

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Investigating of the effect of educational-psychological intervention on anxiety and worry of pregnant women in the process of fetal screening tests: randomized clinical trial with control group.

Protocol summary

Study aim

Comparison of anxiety, worry, informed choice and decision conflict of pregnant women participating in the control and two intervention groups before and 8-10 weeks after the intervention

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, on 159 people. The rand function of the Excel software was used for randomization.

Settings and conduct

The study field will be prenatal clinics of hospitals affiliated to Tehran University of Medical Sciences. Sampling will be done in an accessible and continuous manner. After obtaining written consent, they will enter the study consciously. The samples will then be divided into intervention and control groups by the Permuted-Blok Randomization method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being Muslim and Iranian; Pregnancy age less than 11 weeks; Finishing at least fifth elementary school level, access and the possibility of using cyberspace. Non-inclusion criteria: previous history of screening or diagnostic tests for fetal chromosomal abnormalities; employment of research units in health centers; History of mental disorders or use of psychiatric drugs; A history of having a fetus or child with Down syndrome or anomaly

Intervention groups

Intervention group 1: Group training counseling is through cyberspace. Intervention group 2: the intervention is designed as a group educational-psychological consultation. control group: will not receive any intervention from the research team during the study.

Main outcome variables

Anxiety and Worry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200518047500N1**

Registration date: **2020-06-21, 1399/04/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-21, 1399/04/01**

Update count: **0**

Registration date

2020-06-21, 1399/04/01

Registrant information

Name

Zohreh Khakbazan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4220

Email address

khakbaza@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating of the effect of educational-psychological intervention on anxiety and worry of pregnant women in the process of fetal screening tests: randomized clinical trial with control group.

Public title

Investigating the Impact of Intervention on Pregnant Women's Concerning About Screening Tests

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being a Muslim and an Iranian pregnant women with <11-week pregnancy age who have referred to health care medical centers for the first time to make medical record for their current pregnancy Finishing at least fifth elementary school level and access and the possibility of using cyberspace Being possible to access him for at least the next 10 weeks.

Exclusion criteria:

previous history of screening or diagnostic tests for fetal chromosomal abnormalities employment of research units in health centers have a fetus with Down syndrome or abnormalities history of known mental disorders, or taking psychiatric drugs

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **159**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted-Blok Randomization. In this way, all possible modes for placing the letters A, B and C in the blocks will be considered. The size of the blocks is randomly selected by the computer (for example, blocks of size 6, 9, 12, and 18 are available in each block with equal numbers of each letter (group)). This will eliminate the possibility of revealing the last allocation in each block by randomly selecting the blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

People in the control group are told that they have been surveyed to achieve the study goals. Both intervention groups receive group training virtually, but are not aware of other group training.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and midwifery & Rehabilitation;
Tehran University of Medical Sciences

Street address

Nosrat street; Tohid square

City

Tehran

Province

Tehran

Postal code

141973317

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.TUMS.FNM.REC.1397.099

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Worry

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score in the Spilberger Anxiety Short Form Questionnaire

Timepoint

Before the start of the study and in the 14th and 20th weeks of pregnancy

Method of measurement

the Spilberger Anxiety Short Form Questionnaire

2

Description

Concern Score in Cambridge Worry Scale

Timepoint

Before the start of the study and in the 14th and 20th weeks of pregnancy

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

For (Group A), the intervention will be designed as group training counseling through cyberspace. This virtual-group counseling is held at two-day intervals in three 45-minute sessions with 6 to 8 pregnant women. The content of the intervention is: □ Introducing the researcher to the participants. People briefly introduce themselves in the group □ The purpose of the training session is to introduce (familiarity with fetal screening tests and methods). □ Introduction of different types of screening tests including: 1- Combination screening test of the first trimester 2-Screening test of the second trimester 3- Non-invasive perinatal test □ Explain the nature of laboratory screening. Schedule scheduling tests □ Interpretation of screening test results (concept of chance or probability). How to track according to the results of the experiments. □ Explanation of diagnostic methods (chorionic villus sampling sampling and amniocentesis) including: technique, timing, possible risks. □ Description of termination or continuation of pregnancy, including: signs and symptoms and characteristics of children with Down syndrome; Conditions for the care of a child with disabilities due to cultural, social and government assistance; Legal and religious conditions for termination of pregnancy in Iran. This content will be presented in the first session as a lecture by the researcher to the participants in the session. In the next session, the researcher will answer the participants' questions and provide the group with a written file of the same content. In the third session, while removing the ambiguities of the participants and answering their possible questions, a PowerPoint file with pictures and educational tables will be provided to the participants.

Category

Prevention

2

Description

Intervention group B: group educational-psychological counseling. The intervention is designed as a group-educational-psychological group consultation in three 45-minute sessions with the presence of 6 to 8 pregnant women and with two-day intervals. In the first session, the same educational content prepared for group A will be presented as a speech, and at the end of the session, a written file with the content of the first session speech will be provided to the group. In the second session, the first and second parts of the psychological intervention will be performed. In the third session, the third part of the psychological intervention will be performed, the assignments of the previous session will be reviewed and

the questions and ambiguities of the participant will be answered, and the PowerPoint file with educational and psychological content along with pictures and tables will be provided.

Category

Prevention

3

Description

Control group: They do not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr Hospital in Imam Khomeini Hospital Complex

Full name of responsible person

Mitra Arjmandifar

Street address

School of Nursing and Midwifery; Nosrat street; Tohid square

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Tehran

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141973317

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+98 21 5592 0380

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arj7087@yahoo.com

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<https://fnm.tums.ac.ir/>

2

Recruitment center

Name of recruitment center

Yas General Hospital

Full name of responsible person

Mitra Arjmandifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Sixth floor, Deputy of Research and Technology,
University headquarters, at the corner of Quds street,
Keshavarz boulevard

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Tehran

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1417653761

Phone

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Email

vcr@tums.ac.ir

Web page address

<http://vcr.tums.ac.ir/#>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Mitra Arjmandifar

Position

PhD student of reproductive health at Tehran
University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Reproductive Health

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Tehran University of Medical Science, School of
Nursing and Midwifery, Nosrat street, Tohid square

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arj7087@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mitra Arjmandifar

Position

PhD student in reproductive health in Tehran
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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mitra Arjmandifar

Position

PhD student in reproductive health in Tehran
University of Medical Sciences

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

A part of the data, such as information about the main consequence or the like, can be shared.

When the data will become available and for how long

It is possible to access the results 6 months after publication

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Only in order to be aware of the research process by academic researchers

From where data/document is obtainable

Email address: Mitra Arjomandi Far arj7087@yahoo.com

What processes are involved for a request to access data/document

Up to one month after receiving the request by email

Comments