pregnancy	Potential longer-term impact of antenatal weight management
		Moderate energy targets according to weight (18–24 kcal/kg) were associated with the greatest reduction in GWG	GWG	All pregnancy	Tailor calorie targets according to weight
		Early intervention contributes to reduced GWG	GWG	All pregnancy	Timing of intervention is important
Hill *et al.* 2013[154]	SR MA	Diet interventions more effective than PA interventions at reducing GWG	GWG	All pregnancy	PA interventions not as effective as diet
		Two of the BCTs in weight management, 'provide rewards contingent on successful behaviour' and 'reward and threat', were associated with significantly less weight gain in pregnancy	GWG	All pregnancy	Important to underpin the intervention with the most effective BCTs
Hussein *et al.* 2016[36]	SR	If mobile phone apps are used in an intervention, particularly when part of multimodal intervention (i.e. a text message or app used in conjunction with another form of electronic communications), then GWG can be reduced	GWG	All pregnancy	Consider multimodal components as part of intervention
iWIP 2017[21]	MA	If women take part in weight management interventions, then there will be a modest effect on GWG but it will not improve maternal or child outcomes, except rates of caesarean sections	GWG	All pregnancy	Unclear relationship between weight management, GWG and maternal outcomes
McGirr *et al.* 2017[153]	SR	'Goals and planning' and 'feedback and monitoring' are key BCTs involved in reducing GWG	GWG	All pregnancy	Key BCTs in GWG
Muktabhant *et al.* 2015[159]	MA	If women take part in an antenatal weight management intervention, then there can be a reduction in the likelihood of excessive GWG	GWG	All pregnancy	GWG can be reduced through antenatal weight management intervention
		For overweight/obese population, exercise interventions may not be as effective at reducing likelihood of GWG as for normal weight population	GWG	Women with overweight/ obesity in pregnancy	Tailoring the intervention for the individual, in particular PA

TABLE 46 Consolidated explanatory accounts: GWG (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Redman *et al.* 2017[116]	RCT	If women take part in an intervention delivered remotely, then they may be more likely to adhere to self-monitoring weight than those in the face-to-face group	GWG	Women with overweight/ obesity in pregnancy	Remote delivery of an intervention can have positive impact on outcomes
Shieh *et al.* 2018[251]	SR MA	For overweight/obese pregnant women, healthy eating interventions had a larger effect size than PA or combined interventions	GWG	Women with overweight/ obesity in pregnancy	Healthy eating is key component of a WLI in pregnancy
Sanders *et al.* 2020[156]	PS	If regular weighing in pregnancy is part of an intervention, then women find this acceptable and can welcome it	GWG	All pregnancy	Self-monitoring of weight
Thangaratinam *et al.* 2012[252]	SR	If women with overweight/obesity take part in any type of weight management intervention, then there is a reduction in GWG	GWG	Women with overweight/ obesity in pregnancy	Dietary interventions in pregnancy help reduce GWG

PA, physical activity.

TABLE 47 Consolidated explanatory accounts: health markers

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Caut *et al.* 2020[33]	SR	Usual preconception diet is insufficient in terms of nutritional guidelines	HM	Preconception and pregnancy	Nutrition
Farpour-Lambert *et al.* 2018[22]	SR/MA	If women with overweight/ obesity take part in a diet and exercise antenatal weight management intervention, then it reduces the risk of pregnancy induced hypertension, macrosomia and neonatal RDS	HM	Pregnancy for women with overweight/obesity	Diet and exercise weight management intervention in pregnancy can reduce risks
Moran *et al.* 2011[192]	PS	If one-off healthy lifestyle advice is given (to control group), then participants can reduce waist circumference	HM	IVF BMI 28–45 kg/m^2; age 18–40 years	Lifestyle advice
Stephenson *et al.* 2018[27]	OC	Many women of reproductive age in low-, middle- and high-income countries will not be prepared nutritionally for pregnancy	HM	International	Nutrition
van Dammen *et al.* 2018[152]	RCT	If women take part in a 6-month intervention prior to IVF with a goal of 5–10% weight loss, then their cardiometabolic health and their self-reported physical quality of life improves	HM	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric and lifestyle counselling – authors suggest result mechanism is due to intrinsic motivation (of achieving a healthy pregnancy)

