

# To evaluate the impact of attending The Lifestyle Course (TLC) on the health of pregnant women with a Body Mass Index (BMI) of 30kg/m<sup>2</sup> or more and their babies

<b>Submission date</b> 28/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/08/2018	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

A pilot randomised controlled trial to evaluate the impact of attending The Lifestyle Course (TLC) on the health of pregnant women with a Body Mass Index (BMI) of 30kg/m<sup>2</sup> or more and their babies

### Acronym

TLC

### Study objectives

This is a pilot study so there is no formal research hypothesis. Instead the suitability and acceptability of the study design is examined and a research hypothesis for the main trial will be generated.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

NHS and University of Manchester approval pending as of 04/05/2011

### Study design

Pilot randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Treatment

### Participant information sheet

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

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

Maternal obesity

### Interventions

The Lifestyle Course (TLC) is innovative as it is a multi-component intervention that addresses a complete healthy lifestyle for the whole family and combines theory-based behaviour change techniques (social cognitive theory) with a healthy eating, physical activity and well-being intervention. TLC is informed by the findings of a feasibility study (N=259) highlighting what intervention aspects were acceptable and suitable to pregnant women with a BMI of 30kg/m<sup>2</sup> or more. TLC runs for two hours per week for 10-weeks and women must be between 12 and 28 weeks gestation. A multi-disciplinary team and a range of experts designed the intervention and tested it for use in a feasibility study with pregnant women with a BMI of 30kg/m<sup>2</sup> or more in Greater Manchester.

Control group - routine maternity care. The 36 women who are randomised to the control arm of the intervention will continue to receive standard maternity care within the NHS trust that they were recruited from (Royal Bolton Hospitals NHS Foundation Trust and The Pennine Acute Hospitals NHS Trust). Their care will follow the individual hospitals maternity care guidelines and care pathways according to their antenatal booking BMI.

TLC group - The women who are randomised to the intervention arm and are offered the opportunity to attend the 10-week TLC will receive the same maternity care within their NHS trust. Any contact made with the research team by control women will be noted, as will any non-research questions that they ask to the research midwives in the data collection sessions.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

The pilot study will inform the main randomised controlled trial by evaluating the suitability and feasibility of the study, design, including conformation of the most appropriate primary endpoint.

This main objective is to inform the main trial by evaluating and providing information on the validity of the study design, will focus specifically on:

- 1.The suitability of the recruitment strategy
- 2.The suitability of the inclusion criteria
- 3.Womens understanding of the study and their reasons for participating or not participating
- 4.The success and suitability of the randomisation method
- 5.The required sample size for the main trial to ensure adequate power
6. Intervention group adherence to the 10week programme, reasons for attending or nonattending and views towards taking part in the study
7. Control group retention rates, views towards the taking part in the study and possible contamination
8. The acceptability and suitability of the data collection followup period length
9. The appropriateness of the primary and secondary outcomes for the study objectives and main trial;~s research question
- 10.The acceptability and suitability of the data collection methods used to collect outcome measures data

### **Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/06/2011

**Completion date**

01/05/2013

## Eligibility

**Key inclusion criteria**

1. Attending antenatal care in Bolton NHS Foundation Trust or Oldham (part of the Pennine Acute Hospital NHS Trust
2. A body mass index (BMI) of 30kg/m<sup>2</sup> or greater
3. Aged 18 or older
4. Between 12 and 28 weeks gestation at the start of the 10 week course (10th October 2011)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

72

**Key exclusion criteria**

1. BMI less than 30
2. Aged under 18
3. If women have been advised by a Health care professional to not take part in physical activity during their pregnancy or if they have any cautions for starting exercise [using the Revised Physical Activity Readiness Questionnaire and the Royal College of Obstetricians and Gynaecologists (RCOG) recommendations] then the research midwife will assess the women's suitability and in unsure cases will ask their consultant obstetrician for approval.
4. Multiple gestation
5. Preexisting preeclampsia
6. Preexisting gestational diabetes

**Date of first enrolment**

01/06/2011

**Date of final enrolment**

01/05/2013

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Manchester**

Manchester

United Kingdom

M13 9PL

**Sponsor information****Organisation**

University of Manchester (UK)

**Sponsor details**

Simon Building

Brunswick Street

Manchester

England

United Kingdom

M13 9PL

**Sponsor type**

University/education

**ROR**

<https://ror.org/027m9bs27>

**Funder(s)****Funder type**

Government

**Funder Name**

Department of Health (UK)

**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?
<a href="#">Protocol article</a>	protocol	27/05/2010		Yes	No