# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effect of hypnosis on anxiety and blood pressure in pregnant women with preeclampsia: a randomized controlled clinical trial

### Protocol summary

**Study aim**
The effect of hypnosis on anxiety and blood pressure in women with preeclampsia

**Design**
Study of a controlled randomized clinical trial

**Settings and conduct**
Randomization: Random block assignment (using computer software and selecting a quadruple block) to Two groups of 22 intervention and control Research population: including pregnant women with preeclampsia under the auspices of Akbarabadi Hospital in Tehran

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: mild preeclampsia, gestational age from 28 to 32 weeks, no fetal distress, singleton pregnancy, literacy, mild to moderate anxiety score (score 14 and below), general health (low score than 23) and consent to participate in research Exclusion criteria: Depression based on information from the Beck Depression Scale (score greater than 9), participation in any educational and counseling programs related to pregnancy and childbirth anxiety before the study, consumption Psychiatric medication according to the patient's medical record, severe depression or suicidal ideation or harm to others, maternal addiction, spotting, cerclage, uncontrolled seizures, psychosis and reluctance to Continue cooperation.

**Intervention groups**
Intervention group: 5 individual intervention sessions will be held twice a week, online for 60-45 minutes, and at the end of each session, the audio recording file of the session will be held for each group participant. The intervention will be send, at least once a day. The interventions will be performed by a master's degree student in counseling midwifery trained, which is supervised by the research team. Interventions: In addition to routine treatment, hypnosis is received and no intervention is performed during the study

**Main outcome variables**
Anxiety and blood pressure

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20110827007422N3**
Registration date: **2021-09-13, 1400/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-13, 1400/06/22**
Update count: **0**

**Registration date**
2021-09-13, 1400/06/22

**Registrant information**

**Name**
Zhila Ganji

**Name of organization / entity**
Mazandaran University of Medical Scinces

**Country**
Iran (Islamic Republic of)

**Phone**
+98 11 3336 7342

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zhila.ganji@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-09-11, 1400/06/20

**Expected recruitment end date**
2021-11-11, 1400/08/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of hypnosis on anxiety and blood pressure in pregnant women with preeclampsia: a randomized controlled clinical trial

**Public title**
The effect of hypnosis on anxiety and blood pressure in pregnant women

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Mild preeclampsia Gestational age from 28 to 32 weeks Absence of fetal distress Single pregnancy Literacy for reading and writing Mild to moderate anxiety score (score 14 or less) Having general health (score lower than 23) Satisfaction to participate in research

**Exclusion criteria:**
Depression is based on information from the Beck Depression Scale (score greater than 9) Participate in any educational and counseling programs related to pregnancy and childbirth anxiety before the study Use of psychiatric drugs (current use) according to the patient's medical record Existence of severe depression or suicidal ideation or harm to others Maternal addiction Spot stain cervical cerclage Existence of uncontrolled seizures Existence of psychosis Reluctance to continue cooperation

**Age**
No age limit

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **44**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
The samples will be divided into two groups of 22 using the blocking method. For this purpose, the samples will be divided into 11 blocks of four. The blocks will be TTCC, TCTC, TCCT, CCTT, CTCT, CTTC, where T is for the intervention group and C is for the control group. The numbers will be randomly generated by the RANDBETWEEN command in Excel software in the range 0 to 6. Depending on the production values of one of the blocks (for production number between 0 to 1 CTTC block, for production number between 1 to 2 CTCT blocks and so on) will be selected and samples will be allocated accordingly.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Blinding will be done at the level of outcome assessor and evaluation at the level of analysis. The person who will evaluate the outcome and analyze the data does not know the status of the samples and does not know which participant is in the control and intervention group.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Mazandaran University of Medical Sciences

**Street address**
Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moalem Square

**City**
Sari

**Province**
Mazandaran

**Postal code**
4816715793

**Approval date**
2021-07-25, 1400/05/03

**Ethics committee reference number**
IR.MAZUMS..REC.1400.9186

## Health conditions studied

### 1

**Description of health condition studied**
Anxiety

**ICD-10 code**
F06.4

**ICD-10 code description**
Anxiety disorder due to known physiological condition

### 2

**Description of health condition studied**
blood pressure

**ICD-10 code**
R03

**ICD-10 code description**
Abnormal blood-pressure reading, without diagnosis

## Primary outcomes

### 1

**Description**
Anxiety

**Timepoint**
Before the intervention, immediately and one month after the intervention

**Method of measurement**
Depression, Anxiety, Stress Scale (DASS-21)

**2**

**Description**
blood pressure
**Timepoint**
Before the intervention, immediately and one month after the intervention
**Method of measurement**
Digital blood pressure gauge

## Secondary outcomes

**1**

**Description**
Satisfaction with the intervention
**Timepoint**
immediately and one month after the intervention
**Method of measurement**
Visual Analog Scale: Satisfaction

## Intervention groups

**1**

**Description**
Intervention group: Twice a week, individually, online (via WhatsApp) for 60-45 minutes, and at the end of each session, the audio recording of the session will be sent to each participant in the intervention group for at least one day Do hypnosis practices at home once (for 45-60 minutes). Mark the number of practices in the form that will be provided to them. In the control group, no intervention is done during the study.
**Category**
Behavior

**2**

**Description**
Control group: Will receive routine care.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Akbarabadi Hospital Health Centers
**Full name of responsible person**
Dr. Mahnaz Ashrafi
**Street address**
Tehran, Molavi St., not far from Molavi intersection, Ferdows Garden Station
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**Full name of responsible person**
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akbar-hedayati@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mazandaran 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**
Mazandaran University of Medical Sciences
**Full name of responsible person**
farzaneh askari
**Position**
Masters student
**Latest degree**
Bachelor
**Other areas of specialty/work**

Midwifery

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sari

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## Person responsible for scientific inquiries

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PhD in Reproductive Health

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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