continued

TABLE 47 Consolidated explanatory accounts: health markers (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
van Dammen *et al.* 2019[247]	RCT	If women take part in a 6-month intervention prior to IVF with goal of 5–10% weight loss, then there is no significant improvement of stress, mood, sleep quality and mental health quality of life 3–8 years following participation	HM	IVF BMI > 28 kg/m^2; aged 18–39 years	Hypocaloric and lifestyle counselling
van Elten *et al.* 2019[248]	RCT	If participants take part in an intervention, then their intake of unhealthy foods will be lower at 3, 6 and 12 months after randomisation	HM	IVFBMI > 28 kg/m^2; aged 18–39 years	Hypocaloric and lifestyle counselling
Wekker *et al.* 2019[249]	RCT	Short-term success predicts long-term success If women reach their target weight during the intervention period, then they will show improved cardiometabolic health 6 years later	HM	Preconception obesity	Achieving targets acts as longer-term motivation

TABLE 48 Consolidated explanatory accounts: knowledge and attitudes

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Beckmann *et al.* 2014[190]	CC	If women are motivated to attend a 90-minute session in a preconception service (including those motivated by subfertility and pre-existing conditions), then they may gain less weight prior to conception	KA	General population attending preconception clinic	Health advice
Delissaint *et al.* 2011[38]	SR	Knowledge, awareness and beliefs of PCC do not lead to preconception health practice	KA	Preconception health	Need a mechanism for knowledge to be translated into change of behaviour
Hussein *et al.* 2016[36]	SR	If women received preconception care and counselling, then maternal knowledge, self-efficacy and health locus of control, and self-reported risk behaviour will improve	KA	Preconception across BMI	Information increases knowledge and changes attitudes
		If women receive PCC and counselling. then it is unclear whether this has any effect on adverse pregnancy outcomes	KA	Preconception across BMI	The relationship between information, attitude and behaviour change is unclear

TABLE 48 Consolidated explanatory accounts: knowledge and attitudes (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Van Dijk *et al.* 2017[138]	QS	MHealth is a useful way of providing information but it needs to be part of an intervention that includes face-to-face contact and to be tailored/personalised	KA	Preconception population	MHealth Personalised care
Weisman *et al.* 2011[49]	RCT	If women in prepregnancy and interpregnancy phase from low-income communities engage with a social cognitive programme to reduce adverse pregnancy outcomes via changing attitudes and behaviours, then their self-efficacy and intention to change health behaviours increases	KA	Non-pregnant women aged 18–35 years in low-income community setting	Social cognitive approach to behaviour change. The group format was intended to motivate women through social support from peers and the lay group facilitators

TABLE 49 Consolidated explanatory accounts: long-term outcomes

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
van Elten *et al.* 2019[248]	RCT	If participants lost weight in an intervention, then they will maintain a lower BMI and lower reported energy intake between 3 and 8 years following randomisation	LT	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric and lifestyle counselling Successful weight loss during the intervention predicts longer-term changes
Wekker *et al.* 2018[249]	RCT	Short-term success predicts long-term success If women reach their target weight during the intervention period, then they will show improved cardiometabolic health 6 years later	LT	Preconception obesity	Achieving targets acts as longer-term motivation

