

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The Effectiveness of Acceptance and Commitment Therapy on Sexual Self Efficacy and Sexual Quality of Life in Reproductive age women

#### Protocol summary

##### Study aim

Determining the effect of counseling approach based on admission and commitment on sexual quality of life and sexual self-efficacy in women of reproductive age

##### Design

Randomized clinical trial with control group

##### Settings and conduct

After obtaining the necessary permissions from the Research and Technology Dept. and the Ethics Committee of the University, eligible women referring to the two selected health centers of Isfahan are invited. After considering the entry and exit criteria of the study, 58 were targeted. Then, according to the random numbers table, the subjects are divided into two equal groups of intervention and control. After obtaining informed consent, women's sexual quality of life questionnaires (SQOL-F) and Waziri and Lotfi's sex-self-efficacy questionnaire and demographic information questionnaire are completed by the subjects. It will consist of eight 90-minute weekly counseling sessions. After completing the classes and one month later, the questionnaires were completed again and the results were analyzed using SPSS software. demographic,

##### Participants/Inclusion and exclusion criteria

The desire to participate in the study, being Iranian, living in Isfahan, age 25-40, having literacy and reading skills, married and having a spouse, the only person to be a spouse. According to the person, alcohol and drug addiction, use of drugs affecting sexual function, diseases affecting sexual function, psychiatric disorders and pregnancy.

##### Intervention groups

Women aged 25 to 40 are spouses

##### Main outcome variables

مشاوره گروهی با رویکرد اکت بر میزان خودکارآمدی جنسی و کیفیت زندگی جنسی زنان همسر دار 25 تا 40 ساله تاثیر دارد

#### General information

##### Reason for update

##### Acronym

ACT.Acceptance Commitment Therapy

##### IRCT registration information

IRCT registration number: **IRCT20181208041893N1**

Registration date: **2019-05-13, 1398/02/23**

Registration timing: **retrospective**

Last update: **2019-05-13, 1398/02/23**

Update count: **0**

##### Registration date

2019-05-13, 1398/02/23

##### Registrant information

##### Name

Marziehsadat Rajaeizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3267 0520

##### Email address

ms.rajaeizadeh@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-01, 1397/09/10

##### Expected recruitment end date

2019-03-30, 1398/01/10

##### 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 Efficacy and Sexual Quality of Life in Reproductive age women

## Public title

The Effectiveness of Acceptance and Commitment Therapy on Sexual Self Efficacy and Sexual Quality of Life in Reproductive age women

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

The desire to participate in the study Being Iranian Resident of esfahan Age 25 - 40 years Having reading and writing skills Married and having a spouse Only being a spouse

### Exclusion criteria:

Drug addiction and alcohol in themselves or in spouse According to Fred, Taking effective drugs on sexual function Diseases Affecting Sexual Function Psychiatric disorders Being pregnant

## Age

From **25 years** old to **40 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **58**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Of the patients referred to the selected clinics of Isfahan University of Medical Sciences, 58 subjects were selected by available sampling which had the criteria for entering the study, and then, after obtaining informed consent, using the random numbers table, they would be divided into equal and equal groups of intervention and control.

## 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 Shahid Sadoughi University of Medical Sciences, Yazd Sciences, Translations of s

## Street address

Faculty of Midwifery Nursing, Bu'ali Alley,Thaisar Fallahi Avenue. Safaiyeh.Yazd

## City

yazd

## Province

Yazd

## Postal code

03538241757

## Approval date

2018-12-01, 1397/09/10

## Ethics committee reference number

IR.SSU.REC.1397.111

## Health conditions studied

### 1

#### Description of health condition studied

Sexual Self Efficacy and Sexual Quality of Life

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Sex quality quality score and self-efficacy score

#### Timepoint

Measure the quality of life quality score and self-efficacy score before and after the month after the consultation

#### Method of measurement

Women's Quality of Life QOL-F Questionnaire and Sexual Self-Efficacy Questionnaire (Text in Persian) Vaziri and Lotfi

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: A female partner of 25 to 40 years of age who has low sexual self-efficacy and low quality of life

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health centers in Isfahan province

##### Full name of responsible person

Marzieh al-Sadat Rajaeizadeh

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no.25 ,allay Golbaran, Bozorgmehr Ave ,22 Bahman Ave

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**Province**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Masoud Mirzaei

**Street address**

Faculty of Midwifery Nursing, Bu'ali Alley,Timsar Fallahi Avenue, Safaiyeh,Yazd

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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**

Yazd University of Medical 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Marzieh al-sadat Rajaeizadeh

**Position**

Master's degree in midwifery counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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

Yazd University of Medical Sciences

**Full name of responsible person**

Dr Mahshid Bokaie

**Position**

PhD in Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

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

**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

**Title and more details about the data/document**

The results of the clinical study will be published as a article

**When the data will become available and for how long**

Immediately after publishing the results

**To whom data/document is available**

all researchers

**Under which criteria data/document could be used**

Scientific use with reference to article

**From where data/document is obtainable**

Email:ms.rajaeizadeh@ssu.ac.ir

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

Up to one week after correspondence by email

**Comments**