

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Revising of Acceptance and Commitment Therapy (ACT) protocol based on psychological problems in women with infertility and (its) effectiveness on their health- related quality of life and sexual satisfaction in women with infertility.

#### Protocol summary

##### Study aim

If the research hypotheses are proven, Acceptance and Commitment therapy (ACT) can be used in treatment centers to help treat women with infertility and have a significant role in improving the quality of life associated with the health and sexual satisfaction of these patients.

##### Design

En Controlled clinical trial, not blind, randomized design

##### Settings and conduct

At the Isfahan ....., patients' files are reviewed and interviewed in the presence of the Dr. Mofid. If satisfied, patients complete the questionnaires in the pre-test and post-test stages. The treatment protocol is performed in 8 sessions on the intervention group at the Dr. Clinic.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 and 40 years; Diagnosed infertility in patients who completed standard therapies; Exclusion criteria: Mental disorders

##### Intervention groups

The ACT Therapy protocol will be administered to the experimental group to improve health-related quality of life and sexual satisfaction in women with infertility , and the control group will continue their treatment.

##### Main outcome variables

The main implications of this study are: sexual satisfaction as measured by sexual satisfaction questionnaire; Quality of life is dependent on health as measured by the questionnaire (SF 36). The main consequences are pre-test and post-test.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200217046527N1**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-19, 1398/12/29**

Update count: **0**

##### Registration date

2020-03-19, 1398/12/29

##### Registrant information

###### Name

Shiva Koohi Kamali

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3448 2848

###### Email address

sh.koohikamali@iaukishint.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-04-08, 1399/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Revising of Acceptance and Commitment Therapy (ACT) protocol based on psychological problems in women with infertility and (its) effectiveness on their health- related

quality of life and sexual satisfaction in women with infertility.

**Public title**

"The effect of Acceptance and Commitment Therapy (ACT) protocol on women with infertility"

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

En Willingness to participate in the research project Age 20-40 years Having a diploma degree At least one year under treatment (with expert approval) No addiction to any drug Completion of consent to participate in the research Low Quality of Life Quality of Life and Sexual Satisfaction Questionnaires

**Exclusion criteria:**

Use of psychoactive drugs

**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**

Since the study groups have equal sample size, we use simple random allocation law which is one of the limited randomization methods and we divide people into two groups of intervention and control. Keep notes of patients on 40 separate sheets and place the sheets inside the draw container and then we randomly record the 20 sheets out of the container into the intervention group and place the remaining 20 sheets in the control group. If there is a loss in treatment sessions, the sample size will be randomly eliminated in order to equalize the sample size and eventually the number of subjects in both groups should be the same. The experimental group (n=20) will have 8 sessions of 120-minute Acceptance and Commitment therapy and the control group will receive no intervention.

**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 Hormozgan University of Medical Sciences

**Street address**

Shahid Chamran Blvd., Hormozgan University of Medical Sciences

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7916613885

**Approval date**

2019-12-07, 1398/09/16

**Ethics committee reference number**

IR.HUMS.REC.1398.310

**Health conditions studied**

1

**Description of health condition studied**

women with infertility

**ICD-10 code****ICD-10 code description****Primary outcomes**

1

**Description**

Scale on sexual satisfaction ; Physical and Mental Health Score in Health Related Quality of Life Questionnaire (SF 36)

**Timepoint**

At the beginning of the study (before the intervention) and after 8 sessions of acceptance and commitment group therapy

**Method of measurement**

Health Related Quality of Life Questionnaire (SF 36); sexual satisfaction

**Secondary outcomes**

1

**Description**

Health-related quality of life score and Scale on sexual satisfaction

**Timepoint**

Health-related Quality of Life Questionnaires (SF 36) and Scale on sexual satisfaction at baseline (before intervention) and after treatment protocol

**Method of measurement**

The sexual satisfaction Questionnaire (DASS 21) Health-related quality of life (SF 36)

## Intervention groups

### 1

#### Description

Intervention group: Acceptance and Commitment Therapy (ACT) has six central processes that lead to psychological flexibility. These six processes are: "Acceptance, Faulting, self as context, present-day communication, recognizing values and committed action Intervention group". In fact the purpose of Acceptance and Commitment therapy, is not to make a direct change in the client. Rather, its purpose is to help clientele communicate their experiences in different ways and be able to engage completely with meaningful, value-based life. The proposed protocol is based on the Acceptance and Commitment Book by Hayes, Straussell and Wilson. In the intervention group: Twenty patients have prostate cancer before the protocol is implemented In the pre-test, they completed the Short Form of sexual satisfaction and Health-Related Quality of Life (SF-36) with full specifications. In the intervention group, the Acceptance and Commitment Therapy protocol (ACT) will be conducted in eight consecutive 90-minute sessions in 4 consecutive weeks.

#### Category

Behavior

### 2

#### Description

Control group: Twenty patients with prostate cancer who complete the pre-test questionnaire of sexual satisfaction and health-related quality of life (SF-36) with complete the specification. The group will receive routine care during this 4-week period and will not perform any additional work. After 4 weeks post-test this group will also complete the questionnaires.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Infertility center of Milad Hospital

##### Full name of responsible person

Dr. Abdollah Ghahiri

##### Street address

Shahrak-e Vali Asr

##### City

Esfahan

##### Province

Isfahan

##### Postal code

8173664433

##### Phone

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##### Email

ghahiriig@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

دکتر علیرضا روستا

##### Street address

Sana'i Boulevard, Free Zone Organization Square,  
Islamic Azad University of Kish International Branch

##### City

kish

##### Province

Hormozgan

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7941775883

##### Phone

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##### Fax

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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

Islamic Azad 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

Islamic Azad University

##### Full name of responsible person

Shiva Koohikamali

##### Position

Student

##### Latest degree

Master

##### Other areas of specialty/work

Psychology

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##### Province

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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**  
دکتر حمید پورشریفی  
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دانشیار روانشناسی سلامت  
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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available