Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of cognitive-behavioral therapy on sexual performance and self-efficacy in reproductive age women with heart disease

Protocol summary

Study aim
Comparing the effectiveness of cognitive-behavioral therapy on sexual performance and self-efficacy in women with heart disease
Design
The samples will be included in the study and random allocation of people into two groups using the permutation block method (size of each block = 6) in the form of available samples and quota method (according to menopausal and non-menopausal women of reproductive age).
Settings and conduct
in Chaharmahal Bakhtiari province
Participants/Inclusion and exclusion criteria
- A resident of Shahrekord - Having minimum reading and writing literacy to complete the questionnaires - Women with class 1 or 2 heart disease confirmed by a doctor - married - Living with a spouse - sexually active - 3 years or more have passed since marriage - Absence of known mental disorders in yourself and your spouse - Absence of other known physical disorders in yourself and your spouse, such as thyroid, blood pressure, diabetes, cancers, etc. - Absence of known sexual disorders in yourself and your spouse - Having a mobile phone and the ability to connect to the Internet
Intervention groups
8 sessions of sexual cognitive behavioral therapy for the intervention group
Main outcome variables
sexual performance score; sexual self-efficacy score; intervention group

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100524004015N2**
Registration date: **2024-11-03, 1403/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-03, 1403/08/13**
Update count: **0**
Registration date
2024-11-03, 1403/08/13

Registrant information
Name
Zeinab Tavakol
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 38 3334 1412
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-16, 1403/07/25
Expected recruitment end date
2024-11-15, 1403/08/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of cognitive-behavioral therapy on sexual performance and self-efficacy in reproductive age women with heart disease

Public title
Investigating the effectiveness of cognitive-behavioral therapy on sexual performance and self-efficacy in reproductive age women with heart disease
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
A resident of Shahrekord Having minimum reading and writing literacy to complete the questionnaires Women with class 1 or 2 heart disease confirmed by a physician married Living with a spouse sexually active 3 years or more have passed since marriage Absence of known mental disorders in yourself and your spouse Absence of other known physical disorders in yourself and your spouse, such as thyroid, blood pressure, diabetes, cancers, etc. Absence of known sexual disorders in yourself and your spouse Having a mobile phone and the ability to connect to the Internet
Exclusion criteria:
Using medical or pharmaceutical interventions or counseling interventions to solve sexual problems being pregnant Alcohol use Drug use
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomly assign the samples to two intervention and control groups, tables of 6 blocks (table of random numbers) will be used. In this way, a number is included for the names of the registered people, then using 6 block tables and random allocation software, these numbers are randomly placed in one of the two groups.
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 Shahrekord University of Medical Sciences
Street address
Kashani Blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۵۷۱۳۴۷۱
Approval date
2024-05-28, 1403/03/08
Ethics committee reference number
IR.SKUMS.REC.1403.030

Health conditions studied

1

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

Primary outcomes

1

Description
Sexual performance score
Timepoint
Before the start of the intervention - after the end of the intervention - one month after the end of the intervention
Method of measurement
The sexual performance questionnaire based on Schwarzer's general self-efficacy questionnaire was created by Vaziri and Lotfi Kashani.

2

Description
Sexual self-efficacy score
Timepoint
Before the start of the intervention - after the end of the intervention - one month after the end of the intervention
Method of measurement
Sexual self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

This study will be conducted on 60 women with heart disease in Shahrekord city. After obtaining the code of conduct and obtaining the necessary permits from the university, sampling will be done. Entry criteria include women living in Shahrekord and suffering from class one or two heart disease confirmed by a doctor, having minimum reading and writing literacy to complete the questionnaires, married, living with their spouse, sexually active, having been married for 3 years or more. , there are no known mental disorders in yourself and your spouse, other physical disorders such as thyroid, blood pressure, diabetes, cancers, etc. are not known in yourself and your spouse, and there are no known sexual disorders in yourself and your spouse. available and with a quota method (according to menopausal and non-menopausal women of reproductive age), will be included in the study through the health network and random allocation of people into two groups of 30 people will be done by the method of permutation blocks (size of each block = 6) . In addition to treatment and routine care, the intervention group will receive a course of CBT treatment for one month and in 8 sessions of 60 minutes. To prepare the content, the texts are first reviewed and after the content is approved by the professors of the psychology department and sexual health specialists, the study will be conducted by the researcher who has acquired the necessary training and skills and provides a valid certificate. Meetings are held virtually in Sky Room.

Category

Treatment - Other

2

Description

Control group: The control group receives only the routine treatment and care that they used to control and treat the heart disease.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers affiliated to Shahrekord University of Medical Sciences and Imam Ali (AS) Heart

Full name of responsible person

Zainab Tavakol

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Kashani Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Elham Raeisi

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Raeisi.e@skums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Zeinab Tavakol

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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Full name of responsible person
Fatemeh Mohammadi Arani

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Master

Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All study data including demographic information, Sexual self-efficacy status and sexual performance index before and after the intervention can be published.

When the data will become available and for how long
Only after publishing the article extracted from this data can be published.

To whom data/document is available
Researchers related to the research field

Under which criteria data/document could be used
In order to generalize the results of the research, after the publication of the article, if the researcher has a convincing reason to use the data and undertakes to refer to the information of this research.

From where data/document is obtainable
Send your request to the responsible person's email.

What processes are involved for a request to access data/document
Email request.

Comments