Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effects of Benson´s relaxation technique and phone Consultation on Depression and Self-esteem among pregnant women

Protocol summary

Study aim
The study was designed to determine the effect of Benson relaxation and phone counseling on Depression and Self-esteem among pregnant women.

Design
This trial has 2 intervention groups (Benson and phone counseling) and 1 control group, each group includes 27 people, with parallel groups, without blinding, randomized, on 81 patients (with Considering the fall, 90 people). For randomization, a table of random numbers is used

Settings and conduct
90 pregnant women referring to Alborz health centers with the characteristics of the research unit are selected and randomly placed in one of the 3 groups receiving phone counseling, Benson group, and control group. In the relaxation group, after one training session, the mother is asked to do relaxation for 15-20 minutes twice a day for 4 weeks. In the counseling group, counseling is given through phone counseling (for 4 weeks). Maternal depression and self-esteem in all three groups before and after the intervention with the Edinburgh and Rosenberg questionnaire will be measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: mother age 18-35 - At least fifth-grade literacy- First pregnancy-Gestational age in the third trimester (28-34 w) - Single pregnancy - having access to the Internet- Low-risk pregnancy Exclusion criteria: obvious fetal abnormalities _ stressful events (accident, etc.) during the last six months_ mental illness_ addiction to drugs_ using alcohol_ history of infertility and speech and hearing disorders

Intervention groups
1-Benson relaxation group, the mother is asked to do relaxation for 15 to 20 minutes twice a day for 4 weeks 2 - A group through counseling by phone (in such a way that during 4 sessions, one 45-60 minute session per week, related topics are held via Skype or Whats-app) 3- The control group receives routine pregnancy care

Main outcome variables
Depression and self-esteem

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210625051699N2**
Registration date: **2022-02-21, 1400/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-21, 1400/12/02**
Update count: **0**

Registration date
2022-02-21, 1400/12/02

Registrant information

Name
Sahar Hasanpoor

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-12, 1400/11/23

Expected recruitment end date
2022-03-14, 1400/12/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effects of Benson´s relaxation technique and phone Consultation on Depression and Self-esteem among pregnant women

Public title
Effects of relaxation Consultation on Depression and Self-esteem during pregnancy

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Mother age 18-35 At least fifth grade literacy First pregnancy Gestational age in the third trimester (28-34) weeks Single pregnancy Low risk pregnancy Having access to the Internet

Exclusion criteria:
Absence of obvious fetal abnormalities Absence of stressful events (accident, etc.) during the last six months Absence of mental illness Not using or addiction to drugs Not using psychedelics and alcohol Not having history of infertility and speech and hearing disorders

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done in a simple way using a table of random numbers. In this way, the members of the research will be numbered from 1 to 90 and we will randomly put the number of people from 1 to 90 in the table without any special order. Then a row and column from the table are randomly selected, the intersection point of the row and column is the starting point of sampling. From this point, and chosen by the researcher, we determine a direction (for example, up, down, right, or left) to read the table numbers, then we assume specific numbers for each of the study groups. For example, the numbers 1-30 enter the first intervention group (Benson) and if it is 31-60 the second intervention group (telephone counseling), the numbers 61-90 enter the control group.

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 Shahid Beheshti University of Medical Sciences

Street address
Shaid Arabi Ave., Yaman Blvd., Tehran Town

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2021-07-20, 1400/04/29

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.088

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
F32.0

ICD-10 code description
Major depressive disorder, single episode, mild

Primary outcomes

1

Description
Depression

Timepoint
Measurement of pregnancy's depression score is done before the intervention and immediately after the intervention.

Method of measurement
Edinburgh questionnaire

Secondary outcomes

1

Description
Self-esteem

Timepoint
Measurement of pregnancy's self-esteem score is done before the intervention and immediately after the intervention.

Method of measurement
Rosenberg questionnaire

Intervention groups

1

Description
Intervention group 1: After holding a Benson relaxation training session, mothers are taught using simple and understandable sentences, and in this way, the mother is in the best position in which she feels calm. She sits or lies down, closes her eyes, in which case she chooses a word that always reminds her of peace (such as the word of the god of rain, flowers, etc.) and begins to take deep, regular breaths. It inhales through the nose and exhales through the mouth, repeating the word in the mind with each exhalation. In this position, release the muscles from the toes and continue this work to the upper muscles of the body until all the muscles are fully expanded and maintain this position for 10 to 20 minutes. We then advise the mother to refrain from changing posture immediately after the technique. For more effect, we recommend relaxing music while performing the technique. The intervention group performs exercises for 4 weeks, twice a day, and each time for 15-20 minutes at home.

Category
Behavior

2

Description
Intervention group 2:A group receives counseling through counseling with mobile software and remotely (in such a way that during 4 weekly sessions, a 45-60 minute session Related content is held via Skype or What's App), and the content of the counseling is based on the Gamble study counseling model and the strategy of this counseling includes: (Therapeutic communication between midwife and mother, in the first week, mother support and Expressing emotions in the second week, providing information in the third week, reinforcing positive thoughts and discovering appropriate solutions to reduce stress in the fourth week), which is taught to mothers virtually and remotely

Category
Behavior

3

Description
Control group: The control group receives routine pregnancy care

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Alborz Health Centers

Full name of responsible person
Sahar Hasanpoor

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No.31, Azar Ave.,Motahari Blvd., Karaj Town

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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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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sahar Hasanpoor

Position

Master student of midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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