

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The impact of cognitive-behavioral therapy on sexual function, sexual satisfaction and self- efficiency in Nulliparous pregnant women

Protocol summary

Summary

The present study aimed to investigate the effect of behavioral-cognitive therapy to improve the sexual function, satisfaction and self-efficiency in first-pregnancy women that increases spouse satisfaction and make the family relations strong. The inclusion criteria involve: first pregnancy, age of 18-35, pregnancy age of 14-16 weeks. The exclusion criteria involve: abortion history, alcohol use, smoking, drugs effective on sexual tendency, having chronic diseases, having sexual disorder before pregnancy, having Pregnancy complications. This clinical trial included three separate questionnaires such as questionnaire of sexual function, satisfaction and self-efficiency. Those who received low score in all three questionnaires (n=32) were selected. Samples are randomly divided into two control and treatment groups. The treatment group received eight session of cognitive- behavior counseling and control group received routine pregnancy care. Then two weeks and 4 weeks after finishing interventions, post-test was performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111230850N1**

Registration date: **2017-01-24, 1395/11/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-24, 1395/11/05

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

University of Jundishapur of Ahvaz

Expected recruitment start date

2016-12-05, 1395/09/15

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of cognitive-behavioral therapy on sexual function, sexual satisfaction and self- efficiency in Nulliparous pregnant women

Public title

The impact of cognitive-behavioral therapy on sexual function, sexual satisfaction and self- efficiency in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: have at least read and write, aged 18 to 35 years; first pregnancy; gestational age 14 to 16 weeks Exclusion criteria: having a history of miscarriage; pregnancy complications (placenta previa threatened abortion, gestational hypertension); sexual disorder

before pregnancy; use alcohol and cigarettes; drugs that affect sexual desire (such as antihypertensive drugs of antidepressants); having chronic physical and mental illnesses

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

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 Jundishapur University of Medical Sciences

Street address

Department of Research and Information Technology
University of Medical Sciences, Ahvaz Jundishapur,
Ground Floor, City University

City

Ahvaz

Postal code

15794-61357

Approval date

2016-11-21, 1395/09/01

Ethics committee reference number

IR.AJUMS.REC.1395.484

Health conditions studied

1

Description of health condition studied

Disorder of sexual function

ICD-10 code

f52.9

ICD-10 code description

lack or disorder of sexual function

Primary outcomes

1

Description

Sexual self-efficacy index

Timepoint

Before the intervention, two weeks and four weeks after the intervention.

Method of measurement

Schwartz sexual self-efficacy questionnaire

2

Description

Female Sexual Function Index(FSFI)

Timepoint

Before the intervention, two weeks and four weeks after the intervention.

Method of measurement

Female Sexual Function Questionnaire

3

Description

Sexual Satisfaction Index(ISS)

Timepoint

Before the intervention, two weeks and four weeks after the intervention.

Method of measurement

Larson Sexual satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Consultations are done a week for 8 sessions of 45-minute sessions on an individual basis and Each session has a specific structure

Category

Behavior

2

Description

The control group only received prenatal care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

East's number one health center in Ahvaz

Full name of responsible person

Minanezamnia
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Ayatollah Behbahani superhighway,7 tir park opposite
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Email
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Ahvaz JundiShapur
University of Medical Sciences
Full name of responsible person
Dr Behzad Makhmal zade
Street address
Ahvaz Jundishapur University of Medical Sciences,
opposite the central building, Vice Chancellor for
Research, Ahvaz University of Medical Sciences
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, Ahvaz JundiShapur
University of Medical Sciences

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

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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