Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of the continuous care model on the resilience of women who referred to the infertility clinic

Protocol summary

Study aim
Determining the impact of continuous care model on resilience of infertile women

Design
Clinical trial with a control group, with crossover groups, double-blind, randomized, on 90 patients. The sample size was calculated according to the probability of type 1 error 0.05, probability of type 2 error 0.8 and effect size 0.6 using Gpower software for each of the test and control groups of 45 people (90 people in total).

Settings and conduct
Sampling is done for 6 months in the infertility clinic of Bint Al-Hadi Hospital in Bojnord city. A semi-experimental study on 90 infertile women. Sampling is available. According to the sample size formula, 45 people have been considered for each group. The data collection tool includes two questionnaires. Personal profile questionnaire and resilience questionnaire are completed. The resilience questionnaire is completed once before training in both control and intervention groups. In the control group, they will receive the routine care of the treatment center, and in the follow-up care group, education will be done based on the stages of the model and educational content.

Participants/Inclusion and exclusion criteria
Entry:age 20-45 years, diagnosis of infertility, period of infertility up to 5 years, failure to participate in programs resilience in the last 6 months,no history of mental illnesses.Failure to enter: pregnancy, the occurrence of stressful incident in the last 6 months, unwillingness

Intervention groups
Two groups have been considered according to the sample size formula of 45 people. The resilience questionnaire is completed once before the training in both the control and intervention groups. Model steps and educational content will be done.

Main outcome variables
The resilience score in infertile women

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230126057235N1**
Registration date: **2023-02-25, 1401/12/06**
Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**
Update count: **0**

Registration date
2023-02-25, 1401/12/06

Registrant information

Name
Narges Sefidi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3223 6553

Email address
a.abbaszadeh@nkums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-09-06, 1402/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of the continuous care model on the resilience of women who referred to the infertility clinic

Public title
Investigating the effect of the continuous care model on the resilience of women who referred to the infertility clinic
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of infertility based on the doctor's diagnosis and the contents of the file, the female cause of infertility, the duration of infertility is up to 5 years, not participating in educational programs affecting resilience in the last 6 months, no history of known mental illnesses, and having minimal literacy
Exclusion criteria:
Getting pregnant while conducting research, the occurrence of an unfortunate and stressful incident in the last 6 months, unwillingness to continue cooperation and not participating in all training sessions.
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization method will be used and randomization unit is Individual. we will use from Flip the coin from the methods of simple randomization because there are 2 groups in this study that actually the tool of randomization is coin. As one of the study groups, I consider the heads and the other group as tails, and according to the size of the sample, the coin is toss-up.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Bojnurd University of Medical Sciences
Street address
Above Imam Ali (AS) Hospital, Shahriar St. Faculty of Medicine- Vice Chancellor for Research and Technology of the University Bojnurd.
City
Bojnurd
Province
North Khorasan
Postal code
94137436941
Approval date
2023-01-16, 1401/10/26
Ethics committee reference number
IR.NKUMS.REC.1401.088

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97.8
ICD-10 code description
Female infertility of other origin

Primary outcomes

1

Description
Resilience score in infertile women according to Connor and Davidson's standard resilience questionnaire (2003) should reach a maximum of 125.
Timepoint
Completing the resilience questionnaire at the beginning of the study (before the start of the intervention) and 2, 3, 6, 8 weeks after the start of the continuous care model project.
Method of measurement
Connor and Davidson Standard Resilience Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In the control group, they receive the routine care of the treatment center
Category
Lifestyle

2

Description
Intervention group: In the continuous care model group,

training will be done based on the stages of the model and educational content

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Bent Al-Hadi Bojnord Hospital

Full name of responsible person

Narges sefidi

Street address

Art street

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Province

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Postal code

94137436941

Phone

+98 58 3223 6551

Email

Sepidin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Amir Ali Ghahramani

Street address

Central Building of North Khorasan University of Medical Sciences, Dolat Blvd, Bojnurd

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Narges sefidi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Resilience score of clients Relationship between demographic characteristics and resilience score The relationship of continuous care model to increasing resilience

When the data will become available and for how long
6 months

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Print the article

From where data/document is obtainable
sepidin@yahoo.com narges sefidi

What processes are involved for a request to access data/document
After analyzing the data and printing the article

Comments