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

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Iran (Islamic Republic of)

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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 & Rehabitation; Tehran University of Medical Scienses

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

Cambridge Worry Scale

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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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Mohammad Ali Sahraeian
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Sixth floor, Deputy of Research and Technology, University headquarters, at the corner of Quds street, Keshavarz boulevard
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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
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Person responsible for updating data

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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