Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of cognitive-behavioral counseling on fertility preferences and attitudes towards fertility and childbearing in single-child women

Protocol summary

Study aim
Determining the effect of cognitive-behavioral counseling on fertility preferences and attitudes towards fertility and childbearing in single-child women referring to health centers in Zanjan province in 2023

Design
A randomized controlled clinical trial with parallel groups with 50 participants. The rand function of Excel software was used for randomization.

Settings and conduct
Sampling will be done in health centers of Zanjan province (Tarom county, Abbar city). First, 50 eligible women are randomly selected and then randomly assigned to the intervention and control groups. The intervention group will receive 9 counseling sessions in person. The participants will complete self-report questionnaires before the intervention, immediately after the intervention and two months after the last counseling session.

Participants/Inclusion and exclusion criteria
All single women eligible to bear children whose names are registered in Sib system and do not intend to get pregnant

Intervention groups
The people of the intervention group will participate in 9 sessions of 60-90 minutes, two sessions of cognitive-behavioral counseling for anxiety per week, which will be provided by the researcher. The control group will receive usual care.

Main outcome variables
Attitude towards fertility and childbearing, fertility preferences

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160608028352N11**
Registration date: **2023-10-28, 1402/08/06**
Registration timing: **prospective**

Last update: **2023-10-28, 1402/08/06**
Update count: **0**

Registration date
2023-10-28, 1402/08/06

Registrant information

Name
Roghieh Kharaghani

Name of organization / entity
Zanjan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of cognitive-behavioral counseling on fertility preferences and attitudes towards fertility and childbearing in single-child women

Public title

The effect of cognitive-behavioral counseling on fertility preferences and attitudes towards fertility and childbearing in single-child women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality Sufficient literacy (at least middle school) Being married Single-child women who are eligible to have children based on the protocol of 2023 Using contraceptive methods (natural or modern methods) A resident of Zanjan province

Exclusion criteria:

Absence of more than 2 sessions Unwanted pregnancy for any reason Existence of acute and chronic diseases and suffering from them Existence of marital problems or addiction of one parent to drugs or alcohol Having any mental or physical disability

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method will be convenient and allocation will be blocked randomization. For this purpose, four-person blocks have been created to determine the two groups of intervention and control. The sample size in the two groups is 50 participants, so the allocation of participants in the intervention and control groups by random selection of 13 four-person blocks (50 people) will be done. The rand function of Excel software will be used for randomization.

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

The ethics Committee of Zanjan University of Medical Sciences

Street address

The ethics committee of Zanjan University of Medical Sciences, north side of Azadi Blvdedical Sciences, first floor

City

Zanjan

Province

Zanjan

Postal code

4525613113

Approval date

2023-10-17, 1402/07/25

Ethics committee reference number

IR.ZUMS.REC.1402.173

Health conditions studied

1

Description of health condition studied

Single-child

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Attitudes towards fertility and childbearing

Timepoint

Before the intervention, immediately after the intervention and two months after the last counseling

Method of measurement

Questionnaire of attitudes towards fertility and child bearing

2

Description

Fertility preferences

Timepoint

Before the intervention, immediately after the intervention and two months after the last counseling

Method of measurement

Miller fertility preferences questionnaire 1995

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The people of the intervention group will participate in nine sessions of 60-90 minutes, two sessions of cognitive-behavioral counseling for anxiety per week, which will be provided by the researcher. The participants of the intervention group will be divided into two groups of eight and one group of nine. The researcher will be taught the content of sessions and

counseling with a cognitive-behavioral approach to anxiety in person by a psychologist consultant and also in the form of online or face-to-face workshops.

Category

Behavior

2

Description

Control group: Participants in this group will not receive any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Attached health center

Full name of responsible person

Elham Mohammadi

Street address

Attached Health Center, East 1st, Tawheed St

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Zanjan

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4591646880

Phone

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2

Recruitment center

Name of recruitment center

Non-attached health center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Samad Nadri

Street address

Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, Northside Boulevard Azadi, Zanjan

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+98 24 3314 8300

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nadri_s@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Elham Mohammadi

Position

Master's student in counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Dr Roghieh Kharaghani

Position
Ph.D of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
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Position
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Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
After completion of the study, information on the main outcome will be shared.

When the data will become available and for how long
Starting the access period from 2024

To whom data/document is available
Data and documentation will be available to medical researchers.

Under which criteria data/document could be used
The data can be used to study, give a citation, create new ideas, and practically apply in medical centers.

From where data/document is obtainable
Email to e.mohammadi9270@gmail.com

What processes are involved for a request to access data/document
The data will be provided to the applicant within one month after reviewing and confirming the request.

Comments