TABLE 50 Consolidated explanatory accounts: recruitment and engagement

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Barker *et al.* 2018[29]	OC	If adults are intending to get pregnant, then the intervention opportunities are to actively support preconception health, for example through text messaging and provide practical support in an engaging way	RE	Intention	Support
		If adults intending to get pregnant are in a specific subgroup, then they need intense, tailored support	RE	Culture	Tailoring
		If adults intending to get pregnant have previously had a pregnancy, then they will be less receptive to pre-pregnancy input and input needs to take previous pregnancy into account	RE	Subsequent pregnancy	Individualised
		If supermarkets could convey healthy preconception nutrition messages (e.g. next to folic acid), then this would be an opportunity to inform a lot of women	RE	Public health messages	Community messages
		If interventions are delivered via digital media, then women experiencing social disadvantage are more likely to engage	RE	Comms strategy	Reach of intervention
Becker *et al.* 2015[148]	RCT	If women on the waiting list for IVF are invited to participate in a WLI, then there is a high take-up rate (100% in this study)	RE	IVF No one refused to take part 1 out of 16 could not comply with intervention	Motivation
Brackenridge *et al.* 2018[80]	PS	If women who agree to delay having their coil removed for 24 weeks in order to lose weight are offered an intensive meal replacement-based weight loss programme, then one-third of those eligible will agree to take part	RE	BMI > 30 kg/m^2; age 18–40 years Community clinic Delay IUD removal	Hypocaloric, 966–1220 kcal/day
Cunningham *et al.* 2018[43]	QS	If women have BMI of > 30 kg/m^2, then raised BMI is regarded as acceptable term as it is factual	RE	Pregnant, with BMI of > 30 kg/m^2	Language
Einarsson *et al.* 2017[243]		If women with BMI of 30–35 kg/m^2 waiting for IVF are offered 16-week very low-calorie meal replacement WLI, then 77% will agree to take part	RE	Nordic countries – IVF threshold is BMI of 35 kg/m^2, so all women already within range	Hypocaloric, 12 weeks at 880 kcal/day

TABLE 50 Consolidated explanatory accounts: recruitment and engagement (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Greenhalgh *et al.* 2015[134]	QS	If beliefs about negative effects of diet and exercise during pregnancy are addressed in a culturally relevant way, then participants are more likely to engage with an intervention	RE	South Asian women with GDM	Cultural relevance
		If health promotion messages are not tailored to different groups of people with protected characteristics, then individuals who are understood to be particularly at risk of marginalisation will be further excluded from health care	RE	South Asian women with GDM	Inequity and marginalisation
Homan *et al.* 2012[244]	PS	If couples undergoing fertility treatment are offered lifestyle advice designed to address lifestyle behaviours potentially influencing fertility and 4 months of weekly support, then 57% will agree to participate and 31% will take part	RE	IVF, all BMI Targeting lifestyle rather than one behaviour such as weight	Engagement/ motivation of couples with lifestyle messages is hard to achieve even in motivated population
Khan *et al.* 2019[144]	QS	If the availability of preconception screening and advice was promoted to the general public, then anxiety would be reduced and people planning a pregnancy would engage in more healthy behaviours	RE	Australia Preconception, pregnancy and postnatal	Community education
Legro *et al.* 2015[44]	RCT	If women with PCOS undergoing IVF are invited to take part in a 16-week RCT delaying IVF in order to lose a goal of 7% weight, then 17% of eligible women will consent to take part	RE	PCOS and IVF BMI 27–42 kg/m^2; age 18–40 years	Hypocaloric – individualised
Mahoney 2014[245]	PS	If women with PCOS are offered a 12-week MI intervention to help with lifestyle change to support fertility, then 22% will participate in the intervention and 16.6% will complete it	RE	PCOS BMI > 27 kg/m^2; age 18–44 years 12 weeks, 6 MI sessions, daily logs, etc.	MI-based intervention
Norris *et al.* 2016[133]	OC	If stakeholders are involved at the development stage of an intervention (Jom Moma) and intervention mapping is used, then the intervention is more likely to be well received by participants	RE	Malaysia population-based intervention	Intervention mapping; coproduction

continued

TABLE 50 Consolidated explanatory accounts: recruitment and engagement (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Rönö *et al.* 2018[137]	RCT	Recruiting women pre conception (in context of GDM) is difficult, but the most effective method is by personal invitation based on risk identified through hospital registers	RE	Gestational diabetes BMI > 30 kg/m^2	Engagement personal
Rothberg *et al.* 2016[146]	FT	If women met the strict eligibility criteria for a 16-week intensive weight loss programme, then 56% would agree to be randomised	RE	Anovulatory subfertility BMI 35–45 kg/m^2; age 18–40 years; goal of 15% weight loss	Hypocaloric VLED. Fortnightly dietetic input. PA advice
Sim *et al.* 2014[145]	RCT	If invited to take part in weekly group VLED programme with tailored intervention and support RCT, then 84% agree to participate	RE	IVF BMI 30–40 kg/m^2; age 18–37 years	Tailoring and group support
Stephenson *et al.* 2014[35]	S	If an intervention is phrased 'eating a healthy diet' rather than 'being a healthy weight', then double the number of people would be interested and engaged	RE	General population pregnancy	Communication and language
Willcox *et al.* 2017[253]	RCT	Interventions delivered remotely can make a significant difference to GWG for pregnant women who have overweight/obesity	RE	Overweight/obesity in pregnancy	Remote delivery acceptable

GDM, gestational diabetes mellitus; MI, motivational interviewing; PA, physical activity; VLED, very low energy diet.

