

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effectiveness of online group acceptance and commitment-based shame therapy on depression, experience of shame, quality of life and marital adjustment in depressed infertile women

Protocol summary

Study aim

To investigate the effectiveness of online group therapy with the approach of shame-based acceptance and commitment therapy on reducing depression among infertile women

Design

A clinical trial with a control group, with parallel groups, without blinding and randomized using a table of random numbers

Settings and conduct

Infertile women in Tehran, who refer to Dr. Zareian's clinic, enter the process of selection, evaluation and placement in intervention and control groups according to the inclusion and exclusion criteria. Sampling will be done purposefully. Evaluation, treatment and allocation to groups are done randomly using a table of random numbers. Shame-based acceptance and commitment treatment protocol has 11 sessions, before the intervention and after the intervention, thresholds are measured in both groups. Also, online intervention on the Google Meet platform will be held weekly for a 2-hour session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Symptoms of depression, Experience shame, The length of infertility is more than one year, Age range from 20 to 40 years, Education at least diploma. Exclusion criteria: Psychotic disorders, personality disorders, Having a childbirth

Intervention groups

The first group includes shame-based acceptance and commitment group therapy online and 2-hour sessions once a week with an 11-session protocol. In this intervention, exposure and self-compassion exercises are used in order to create cognitive changes. The second group is a group in which the people are defined as the waiting group and no intervention is done for them in order to control the test error.

Main outcome variables

Beck Depression Inventory Score, Young Shame and Defect Schema Questionnaire Score, Quality Of Life Questionnaire Score, Marital Adjustment Questionnaire Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230502058049N1**

Registration date: **2023-09-16, 1402/06/25**

Registration timing: **retrospective**

Last update: **2023-09-16, 1402/06/25**

Update count: **0**

Registration date

2023-09-16, 1402/06/25

Registrant information

Name

Najmeh Amiri

Name of organization / entity

Shiraz university

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of online group acceptance and commitment-based shame therapy on depression, experience of shame, quality of life and marital adjustment in depressed infertile women

Public title
Effect of online group therapy of shame in depressed infertile women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Infertile women with symptoms of depression Infertile women who experience shame The length of waiting (infertility) is more than one year The duration of marriage is more than 2 years Age range from 20 to 40 years Education at least diploma
Exclusion criteria:
 Specific disorders such as psychotic and personality disorders Substance dependence disorder Suicidal thoughts or attempts during the current period of depression Having a history of a previous pregnancy or childbirth Women who are currently undergoing medication or psychotherapy due to depression and anxiety disorders or were undergoing psychotherapy in the last 3 months.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is a simple randomization that the participants will be placed in two treatment and control groups in a simple and individual way using a Random number table.

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 Faculty of Educational Sciences and Psychology of Shiraz University

Street address

Ground floor, Faculty of Educational Sciences and Psychology, Eram Campus, Eram Dormitory, Eram Square

City

Shiraz

Province

Fars

Postal code

7194684759

Approval date

2023-04-18, 1402/01/29

Ethics committee reference number

IR.US.PSYEDU.REC.1402.006

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

2

Description of health condition studied

Major Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Beck Depression Inventory Score

Timepoint

Before starting the treatment (Pre-test) and After treatment (Post-test)

Method of measurement

Beck Depression Inventory

2

Description

Young Shame and Defect Schema Questionnaire Score

Timepoint
Before starting the treatment (Pre-test) and After treatment (Post-test)

Method of measurement
Young Shame and Defect Schema Questionnaire

Secondary outcomes

1

Description
Quality Of Life Questionnaire Score

Timepoint
Before starting the treatment (Pre-test) and After treatment (Post-test)

Method of measurement
Quality Of Life Questionnaire

2

Description
Marital Adjustment Questionnaire Score

Timepoint
Before starting the treatment (Pre-test) and After treatment (Post-test)

Method of measurement
Marital Adjustment Questionnaire

Intervention groups

1

Description
Intervention group: Shame-based acceptance and commitment treatment plan is designed in 11 sessions. Also, meetings are held online once a week and each meeting lasts for two hours. The first 3 sessions of this protocol include the assessment of shame and defect schemas, clinical symptoms such as depression, and shame-based coping behaviors. In the fourth session, practical training on changing the direction from avoidance to commitment is provided. In the fifth, sixth, and seventh session, the practice of seeing thirty seconds, defining and clarifying values, and dissociative techniques are discussed, respectively. Next, confrontation and self-compassion exercises form the content of the eighth to tenth sessions. Finally, the 11th session deals with relapse prevention training and terminating the treatment. It should be noted that before the intervention and after the intervention, the baseline assessment is done.

Category
Treatment - Other

2

Description
Control group: It is a group in which the people are defined as the waiting group and no intervention is done for them in order to control the test error.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Zahra Zareian Clinic

Full name of responsible person
Mahdi Imani

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zzareian@gmail.com

Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University

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
Shiraz University

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
Shiraz University
Full name of responsible person
Mahdi Imani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
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Person responsible for updating data

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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

Due to compliance with ethical standards

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Sharing the protocol and data from the intervention

When the data will become available and for how long

The access period will start 6 months after the official publication of the article.

To whom data/document is available

Access is allowed only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

It can be used after official publication in reputable scientific journals.

From where data/document is obtainable

Just send their request via email 1- n-amiri@shirazu.ac.ir
2- najmehamiri.psy@gmail.com

What processes are involved for a request to access

data/document

After the official publication of the article, the applicant can obtain the protocol and treatment results (about one

or two years later)

Comments