

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect of counseling based on acceptance and commitment therapy on mental health and quality of life in infertile couples: a randomized controlled trial

#### Protocol summary

##### Study aim

Determining the effect of counseling based on acceptance and commitment on mental health and quality of life in infertile couples referring to the infertility center of Besat city of Sanandaj

##### Design

A randomized controlled clinical trial with parallel groups of 54 infertile couples referring to the Sanandaj Infertility Clinic in 1396

##### Settings and conduct

The researcher contacted the clients of the Infertility Clinic of Besat in Sanandaj city and, meanwhile a Brief description of the research, invite them to cooperate. Written consent is obtained from individuals wishing to participate in the study. Then, individual social questionnaire, GHQ-28 questionnaire and FertiQoL questionnaire will be completed. These samples are randomly assigned to counseling and control groups and will be scheduled for consultation sessions. One month after the intervention, the questionnaires will be completed and analyzed.

##### Participants/Inclusion and exclusion criteria

Entry requirements: 1) Primary infertility 2) Have a history of one to ten years of primary infertility. 3) Couples aged 20 to 45 years. 4) Have at least reading and writing education Non-arrival conditions: 1) Positive pregnancy test during the sampling and intervention. 2) The incidence of adverse events during the 6 months before the study (death or acute illness of close relatives) 3) A person's mental or physical illness (such as diabetes, depression, etc.) 4) Participate in another intervention study 5) Receive a high score of 41 from the mental health questionnaire

##### Intervention groups

For the intervention group: With couples in groups of 8 to 12-member, Consultation sessions based on acceptance and commitment approach will be held. Eight weekly

counseling sessions, Each session is 90 minutes.

##### Main outcome variables

Mental Health status fertility Quality of life status

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111122008170N13**

Registration date: **2018-06-11, 1397/03/21**

Registration timing: **retrospective**

Last update: **2018-06-11, 1397/03/21**

Update count: **0**

##### Registration date

2018-06-11, 1397/03/21

##### Registrant information

##### Name

Jamileh Malakouti

##### Name of organization / entity

Nursing Faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1477 2699

##### Email address

malakoutij@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-04, 1396/01/15

##### Expected recruitment end date

2017-06-22, 1396/04/01

##### Actual recruitment start date

2017-06-22, 1396/04/01  
**Actual recruitment end date**  
2017-09-23, 1396/07/01  
**Trial completion date**  
empty

**Scientific title**

The effect of counseling based on acceptance and commitment therapy on mental health and quality of life in infertile couples: a randomized controlled trial

**Public title**

The effect of counseling on infertile couples

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Couples with initial infertility of 1 to 10 years  
Couples 20 to 45 years old  
Have at least reading and writing education  
At least once failed treatment of infertility experience

**Exclusion criteria:**

Earning a score of 41 from the mental health questionnaire  
Occurrence of an adverse event during the 6 months before the study (death or acute illness of relatives)  
they have no known mental or physical illness such as diabetes, depression (According to the participant)  
Participate in another intervention study  
Positive pregnancy test during the sampling and intervention

**Age**

From **20 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **108**

Actual sample size reached: **108**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

individuals selected will be assigned by random blocking using the RAS software with blocks 4 and 6 with a ratio of 1: 1 to two groups (Consultation recipient and control, 54 people for each group), the type allocation will be written on the paper and placed in the opaque packets numbered down, the pockets will be opened in the order of the individuals entering the study and the type of group will be specified. The allocation sequence will be performed by the person not involved in the sampling and collecting of data

**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 Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences Research & Technology, Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51665118

**Approval date**

2016-12-13, 1395/09/23

**Ethics committee reference number**

IR.TBZMED.REC.1395.1179

## Health conditions studied

### 1

**Description of health condition studied**

infertility

**ICD-10 code**

N46

**ICD-10 code description**

Male infertility

## Primary outcomes

### 1

**Description**

Mental Health Status

**Timepoint**

Before intervention and one month after the intervention

**Method of measurement**

Goldberg general health questionnaire 28

### 2

**Description**

Quality of Fertility life

**Timepoint**

Before intervention and one month after the intervention

**Method of measurement**

Fertility Quality of Life Questionnaire (FertiQoL)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 8 weekly 90-minute sessions based on acceptance and commitment. Acceptance and Commitment Therapy (ACT, typically pronounced as the word "act") is a behavioral therapy that uses mindfulness, acceptance and cognitive defusion skills to increase psychological flexibility and promote behavior change in the direction of chosen values. "Psychological flexibility" is the main goal of act. Psychological flexibility is established through six core ACT processes: Acceptance, Cognitive Defusion, Being Present, Self as Context, Values and Committed Action. These 6 processes will be explained in consultation sessions With exercises and related metaphors. A session on reproductive process and infertility treatment will be explained.

#### Category

Prevention

### 2

#### Description

Control group: Get routine care

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat clinic of infertility

##### Full name of responsible person

Masoumeh Hosseinpahani

##### Street address

Kurdistan, Sanandaj, Abidar Street

##### City

Sanandaj

##### Province

Kurdistan

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6618634683

##### Phone

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masume.hosseinpahani@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Abolgasem Jouyban

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research-vice@tbzmed.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Malakouti.Jamileh

##### Position

Master of Midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery, South Shariati Street, Tabriz

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

### Contact

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Student of Master in Midwifery  
**Latest degree**  
Bachelor  
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+98 87 3872 3984  
**Email**  
masume.hosseinpanahi@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no more information

### 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

Yes - There is 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

The results of the clinical study will be published as a paper.

### When the data will become available and for how long

Immediately after printing the results

### To whom data/document is available

All researchers

### Under which criteria data/document could be used

Scientific use with reference to article

### From where data/document is obtainable

E-mail: malakoutij@tbzmed.ac.ir

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

Up to a week after correspondence by email

### Comments