Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of Benson´s relaxation technique and phone consultation on pregnancy's worries and stress

Protocol summary

Study aim
The study was designed to determine the effect of Benson relaxation and telephone counseling on pregnancy's worries and stress

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 then randomly placed in one of the 3 groups receiving telephone 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 telephone counseling (for 4 weeks). Maternal worries and stress in all three groups before and after the intervention with the pregnancy's worries and stress questionnaire (PWSQ) 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 - Pregnant mothers have 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 group, the mother is asked to do relaxation for 15 to 20 minutes twice a day for 4 weeks 2 - A group through counseling telephone (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
Worries and stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210625051699N1**
Registration date: **2021-08-01, 1400/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-01, 1400/05/10**
Update count: **0**

Registration date
2021-08-01, 1400/05/10

Registrant information

Name
Sahar Hasanpoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6551 2606

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saharhasanpoor@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2021-09-21, 1400/06/30

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 pregnancy's worries and stress

Public title

The effects of relaxation and consultation on pregnancy's stress

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

2021-06-29, 1400/04/08

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.073

Health conditions studied

1

Description of health condition studied

Worries and stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

Primary outcomes

1

Description

Pregnancy's worries and stress

Timepoint

Measurement of pregnancy's worries and stress score is done before the intervention and immediately after the intervention.

Method of measurement

Pregnancy's Worries and Stress Questionnaire

Secondary outcomes

empty

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. He 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 to reduce worries and stress (in such a way that during 4 weekly sessions, a 45-60 minute session Related content is held via Skype or Whats 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 and worry 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

Street address

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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Yaman Ave., Blvd., Chamran highway ., TehranTown

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Web page address

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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Person responsible for scientific inquiries

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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