TABLE 51 Consolidated explanatory accounts: staff-related

Author and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Barker *et al.* 2018[29]	OC	If practitioners are trained in Healthy Conversation Skills, then they will be able to engage and motivate patients and clients about nutrition and PA during brief consultations	ST	Staff skills	Self-efficacy Relationship between competence and confidence of staff
Heslehurst *et al.* 2014[142]	SR	If we want to change practice of managing obesity in pregnancy, then we need to address the barriers for staff in dealing with obesity, not just behaviour change for women	ST	Pregnancy and obesity	Staff-, individual- and organisational-level barriers to management of obesity in pregnancy
Jelsma *et al.* 2017[233]		If the WLI includes training in motivational interviewing, then only some of the practitioners will be able to deliver the intervention with fidelity	ST	Women with overweight/ obesity in pregnancy	Fidelity to the intervention needs to be measured to understand impact of the intervention
Khan *et al.* 2019[144]	QS	If national evidence-based guidance and preconception checklists were developed, then clinicians would feel more able to give appropriate advice and people planning pregnancy would feel less anxious about doing the right thing	ST	Australia Preconception, pregnancy and postnatal	National guidelines needed
Montanaro 2019[246]	FS	If a preconception risk assessment tool is going to be introduced into primary care services, then there can be significant challenges in implementation	ST	Primary care services	Organisational challenges
Willcox *et al.* 2015[135]	QS	If antenatal care includes mHealth components, then women will embrace these but health-care practitioners experience barriers to including them in the care pathway	ST	All pregnancy	MHealth can be important component of engagement and service delivery but there are barriers in incorporating mHealth into care pathway

TABLE 52 Consolidated explanatory accounts: weight loss intervention up to 16 weeks' duration

			Outcome (O), context (C), mechanism (M)		
Authors and year	Source	Explanatory account	O	C	M
Becker *et al.* 2015[148]	RCT	If women aged 18–35 years, with BMI 25–40 kg/m^2 waiting for their first round of IVF treatment engage in 12 weeks of an individualised low-GI diet plan, then they can achieve a 5.5% weight loss	W16	IVF No one refused to take part 1/16 could not comply with intervention	Hypocaloric and low-GI individualised plan (20 kcal/kg bodyweight)
Einarsson *et al.* 2017[243]	RCT	If participants have a high level of engagement in a 16-week intervention of very low-calorie meal replacement diet plus support every 2–3 weeks, including dietetic input, then they will experience significant weight loss of average 9.44 kg (group mean BMI was 29.8 kg/m^2)	W16	IVF BMI 30–35 kg/m^2 Nordic countries' IVF threshold is BMI 35 kg/m^2, so all women were already within range	Hypocaloric, 12 weeks at 880 kcal/day
Espinós *et al.* 2017[149]	RCT	If women with BMI 30–40 kg/m^2 waiting for IVF take part in a 12-week diet and exercise programme, then they will lose an average of 6.97% weight	W16	IVF BMI 30–40 kg/m^2; age 18–37 years	Reduction of calories by 500–800 per day plus exercise plus support
Homan *et al.* 2012[244]	PS	If couples undergoing fertility treatment are overweight and are motivated to receive lifestyle intervention using MI principles designed to address lifestyle behaviours potentially influencing fertility and receive weekly follow-up support telephone calls, then 47% of those who take part will lose between 1 kg and 5 kg in 4 months	W16	IVF all BMI Targeting lifestyle rather than one behaviour such as weight	Motivation – using MI to engage with lifestyle behaviours Couples – mutual support
Legro *et al.* 2015[44]	RCT	If the intervention is tailored and includes meal replacements and weight loss medication, then participants can experience significant weight loss (between 6.2% and 6.4%) over the 16-week period	W16	PCOS and IVF BMI 27–42 kg/m^2; age 18–40 years	Hypocaloric (between 1200 and 2000 kcal/day) plus lifestyle modification (including meal replacements, weight loss medication, either sibutramine or orlistat) and increased PA
Mahoney 2014[245]		If individual tailored MI is used, then participants can report behaviour change and lose an average of 7 lb in 12 weeks	W16	PCOS BMI > 27 kg/m^2; age 18–44 years 12 weeks, 6 MI sessions, daily logs	MI, monitoring
Moran *et al.* 2011[192]	PS	If women follow a reduced-calorie high-protein diet, there is a meal replacement aspect and they receive lifestyle advice, then participants can lose an average of 3.8 kg in the 5- to 9-week intervention period	W16	IVF BMI 28–45 kg/m^2; age 18–40 years	Hypocaloric, 1200 kcal/day including one meal replacement and three contacts

