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To evaluate the impact of attending The Lifestyle Course (TLC) on the health of pregnant women with a Body Mass Index (BMI) of 30kg/m2 or more and their babies

Submission date
28/04/2011

Recruitment status
No longer recruiting

Registration date
17/06/2011

Overall study status
Completed

Last Edited
29/08/2018

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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/m2 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

Study type(s)
Treatment

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/m2 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/m2 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(s)
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

Key secondary outcome(s))
No secondary outcome measures

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/m2 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

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
Female

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
United Kingdom

England

Study participating centre
University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK)

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?
Protocol article	protocol	27/05/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes