

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effectiveness comparison of online and telephone counseling on rational-emotional-behavioral therapy on sexual function of women undergoing cardiac rehabilitation

Protocol summary

Study aim

Effectiveness comparison of online and telephone counseling on rational-emotional-behavioral therapy on sexual function of women undergoing cardiac rehabilitation

Design

Clinical trial with online intervention group and control of rational-emotional-behavioral telephone intervention with parallel, randomized groups on 48 patients. Random allocation online site was used for randomization.
[Http://www.randomization.com](http://www.randomization.com)

Settings and conduct

Research environment of Afsharizd Hospital Using the online site of random allocation of women, they were divided into two groups of telephone intervention and online intervention control. Both groups receive eight 30- to 90-minute individual counseling sessions with the same content. Data collection tools at the beginning of the study are demographic questions. At the beginning of the study, the women's sexual function questionnaire is completed at the end of weeks 8 and 12 of the study. Data are analyzed by descriptive and inferential statistical tests.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women undergoing cardiac rehabilitation, Iranian ethnicity, literacy, internet literacy, having a file in the heart center of Afshar Hospital, heart disease and confirmation that sex is permissible for them, willingness to participate in the study, Do homework

Intervention groups

They are divided into two groups: telephone intervention and online control of intellectual-emotional-behavioral intervention.

Main outcome variables

1. Women's sexual function 2- Satisfaction with the counseling method

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201222049797N1**

Registration date: **2021-02-07, 1399/11/19**

Registration timing: **prospective**

Last update: **2021-02-07, 1399/11/19**

Update count: **0**

Registration date

2021-02-07, 1399/11/19

Registrant information

Name

fatemeh zahra memor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5227 4486

Email address

memar_fateme@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness comparison of online and telephone counseling on rational-emotional-behavioral therapy on sexual function of women undergoing cardiac rehabilitation

Public title

Effectiveness comparison of online and telephone counseling on rational-emotional-behavioral therapy on sexual function of women undergoing cardiac rehabilitation

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women undergoing cardiac rehabilitation Iranian ethnicity Literacy and literacy for both online and telephone counseling groups Internet and smart phone literacy for both groups Having a file at the heart center of Afshar Hospital Having heart disease approved by a cardiologist Sex is permissible for them They are being treated at the heart center of Afshar Hospital. Having the desire and interest to participate in the study is an agreement to do the relevant homework

Exclusion criteria:

Pregnancy Simultaneously participate in another study a history of other chronic mental and physical illnesses self-reported use of drugs other than drugs related to heart disease self-reported

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)

Randomized

Randomization description

The sample size includes 48 women. Each woman can be assigned a number between 1 and 48, which can be done by referring to the online site of random allocation. Currently, there are three models of random allocation, and considering that this model is in two groups, the first generation randomization model can be used. Each sample is placed in a treatment group and is done through the site.<http://www.randomization.com> Through the blocks that are on the site, groups A and B are entered in the treatment groups section, and then the number of samples, which is 48, is entered in the number of people in the treatment blocks, where the software of each sample They are randomly assigned to one of the two groups A and B, which means that the allocation of samples to each of the two groups does not occur in A and B, respectively, but in the order in which the software output is placed.

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 Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Murad Maleki.no 99

City

Zarrinshahr

Province

Isfahan

Postal code

8471846596

Approval date

2020-12-22, 1399/10/02

Ethics committee reference number

IR.SSU.REC.1399.205

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

Sexual function of patients undergoing cardiac rehabilitation

ICD-10 code

I24

ICD-10 code description

Other acute ischemic heart diseases

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

Change in the mean scores of sexual function, which is measured with the Mohammadi Women's Sexual Function Questionnaire

Timepoint

The female sexual function questionnaire is completed at the beginning of the baseline study, at the end of week 8 of the intervention and at week 12 at the end of the study.

Method of measurement

Women's sexual function, which is based on the questionnaire of Iranian species Mohammadi et al., Which measures women's sexual function in 6 areas, indicates a higher score of better sexual function.

Secondary outcomes

1

Description

Satisfaction with the counseling method is measured on a ten-part scale with a researcher-made questionnaire

Timepoint

At the end of week 8 and the end of week 12, the intervention of the intervention method is measured by a researcher-made questionnaire.

Method of measurement

Satisfaction with the consulting approach with a researcher-made questionnaire using related references (Cronbach's alpha 0.87) with four questions and a ten-part scoring scale with a minimum score of 4 and a maximum of 40

Intervention groups

1

Description

Intervention group: Intellectual-emotional-behavioral telephone counseling with 8 sessions of 30-90 minute individual counseling with the content of intellectual-emotional-behavioral counseling sessions once a week, according to the plan between the researcher and the client by the researcher after prior coordination with the women in this group. It is done individually by phone for 8 weeks. The cost of the phone call will be charged to the women's SIM cards until the end of the study

Category

Treatment - Other

2

Description

Control group: Online rational-emotional-behavioral counseling that received 8 sessions of 30-90 minute individual counseling with the content of intellectual-emotional-behavioral counseling sessions, through WhatsApp software and Skyroom software equipped with private space security in the form of multimedia and chat. The internet package is given to women free of charge in the online counseling group on a weekly basis until the end of the study period

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Heart Center of Mohammad Sadegh Afshar Hospital, Yazd

Full name of responsible person

Dr. Khalil Forouzannia

Street address

Jomhory St. - Mohammad Sadegh Afshar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masoud Mirzaei

Street address

5 km of Bafgh Old Road - International Branch of Shahid Sadoughi University of Medical Sciences and Health Services, Yazd

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Tahmineh Faraj Khoda

Position

PhD in Reproductive Health Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Yazd - Safaieh - Timsar Fallahi St. - Bouali Alley School of Midwifery Nursing

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Dr. Tahmineh Faraj Khoda

Position

PhD in Reproductive Health Associate Professor
Shahid Sadoughi University of Medical Sciences

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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