

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of group therapy based on the mutual behavioral analysis versus no group therapy on marital satisfaction and resilience in infertile women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of group therapy based on mutual behavioral analysis versus no group therapy on marital satisfaction and resilience in infertile women

Design

Design: This is a randomized clinical trial, in which 30 eligible infertile women will to the intervention and control groups

Settings and conduct

The eligible infertile women who will refer to Mahdiah Hospital in Tehran City during the study period will in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years; Infertility; Literate
Exclusion criteria: Mental disorders

Intervention groups

Intervention group: Routine counseling and group therapy based on mutual behavioral analysis 2 hours a week for 8 weeks
Control group: Just routine counseling

Main outcome variables

Primary outcome: Assessing the marital satisfaction before intervention and 8 weeks after intervention using the standard questionnaire
Assessing the resilience before intervention and 8 weeks after intervention using the standard questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N255**

Registration date: **2018-12-20, 1397/09/29**

Registration timing: **retrospective**

Last update: **2018-12-20, 1397/09/29**

Update count: **0**

Registration date

2018-12-20, 1397/09/29

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2018-09-18, 1397/06/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of group therapy based on the mutual behavioral analysis versus no group therapy on marital satisfaction and resilience in infertile women: a randomized clinical trial

Public title

Effect of group therapy based on the mutual behavioral analysis versus no group therapy on marital satisfaction

and resilience in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 40 years; Infertility; Literate

Exclusion criteria:

Mental disorders

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots

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 Shahid Beheshti University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences, Niayesh Crossroad, Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-07-01, 1396/04/10

Ethics committee reference number

IR.SBMU.PHNM.1396.759

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Assessing the marital satisfaction

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Using the standard questionnaire

2

Description

Assessing the resilience

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Using the standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine counseling and group therapy based on the mutual behavioral analysis 2 hours a week for 8 weeks

Category

Treatment - Other

2

Description

Control group: Just routine counseling

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital in Tehran City

Full name of responsible person

Atefeh Haghighi

Street address

School of Nursing and Midwifery, Niayesh Crossroad,

Valiasr Ave.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

haghighi.atefeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Moghimi

Street address

Shahid Beheshti University of Medical Sciences,
Niayesh Crossroad, Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

info.research@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Atefeh Haghighi

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Niayesh Crossroad,
Valiasr Ave.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

haghighi.atefeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Jamileh Mohtashami

Position

PhD in Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Niayesh Crossroad,
Valiasr Ave.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

j_mohtashami@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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