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Can Antenatal yoga Lower Maternal Anxiety (CALMA)

Submission date
10/09/2013

Recruitment status
No longer recruiting

Registration date
10/09/2013

Overall study status
Completed

Last Edited
27/04/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised interventional treatment trial

Study type(s)
Treatment

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

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

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
United Kingdom

England

Study participating centre
St. Mary's Hospital
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
University of Manchester (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

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