

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of cognitive behavioral therapy on sexual self-esteem and sexual function in women of reproductive age with urinary incontinence

Protocol summary

Study aim

Determining the effect of cognitive-behavioral therapy on sexual self-esteem and sexual function in women of reproductive age with urinary incontinence

Design

This study is a Randomized clinical trial. The number of sample members is estimated at 84. Sampling will be performed by sequential non-probability method. Sample members will be divided into intervention (n = 42) and control (n = 42) groups. Assignment of individuals to each group will be done by random block method (6 blocks)

Settings and conduct

Research location: Dezful health centers. The short form of the ICIQ-SF questionnaire will be given to women who are eligible to enter the study, and, people who score equal to or higher than 1 will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Married women 2. reproductive ages (15-45 years) 3. Literate (diploma education) 4. Resident in Dezful 5. Age gap less than 10 years from the spouse. Exclusion criteria: 1. No history of serious physical or mental illness (such as psychotic disorders; schizophrenia or major depression,...) 2. Occurrence of diseases affecting the sexual function of a woman or her husband (such as: cardiovascular disease, psychiatric thyroid, ...) 3. Participate in sex education classes 4. Taking medication to improve sexual function

Intervention groups

People in the intervention group will receive 8 sessions (for 45 minutes) of face-to-face cognitive-behavioral therapy, While the control group will not receive any intervention except of routine care.

Main outcome variables

Sexual function and sexual self-esteem of women of childbearing age with urinary incontinence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210516051312N1**

Registration date: **2021-05-19, 1400/02/29**

Registration timing: **prospective**

Last update: **2021-05-19, 1400/02/29**

Update count: **0**

Registration date

2021-05-19, 1400/02/29

Registrant information

Name

Salimeh Moradinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4242 8477

Email address

moradi.sal@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive behavioral therapy on sexual self-esteem and sexual function in women of reproductive age with urinary incontinence		Golestan Blvd, Ahwaz	
Public title		City	ahwaz
The effect of cognitive behavioral therapy on sexual self-esteem and sexual function in women of reproductive age with urinary incontinence		Province	Khouzestan
Purpose		Postal code	61357-15794
Treatment		Approval date	2021-05-16, 1400/02/26
Inclusion/Exclusion criteria		Ethics committee reference number	IR.AJUMS.REC.1400.102
Inclusion criteria:		Health conditions studied	
Married women Reproductive ages (15-45 years) afflicted to urinary incontinence Literate (diploma education) Resident in Dezful Age gap less than 10 years with spouse		1	
Exclusion criteria:		Description of health condition studied	
No history of serious physical or mental illness (such as psychotic disorders; schizophrenia or major depression, need special diet or medication) Occurrence of diseases that affect the sexual function of a woman or her husband (such as: cardiovascular disease, psychiatric thyroid, cancer Participate in sex education classes Taking medication to improve sexual function		urinary incontinence	
Age		ICD-10 code	
From 15 years old to 45 years old		ICD-10 code description	
Gender		Primary outcomes	
Female		1	
Phase		Description	
N/A		Sexual function in women of childbearing age afflicted to urinary incontinence	
Groups that have been masked		Timepoint	
No information		Before the intervention - at the end of the intervention - 1 month after the intervention	
Sample size		Method of measurement	
Target sample size: 84		Sexual Function Questionnaire in People with Urinary Incontinence (PISQ-12)	
Randomization (investigator's opinion)		2	
Randomized		Description	
Randomization description		Sexual self-esteem of women of childbearing age afflicted to urinary incontinence	
Assignment of individuals to each of the treatment groups will be done by randomly blocking method and using 6 blocks (7 groups of 6 people).		Timepoint	
Blinding (investigator's opinion)		Before the intervention - at the end of the intervention - 1 month after the intervention	
Not blinded		Method of measurement	
Blinding description		Sexual Self-Esteem Questionnaire (SSEI-W -SF)	
Placebo		Secondary outcomes	
Not used		empty	
Assignment		Intervention groups	
Other		1	
Other design features		Description	
		Intervention group: 8 sessions of cognitive-behavioral therapy, once a week (each session: 45 minutes)	
Secondary Ids		Category	
empty		Behavior	
Ethics committees			
1			
Ethics committee			
Name of ethics committee			
Ethics Committee of Ahwaz Jundishapur University of Medical Sciences			
Street address			

2

Description

Control group : Except of routine care, no intervention is performed in the control group. After the intervention, they will receive training based on cognitive-behavioral therapy

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

health centers of Dezful

Full name of responsible person

Salimeh Moradinasab

Street address

No. 10, Golestan st, vahed Ave, Dezful

City

Dezful

Province

Khouzestan

Postal code

۶۴۶۱۶-۵۷۵۱۴

Phone

+98 61 4242 8477

Email

Salimeh268@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Ahwaz Jundishapur University

Full name of responsible person

Mehdi Ahmadi Moghadam

Street address

Golestan Blvd, Ahwaz

City

Ahwaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8383

Email

ahmadi-m@ajums.ac.ir

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 and Technology, Ahwaz Jundishapur 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

Ahwaz University of Medical Sciences

Full name of responsible person

Mina Iravani

Position

Associate Professor of Reproductive Health
Department of Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Golestan Blvd, Ahwaz

City

Ahwaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8395

Email

minairavani2004@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahwaz University of Medical Sciences

Full name of responsible person

Mina Iravani

Position

Associate Professor of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Golestan Blvd, Ahwaz

City

Ahwaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8395

Email

minairavani2004@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Salimeh Moradinasab

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No. 10, Vahed Ave, Golestan st, Dezful Town

City

Dezful

Province

Khouzestan

Postal code

64616-57514

Phone

+98 61 4242 8477

Email

Salimeh268@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available