

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

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+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 Hosseinpanahi

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Kurdistan, Sanandaj, Abidar Street

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Kurdistan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Latest degree
Bachelor
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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