Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Country
Iran (Islamic Republic of)
Phone
+98 21 4448 5228
Email address
n-amiri@shirazu.ac.ir

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

Street address

No. 41, Noorani St., Farahzadi St., Qods Town

City

Tehran

Province

Fars

Postal code

1468963143

Phone

+98 21 2238 6106

Email

zzareian@gmail.com

Web page address

https://drzahrazareian.com/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University

Full name of responsible person

MohammadHadi Sadeghi

Street address

5th Floor, Management Area, Shiraz University, Islamic Republic Blvd.

City

Shiraz

Province

Fars

Postal code

7194684759

Phone

+98 71 3613 4000

Email

Sadeghi@Shirazu.ac.ir

Web page address

https://law.shirazu.ac.ir/fa/~sadeghi

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

Street address

No.14, First Floor, Shiraz University,Islamic Republic Boulevard

City

Shiraz

Province

Fars

Postal code

7194684759

Phone

+98 21 4448 5228

Email

dr.mahdiimani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz university

Full name of responsible person

Najmeh Amiri

Position

Phd Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Unit13, No. 21, Shahid Islamian Street, Ashrafi Esfahani Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1469619884

Phone

+98 21 4448 5228

Fax

Email

n-amiri@shirazu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz university

Full name of responsible person

Najmeh Amiri

Position

Phd Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Unit13, No. 21, Shahid Islamian Street, Ashrafi Esfahani Highway, Tehran

City

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Province

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1469619884

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+98 21 4448 5228

Fax

Email

n-amiri@shirazu.ac.ir

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