ISRCTN14733020 https://doi.org/10.1186/ISRCTN14733020

The Plan-it Study: the acceptability and feasibility of a planned pre-pregnancy weight loss intervention

Submission date
30/04/2019

Recruitment status
No longer recruiting

Registration date
10/05/2019

Overall study status
Completed

Last Edited
24/01/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

About 50% of women of childbearing age in England are overweight or obese (Public Health England, 2015). With the known health risks this presents in pregnancy to mother and child, services need interventions to support women planning a pregnancy with weight loss. Current weight loss interventions in pregnancy do not make enough difference and so attention has turned to interventions before the woman becomes pregnant (pre-pregnancy). This is not a group that services could specifically identify, with the exception of women using long-acting reversible contraception (LARC) such as the intrauterine device (“coil”) or sub-dermal implants, who need them removed by a GP or Sexual Health Practitioner (clinician) before they can become pregnant. However, it may be difficult to ask women to delay the removal in order to lose weight, as it is likely that they have decided about removal and the possibility of pregnancy already. The aim of this study is to discover if it is possible to do a research study that asks women who are overweight/obese to delay LARC removal and take part in a pre-pregnancy weight loss intervention. The researchers want to find out i) how many women request a LARC removal each year and if it is possible to identify from clinic data if they are overweight/obese, ii) what type of weight loss intervention might suit them, iii) if the clinicians who remove LARCs are prepared to refer patients to weight loss interventions, iv) how best to design a study to see whether such an intervention will work. Some of the possible problems have been identified in other studies, for example women do not feel they have time to attend weight loss sessions, and clinicians lack confidence in discussing weight when it is not the reason for the consultation. Also women attending for LARC removal may already be committed to becoming pregnant and hesitant to delay trying for a baby. The researchers want to understand this combination of elements to ensure that they design a study that is acceptable and feasible, or explain why this study cannot currently be done.

Who can participate?

Women of reproductive age (16-48 years old) who have experience of using LARC and who think /know either that their current weight would put them in the overweight/obese category, or their weight when they were planning a pregnancy would have put them in the overweight /obese category

What does the study involve?
The study focuses on finding out the views of women and clinicians about this type of intervention and to see if participants can be identified from information collected by NHS clinicians (routine data). The researchers will find out if they can use routine data to identify the number of LARC removals and if those women are overweight/obese. They will run online surveys through social media e.g Facebook, weight loss forums etc, asking women who have used LARCs and are overweight/obese what they think would be the reasons to take part or not in such an intervention, whether they think it can be done and if so how they could imagine it working. They will ask clinicians and people who run weight loss interventions the same type of questions and also their views about asking women to take part in a study. They will look at the types of weight loss interventions that might work and also any guidelines that might affect clinicians' practice. They will put this information together and work with groups of women and professionals (stakeholder advisory groups, SAGs) to translate this into possible interventions and study designs. They will ask women and professionals in individual/group interviews for their views on their suggestions and then draft a proposal that will be finalised by discussion with the SAGs. The final study design, or reasons for no study, will be written up as the final report, published, put on the study website and presented at conferences.

What are the possible benefits and risks of participating?
Participation in the interview is not likely to involve any particular risks although it may bring back memories of difficult conversations for participants. If participants do become upset they can stop the interview at any time. The main disadvantage in taking part is participants giving up their time to take part in the interview. The main advantage is that participants will be able to share their experiences to help improve understanding of managing conversations about weight in relation to family planning and pregnancy.

Where is the study run from?
Centre for Trials Research (UK)

When is the study starting and how long is it expected to run for?
May 2019 to October 2020

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA 17/130/05

Study information

Scientific Title
The Plan-it Study: the acceptability and feasibility of a planned pre-pregnancy weight loss intervention

Acronym
Plan-it

Study objectives
Despite many studies of weight loss interventions in pregnancy, systematic reviews have demonstrated limited effectiveness. The recently published Preconception Health series in the Lancet argues the need to target the preconception period for weight loss intervention. However, there are several perceived challenges to incorporating a weight loss intervention into preconception care. In order to identify ways of ameliorating the difficulties and develop an acceptable intervention deliverable by the NHS, we need to better understand the LARC pathway from an individual and population perspective and its interface with weight management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/04/2019, School of Medicine Research Ethics Committee Cardiff University (Cardiff University, Main Building, Heath Park, Cardiff, CF14 4XN; +44 (0)2920743738; SOMREC@tcd.ie), ref: 19/42

Study design
Feasibility study

Primary study design
Observational

Secondary study design
Qualitative study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Overweight obesity in preconception period

Interventions
In Work Package 1, individual level anonymised patient data will be accessed from The Clinical Practice Research Datalink (CPRD) and Public Health Wales (PHW) to assess: the pattern of LARC use; the annual number of women in the UK requesting removal of LARC without replacing it for alternative contraception; rates of women who subsequently become pregnant following LARC removal and time from LARC removal to conception. Aggregrate data will be requested from SHCD from Scotland (via National Sexual Health System) and England (via NHS Digital) to compare rates.

In Work Package 2, participants will be recruited via social media advertising to complete open-text qualitative surveying. A minimum of 200 and a maximum of 500 responses will be collected. There will be no follow-up assessment. Professionals (clinicians and weight loss consultants will be identified at relevant professional meetings and qualitative interviewed. There will be no follow-up assessment. All participants will provide contact details if they are willing to be contacted for a follow-up interview. Up to 20 participant interviews and 10 professional interviews will be conducted.

Intervention Type
Other

Primary outcome measure
1. Rates of women in the UK who request LARC removal and subsequently have a pregnancy through routine data, collected via routine data for the period 01/01/2009 to 31/12/2018
2. Identification of opportunities to intervene in preconception pathway, identified from routine data analysis for the period 01/01/2009 to 31/12/2018
3. Assessment of the barriers and facilitating factors for incorporating a weight loss intervention in the preconception period from the perspective of all stakeholders. This will be assessed via qualitative online surveys or interviews in Work Package 2. There is no follow-up so all interviews will be carried out at baseline
4. Identification of suitable weight loss interventions that are acceptable to the stakeholders. This will be assessed via qualitative online surveys or interviews in Work Package 2. There is no

follow-up so all interviews will be carried out at baseline
5. Assessment of the views of eligible women and potential recruiting clinicians as to the feasibility of the intervention and acceptability of future research. This will be assessed via qualitative online surveys or interviews in Work Package 2. There is no follow-up so all interviews will be carried out at baseline

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/05/2019

Completion date
31/10/2020

Eligibility

Key inclusion criteria
1. Women of reproductive age (16-48 years old)
2. Have experience of using LARC
3. Who think/know either that their current weight would put them in the overweight/obese category or their weight when they were planning a pregnancy would have put them in the overweight/obese category

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
200 responses / qualitative interviews

Key exclusion criteria
Insufficient written English to participate in online surveys and consent to participate in the study

Date of first enrolment
01/08/2019

Date of final enrolment
30/07/2020

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Centre for Trials Research
4th Floor Neuadd Meirionnydd
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CF14 4YS

Sponsor information

Organisation
Cardiff University

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Sponsor type
University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. The researchers will publish the study protocol (not as yet published). No other documents will be available.
2. Results will be published as an academic journal article, at academic conferences, on the study website and disseminated to participants.

Intention to publish date
31/10/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/10/2022	19/10/2022	Yes	No
Results article		01/01/2023	24/01/2023	Yes	No