Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Acceptance and Commitment Therapy (ACT) on infertility-related stress and adoption in infertile women

Protocol summary

Summary

The purpose of this study is investigating the effect of Acceptance and Commitment Therapy (ACT) on infertility-related stress and child adoption. Infertile women referred to Isfahan Fertility and Infertility Center and Infertility Clinic of Isfahan Shahid Beheshti Hospital are the population of the study in this Randomized Control Trial. The samples of the study are 30 women with eligibility criteria and willingness to participate in this study. Inclusion criteria include: women 30-45 years old with primary infertility for 5 years and more, the history of Assisted Reproductive Technology failure (at least 1 time In Vitro Fertilization (IVF) or 3 times Intra Uterine Insemination (IUI) failure) and child adoption questionnaire's score less than 53 (mild and moderate attitude toward adoption). Participants randomly assign into control and experimental groups (15 people in each group). The experimental group receives ACT for 8 sessions for 2 hours twice a week and individuals in control group did not receive any intervention. All participants will complete Fertility Problem Inventory (FPI) and Child Adoption Questionnaire before the intervention, immediately after the intervention and one month after the intervention completion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120825428N1**
Registration date: **2016-08-28, 1395/06/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name
Tayebe Hajiyan
Name of organization / entity
Ahvaz Jundishapur University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Jundishapur University of Medical Science

Expected recruitment start date

2015-09-19, 1394/06/28

Expected recruitment end date

2015-11-19, 1394/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Acceptance and Commitment Therapy (ACT) on infertility- related stress and adoption in infertile women

Public title

The effect of Acceptance and Commitment Therapy (ACT) on infertility- related stress and adoption in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women age 30-45 years; primary

infertility 5 years and more; the history of Assisted Reproductive Technology (ART) failure (at least 1 time IVF or 3 time IUI failed); no history of psycological treatment; child adoption questionaire's score less than 53 (mild and moderate attitude toward adoption); tend to participate in the study Exclusion criteria: the absence of more than two sessions; the case of psychological disorder ; pregnancy during sessions

Age
From **30 years** old to **45 years** old

Gender
Female

Phase
2

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 Ahvaz Jundishapour University of Medical Science

Street address
Golestan blvd. Ahvaz Jundishapour University of Medical Science, Ahwaz, Iran

City
Ahvaz

Postal code
15794-61357

Approval date
2015-09-19, 1394/06/28

Ethics committee reference number
IR.AJUMS.REC.1394.368

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
Infetility-related stress

Timepoint
Befor intervention, immediately after intervention and one month later

Method of measurement
Fertility Problem Inventory (FPI)

2

Description
Adopton

Timepoint
Befor intervention, immediately after intervention and one month later

Method of measurement
Child adoption questionnaire

Secondary outcomes

1

Description
Social concern

Timepoint
Befor intervention, immediately after intervention and one month later

Method of measurement
Fertility Problem Inventory (FPI)

2

Description
Relational concern

Timepoint
Befor intervention, immediately after intervention and one month later

Method of measurement
Fertility Problem Inventory (FPI)

3

Description
Sexual concern

Timepoint
Befor intervention, immediately after intervention and one month later

Method of measurement
Fertility Problem Inventory (FPI)

4

Description
Need for parentood

Timepoint
Befor intervention, immediately after intervention and one month later
Method of measurement
Fertility Problem Inventory (FPI)

5

Description
Rejection of childfree lifestyle
Timepoint
Befor intervention, immediately after intervention and one month later
Method of measurement
Fertility Problem Inventory (FPI)

Intervention groups

1

Description
Experimental group receive group counseling based on Acceptance and Commitment Therapy (ACT) in two-hour sessions twice a week for a total of eight sessions.
Category
Behavior

2

Description
Control group: individuals in control group did not receive any intervention. For ethical consideration, after 3 evaluation, apply ACT session for control group if they want.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Clinic, Shahid Behesht Hospital
Full name of responsible person
Tayebe Hajiyan
Street address
Motahary St. Infertility Clinic, Shahid Behesht Hospital, Isfahan
City
Isfahan

2

Recruitment center
Name of recruitment center
Isfahan Fertility and Infertility Center
Full name of responsible person
Tayebe Hajiyan
Street address
Moshtagh St. Isfahan Fertility and Infertility Center, Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahwaz Jondishapour University of Medical Science
Full name of responsible person
Dr. Nader Saki
Street address
Golestan blvd. Ahvaz Jondishapour University of Medical Science, ahwaz, Iran
City
Ahvaz
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, Ahwaz Jondishapour 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
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Ahvaz Jondishapour University of Medical Science
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Tayebe Hajiyan
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Person responsible for scientific inquiries

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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