Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Cognitive-Behavioral counseling on sexual function in near-death mothers at health centers

Protocol summary

Study aim

The effect of cognitive-behavioral counseling on sexual function in near-death women

Design

The Clinical trial that is: with control group, with parallel groups, not blinded, randomized method was used, was based on the findings from previous studies. 48 cases (24 cases in each group) were determined for randomization with the help of med-calc statistical software with 95% power and 5% error.

Settings and conduct

Sampling will be administrated based on inclusion and exclusion criteria of the study by inviting women who are listed as near-death patients in hospitals. the study will be conducted in the west public health center of Ahvaz, after obtaining written informed consents from all participants. cognitive-behavioral therapy (CBT) sessions, as the method of the study, will be delivered weekly to the participants for eight continuous weeks. Due to advisory nature of this study, blinding will not be possible.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Severe morbidity during labor 2- History of at least one delivery 3. Passing eight to twelve weeks since delivery 4- Having minimum literacy 5- Women whose sexual function score is less than 26 Exclusion criteria 1- Having a known mental illness 2- Taking psychiatric drugs 3. Reluctance to participate in the study 4- Abortion in the recent pregnancy.

Intervention groups

For the intervention group, cognitive-behavioral counseling is used as the intervention. In this method, counseling is given for 8 weeks, one session per week and90minutes per session. Session 1:Interview, Session 2:Helping to Understand the Problem, Session 3:Cognitive Reconstruction, Session 4:Raising sexual knowledge, Session 5:Asexual Sensitivity Training, Session 6:Sex Sensitivity Training, Session 7:Teaching how to have sex, Session 8:Expression of results and conclusions. Control group: do not receive any intervention.

Main outcome variables

sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200612047744N1**
Registration date: **2020-12-09, 1399/09/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-09, 1399/09/19**
Update count: **0**

Registration date

2020-12-09, 1399/09/19

Registrant information

Name

Shohreh Dasht peyma

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3376 5834

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Cognitive-Behavioral counseling on sexual function in near-death mothers at health centers

Public title
The effect of Cognitive-Behavioral counseling on sexual function in near-death women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Near-death mothers with severe pregnancy complications A history of at least one delivery Passing eight to twelve weeks since delivery Having minimum literacy Women whose sexual function score is below 26
Exclusion criteria:
Having a known mental illness Taking psychiatric medication Reluctance to participate in the study Abortion in her recent pregnancy
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Not 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 Ahwaz Jundishapur University of Medical Sciences
Street address
Central Organization Building , Esfand Ave , Golestan Blvd , Golestan District
City
Ahwaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2020-06-13, 1399/03/24
Ethics committee reference number
IR.AJUMS.REC.1399.255

Health conditions studied

1

Description of health condition studied
Sexual function
ICD-10 code
F52.9
ICD-10 code description
Unspecified sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
sexual function quality
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Female Sexual Function Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For this group, cognitive-behavioral counseling is used. In this method, counseling is given for 8 weeks, one session per week and 90 minutes per session. This is a type of psychotherapy that helps patients understand the thoughts and feelings that affect behaviors. Session 1: Interview, Session 2: Helping to understand the problem, Session 3: Cognitive reconstruction, Session 4: Raising sexual knowledge, Session 5: Teaching asexual sensing, Session 6: Sexual sensing training, Session 7: Teaching how to have sex, Session 8: Expression of results and conclusions. Meetings will be held by a trained researcher in the presence of a consultant professor in some sessions.
Category
Behavior

2

Description
Control group: This group will not receive any

intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz West Health Center

Full name of responsible person

Shohreh Dashtpeyma

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Ahmadi Moghaddam

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Shohreh Dashtpayma

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data set used in this study will be available upon request from the corresponding person.

When the data will become available and for how long
After the publication of the manuscript

To whom data/document is available
For public

Under which criteria data/document could be used
Upon the request from the corresponding author

From where data/document is obtainable
shohreh.dashtpeyma3693@gmail.com

What processes are involved for a request to access data/document
After sending an e-mail to the corresponding author

Comments