

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Assesing the Effect of problem solving skill based intervention on Stress, Anxiety and Depression associated with infertility in Infertile couples

Protocol summary

Study aim

Determining the effect of intervention based on problem-solving skills on stress, anxiety and depression associated with infertility on infertility couples between two group and inside each of them ,before and after intervention

Design

A clinical control trial with two intervention and control groups, based on problem-solving skills, is randomized[gs

Settings and conduct

counseling sessions will be held at Urmia Shahid Motahari Hospital

Participants/Inclusion and exclusion criteria

Infertile couples who have high grade of stress and anxiety and can attend counseling sessions They are between 18 and 40 so far they have no children and they have no physical or mental illness

Intervention groups

The intervention includes five sessions)every is 90 min) the first two sessions are for general information about infertility and problem-solving skills run for all participants together, and the other three sessions will be run on problem-based issues like as couple counseling The control group will also undergo a routine infertility treatment process

Main outcome variables

scores of stress , anxiety and depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024340N14**

Registration date: **2018-09-19, 1397/06/28**

Registration timing: **retrospective**

Last update: **2018-09-19, 1397/06/28**

Update count: **0**

Registration date

2018-09-19, 1397/06/28

Registrant information

Name

Hamideh Mohaddesi

Name of organization / entity

Urmia University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4963

Email address

mohaddesi.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesing the Effect of problem solving skill based intervention on Stress, Anxiety and Depression associated with infertility in Infertile couples

Public title

the Effect of problem solving skill based intervention on Stress, Anxiety and Depression associated with infertility in Infertile couples

Purpose

Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being Iranian Resident of urmia Ages 18 to 40 Minimum elementary education Primary infertility The first couple visit for the infertility treatment Earning a score below 28 from the GHQ-28 questionnaire Earn a minimum score of milder and higher grades based on the DASS questionnaire sub-scales Having no child The possibility of spouse joining in meetings notice about the infertility factor Being a single wife Not having a medical condition Non-use of narcotic's drug, and alcohol The absence of a history or current condition for mental problems No severe stressful incident occurred during the last 6 months, except for the diagnosis of infertility Having a mobile phone
Exclusion criteria:
Age over 40 years Secondary infertility Residents of cities other than Urmia Illiteracy History of mental illness

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done in a simple way. Our randomized units were paired in this study the randomization method was using sealed envelopes.

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 Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran (Postal Code:571478334)

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-03-07, 1396/12/16

Ethics committee reference number

IR.UMSU.REC .438

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

inability to achieve a pregnancy, sterility

Primary outcomes

1

Description

stress questionnaire

Timepoint

Before intervention and 1 month after intervention

Method of measurement

Depression ,Anxiety and Stress 42 (DASS42) Questionnaire

2

Description

Anxiety

Timepoint

Before start the intervention and 1 month after finished the intervention

Method of measurement

Depression , Anxiety and Stress 42 (DASS42) Questionnaire

3

Description

Depression DASS-42 questionnaire

Timepoint

Before start the intervention and 1 month after finished the intervention

Method of measurement

Depression , Anxiety and Stress 42 (DASS42) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention includes five sessions (every is 90 min) the first two sessions are for general information about infertility and problem-solving skills run for all participants together, and the other three sessions will be run on problem-based issues like as couple counseling. First session: introduction, presentation of information about infertility, explanation of cognitive-behavioral counseling and discussion of positive and negative thoughts, A.B.C training. Teaching conflict management techniques and challenging inefficient thoughts. Second Session: Complete problem solving skills training and multiple practice exercises with couples and provide a checklist as a homework assignment. Third Session: Diagnostic interviews and identification of beliefs and types of coping ways of couples specifically against problems. Fourth Session: Teaching Mindfulness Techniques to Improve Couple's Consciousness in Addressing the Issues. Fifth Session: summarizing and reviewing the contents of the sessions.

Category

Behavior

2

Description

Control group: receive the routine treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahhari hospital of Urmia

Full name of responsible person

Mahsa Hasanzadeh

Street address

Kashani Ave.

City

Urmia

Province

West Azarbaijan

Postal code

575611-5111

Phone

+98 44 3223 7077

Email

mah.hasanzadeh68@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Orjhans Street, Resalat Blvd, Urmia, Iran (Postal

Code: 571478334)

City

Urmia

Province

West Azarbaijan

Postal code

575611-5111

Phone

+98 44 3223 4897

Email

mah.hasanzadeh68@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Mahsa Hasanzadeh

Position

Master's student in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Nursing and Midwifery Faculty Urmia, Urmia University Of Medical Science

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3275 4963

Email

mah.hasanzadeh68@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Hamideh Mohaddesi

Position

Master Educated of Midwifery, Science Committee
Member of Nursing & Midwifery Faculty, Urmia Medical
Sc

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Urmia Medical Science University, Nursing & Midwifery
Faculty

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3275 4963

Email

hmohaddesi.han@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Mahsa Hasanzadeh

Position

Master Student of Midwifery Counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Urmia Medical Science University Nursing & Midwifery
Faculty Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3275 4963

Email

mah.hasanzadeh68@yahoo.com

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Publishing research results in the form of article
publishing

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

public

Under which criteria data/document could be used

Consultation and support program in health centers

From where data/document is obtainable

Hamideh Mohaddesi Contact number 00989143413242 E-
mail: Mohaddesi.han@gmail.com

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

Login to Urmia University of Medical Sciences and search
for thesis

Comments