

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effectiveness of Acceptance and Commitment Therapy on sexual self-esteem and couple burnout of infertile women

Protocol summary

Study aim

Determining the effectiveness of acceptance and commitment therapy on sexual self-esteem and couple burnout of infertile women

Design

A single case experiment using multiple baseline design (A-B-A) that includes 4 women referring to infertility treatment centers and private gynecological offices in Tehran. Targeted sampling of the available type will be performed by repeated measurements.

Settings and conduct

Using the available purposive sampling method with repeated measurements, 4 women referring to infertility treatment centers and private gynecological offices in Tehran will be selected and Hayes Acceptance and Commitment Therapy method (2004) will be used to teach admission and commitment therapy. The number of training sessions is 8 sessions, which will be one hour and forty minutes per week.

Participants/Inclusion and exclusion criteria

Inclusion Criteria :aged 20 years to 40 years; At least four years of cohabitation (duration of infertility awareness for at least two years); Infertility due to female physical problems (ovulation disorders; uterine tube disorders; endometriosis; immune system problems) and its diagnosis and approval by a gynecologist according to her medical record at the Infertility Center; Failure to confirm false infertility (due to fertility stress) using the initial interview. Exclusion Criteria: Major psychiatric disorder and history of hospitalization and use of psychiatric drugs (according to the medical record and using interviews and confidentiality of clients).

Intervention groups

This treatment teaches people to live in the present by accepting feelings of self-control and experiential avoidance, and to better cope with the challenges ahead.

Main outcome variables

Improve flexibility and reduce negative thoughts about

yourself and increase sexual self-esteem and reduce couple burnout

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210403050822N1**

Registration date: **2021-04-22, 1400/02/02**

Registration timing: **prospective**

Last update: **2021-04-22, 1400/02/02**

Update count: **0**

Registration date

2021-04-22, 1400/02/02

Registrant information

Name

fateme asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6557 7990

Email address

elham.asadi7488@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Acceptance and Commitment Therapy on sexual self-esteem and couple burnout of infertile women

Public title

The effectiveness of Acceptance and Commitment Therapy on sexual self-esteem and couple burnout of infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

aged 20 years to 40 years At least four years of cohabitation (duration of infertility awareness for at least two years) Infertility due to female physical problems (ovulation disorders, uterine tube disorders, endometriosis, immune system problems) and its diagnosis and approval by a gynecologist according to her medical record at the Infertility Center Failure to confirm false infertility (due to fertility stress) using the initial interview

Exclusion criteria:

Major psychiatric disorder History of hospitalization in psychiatric department Use of psychiatric drugs (according to the medical record and using interviews and confidentiality of clients)

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: **4**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address

Sadaf Town, Mehdi Bayat St., North Bahman Alley, No. 48, Unit 5

City

Andishe

Province

Tehran

Postal code

3168963489

Approval date

2021-03-04, 1399/12/14

Ethics committee reference number

IR.USWR.REC.1399.247

Health conditions studied**1****Description of health condition studied**

infertile women

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Sexual self-esteem of infertile women

Timepoint

Before and during the intervention and after the intervention

Method of measurement

Sexual Self-Esteem Index for Woman-Short Form (SSEI-W-SF)

2**Description**

Marital boredom of infertile women

Timepoint

Before and during the intervention and after the intervention

Method of measurement

Couple burnout questionnaire (CBM) of Pines

Secondary outcomes**1****Description**

Physical dimension of marital boredom

Timepoint

Before, during and after the study

Method of measurement

Pineas Marital Boredom Questionnaire

2

Description

Emotional dimension of marital boredom

Timepoint

Before, during and after the study

Method of measurement

Pineas Marital Boredom Questionnaire

3

Description

Mental dimension of marital boredom

Timepoint

Before, during and after the study

Method of measurement

Pineas Marital Boredom Questionnaire

Intervention groups

1

Description

Individual training with an approach based on acceptance and commitment, which is held in the form of 8 sessions two hours a week .Step A Baseline measurement using a questionnaire, Step B Intervention and re-measurement with a questionnaire, Step C Follow up the effects of the intervention after its completion. Acceptance and commitment therapy (ACT) has six central processes that lead to psychological flexibility. These six processes are: "acceptance, failure, self as context, present-day communication, recognizing values, and committed action." Acceptance and commitment therapy, in fact, is not intended to bring about a direct change in clients, but rather to help clients to relate to their experiences in different ways and to be able to fully live a meaningful and value-based life. (Protocol based on Hayes, Estrosal, and Wilson's book of Acceptance and Commitment). Intervention group: There are 4 infertile women who complete marital boredom with full insertion of details in the pre-test of sexual self-esteem form questionnaires before implementing the protocol. In the intervention group, the treatment protocol based on acceptance and commitment (act) will be held during 8 sessions of 2 hours. During the treatment and after that, questionnaires will be used to evaluate the changes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Leila Raiesi Women's Clinic

Full name of responsible person

Leila Raiesi

Street address

Andisheh, Phase one, 7th Street, West Golnar Dead

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Elham Asadi

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Fateme Asadi

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

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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****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Fateme asadi

Position**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

Only part of the data, such as information about the main outcome or the like, can be shared

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Accurate reading of study and researcher information for reference without changing it

From where data/document is obtainable

Email addresses, telephone numbers

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

Send a request via email and check the cause and rank of the university and receive a response

Comments