Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

City
Kermanshah

Postal code

Phone
+98 88338279899

Fax

Email
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

Street address
Kermanshah, University of Nursing and Midwifery

City
Kermanshah

Postal code

Phone
+98 888338279899

Fax

Email
farzanehgolboni@kums.ac.ir

Web page address

Person responsible for updating data

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

City
Kermanshah

Postal code

Phone
+98 88338279899

Fax

Email
saadatmand66@gmail.com

Web page address

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