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Healthy Eating and Lifestyle in Pregnancy (HELP)

Submission date	Recruitment status
11/01/2010	No longer recruiting
Registration date	**Overall study status**
16/04/2010	Completed
Last Edited	**Condition category**
24/05/2021	Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cf.ac.uk/medic/subsites/sewtu/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0802038

Study information

Scientific Title
Healthy Eating and Lifestyle in Pregnancy (HELP): a cluster randomised trial to evaluate the effectiveness of a weight management intervention in pregnancy on weight at 12 months following birth, gestational weight gain and pregnancy and birth outcomes

Acronym
HELP

Study objectives
Is a weight management intervention for obese pregnant women, which targets physical activity and healthy eating, effective in reducing womens body mass index (BMI) at 12 months from giving birth and at what cost?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee for Wales, 15/12/2009, ref: 09/MRE09/58

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions

Women will be invited to attend a weekly 1.5 hour group run jointly by NHS midwives and 'Slimming World' (SW) consultants. These groups differ from usual SW sessions because in addition to the diet and lifestyle advice there is midwife input and additional exercise advice and monitoring.

Women will be recruited at 12 - 20 weeks gestation and the intervention will run until 6 months post-partum. The treatment period will therefore vary dependent on what stage in pregnancy the woman was recruited and when she gives birth. However, it will be between 43 and 56 weeks (taking into account normal gestation is 37 - 42 weeks).

Those in the control group will receive usual care from their midwife which includes between 7 and 10 antenatal consultations, as well as a leaflet on healthy eating and physical activity in pregnancy.

The follow up is until one year from giving birth for both arms of the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Maternal BMI at one year from birth

Secondary outcome measures
Current secondary outcome measures as of 19/03/2020:
1. General mental health measured at 36 weeks during pregnancy, 6 weeks post-birth, 6 months and 1 year from birth
2. Breastfeeding intentions, measured at 36 weeks during the pregnancy and breastfeeding behaviour and weaning (6 weeks, 6 months and 1 year)
3. Child weight centile, collected at birth, 6 weeks, 6 months and 1 year
4. Pregnancy and birth outcomes known to be related to obesity, collected at birth
5. Health service costs, measured at 36 weeks during pregnancy, 6 weeks post-birth, 6 months and 1 year from birth
6. Pregnancy weight gain (36 weeks)
7. Waist circumference and waist-hip ratio (12 months)
8. Self-report physical activity (36 weeks while pregnant, 6 weeks post-birth, 6 months and 12 months)
9. Self-report diet (36 weeks while pregnant, 6 weeks post-birth, 6 months and 12 months)
10. Self-report alcohol and smoking (36 weeks while pregnant, 6 weeks post-birth, 6 months and 12 months)
11. Health-related quality of life 36 weeks while pregnant, 6 weeks post-birth, 6 months and 12 months)

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Previous secondary outcome measures:
1. Psychological factors, measured at 36 weeks during pregnancy, 6 weeks post-birth, 6 months and one year from birth
2. Breast feeding intentions, measured at 36 weeks during the pregnancy
3. Child weight centile, collected at birth, 6 weeks, 6 months and one year
4. Pregnancy and birth outcomes known to be related to obesity, collected at birth

5. Health service costs, measured at 36 weeks during pregnancy, 6 weeks post-birth, 6 months and one year from birth

Overall study start date
01/02/2010

Completion date
31/01/2014

Eligibility

Key inclusion criteria
Women will be included in the trial if they:
1. Are 18 years or over
2. Have a BMI of greater than or equal to 30 kg/m^2
3. Are at the earliest hospital contact (around 12 weeks) up to 20 weeks (and 6 days)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
570

Total final enrolment
598

Key exclusion criteria
Women will not be eligible for the trial if:
1. They are greater than 20 weeks gestation
2. They are unable to understand the intervention, e.g. insufficient understanding of spoken English
3. They have antenatal maternal or foetal complications; serious physical or psychological disorders and previous surgery for weight problems

Date of first enrolment
28/02/2011

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
Cardiff
United Kingdom
CF14 4YS

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and Commercial Division
7th Floor, 30 - 36 Newport Road
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United Kingdom
CF24 0DE
+44 (0)29 2087 9274
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Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Research council

Funder Name

Medical Research Council (MRC) (UK) - National Prevention Research Initiative (NPRI)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/05/2014		Yes	No
Other publications	process evaluation framework	01/07/2014		Yes	No
Results article	results	01/07/2014		Yes	No
Results article		01/08/2021	24/05/2021	Yes	No
HRA research summary			28/06/2023	No	No