

Can Antenatal yoga Lower Maternal Anxiety (CALMA)

Submission date 10/09/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/09/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/04/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Anxiety while pregnant is associated with poorer outcomes for both the mother and the fetus. We are carrying out a study to assess the immediate and long-term effects of attending sessions of antenatal yoga on subjective and physiological measures of anxiety. This study will answer the following questions: Do women who attend yoga while pregnant show less anxiety than women who receive standard care? What effect does a single session of yoga have on self-reported anxiety symptoms and stress hormone levels? Is any single-session effect consistent after repeated sessions?

Who can participate?

Eligible pregnant women must be over 18 years old with their first pregnancy lasting beyond 13 weeks.

What does the study involve?

Participants are randomly allocated to either the yoga group or the control group. The yoga group women will attend our yoga programme. The control group women are asked not to attend our yoga sessions during their pregnancy (but may attend other yoga classes). Regardless of which group participants are placed in, we would like them to complete a postal questionnaire at baseline and once the yoga group have completed the 8-week course of yoga. Participants allocated to the yoga group will be asked to complete a brief questionnaire and to provide a saliva sample both before and after the class at the first and final sessions of the 8-week programme. This will allow us to measure your level of the stress hormone cortisol and subjective reports of anxiety.

What are the possible benefits and risks of participating?

If allocated to the yoga group, participants will benefit from free yoga sessions. Participants in the control group will be given the opportunity to answer questions on how they feel about their pregnancy. In the initial small study, many reported this opportunity to describe their pregnancy anonymously as therapeutic. There will be no physical risk in taking part in the study. Chewing on the cotton bud to provide the saliva sample may taste peculiar, but will not cause any physical harm or discomfort. Participants do not have to answer any questions in the questionnaire packs which they find difficult to answer.

Where is the study run from?

This study has been set up by the University of Manchester, UK.

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

Recruitment for this study started at the end of 2010 and recruitment was completed in May 2011.

Who is funding the study?

Funding has been provided by Tommy's, the baby charity.

Who is the main contact?

Dr James Newham

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8992

Study information

Scientific Title

Can Antenatal yoga Lower Maternal Anxiety (CALMA): a randomised controlled trial

Acronym

CALMA

Study objectives

Pregnant women in the second or third trimester will be approached by midwives or sonographers regarding whether they would be interested in taking part in a randomised controlled trial. Those who consent to take part will be randomised to either an 8-week course of antenatal yoga or treatment as usual. Participants in both groups will complete questionnaires assessing mood both before and after the intervention period to determine whether antenatal yoga has within-group reductions in maternal anxiety that significantly differ from those who receive standard care.

More details can be found at: <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=8992>

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West 9 Research Ethics Committee - Greater Manchester West, 14/07/2010, ref: 10/H1014/43

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network, Reproductive Health and Childbirth; Subtopic: Anxiety, Reproductive Health and Childbirth (all Subtopics); Disease: Anxiety, General Obstetrics /Midwifery

Interventions

Treatment-as-usual

Standard care; Yoga, 8-week relaxation-based intervention

Follow-Up Length: 2 months

Study Entry : Single Randomisation only

Intervention Type

Behavioural

Primary outcome measure

Wijma Delivery Expectancy Questionnaire; Timepoint(s): pre and post intervention

Secondary outcome measures

1. Edinburgh Postnatal Depression Scale; Timepoint(s): pre and post intervention
2. State trait Anxiety Inventory; Timepoint(s): pre and post intervention

Overall study start date

01/12/2010

Completion date

27/05/2011

Eligibility**Key inclusion criteria**

1. Pregnant women between 18-40 years of age
2. With their first pregnancy lasting beyond 13 weeks, in the first 6 months of pregnancy (<26 weeks gestation)
3. Who can speak and understand English fluently

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Female

Target number of participants

Planned Sample Size: 72; UK Sample Size: 72; Description: Randomised to Intervention = 36
Randomised to Control = 36

Key exclusion criteria

1. Participants will be excluded if they are on any prescription medication other than pregnancy supplements
2. Are expecting multiple pregnancies (e.g. twins)
3. Are already attending antenatal yoga classes
4. Expecting a child with any abnormality

5. Are surrogate mothers or are planning to put their child up for adoption
6. Have pre-existing diabetes or have any heart or kidney disease. After consulting yoga instructors (who allowed us to recruit from their yoga classes in the pilot study we ran), no exclusion criteria for attending antenatal yoga was stipulated

Date of first enrolment

01/12/2010

Date of final enrolment

27/05/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St. Mary's Hospital

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

Guild Lodge

Whittingham

Manchester

England

United Kingdom

M13 9PL

Sponsor type

University/education

Website

<http://www.manchester.ac.uk/>

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Manchester Statistical Society (UK)

Funder Name

Tommy's (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?
Results article	results	01/08/2014		Yes	No