ISRCTN52045980 https://doi.org/10.1186/ISRCTN52045980

Effect of stress inoculation training based on the WeChat platform on pregnant women with assisted reproduction

Submission date
21/03/2025

Recruitment status
No longer recruiting

Registration date
27/03/2025

Overall study status
Completed

Last Edited
26/03/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether stress inoculation training (SIT) through the WeChat platform can effectively relieve the perinatal psychological pressure of pregnant women undergoing assisted reproduction.

Who can participate?
Pregnant women aged 18-35 years undergoing assisted reproduction (in vitro fertilization-embryo transfer [IVF-ET])

What does the study involve?
Participants are randomly divided into the control group and the experimental group. The control group was given routine nursing intervention and the experimental group was given SIT based on the WeChat platform.

What are the possible benefits and risks of participating?
SIT may relieve the perinatal psychological pressure of pregnant women with assisted reproduction, relieve the tension during delivery, increase the natural delivery rate and reduce the incidence of premature delivery.

Where is the study run from?
Suzhou Municipal Hospital (China)

When is the study starting and how long is it expected to run for?
September 2022 to October 2023

Who is funding the study?
1. Gusu School of Nanjing Medical University (China)
2. Suzhou Municipal Hospital (China)

Who is the main contact?
Jia Liu, fngsajia@126.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Jia Liu

ORCID ID
http://orcid.org/0000-0002-6646-8787

Contact details
No. 458 Shizi Street
Gusu District
Suzhou
China
215006
+86 (0)13584890104
fngsajia@126.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of stress inoculation training based on the WeChat platform on perinatal psychological stress and delivery outcome of pregnant women with assisted reproduction

Study objectives
Stress inoculation training (SIT) can effectively relieve the perinatal psychological pressure of pregnant women with assisted reproduction, relieve the tension during delivery, increase the natural delivery rate and reduce the incidence of premature delivery.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 24/09/2022, The ethics committee of Suzhou Municipal Hospital (No. 26 Daoqian Street, Gusu District, Suzhou, 215002, China; +86 (0)51262362550; webmaster@smh.cc), ref: K-2022-103-H01

Study design
Single-center interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Perinatal psychological stress and delivery outcome of pregnant women with assisted reproduction

Interventions
110 pregnant women who have In Vitro Fertilization-Embryo Transfer (IVF-ET) will be randomly divided into a control group and an experimental group with 55 cases in each group. The control group will be given routine nursing intervention and the experimental group will be given SIT based on the WeChat platform.

Patients in the control group received routine early pregnancy health guidance and psychological screening. At 13 + 6 weeks of gestation, the control group filled in the demographic data questionnaire, including age, height, weight, residence during pregnancy, occupation, education, monthly family income, medical expenses, pregnancy history, etc.. After scanning the QR code, the Edinburgh postnatal depression scale (EPDS) and State-Trait Anxiety Inventory (STAI) were completed in the questionnaire star, and routine early pregnancy health guidance was given. At 24-27 + 6 weeks of gestation, patients attend school courses for pregnant women, including diet during pregnancy, self-monitoring of fetal movement, pregnancy activities and weight management, and distribute health education materials. At 28-37 weeks of gestation, patients attend the simulated delivery training courses, regular pre-delivery guidance. At 32 weeks and 37 weeks of gestation, one-to-one perinatal consultation and guidance were conducted in the midwife clinic. After 37 weeks of pregnancy, the psychological stress of the control group was assessed again, and the EPDS and STAI questionnaires were completed in the questionnaire star. In addition to routine early pregnancy health guidance and psychological screening, patients in the intervention group were given SIT.

Intervention Type
Behavioural

Primary outcome measure
Psychological stress is measured using the WeChat version of the psychological questionnaire before and after the study

Secondary outcome measures
The rate of natural delivery is measured using the delivery records in the hospital before and after the study

Overall study start date
24/09/2022

Completion date
01/10/2023

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Infertility patients who had undergone IVF-ET and successfully conceived
3. Permanent residents in the area surveyed
4. Regular antenatal examination, cooperation with training and completion of questionnaire survey
5. Voluntary participation, and signed the informed consent
6. Individuals who can fully understand or accurately answer the questionnaire questions

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Female

Target number of participants
120

Total final enrolment
110

Key exclusion criteria
1. Patients with severe depression and anxiety
2. Patients with severe basic diseases such as heart, lung and immunity
3. Patients with mental retardation
4. Patients with mental retardation, failure to cooperate and complete all investigations

Date of first enrolment
25/09/2022

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
China

Study participating centre
Suzhou Municipal Hospital
No. 26 Daoqian Street
Gusu District
Suzhou
China
215002

Sponsor information

Organisation
Suzhou Municipal Hospital

Sponsor details
No. 26 Daoqian Street
Gusu District
Suzhou
China
215002
+86 (0)51262362550
webmaster@smh.cc

Sponsor type
Hospital/treatment centre

Website
http://smh.cc

ROR
https://ror.org/02cdyrc89

Funder(s)

Funder type
University/education

Funder Name
Gusu School of Nanjing Medical University

Funder Name
Suzhou Municipal Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/06/2025

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

IPD sharing plan summary
Not expected to be made available