

Cognitive behavioural stress management during pregnancy

Submission date 07/10/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/10/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/10/2018	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

N/A

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

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

Funder(s)

Funder type

Government

Funder Name

Educational Commission of Anhui Province of China

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes