Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Internet-Based Cognitive Behavior Therapy on sexual intimacy in woman whose husbands have spinal cord lesion

Protocol summary

Study aim
Determining the effect of counseling approach based on Internet-Based Cognitive Behavior Therapy on sexual intimacy in woman whose husbands have spinal cord lesion

Design
Clinical trials with community based and pragmatic control group, with parallel groups, Not blinded, randomized

Settings and conduct
After obtaining the necessary permits from the Vice Chancellor for Research and Technology and the University Ethics Committee, eligible women are invited to refer to the Yazd Spinal Cord Injury Association. After considering the inclusion and exclusion criteria, 60 people were targeted and based on the table of random numbers, people were divided into two equal groups of intervention and control. After obtaining informed consent, a sexual intimacy questionnaire and a demographic information questionnaire were completed by the subjects. Including 8 sessions of 90-minute weekly counseling after the classes and a month later the questionnaires were completed again and the results were analyzed using SPSS software.

Participants/Inclusion and exclusion criteria
inclusion criteria: The desire to participate in the study, being Iranian, age 18-45, having literacy and reading skills, married and having a spouse, the only person to be a spouse. exclusion criteria: alcohol and drug addiction, use of drugs affecting sexual function, diseases affecting sexual function, psychiatric disorders and pregnancy.

Intervention groups
Intervention group: 18- to 45-year-old women with spinal cord injury spouse who have low sexual intimacy. The intervention is performed in 8 sessions of 90 minutes for cognitive-behavioral therapy. Control group: 18- to 45-year-old women with spinal cord injury spouse who Receive general sexual health information in the form of pamphlets. (Active control)

Main outcome variables
Sexual intimacy score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220227054139N1**
Registration date: **2022-06-30, 1401/04/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-30, 1401/04/09**
Update count: **0**

Registration date
2022-06-30, 1401/04/09

Registrant information

Name
Maryam Malboubi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3824 1751

Email address
m.malboubi@stu.ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-23, 1401/03/02

Expected recruitment end date
2022-08-24, 1401/06/02

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Internet-Based Cognitive Behavior Therapy on sexual intimacy in woman whose husbands have spinal cord lesion

Public title

The effect of Internet-Based Cognitive Behavior Therapy on sexual intimacy in woman whose husbands have spinal cord lesion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women between the ages of 18-45 and their husbands have a spinal cord injury Be the only wife of the man Have at least one year of living together Live in a house during the research period and do not intend to divorce Have access to smart phone and internet Be willing to participate in virtual meetings Fill out a voluntary and informed online written consent form

Exclusion criteria:

The addiction of himself and his wife to drugs, according to the patient The use of psychiatric drugs by oneself and one's spouse according to the patient Pregnancy Participate in simultaneous psychological and psychiatric interventions

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 Shahid Sadoughi University of Medical Sciences, Yazd Sciences

Street address

Faculty of Midwifery Nursing، Bu'ali Alley،Thaisar Fallahi Avenue، Safaiyeh،Yazd

City

Yazd

Province

Yazd

Postal code

03538241757

Approval date

2021-12-21, 1400/09/30

Ethics committee reference number

IR.SSU.REC.1400.193

Health conditions studied

1

Description of health condition studied

Sexual intimacy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual intimacy score in the invalidity questionnaire

Timepoint

Measurement of sexual intimacy score before and after the intervention and one month after the intervention

Method of measurement

Sexual Intimacy Questionnaire (Persian text) based on Bagarozi Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Women 18-45 years old with a spinal cord injury spouse who has low sexual intimacy. The intervention is performed in 8 sessions of 90 minutes based on cognitive behavioral therapy.

Category

Behavior

2

Description

Control group: 18- to 45-year-old women with spinal cord injury who have low sexual intimacy and receive general sexual health information in the form of a pamphlet. (Active control)

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd Spinal Cord Association

Full name of responsible person
Maryam Malboubi

Street address
14th Alley, 52 meters from Imam Shahr (Valiasr Boulevard), 17 Shahrivar Boulevard, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Amir Houshang Mehrparvar

Street address
Faculty of Midwifery Nursing، Bu'ali Alley،Timsar Fallahi Avenue، Safaiyeh،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
Maryam Malboubi

Position
Master's degree in midwifery counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr Mahshid Bokaie

Position
PhD in Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
The results of the clinical study will be published as a article
When the data will become available and for how long
Immediately after publishing the results
To whom data/document is available
all researchers
Under which criteria data/document could be used
Scientific use with reference to article
From where data/document is obtainable
Email: m.malboubi@stu.ssu.ac.ir
What processes are involved for a request to access data/document
Up to one week after correspondence by email
Comments