

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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 and 90 minutes 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

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Central Organization Building , Esfand Ave , Golestan Blvd , Golestan District

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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

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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

Ahwaz 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

Ahwaz 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 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