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

[1]Centre for Trials Research, Cardiff University, Cardiff, UK
[2]The Welsh Centre for Primary and Emergency Care Research (PRIME), Division of Population Medicine, Cardiff University, Cardiff, UK
[3]School of Healthcare Sciences, College of Biomedical and Life Sciences, Cardiff University, Cardiff, UK
[4]Cardiff and Vale University Health Board, Department of Sexual Health, Cardiff Royal Infirmary, Cardiff, UK
[5]Public Health Wales NHS Trust, Public Health Wales, Cardiff, UK

*Corresponding author channons2@cardiff.ac.uk

Declared competing interests of authors: Rebecca Cannings-John was a National Institute for Health and Care Research (NIHR) Health Technology Assessment Associate Board member (16 May 2018 to 30 November 2020). Freya Davies was a co-applicant and named researcher at a research centre funded by Health and Care Research Wales [PRIME (Wales Centre for Primary and Emergency Care)]. Caroline Scherf received financial support from Gedeon Richter for attending the European Society of Contraception and Reproductive Health meeting in 2018 in Budapest. Julia Sanders acts as a self-employed independent midwifery expert witness and is chief investigator of the NIHR-funded POOL study, co-investigator of the NIHR-funded CHOICE study, co-investigator of the NIHR-funded iHOLDS study, co-investigator of the NIHR funded HOLDS study, co-investigator of the NIHR funded ANODE study and a funded co-investigator with Policy Research Unit NPEU, University of Oxford (Oxford, UK).

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

Published January 2023
DOI: 10.3310/NKIX8285

Scientific summary

The Plan-it mixed-methods study

Health Technology Assessment 2023; Vol. 27: No. 1
DOI: 10.3310/NKIX8285

NIHR Journals Library www.journalslibrary.nihr.ac.uk

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.

Funding

This project was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 27, No. 1.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.014

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 4.014 and is ranked 27th (out of 108 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2021 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), Embase (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded™ (Clarivate™, Philadelphia, PA, USA).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta.

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 17/130/05. The contractual start date was in May 2019. The draft report began editorial review in May 2021 and was accepted for publication in October 2021. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).