TABLE 52 Consolidated explanatory accounts: weight loss intervention up to 16 weeks' duration (*continued*)

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Rothberg *et al.* 2016[146]	FT	If women were able to complete the 16-week intensive weight loss programme ($n = 6$), then they lost an average of 13% body weight	W16	Subfertility BMI 35–45 kg/m^2; age 18–40 years; goal of 15% weight loss	Hypocaloric VLED, 800 kcal/day for up to 12 weeks. Fortnightly dietetic input. PA advice
Sim *et al.* 2014[145]	RCT	If participants take part in a group programme and if the intervention is flexible/tailored and the intervention includes support, then they can lose an average of 6.6 kg in the 12-week period	W16	IVF BMI 30–40 kg/m^2; age 18–37 years	Hypocaloric VLED , 6 weeks at ≈ 650 kcal/day, then 6-week 'refeeding' with ≈ 650 deficit calories described as individually tailored Group process as support mechanism (but not measured)
van Elten *et al.* 2019[248]	RCT	If women take part in a 6-month intervention prior to IVF with goal of 5–10% weight loss, then the largest effect of the intervention was within 3 months of randomisation. Therefore, it seems that the higher intensity of guidance in the first 3 months of the intervention programme encouraged healthy changes in diet and PA	W16	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric and lifestyle counselling

MI, motivational interviewing; PA, physical activity; VLED, very low energy diet.

TABLE 53 Consolidated explanatory accounts: weight loss intervention programme of > 16 weeks

Authors and year	Source	Explanatory account	Outcome (O), context (C), mechanism (M)		
			O	C	M
Brackenridge *et al.* 2018[80]	PS	If women agree to delay having their coil removed for 24 weeks and can follow a low-energy liquid diet weight loss programme plus fortnightly 15-minute motivational support, then they will lose a clinically significant amount of weight (median BMI reduction of 14.2% for completers, 6.6% ITT of all starters)	W17	BMI > 30 kg/m^2; age 18–40 years Community clinic delay IUD removal	Hypocaloric, 966–1220 kcal/day
LeBlanc *et al.* 2021[53]	RCT	If women take part in a remotely delivered tailored behavioural WLI, then they can lose 3.5% of their weight before conception	W17	USA; preconception and pregnancy	Behavioural weight loss support
		If women lose a significant amount of weight prior to pregnancy, then there is a risk of weight regain in pregnancy	W17	USA; preconception and pregnancy	Weight loss support needs to continue into pregnancy
		If women lose weight in a preconception intervention, then it is important to continue with support through pregnancy if this loss is to be maintained by the end of the third trimester of pregnancy	W17	USA; preconception and pregnancy	Weight loss support needs to continue into pregnancy
Mutsaerts *et al.* 2016[150]	RCT	If women are recruited to take part in a 6-month intervention prior to IVF with goal of 5–10% weight loss, then there will be a 22% discontinuation rate and 37.7% will lose ≥ 5% (43% of the completers)	W17	IVF BMI > 28 kg/m^2; age 18–39 years	Hypocaloric individual – reduced by 600 calories with minimum of 1200 kcal/day Lifestyle motivational counselling Motivation of early IVF if weight loss hit 5–10%

