

Healthy Eating and Lifestyle in Pregnancy (HELP)

Submission date 11/01/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 16/04/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 24/05/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sharon Simpson

Contact details
Department of Primary Care and Public Health
South East Wales Trials Unit
7th floor Neuadd Meirionnydd
Cardiff University
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 (0)29 2068 7181
SimpsonSA@cf.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Maternal BMI at one year from birth

Key secondary outcome(s)

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)

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

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/m²
3. Are at the earliest hospital contact (around 12 weeks) up to 20 weeks (and 6 days)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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)

ROR

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
Results article	results	01/07/2014		Yes	No
Results article		01/08/2021	24/05/2021	Yes	No
Protocol article	protocol	10/05/2014		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	process evaluation framework	01/07/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes