Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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+98 51 3882 5433
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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 Questionaire(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
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
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Web page address

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