Appendix 14 Consolidated explanatory accounts grouped by outcome

TABLE 54 Consolidated explanatory accounts grouped by outcome

Consolidated accounts for preconception interventions grouped by outcomes	Potential key ideas/ theoretical concepts
Recruitment and engagement *In the context of the general adult population*	
If the aim of a service or research project is to maximise recruitment and engagement of people planning a pregnancy to a preconception intervention	
Then: • the design of the intervention should include co-production with service users[133] • the intervention must provide active and engaging support, for example through text messaging and practical support of preconception health behaviours[29] • the engagement approach should include social media to ensure connection with women experiencing social disadvantage[29] • the intervention and the engagement approach must include some element of tailoring, for example to take cultural beliefs (e.g. exercise in pregnancy) and life experiences (e.g. of previous pregnancy) into account[29,134,137] • mHealth is useful to impart information, but there needs to be a face-to-face component and personalised algorithms[138] • preconception health messages need to be more widely promoted (e.g. in places such as supermarkets)[29] • the term 'eating a healthy diet' rather than 'being a healthy weight' could double the number of people who would be interested and engaged[35]	• Relevance • Importance • Opportunity • Competence • Confidence • Attitudes • Societal attitude • Equity of access • Autonomy • Language
If the aim of an intervention is to target women with BMI > 25 kg/m^2	
Then women will need to be weighed and BMI identified, as 70.8% of those with BMI over 25 kg/m^2 (and 18.4% of those with BMI > 30 kg/m^2) would not identify themselves as overweight[129]	• Perception • Societal attitude • Weight awareness
In the context of people on the waiting list for fertility treatment	
• Then there is a large range of recruitment rates to interventions from 17%[44] to 100%[148]	
In the context of a meal replacement intervention	
• Then there is a large range of recruitment rates to interventions from 17%[44] to 84%[145]	
Behaviour change *In the context of the general population:*	
If a couple are planning a pregnancy	
Then the male partners were more likely than other men (non-planners) to report reducing smoking, reducing alcohol consumption and eating more healthily (in preparation for pregnancy)[130]	• Social support • Attitudes • Societal attitude
If a woman's partner engages with an online preconception intervention	
Then the woman is more likely to achieve positive behaviour changes and pregnancy outcomes[138]	• Social support
If the availability of pre-conception screening and advice were promoted to the general public	
Then anxiety would be reduced and people would engage in more healthy behaviours[144]	• Societal attitude • Reduced anxiety

continued

TABLE 54 Consolidated explanatory accounts grouped by outcome (*continued*)

Consolidated accounts for preconception interventions grouped by outcomes	Potential key ideas/ theoretical concepts
If children and young adults are engaged with health behaviour promotions prior to childbearing capabilities developing	
The there is a better chance that they will continue with healthy behaviours in the preconception period[29]	• Habit formation
If adults with no immediate intention to get pregnant are informed of risk of future loss of ability to have a healthy child	
Then they may be more motivated by loss aversion[29]	• Loss aversion
In the context of fertility treatment/PCOS	
If individuals or couples are motivated enough to take part in an intervention incorporating motivational interviewing focusing on lifestyle behaviours	
Then they will have success in making the lifestyle changes,[245] increasing the likelihood of a healthy pregnancy[244]	• Attitudes • Perceived control
If participants take part in lifestyle counselling intervention	
Then their intake of unhealthy foods will be lower 3, 6 and 12 months after randomisation[248]	• Knowledge • Attitudes
Staff behaviour *If practitioners are trained in Healthy Conversation Skills*	
Then they will be able to engage and motivate patients and clients about nutrition and physical activity during brief consultations[29]	• Competence • Attitudes
If national evidence-based guidance and preconception checklists were developed	
Then clinicians would feel more able to give appropriate advice and people planning pregnancy would feel less anxious about doing the right thing[144]	• Knowledge • Societal attitudes
If a preconception risk assessment tool is going to be introduced into primary care services	
Then there can be significant challenges in implementation[246]	• Organisational change
Knowledge and behaviour change *If an intervention just provides information and knowledge relating to preconception health*	
Then it is unclear if it will be sufficient to impact on behaviour; there were mixed findings of reviews/studies. For example, self-report risk behaviours change but pregnancy outcomes do not[36]; knowledge, awareness and beliefs of preconception care do not lead to preconception health practice[38]; reduced weight gain[190]; no change in anthropomorphic results but self-report change in BMI at 12 months[49]	
Health markers *If women take part in a 6-month intervention involving hypocaloric diet and lifestyle counselling prior to IVF with goal of 5–10% weight loss*	
Then: • their intake of unhealthy foods will be lower 3, 6 and 12 months after randomisation • their cardiometabolic health and their self-reported physical quality of life improves[152,248]	• Competence • Attitudes • Habit formation
If there is no intervention to improve nutrition	
Then most women will not meet the nutritional guidelines for pregnancy[27,33]	
Fertility *If women follow too strict a weight loss regimen*	
Then the effect on fertility is uncertain[148]	

