Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of effectiveness of computerized stress inoculation therapy (SIT) with Part-time face-to-face SIT in improvement of symptoms of anxiety, depression and stress in pregnant women with psychological distress

Protocol summary

Study aim

Comparison of effectiveness of computerized Stress Inoculation Therapy (SIT) with Part-time face-to-face SIT in improvement of symptoms of anxiety, depression and stress in pregnant women with psychological distress

Design

A non-inferiority randomized controlled clinical trial with two parallel arms

Settings and conduct

Pregnant women who go to Rouhani and Yahya Nejad Hospitals in Babol for routine prenatal care are selected by availability and then complete the BSI-18 Psychiatric Distress Screening Questionnaire. Pregnant women with a T-score above 63 on the Global Severity Index (GSI) are diagnosed with psychological distress. At the same clinic, a nurse or midwife outside the research team first completes the NuPDQ-17 Pregnancy Stress Questionnaire and the General Perceived Stress Questionnaire (PSS-14). Then, they are randomly assigned to the intervention and routine pregnancy care groups in a block method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being in the 14-32 weeks of pregnancy, at least a third year of middle school, Internet access and the ability to use a computer, not using psychotherapy services right now Exclusion criteria: women with mental disabilities, severe psychiatric disorders, drug abuse

Intervention groups

Intervention group A will be received computerized SIT. Intervention group B receives individually Part-time face-to face SIT. Group B receives treatment sessions with 3 face-to-face sessions and 3 computer sessions as one in between. Both groups receive routine prenatal care. The duration of treatment for both groups is similar, 6 sessions, once a week for 60 minutes.

Main outcome variables

Psychological symptoms of the BSI-18 and the specific stress of pregnancy NuPDQ-17. A secondary outcome is generalized perceived stress (PSS-14).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200122046228N1**
Registration date: **2020-10-28, 1399/08/07**
Registration timing: **prospective**

Last update: **2020-10-28, 1399/08/07**
Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Fatemeh Nasiri Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-31, 1399/08/10

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of effectiveness of computerized stress inoculation therapy (SIT) with Part-time face-to-face SIT in improvement of symptoms of anxiety, depression and stress in pregnant women with psychological distress

Public title
The effect of computerized stress inoculation therapy (SIT) vs Part-time face-to-face SIT on anxiety , depression , and stress in pregnant women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Being in the 14th-32nd week of pregnancy No current psychotherapy services Lack of a history of psychiatric disorder At least a third year of middle school Internet access and the ability to use of computer
Exclusion criteria:
People with mental disabilities Severe psychiatric disorders such as Psychotic disorder, Bipolar disorder, Suicide risk, Drug abuse
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
After checking inclusion and exclusion criteria, participants are allocate randomly into two groups by permuted block randomization method. The block size is 4 and by using the statistical software, 4 part blocks will be produced 24 times. Due to the fact that sampling is done in two centers, two samples of 96-list will be produced. Using this randomly generated list, participants are divided into two groups of 48 people.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Babol University of Medical Sciences
Street address
Ganj Afrooz St., Babol University of Medical Sciences
City
Babol
Province
Mazandaran
Postal code
47176-47745
Approval date
2020-08-23, 1399/06/02
Ethics committee reference number
IR.MUBABOL.REC.1399.277

Health conditions studied

1

Description of health condition studied
Anxiety, depression, and stress
ICD-10 code
F41.2
ICD-10 code description
Mixed anxiety and depressive disorder

Primary outcomes

1

Description
Anxiety, depression, somatization, pregnancy-specific stress
Timepoint
Before the intervention and immediately after the intervention
Method of measurement
Anxiety and depression and somatization with Brief Symptom Inventory–18 (BSI-18) pregnancy-specific stress questionnaire (NuPDQ-17) for pregnancy-specific stress

Secondary outcomes

1

Description
General perceived stress
Timepoint
Before the intervention and immediately after the intervention
Method of measurement

Cohen General Perceived Stress Questionnaire (PSS-14)

Intervention groups

1

Description
Intervention group 1: The participants in this group at 14 to 34 weeks of pregnancy in addition to receiving prenatal care, receive computerized Stress Inoculation Therapy (SIT), 6 session , 60 minutes, once a week. Content of SIT: Session 1: Introducing and explaining the goals, describing the symptoms and their effects on mother and baby, conceptualizing the problem, explaining how this method reduces distress and anxiety. Session 2: Teaching body relaxation and continuing these exercises at home in Intervals between sessions, Session 3: Relaxing the body, challenging stressful thoughts, learning to talk to yourself and identifying the role of negative thoughts in creating these feelings, assign homework and practice body relaxation at home. Session 4: Body relaxation, teaching problem solving skills, assigning tasks, and practicing body relaxation at home, Session 5: Relaxation of the body, training techniques of concentration and distraction of the mind, away from unsolvable stressful issues, assigning homework and practicing body relaxation at home, Session 6: Practicing the skills learned in previous sessions in the training session and then gradually in real life events, especially in stressful situations

Category
Treatment - Other

2

Description
Intervention group 2: The participants in this group at 14 to 34 weeks of pregnancy in addition to receiving prenatal care, receive individually Part-time face-to-face stress inoculation therapy, 6 sessions, 60 minutes, once a week. They receive treatment sessions with 3 face-to-face sessions and 3 computer sessions as one in between. Content and duration of treatment for both groups is similar, 6 sessions, once a week for 60 minutes.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yahya Nejad Hospital
Full name of responsible person
Dr. Angella Hamidya
Street address
Modares St, Shahid Mostafa Khomeini Ave, Shahid Yahya Nejad Hospital
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
Street address
Vice-Chancellor's Office for Research, Babol University of Medical Sciences, Ganj Afrooz St., Babol, Iran
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4717647745
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r.ghadimi@mubabol.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Nasiri- Amiri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available