

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of the effect of sexual rehabilitation training on anxiety and sexual satisfaction of spinal cord injury women

Protocol summary

Study aim

Determining the effectiveness of sexual rehabilitation training on anxiety and sexual satisfaction of women with spinal cord injuries

Design

In this study, the type of research is quasi-experimental with the control group. The sampling method is continuous and then randomly to be placed in two groups of control and intervention and the sample size in each group is 50 people. Data collection before and one Will be performed one month after the intervention.

Settings and conduct

The population of this study will be all people with spinal cord injuries who refer to the Iranian Spinal Cord Injury Support Association. And will include an introductory session and 2 training sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria of Women with spinal cord injuries: Age 18 to 55 years No underlying diseases Having literacy Lack of psychological diseases Do not use drugs Passing the spinal shock stage Willingness to participate in the study Exclusion criteria: Absence from attending training sessions Death of the patient

Intervention groups

Training intervention using video is based on a booklet that includes topics introducing spinal cord injury/sexual disorders caused by spinal cord injury/body image after the lesion and its recovery/regulation of bladder and intestinal activity/prevention of pressure ulcers/pain management/Spasticity/Appropriate environment/Time of use and side effects of medications and personal hygiene. In order to maintain ethics, the booklet will be given to the control group at the end of the intervention.

Main outcome variables

Anxiety is an adaptive reaction to the occurrence of coping behaviors to face potential risks and in this study, is based on the score obtained from the BAI. Sexual satisfaction is the degree to which people are satisfied with their sexual activity. In this study, sexual

satisfaction is the score of Larson Sexual Satisfaction Q.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210915052483N1**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **retrospective**

Last update: **2022-05-23, 1401/03/02**

Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

mahsa soleimani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3378 1332

Email address

mahsasoli74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

2021-10-25, 1400/08/03

Actual recruitment end date

2022-03-01, 1400/12/10

Trial completion date

2022-03-01, 1400/12/10

Scientific title

Evaluation of the effect of sexual rehabilitation training on anxiety and sexual satisfaction of spinal cord injury women

Public title

sexual rehabilitation training of women with spinal cord injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 55 years old Not having underlying diseases such as heart and lung diseases Having literacy (if not literate, having a literate caregiver present in the patient's cognitive rehabilitation process) Not having psychological illnesses According to the patient's statements not using drugs Passing the stage of spinal shock (having muscle tone and deep tendon reflexes) Willingness to participate in the study

Exclusion criteria:

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

☞The allocation of samples to the two groups will be randomly using Random allocation software. In this way, in addition to simple randomization, this software is also able to generate a random sequence by blocking method, which is the good for our study because the sample size of intervention and control group is the same.

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 Iran University of Medical Sciences

Street address

13th floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Iran TV Street, Ghods Town (West) - between South Flamek and Zarafshan,

City

Tehran

Province

Tehran

Postal code

1965441874

Approval date

2021-07-27, 1400/05/05

Ethics committee reference number

IR.IUMS.REC.1400.399

Health conditions studied

1

Description of health condition studied

spinal cord injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety is measured by the Beck Anxiety Inventory. A score of 0 to 21, a sign of very mild anxiety 22 to 35 indicates moderate anxiety and above 36 severe anxiety .Sexual satisfaction will be measured by the Larson Sexual Satisfaction Questionnaire. A score less than 50 indicates sexual dissatisfaction, 51-75 indicates low satisfaction, 76-100 indicates moderate satisfaction, and more than 100 indicates high sexual satisfaction.

Timepoint

Data collection will be done before and one month after the intervention.

Method of measurement

In this study, anxiety will be measured with Beck Anxiety Inventory and sexual satisfaction will be measured with Larson Sexual Satisfaction Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

2

Description

Control group:

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

protection center of spinal cord disables of Iran

Full name of responsible person

Ali zarrabi

Street address

Rehabilitation and Training Center for the Spinal Cord Injured of Jalaipour Martyrs, in front of Drapery Bazaar, Atashneshani St, behind Shahid Akbarabadi Hospital, Molavi St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hosein Keivani

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fifth floor of the headquarters, Iran University of Medical Sciences, Hemmat Highway next to Milad Tower,

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mahnaz Seyedoshohadayi

Position

Professor

Latest degree

Master

Other areas of specialty/work

Nursery

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Iran School of Nursing and Midwifery, Rashid Yasemi St, above Vanak Sq, Vali-e-Asr St.

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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

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data from the information of the questionnaires filled out by the participants, including the demographic questionnaire, Beck Anxiety Questionnaire and Larson Sexual Satisfaction Questionnaire, and the analysis of the answers as well as the informed satisfaction filled out by the participants are possible without mentioning the participants' information.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The use of documentation in similar studies is permitted.

From where data/document is obtainable

Mahnaz Seyedoshohadaee / Email:
Seyedoshohadaee.m@iums.ac.ir Mahsa Soleimani /
Email: mahsasoli74@gmail.com

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

The applicant must send his / her academic information along with the title of the research to the mentioned persons.

Comments