ISRCTN54477888 https://doi.org/10.1186/ISRCTN54477888

Cognitive behavioural stress management during pregnancy

Submission date
07/10/2018

Recruitment status
No longer recruiting

Registration date
17/10/2018

Overall study status
Completed

Last Edited
24/10/2018

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Pregnancy is a stressful life event, and according to Social Readjustment Rating Scale, it has been ranked 12th of the 43 most stressful life events. Pregnancy stress is common and comes from a variety of pregnancy-specific problems, including physical symptoms and changes, changes in body image, medical problems, anxiety about delivery, and concerns about birth and the baby's health. Previous studies have examined the incidence and prevalence of stress levels during pregnancy. The impact of pregnancy stress on women and fetal health can lead to adverse outcomes, including miscarriage, premature labor and birth defects. Maternal psychological stress can also be responsible for any learning and cognitive developmental delays in the child. Many researchers have used cognitive behavioral therapy (CBT) to release stress. Elements of CBT include cognitive restructuring, raising awareness about stress, relaxation training, problem-solving training, self-management and adequate social support. Cognitive behavioral stress management has been applied successfully in many physical and emotional conditions, such as cancer, depression, insomnia and heroin-dependent individuals. However, cognitive behavioral stress management has not yet been fully applied to pregnant women in reducing their pregnancy stress. Thus, this study aims to examine the effects of cognitive behavioral stress management, with cognitive intervention, relaxation techniques, problem-solving training and social support, to reduce pregnancy stress among pregnant women.

Who can participate?
Pregnant women (at early stage of pregnancy, i.e., 6 to 8 weeks of the pregnancy) aged 20-38 years, who are able to come to the hospital for antenatal examinations

What does the study involve?
Participants will be asked to join this study while they came to the hospital obstetric outpatient clinic for antenatal examination. Participants must pass the screening to ensure that they meet the inclusion criteria. Participants will be randomly assigned to either the intervention group and the control group.
The control group receive routine antenatal examination and pregnancy health education instructions (including advice on diet, fetal monitoring and daily care during pregnancy) and the intervention group receive an extra seven cognitive behavior stress management sessions between weeks 8 and 38 of their pregnancy. Participants will be asked to complete a

questionnaire at the beginning and end of the study to assess the effectiveness of intervention in terms of reducing pregnancy stress levels.

What are the possible benefits and risks of participating?
The possible benefit of participating is that the intervention may help to reduce pregnancy stress, and the results may enable the improvement of the quality of antenatal care received by women in the future. There are no known risks to participants taking part in this study.

Where is the study run from?
The study is being run by Bengbu Medical College, Anhui, China and takes place in obstetrics of Obstetrics department of the First Affiliated Hospital of Bengbu Medical College, Anhui Prov, China

When is the study starting and how long is it expected to run for?
November 2015 to December 2018

Who is funding the study?
Educational Commission of Anhui Province of China (China)

Who is the main contact?
Prof. Jin zhi Li
lijinzhi@bbmc.edu.cn

Contact information

Type(s)
Scientific

Contact name
Prof jinzhi li

ORCID ID
http://orcid.org/0000-0002-4372-2340

Contact details
Nursing of school, Bengbu Medical College
No. 2600, the East China Sea Road, Bengbu City, Anhui Prov, China 233030
Bengbu city
China
233000
+86 (0)552 3175212.
lijinzhi@bbmc.edu.cn

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SK2015A403

Study information

Scientific Title
Effective cognitive behavioural stress management to reduce pregnancy stress among pregnant women: a randomised controlled trial

Study objectives
Pregnancy is a normal physiological process, but a stressful life event. The impact of maternal psychological stress during the pregnancy could lead to adverse health outcomes for both mother and child. Effective cognitive behavior stress management can reduce pregnancy stress among pregnant women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Bengbu Medical College in China, 22/07/2015, SK2015A403

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

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

Interventions
All pregnant women were required to undergo 7 antenatal visits in accordance with the "Chinese Guidelines for pre-pregnancy and prenatal care" from 12 to 41 weeks of their pregnancy. 100 participants were randomly divided into the control group (N=50) and the intervention group (N=50) using a computerized random number generator.
The control group received routine antenatal care and pregnancy health education instruction (including advice on diet, fetal monitoring and daily care during pregnancy).
Participants in the intervention group underwent an extra 7 cognitive behavioural stress

management sessions between weeks 8 and 38 of their pregnancy. The sessions covered information on the physiological and psychological changes in pregnancy, coping methods for pregnancy stress, relaxation techniques, and family support. Following each seminar, the facilitator invited participants to participate in group discussions to share their pregnancy experience, including their problem-solving strategies. The facilitator recorded the process but did not participate the discussion. At the end of the session the facilitator summarized the results of the group discussion and proposed strategies of reducing pregnancy stress to participants. Additionally, individual counseling was provided if the participants required this. The cognitive behavioral stress management was delivered mainly through face-to-face communication in the hospital, but in some cases, it was delivered via phone and e-mail. The whole process for each intervention lasted 40-60 minutes.

Intervention Type
Behavioural

Primary outcome measure
Pregnancy stress level, assessed using the Pregnancy Pressure Scale (PPS) at the baseline and after 39 weeks of pregnancy

Secondary outcome measures
N/A

Overall study start date
01/11/2015

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. Pregnant
2. Able to communicate and understand Chinese
3. No severe medical conditions, including heart disease, diabetes and kidney disease
4. Aged 20-38 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100 participants (50 in the intervention group; 50 in the control group)

Key exclusion criteria

1. Pregnancy complications, such as incipient abortion
2. Pre-existing mental ilness, such as depression

Date of first enrolment
01/04/2016

Date of final enrolment
30/05/2017

Locations

Countries of recruitment
China

Study participating centre
Department of obstetrics, The First Affiliated Hospital of Bengbu Medical College
No. 287, Changhuai Road, Bengbu City, Anhui Prov
Bengbu
China
233000

Sponsor information

Organisation
Educational Commission of Anhui Province of China

Sponsor details
No. 321, the Jin ZHai Road, Hefei City, Anhui Prov, China 0061
Hefei
China
230061

Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name

Educational Commission of Anhui Province of China

Results and Publications

Publication and dissemination plan
We expect that the study results will be published before 30/12/2019.

Intention to publish date
30/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available