Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effects of motivational interviewing focused on some principles of Hefz – Alsehe in Persian medicine on stress and quality of life of infertile women

Protocol summary

Study aim
Determining the effects of motivational interviewing focused on some principles of Hefz – Alsehe in Persian medicine on stress and quality of life of infertile women

Design
From all women who meet the inclusion criteria, 56 participants will be selected by convenient method and allocated to two control and intervention groups by stratified random method according to primary and secondary infertility in four-person blocks.

Settings and conduct
Sampling will be done in Ayatollah Mousavi Hospital Infertility Clinic. Firstly, 56 eligible women will be selected by convenience Method and then participants will be allocated to two control and intervention groups by stratified random method according to primary and secondary infertility in four-person blocks. Participants will complete the questionnaires as a self-report before the intervention, immediately after the sessions and three months after the last consultation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having at least reading and writing literacy; informed participation of research participants; medical diagnosis of female factor infertility; age range from 20 to 40 years old; obtaining a stress score of 92 and above based on Newton's infertility stress questionnaire. Exclusion criteria: Male infertility factor; having a divorce case or marital dispute, A history of known mental illness; people who don't want to continue participating in the study or don't participate in more than one counseling session.

Intervention groups
The intervention group includes motivational counseling with the content of some principles of Hefz – Alsehe of Iranian medicine. Motivational interviewing sessions will be held individually during five weekly and face-to-face meetings. The maximum time of each session is 45 minutes.

Main outcome variables
Stress; quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160608028352N13**
Registration date: **2023-11-28, 1402/09/07**
Registration timing: **prospective**

Last update: **2023-11-28, 1402/09/07**
Update count: **0**

Registration date
2023-11-28, 1402/09/07

Registrant information

Name
Roghieh Kharaghani

Name of organization / entity
Zanjan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 24 3314 8144

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r.kharaghani@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-09, 1402/09/18

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of motivational interviewing focused on some principles of Hefz – Alsehe in Persian medicine on stress and quality of life of infertile women

Public title

The effects of motivational interviewing focused on some principles of Hefz – Alsehe in Persian medicine on stress and quality of life of infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least reading and writing literacy Informed participation of research participants Medical diagnosis of female factor infertility Age range from 20 to 40 years Obtaining a stress score of 92 and above based on Newton's infertility stress questionnaire

Exclusion criteria:

Male infertility factor Having a divorce case or marital dispute A history of known mental illness People who don't want to continue participating in the study or don't participate in more than one counseling session.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method will be convenient. The participants will be allocated to two control and intervention groups by stratified random method according to primary and secondary infertility in four-person blocks. The sample size in the two groups is 56 participants, so the allocation of participants in the intervention and control groups by random selection of 14 four-person blocks (50 people) will be done.The selection of each block will be done using random table numbers.

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

Zanjan University of Medical Sciences, north side of Azadi Blvd.

City

Zanjan

Province

Zanjan

Postal code

4525613113

Approval date

2023-11-15, 1402/08/24

Ethics committee reference number

IR.ZUMS.REC.1402.196

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Stress

Timepoint

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

Method of measurement

Questionnaire of Fertility problem inventory

2

Description

Quality of Life

Timepoint

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

Method of measurement

Questionnaire of fertility quality of life tool

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention includes motivational counseling with the content of some principles of Hefz – Alsehe of Iranian medicine. These principles include proper physical activity, eating and drinking, and sleep management. Motivational interviewing sessions will be held individually during five weekly and face-to-face meetings. The maximum time of each session is 45 minutes.
Category
Lifestyle

2

Description
Control group: Participants in this group will not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital Infertility Clinic
Full name of responsible person
Maede Feizy
Street address
Ayatollah Mousavi Hospital, Road Gavazang
City
Zanjan
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Postal code
4513956183
Phone
+98 901 511 0062
Email
feizymaede788@gmail.com

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 Reasearch and Technology of Zanjan University of Medical Sciences, First floor, Northside Boulevard Azadi, Zanjan
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4515613191
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Email
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
Maede Feizy
Position
Master's student in counseling in midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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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

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Full name of responsible person

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Position

Master's student in counseling in midwifery

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

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 feizymaede788@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