

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of acceptance and commitment therapy on emotional, cognitive, physiological functions and quality of life in infertile women who undergoing in vitro fertilization

Protocol summary

Summary

Objectives: Acceptance and commitment therapy is one of the third-generation behavioral therapies in which it is attempted to increase one's psychological relationships with their own thoughts and feelings, instead of cognitive changes. The present study aims to determine the effect of acceptance and commitment therapy on emotional, cognitive and physiological performance and quality of life in infertile women who have gotten pregnant through in vitro fertilization (IVF). **Experimental design:** The present research is a quasi-experimental study with pretest, post test, and one-month follow-up. **Methodology:** Measurement tools include the SCID semi-structured interview for diagnosis of anxiety and depression, Beck Depression Inventory, and Beck Anxiety Inventory. In addition, working memory, everyday memory, and autobiographical memory tests will be performed and Quality of Life Questionnaire (WHOQoL-Brief) will be filled out. **Participants:** Based on convenience sampling method, 30 women with primary or secondary infertility who have gotten pregnant through in vitro fertilization (IVF) will be selected as subjects and then randomly assigned to the intervention and control groups. Those with a history of previous psychiatric disorders, certain medical conditions such as pregnancy problems, cardiovascular diseases, diabetes, etc will be excluded from the study. **Interventions:** Subjects in the test group will attend in eight 90-minute sessions of a training course in acceptance and commitment therapy and those in the control group will receive no training. **Variables of the main outcome:** Anxiety, depression, working memory, everyday memory, and autobiographical memory

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121331391N1**

Registration date: **2017-05-17, 1396/02/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-17, 1396/02/27

Registrant information

Name

Zhaleh Feyzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 5433

Email address

feyzij1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-23, 1396/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of acceptance and commitment therapy on

emotional, cognitive, physiological functions and quality of life in infertile women who undergoing in vitro fertilization

Public title

The efficacy of acceptance and commitment therapy on emotional, cognitive, physiological functions and quality of life in infertile women who undergoing in vitro fertilization

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: An infertile woman who undergoing IVF; Primary or secondary infertility; Age of pregnancy is 14-22 week; At least 2 years after marriage. Exclusion criteria: History of any psychiatric diseases; Spacial medical diseases like diabetes, Cardiovascular diseases...

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

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 mashad university of medical sciences

Street address

Ghorshy bulding. Daneshgah street

City

Mashad

Postal code

Approval date

2017-04-26, 1396/02/06

Ethics committee reference number

IR.MUMS.REC.1396.28

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Depressive episode

2

Description of health condition studied

Anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

3

Description of health condition studied

Memory

ICD-10 code

F06

ICD-10 code description

Other mental disorders due to brain damage and dysfunction and to physical disease

4

Description of health condition studied

Quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression

Timepoint

Before, After, One-month follow-up

Method of measurement

Beck depression scale, SCID

2

Description

Cortisol(Phisiologic changes)

Timepoint

Before, After, One-month follow-up

Method of measurement

Blood cortisole

3

Description

Every day memory

Timepoint

Before, After, One-month follow-up

Method of measurement

Rivermead Behavioural Memory Test- Third Edition

4

Description

Working memory

Timepoint

Before, After, One-month follow-up

Method of measurement

Riding test

5

Description

Authobiographical memory

Timepoint

Before, After, One-month follow-up

Method of measurement

AMT(Autobiographical Memory Test)

6

Description

Quality of life

Timepoint

Before, After, One-month follow-up

Method of measurement

World Health Organization Quality Of Life
Questionnaire(WHOQOL Brief)

7

Description

Anxiety

Timepoint

Before, After, One-month follow-up

Method of measurement

Beck anxiety scale, SCID

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention is designed as a group therapy. There are 8-10 members in each group. There are 8 sessions: Session1: "Problem is control" . "Present moment". In this session members are introduced to each others. Depression and anxiety are explained. The act perspective and present moment and brief mindfulness practice are discussed. Session 2: "Diffusion". In this session, " Brief mindfulness" and "Leaves on a Stream" practices are done. Home works are reviewed and the challenges of them discussed. The concept of workability is explained. Session3: "Acceptance/Willingness". Acceptance which is also called willingness, coming back to present moment and brief mindfulness practice, group discussion about

homework of workability are clarified. Session 4: "Values". Plans for this session are including: Review of mindfulness practice of the last session, doing practice in the small groups and discussing in the large group, clarify the concept of "Values", doing practice and a brief explanation of values in ACT. Stress the point that values are about action, how you want to "be" and "act" in the world. And focus on commitment action to the values. Session 5: "Self observation". The exercise" Mindfulness +Values", review of homeworks, group discussion, exercise" self-observation+Values", explaining of homework for next week are assigned for the 5th session. Session 6: "Commitment action". Description of the sixth session is: mindfulness practice, discussion about mindfulness, clarifying willingness with an exercise" Self-image", discussion again and doing practice. Session 7,8: All the last processes with concentration on making a larger frame according to commitment action with values are done. All majors are described in the last sessions and reviewed.

Category

Treatment - Other

2

Description

Control group: They are just under prenatal cares and do not receive any education and practice.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad infertility Center

Full name of responsible person

Zhaleh Feyzi

Street address

Beside Sina hospital, Jihad st, Bisim crossroad,
Lashkar crossroad.

City

Mashad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of
Medical Science

Full name of responsible person

Mohsen Tafaghodi

Street address

School of Pharmacy, Park Square

City

Mashad

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Mashhad University of Medical Science

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kharazmi university

Full name of responsible person
Zhaleh Feyzi

Position
Ph.D student of clirical health psychology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty