Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 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

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 memar

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
Isfehan

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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8917945556
Phone
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Email
afsharhospital@ssu.ac.ir

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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Province
Yazd
Postal code
8944158318
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+98 35 3836 7634
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international@ssu.ac.ir
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
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Person responsible for updating data

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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