

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 Bagarozzi 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

City

Yazd

Province

Yazd

Postal code

8917744499

Phone

+98 35 3525 2025

Email

maryam.malboubi@gmail.com

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

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3824 1757

Email

maryam.malboubi@gmail.com

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

Street address

Faculty of Midwifery Nursing, Bu'ali Alley,Timsar Fallahi Avenue. Safaiyeh.Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 38241757035

Email

maryam.malboubi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Mahshid Bokaie

Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Faculty of Midwifery Nursing, Bu'ali Alley,Timsar Fallahi Avenue. Safaiyeh.Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 38241757035

Email

mah_bokaie@yahoo.com

Person responsible for updating data

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

Street address

Faculty of Midwifery Nursing, Bu'ali Alley, Timsar
Fallahi Avenue, Safaiyeh, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 38241757035

Email

maryam.malboubi@gmail.com

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