# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 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**
Ayatollah Rouhani Hospital
**Full name of responsible person**
Dr. mahbobeh Faramarzi
**Street address**
Babol, University Square, Ganj Afrooz St., Ayatollah Rouhani Hospital
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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
**City**
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**Email**
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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## Person responsible for updating data

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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