

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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

**City**

Bojnord

**Province**

North Khorasan

**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

**City**

Bojnurd

**Province**

North Khorasan

**Postal code**

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**Phone**

+98 58 3223 6551

**Email**

Sepidin@yahoo.com

**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

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

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## Person responsible for updating data

### Contact

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Bojnourd University of Medical Sciences

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**Email**

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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**