TABLE 54 Consolidated explanatory accounts grouped by outcome (*continued*)

Consolidated accounts for preconception interventions grouped by outcomes	Potential key ideas/ theoretical concepts
Weight loss	
In the context of PCOS/fertility treatment	
If women are motivated to engage with a WLI based on a very low energy diet over 12–16 weeks	
Then they can lose an average of between 6.9% (12 weeks)[145] and 13% (16 weeks)[146] of their body weight	
If women are motivated to engage with an hypocaloric WLI that includes an element of meal replacement over 16 weeks	
Then they can lose an average of 6%[44] of their body weight	
If women are motivated to engage with an individualised hypocaloric WLI without meal replacement (calorie intake determined by body weight) over 12 weeks	
Then they can lose an average of 5% (BMI 25–40 kg/m^2)[148] to 6.97% (BMI 30–40 kg/m^2)[149] of their body weight	
If women take part in a 6-month hypocaloric and lifestyle counselling intervention with goal of 5–10% weight loss	
Then the largest effect of the intervention is within 3 months of randomisation[150,248]	
If women are motivated to attend a motivational interviewing intervention over 12–16 weeks	
Then they will lose between 1 and 5 kg[243,245]	
In the context of women with raised BMI	
If women agree to delay having their IUD removed for 24 weeks and can follow a low energy liquid diet weight loss programme plus fortnightly 15-minute motivational support	
Then they will lose a clinically significant amount of weight (median BMI reduction of 14.2% for completers)[80]	
If women take part in a remotely delivered tailored behavioural WLI	
Then they can lose 3.5% of their weight before conception[53]	
Long-term outcomes	
If women take part in a 6-month intervention prior to IVF with goal of 5–10% weight loss	
Then there is: • no significant improvement of stress, mood, sleep quality and mental health quality of life at 3–8 years following participation[152,247] • they will maintain a lower BMI and lower reported energy intake between 3 and 8 years following randomisation[248] Short-term success predicts long-term success: if women reach their target weight during the intervention period, then they will show improved cardiometabolic health 6 years later[243]	
If women take part in a remotely delivered tailored behavioural WLI	
Then the weight they lose pre conception may be regained during pregnancy[53]	
Barriers	
If services have designed and evaluated PCC intervention	
Weight is not included in the intervention[36]	• Attitudes • Perceived relevance
If services/intervention are offered to women who are overweight	
Then 49.6% of women with raised BMI will not think it applies to them (70.8% of those with BMI of > 25 kg/m^2 and 18.4% of those with BMI of > 30 kg/m^2)[129]	• Identity/relevance • Societal attitude

continued

TABLE 54 Consolidated explanatory accounts grouped by outcome (*continued*)

Consolidated accounts for preconception interventions grouped by outcomes	Potential key ideas/ theoretical concepts
If women with a BMI over 3 kg/m^2 accessing fertility treatment are invited to take part in a 16-week intensive weight loss programme	
Then nearly half of those eligible declined to take part Barriers to taking part were: • time necessary to achieve weight loss • concerns about the limited success of weight loss • a perception that ovulation induction is a faster route to pregnancy • a belief that the risks of pregnancy associated with obesity are small and manageable Barriers that led to withdrawal were disappointment at randomisation to standard-of-care therapy and inability to adhere to the programme[146]	• Confidence • Beliefs • Attitudes • Aversive protocol
If women do not delay getting pregnant while taking part in an intervention	
Then weight loss will not be significant before pregnancy[137]	• Motivation • Commitment • Competing priorities

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