

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The effectiveness of PLISSIT, a sexual counseling model on sexual function and sexual adaption of women with spinal codr injury refered to Brain and spinal injury Repair Research Center(BASIR), Institution of Neuroscience

Protocol summary

Summary

Spinal cord injury is a common disability around the world and is a terrible event for patient, family and community. This situation can effect on several aspects of the patients including sexual life. Sexual dysfunctions following spinal cord injury usually occur due to autonomous sensory and motor nerves that may present as vaginal lubrication disturbance in women and erection disorder in men. Despite the medical treatment for the rehabilitation of patients, sexual adaption is a serious problem. Sexual adaptation in spinal cord injured patients include individual and interpersonal aspects. The aim of this study is assessment of the effectiveness of PLISSIT sexual counseling on sexual function and sexual adaption of women with spinal cord injury. This study is Randomised Clinical Trial (RCT) on 50 women with spinal cord injuries having at least one sexual problem that will be recruited purposefully. Random allocation to intervention and control groups will be done after obtaining informed consent. Intervention group will receive three 45 minute individual counseling sessions and control group just will receive routine care. The participants will be assessed for sexual function and adaptation, before, two weeks, and 8 weeks after intervention, and data collection will be done by FSFI and SAQ questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061631662N3**

Registration date: **2017-07-30, 1396/05/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-30, 1396/05/08

Registrant information

Name

Razieh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

raziehlotfi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Alborz University of Medical Sciences

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of PLISSIT, a sexual counseling model on sexual function and sexual adaption of women with spinal codr injury refered to Brain and spinal injury Repair Research Center(BASIR), Institution of Neuroscience

Public title

The effectiveness of PLISSIT, a sexual counseling model on sexual function and sexual adaptation of women with spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: participating in sessions regularly; having sexual activity; incomplete spinal cord injury; ability to read and write; to be available in the future month; having Iranian nationality; not having sexual disorder and chronic disease in partner. Exclusion criteria: become pregnant; marriage conflicts; occurring bitter events (death,...); well-known disease influence on sexual function; use some drugs that influence on sexual function.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Alborz University of Medical Sciences

Street address

North Takeghani-Azimiyeh

City

Karaj

Postal code

Approval date

2017-04-22, 1396/02/02

Ethics committee reference number

IR.ABZUMS.REC.1396.5

Health conditions studied

1

Description of health condition studied

Spinal cord injury

ICD-10 code

G80-G83

ICD-10 code description

Cerebral palsy and other paralytic syndromes

Primary outcomes

1

Description

Sexual function

Timepoint

Before, 4 weeks , and 8 weeks after intervention

Method of measurement

FSFI questionnaire

2

Description

Sexual adaptation

Timepoint

Before, 4 weeks , and 8 weeks after intervention

Method of measurement

SAQ

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will receive three 45 minute PLISSIT based (the first three stages) individual sexual counseling sessions weekly. Stage1: Permission Stage 2: Limited information Stage3: Specific suggestions

Category

Behavior

2

Description

The control group will receive routine care (an educational pamphlet).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and Spinal injury Repair Research Center (BASIR)-TUMS

Full name of responsible person

Mona Rezaei Fard

Street address

Imam Khomeini Hospital, Keshavarz Boulevard

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Mohammad Noorisepehr

Street address

North Taleghani street-Azimyeh

City

Karaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Alborz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences- School of Nursing and Midwifery

Full name of responsible person

Razieh Lotfi

Position

PhD.

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty