ISRCTN10035244 https://doi.org/10.1186/ISRCTN10035244

Self-weighing in pregnancy: experiences

Submission date
12/08/2019

Recruitment status
No longer recruiting

Registration date
29/10/2019

Overall study status
Completed

Last Edited
22/02/2021

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
Gaining too much weight whist pregnant causes risks to mother and baby. In 2009 the Institute of medicine developed guidelines which help doctors and midwives guide women on an appropriate amount of weight to gain during pregnancy to achieve the best pregnancy outcomes. However, it is estimated that almost half of expectant mothers gain much more weight during pregnancy than is recommended. Whatsmore women who start pregnancy heavier are more likely to gain the most weight. This highlights the urgent need for effective ways to help women reduce the amount of weight they gain during pregnancy, particularly in women who enter pregnancy carrying too much weight

We already know that regular weighing yourself is one way that can help people to successfully manage their body weight, and might be useful to help pregnant women manage their weight. However, little is known about the impact of self-weighing on weight gain during pregnancy. The current guidelines for doctors and midwives is not to routinely weigh women during pregnancy. Previous attempts to get pregnant women to weigh themselves regularly have been unsuccessful, but it is still unclear why pregnant women are resistant to regularly weighing themselves during pregnancy. The purpose of this study is to explore naturally occurring thoughts and feelings associated with self-weighting during pregnancy. The aim is that the views will help us identify barriers and facilitators to self-weighing during pregnancy

Who can participate?
Participants will be identified from patients attending the first-trimester scan. To be eligible to take part they must:
1. Have a BMI ≥25kg/m2 based on measured first-trimester weight
2. Be pregnant at gestational age 9 to 15 weeks at enrolment
3. Have the ability to provide informed consent
4. Have access to a mobile phone with voice recording capabilities

And must not:
1. Have a foetal anomaly detected on first-trimester scan
2. Be Planning a termination
3. Have a history of an eating disorder
4. Have had bariatric (weight loss) surgery in the past

What does the study involve?
Demographic and personal contact information will be collected from participants and they'll be asked to complete a short questionnaire on their opinions, attitudes and beliefs to gestational weight gain and self-weighing during pregnancy.

Participants will be provided with verbal and written instructions on how to weigh themselves and record thoughts and feelings using the 'think aloud' procedure. They'll be asked to weigh themselves at least weekly for the next eight weeks. We will provide them with scales for these purposes if they do not have scales at home. Participants will receive a demonstration of how to make the 'think aloud' audio recordings on their own smartphone. They will be coached that each thinks aloud recording should consist of:
1. The date
2. The weight displayed on scales (any difference in weight from the previous reading)
3. All naturally occurring thoughts and during the weighing process

Participants will be asked to send these 'think-aloud' recordings to the research team immediately using a secure messaging service enabled with end-to-end encryption so that the researchers can ensure that the quality of the recording is adequate and that the participant has included all the required information in the gobbet. Participants will receive reminder text messages every week for the duration of the 8 weeks to remind them to conduct the task, and they will be contacted by telephone mid-way through the study (approx. 4 weeks) to collect any feedback and address any issues that may arise. The information provided in the think-aloud recordings is regarded as sensitive and will be handled accordingly.

The follow-up session will be scheduled at the same time as the participants' 20-week scan, which is usually scheduled immediately following the 12-week scan. During this appointment, participants will be asked to return any weighing scales borrowed, or return shipping will be arranged. Participants will be asked to complete a questionnaire about their experience of self-weighing.

What are the possible benefits and risks of participating?
Participants might feel embarrassed or distressed when talking about their weight.

Where is the study run from?
The study is being run by researchers from The University of Oxford

When is the study starting and how long is it expected to run for?
The study will start in November 2019 and will run for approximately 6 months

Who is funding the study?
The study is funded by the National Institutes of Health Research (NIHR) Biomedical Research Centre Oxford

Who is the main contact?
Dr Nerys Astbury:
nerys.astbury@phc.ox.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Nerys Astbury

ORCID ID
http://orcid.org/0000-0001-9301-7458

Contact details
Radcliffe Primary Care
Woodstock Road
Oxford
United Kingdom
OX2 6GG
01865 617871
swipe@phc.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
19/NE/0083

Study information

Scientific Title
Self-weighing In Pregnancy: Experiences

Acronym
SWIPE

Study objectives
This is a qualitative study to explore the thoughts and feelings of pregnant women to regular self-weighing

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/03/2019, the North East- Newcastle and Tyneside 2 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; 0207 104 8082; nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net), ref: 19/NE/0083.

Study design

Qualitative study

Primary study design
Observational

Secondary study design
Qualitative study

Study setting(s)
Home

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Pregnancy

Interventions
Participants are asked to weigh themselves at least weekly (but more often if they wish) for 8 weeks. Each time they do this they're asked to use the voice memo function of their phone to record how they think and feel about the experience "Think Aloud". After each recording they'll be asked to send the recording to the research team using a secure messaging service.

Intervention Type
Other

Primary outcome measure
Participant thoughts and feelings are determined using Think aloud audio recordings collected from participants during regular self-weighing.

Secondary outcome measures
none

Overall study start date
01/01/2019

Completion date
30/04/2020

Eligibility

Key inclusion criteria
1. Singleton viable pregnancy
2. BMI ≥25kg/m2 based on measured first-trimester weight

3. Gestational age 9 to 15 weeks at enrolment
4. Ability to provide informed consent
5. Access to a mobile phone with voice recording capabilities

Participant type(s)
Other

Age group
Adult

Sex
Female

Target number of participants
Up to 30

Total final enrolment
25

Key exclusion criteria
1. Maternal age <18 years
2. Foetal anomaly detected on first-trimester scan
3. Planned termination
4. History of eating disorder
5. Bariatric surgery

Date of first enrolment
04/11/2019

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Joint Research Office
Second Floor
OUH Cowley
Unipart House Business Centre,
Garsington Road
Oxford
United Kingdom
OX4 2PG

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Address: Joint Research Office
1st floor, Boundary Brook House
Churchill Drive
Headington
Oxford
England
United Kingdom
OX3 7GB
01865 0000000
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/ctrg

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results may be presented at a conference and will be published in a peer-reviewed journal in 2020.

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to data being inherently identifiable.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/02/2021	22/02/2021	Yes	No
HRA research summary			28/06/2023	No	No