

# WEight Loss Looking for Baby And mum's BETter outcomes (WELLBABE)

|                                        |                                                       |                                                                                                              |
|----------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>12/02/2015   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>24/02/2015 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>23/02/2015       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

The aim of this study is to see whether a reduced calorie diet can be used to treat diabetes that develops during pregnancy (gestational diabetes). We know that this treatment can be very successful for people with late-onset (type 2) diabetes; the question is whether it can also be used to treat gestational diabetes. We are also interested in the effects of the diet on the body, in particular the effect on the liver. It is thought that gestational diabetes occurs due to too much fat in the liver. This study looks to see whether liver fat is reduced by diet.

### Who can participate?

Pregnant women with gestational diabetes. Gestational diabetes is usually diagnosed after 20 weeks gestation by an oral glucose tolerance test arranged by your NHS midwife or antenatal clinic. Women can enter the study between 20 and 32 weeks gestation.

### What does the study involve?

The study involves two visits to the Newcastle Magnetic Resonance Centre. At each visit you will be asked not to eat or drink overnight. You will have a magnetic resonance scan of the liver. This is perfectly safe in pregnancy. You will then be given breakfast (cereal, bread roll, margarine, jam and fruit juice). Blood samples will be taken over the next three hours to measure your body's response to breakfast. During your first visit you will be seen by a dietician. We will explain how to reduce your calorie intake to 1,200 kcal. Food suggestions, recipes and portion sizes will be discussed in order to give you a balanced diet containing all necessary nutrients. You will be asked to keep a food diary on MyFitnessPal (a smartphone app). We will show you how to do this. The diary is reviewed regularly by one of the research team and we will contact you by text or telephone regularly during the diet. After 4 weeks of dieting you will be asked to return to the Newcastle Magnetic Resonance Centre for a repeat scan of the liver and meal test. We will be able to tell you how much fat you have lost from the liver and see the effect of the diet on your glucose control during the meal.

### What are the possible benefits and risks of participating?

The main benefit of the study is an improvement in your glucose control. This is of huge benefit to both you and your baby and reduces the risks associated with gestational diabetes. Additionally, there are benefits of a more healthy weight in terms of reducing pregnancy risks

such as blood clots and infection. You will benefit from more intense medical input during your pregnancy. You will gain knowledge about your body during pregnancy and get feedback with regards to the effect of diet on your metabolism. There are no risks of participating in this study.

Where is the study run from?

The study recruits patients from the Obstetric Medicine Antenatal Clinic at the Royal Victoria Infirmary, Newcastle upon Tyne Hospitals Foundation NHS Trust. The study is run at the Newcastle Magnetic Resonance Centre, Newcastle University (UK).

When is the study starting and how long is it expected to run for?

The study starts in January 2015 and is expected to run until August 2015.

Who is funding the study?

The study is funded by a grant from the North East Diabetes Trust (UK).

Who is the main contact?

Dr Ken Hodson

kenneth.hodson@ncl.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Kenneth Hodson

**ORCID ID**

<https://orcid.org/0000-0003-3091-6952>

**Contact details**

Newcastle Magnetic Resonance Centre

Campus for Ageing and Vitality

Newcastle University

Newcastle upon Tyne

United Kingdom

NE4 5PL

## Additional identifiers

**Protocol serial number**

N/A

## Study information

**Scientific Title**

Dietary intervention for the treatment of gestational diabetes: a magnetic resonance study

**Acronym**

WELLBABE

**Study objectives**

Calorie restriction in women with gestational diabetes reduces liver fat, thereby improving insulin resistance and improved glycaemic control.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee North East - Newcastle & North Tyneside 2, 22/10/2014, ref: 14/NE/1085

**Study design**

Interventional non-randomised study

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Gestational diabetes: hyperglycaemia that is first recognised in pregnancy

**Interventions**

Dietary intervention: calorie reduction to 1,200 kcal for four weeks.

Magnetic resonance spectroscopy will be used to quantify liver fat before and after a four-week dietary intervention. A standardised meal test will be used to quantify insulin resistance and glycaemic control.

**Intervention Type**

Behavioural

**Primary outcome(s)**

1. Liver fat – measured at baseline and after 4 weeks of dietary intervention by magnetic resonance spectroscopy
2. Glycaemic control – measured by home blood glucose monitoring in the first and fourth weeks

**Key secondary outcome(s))**

1. Insulin/C peptide/glucose response to a standardised meal test. Measured at baseline and after 4 weeks of dietary intervention
2. Lipid profile – measured using nuclear magnetic spectroscopy at baseline and 4 weeks of dietary intervention
3. HBA1c – measured at baseline and after 4 weeks of dietary intervention
4. Feasibility and acceptability of dietary intervention in pregnancy (qualitative study) – assessed by semi-structured interview after the dietary intervention and analysed using the theory domain framework

**Completion date**

01/01/2017

# Eligibility

## Key inclusion criteria

1. Female
2. Greater than 20 weeks pregnant
3. Gestational diabetes (oral glucose tolerance test greater than/equal to 5.1 mmol/l, or 2-hour glucose greater than/equal to 7.8 mmol/l)

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

Female

## Key exclusion criteria

Contraindication to MRI:

1. Pacemaker/ferromagnetic implants
2. Metallic fragments in eye
3. Piercings that cannot be removed
4. Claustrophobia

## Date of first enrolment

05/01/2015

## Date of final enrolment

01/08/2015

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

Newcastle upon Tyne Hospitals NHS Foundation Trust

Royal Victoria Infirmary

Queen Victoria Road

Newcastle upon Tyne

United Kingdom

NE1 4LP

**Study participating centre**  
**Newcastle Magnetic Resonance Centre**  
Newcastle University Campus for Ageing and Vitality  
Newcastle upon Tyne  
United Kingdom  
NE4 5PL

## Sponsor information

**Organisation**  
Newcastle upon Tyne Hospitals NHS Foundation Trust

**ROR**  
<https://ror.org/05p40t847>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
North East Diabetes Trust (UK)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Available on request

### Study outputs

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |