

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The survey of cognitive-behavioral counseling effect on mothers sexual satisfaction who have children with autism

#### Protocol summary

##### Summary

The aim of this study is to determine the effectiveness of cognitive-behavioral counseling on sexual satisfaction of mothers with autistic children. This study is a randomized clinical trial, single-blind and without a placebo and is conducted on the mothers of children with autism in a control and an intervention group. The sample size has been considered 15 each group and 30 subjects in total. The criteria for inclusion are as follow: participants must be mothers of ages 25 to 45, must not be pregnant, must not be using psychotropic or psychiatric drugs, must not suffer from any addiction, must have completed at least the fifth grade of elementary school, must have a good command of Farsi, must be living with her husband, must not have any psychiatric history of depression requiring treatment, must have a child over 5 years old with severe autism (confirmed by a psychotherapist of a credible academic center), must not have another child suffering from autism or any other disease, must not have sexual dissatisfaction prior to the birth of child with autism. Criteria for exclusion from the study are as follow: mothers who have complete sexual satisfaction on the basis of Sexual Satisfaction Scale designed by Linda Berg and Cresy, Severe psychiatric disorders or suicidal thoughts, a history of psychosis or suicide, attending relaxation or yoga classes and the like, failure to attend two or more of counseling sessions, lack of consent to participate in research. Members of both groups complete Linda Berg's Sexual Satisfaction Scale designed by Linda Berg and Cresy and the demographic before the intervention. The intervention group receives individual counseling with cognitive behavioral approach over eight 1.5 hour sessions at Qom province autism schools. For the control group, A two-hour training program will be held. Immediately and one month after the counseling sessions, both groups answer a post-test. Sexual satisfaction score will then be compared between the intervention and control groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016111130830N1**  
Registration date: **2017-01-02, 1395/10/13**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-01-02, 1395/10/13

##### Registrant information

##### Name

Leila Arbhl

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3826 1081

##### Email address

farzanehgolboni@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2017-01-04, 1395/10/15

##### Expected recruitment end date

2017-04-18, 1396/01/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The survey of cognitive-behavioral counseling effect on mothers sexual satisfaction who have children with autism

**Public title**

The counseling effect on mothers sexual satisfaction who have children with autism

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

The criteria for inclusion are as follow: participants must be mothers of ages 25 to 45, must not be pregnant, must not be using psychotropic or psychiatric drugs, must not suffer from any addiction, must have completed at least the fifth grade of elementary school, must have a good command of Farsi, must be living with her husband, must not have any psychiatric history of depression requiring treatment, must have a child over 5 years old with severe autism (confirmed by a psychotherapist of a credible academic center), must not have another child suffering from autism or any other disease, must not have sexual dissatisfaction prior to the birth of child with autism. Criteria for exclusion from the study are as follow: mothers who have complete sexual satisfaction on the basis of Sexual Satisfaction Scale designed by Linda Berg and Cresy, Severe psychiatric disorders or suicidal thoughts, a history of psychosis or suicide, attending relaxation or yoga classes and the like, failure to attend two or more of counseling sessions, lack of consent to participate in research.

**Age**

From **25 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single 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 Kermanshah University of Medical Sciences

**Street address**

Kermanshah, Shahid Beheshti Blvd, Building No. 2, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Postal code**

6714673159

**Approval date**

2016-12-14, 1395/09/24

**Ethics committee reference number**

IR.KUMS.REC.1395.536

**Health conditions studied****1****Description of health condition studied**

Sexual Satisfaction

**ICD-10 code**

Z70.0

**ICD-10 code description**

Counselling related to sexual attitude

**Primary outcomes****1****Description**

Sexual Satisfaction

**Timepoint**

Before intervention, Immediately after the intervention  
And a month later

**Method of measurement**

Sexual satisfaction questionnaire of Linda berg & Cresy

**Secondary outcomes**

empty

**Intervention groups****1****Description**

individual counseling with cognitive behavioral approach over eight 1.5 hour sessions

**Category**

Prevention

**2****Description**

For the control group, A two-hour training program will be held.

**Category**

Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Welfare Organization of Qom

**Full name of responsible person**

Leila Arbil

**Street address**

Qom, Imam street, Shahid Beheshti square, Welfare Organization

**City**

Qom

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research Department of Kermanshah University of Medical Sciences

**Full name of responsible person**

Kourosh Hamzehei

**Street address**

Kermanshah, Shahid Beheshti Blvd, Building No. 2, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Department of Kermanshah 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

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Leila Arbil

**Position**

Graduate student in midwifery counseling

**Other areas of specialty/work**

**Street address**

Kermanshah, University of Nursing and Midwifery

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**Phone**

+98 88338279899

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saadatmand66@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farzaneh Golboni

**Position**

Master's Degree of Midwifery- faculty member

**Other areas of specialty/work**

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farzanehgolboni@kums.ac.ir

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

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Leila Arbil

**Position**

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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*