Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of group meaning therapy intervention on the psychological well-being of infertile women

Protocol summary

Study aim
Determining the effect of group meaning therapy intervention on psychological well-being of infertile women in Qazvin city

Design
Clinical trial , Purposive sampling, With intervention and control parallel groups, Randomized, on 68 infertile women. For randomization, double and quadruple blocking was used in Excel software.

Settings and conduct
The research environment will be the infertility clinic of "Velayat hospital" and "Jahad daneshgahi" infertility center of Qazvin city. The study sample will be 68 infertile women. Eligible people will be registered through purposive sampling. The short form of Reef psychological well-being and demographic questionnaire will be provided to them. People who get a score less than 54 from the Reef questionnaire will be randomly allocated to two intervention and control groups (34 people in each group). The intervention group will receive 8 sessions of 90 minutes group and virtual meaning therapy intervention . The control group will not receive any intervention. Follow-up will be done immediately and two months after the intervention.

Participants/Inclusion and exclusion criteria
entry criteria: Being Iranian, female primary infertility, Tend to participate, minimal literacy, Score less than 54 on Reef questionnaire, Speak and understand Persian, Have a smartphone؛ Exit criteria: severe marital conflicts, participating in other psychological intervention , having mental illness, occurrence of stressful events In the last quarter

Intervention groups
The intervention group will receive 8 sessions of 90 minutes of virtual group meaning therapy intervention in "Google meet" or "Qarar" application, once a week, include each session content presentation, an educational booklet and other materials in the form of audio and videos. The control group receives only routine ward care and education.

Main outcome variables
Psychological well-being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240514061791N1**
Registration date: **2024-08-14, 1403/05/24**
Registration timing: **prospective**

Last update: **2024-08-14, 1403/05/24**
Update count: **0**

Registration date
2024-08-14, 1403/05/24

Registrant information

Name
mahya shokoohifard

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6625 9252

Email address
mahyashokohifard@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of group meaning therapy intervention on the psychological well-being of infertile women

Public title

Investigating the effect of group meaning therapy intervention on the psychological well-being of infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Suffering from primary infertility due to female causes Tending to participate in research Having at least the minimum of literacy Gaining a score less than 54 on Reef psychological well-being questionnaire Having ability to speak and understand Persian (Farsi) language Having a smartphone and access to the Google meet platform or Qarar application

Exclusion criteria:

presence of severe marital conflicts (according to the participant) participating in other psychological intervention sessions during the last six months Suffering from a known and diagnosed mental illness based on self-report and health records occurrence of stressful events In the last quarter

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Purposive sampling will be done in infertility clinic of "Velayat hospital" and "Jahad daneshgahi" infertility center in Qazvin city. People who have study entry criteria will be registered. Infertile women who have scored less than 54 from the Reef psychological well-being questionnaire and are willing to participate in the study will be randomly allocated to intervention and control groups in the next step. For random allocation, given that there is an intervention method (group meaning therapy) and two control and intervention groups and given that the randomization unit will be individual, random allocation sequence generation application will be used to determine the allocation sequence with binary and quadruple blocks methods. After determining the allocation sequence by binary and quadruple blocks in order to hide the allocation sequence, the sequence of blocks will be written on the papers specifying the group of people (control (C) and intervention (T)) and will be put respectively inside the closed and unspecified envelopes and entered into groups in the same order. If there is a significant difference in the two groups in terms of demographic information, the analysis of covariance test will be used to minimize the difference in the two groups.

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 the Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Qazvin City, Qazvin Province, Iran

City

Qazvin

Province

Qazvin

Postal code

59811-34197

Approval date

2024-08-05, 1403/05/15

Ethics committee reference number

IR.QUMS.REC.1403.182

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

The score of psychological well-being of infertile women according to Reef psychological well-being questionnaire (PWBS)

Timepoint

once before beginning of study, once immediately after

completion of the intervention, once two months after completion of intervention

Method of measurement

Reef psychological well-being questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After replacing the people in the intervention and control groups, people in the intervention group members will be divided into 4 groups of 7 people and one group of 6 people. The meaning therapy intervention will be done in 8 sessions of 90 minutes and one session per week, the first session will be held in person and individually in order to familiarize the members with the researcher, the process and goals of the research. The other sessions will be virtual and group and in application that is available for the participants ("Google meet" or "Qarar" application). In addition to the online meetings, a group will be formed in social media that is available for participants, after each meeting, their questions will be answered in this group. Researcher's personal number will be available for answering personal questions. Generally, intervention group will receive presentation of the content of meaning therapy in virtual form, the educational booklet and other materials as audios and educational videos that will be shared in the group in social media. The content of the sessions is as follows: The first session: Greeting with members, Familiarizing the members with infertility problems and psychological well-being concept, Introducing intervention "group meaning therapy", Familiarizing the members with the rules of the group. The second session: Creating self-awareness in people, Raising the concept of freedom and authority in life. The third session: Explaining choices responsibility. The fourth session: Recognition of existential anxiety, teaching strategies to deal with anxiety and controlling pessimistic thoughts. The fifth session: Finding meaning from life, Communication with others and Self-development. The sixth session: Examining the meaning of suffering as one of the meaningful aspects of life. The seventh session: Finding meaning through values. Eighth session: Finding meaning through explaining goals and self-improvement, Appreciation and thanks, post-test implementation. The content of the sessions will be presented based on Frankel's meaning therapy approach and Hatzel's plan.

Category

Treatment - Other

2

Description

Control group: In this study, the control group receives only the care and routine training of the ward. In order to comply with the ethical standards at the end of the research, the presented content will be available to the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

infertility clinic of Velayat hospital

Full name of responsible person

Mahya Shokoohifard

Street address

Velayat hospital, Taavon Square, 22 Bahman Blvd., Koi Elahih, Minodar town, Qazvin, Qazvin, Iran

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Phone

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2

Recruitment center

Name of recruitment center

"Jahad daneshgahi" infertility center

Full name of responsible person

Mahya Shokoohifard

Street address

"Jahad daneshgahi" Infertility Center, between Azadi Square and Shahid Akhwan Nouri Fard, Ferdowsi St., Qazvin city, Qazvin province, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Seyed Mehdi Mirhashmi

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Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Qazvin City, Qazvin Province, Iran.

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Grant name

Grant code / Reference number

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

Title of funding source
Qazvin University of Medical Sciences

Proportion provided by this source
1

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
Qazvin University of Medical Sciences
Full name of responsible person
Mahya Shokoohifard
Position
Master's student of counseling in midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Anonymized coded data, research protocol, outcome information

When the data will become available and for how long

5 months after the publication of the results until one year

To whom data/document is available

Researchers, universities, institutions

Under which criteria data/document could be used

Receiving research data and information in order to design new research is unimpeded. Send an email to the responsible person. Response will be received within two weeks.

From where data/document is obtainable

Send an email to the responsible person. Response will be received within two weeks.

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

Send an email to the responsible person. Response will be received within two weeks.

Comments

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