

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

A Comparative Study of the Effectiveness of a Combined Therapeutic Model with a Sexual Therapeutic-counselling Model on level of Sexual Satisfaction and Sexual Interactions of Couples with Spinal Cord Injury

Protocol summary

Study aim

Educational counseling

Design

Randomization method is a random assignment, and this method represents a large block for the total sample size, which means that the balance in the number of people assigned to each of the groups will be at the end of the study. For this purpose, the researcher will first complete a total sample volume Then randomly assign a set of them to the test group and assign the remainder to the control group. Inside, a lot of balls are placed inside a lot of balls. In this research half of the balls are assigned to the intervention group and the other half to the control group. Then, the balls are randomly taken out of the container without replacement and the resulting sequence is recorded. The sample size includes twenty-eight couples, one of them with spinal cord injury. They are divided into two groups of control and test. For the experimental group, a combined intervention (8 sessions and 2 sessions for pretest and post-test once a week), and for the routine group (control of general sexual education) The duration of one session for couples will be shared jointly. Is the same. After a referral session, treatment will continue. This was done in one blind spot and the participants were unaware of which section they were belonging to.

Settings and conduct

Blind rehabilitation centers

Participants/Inclusion and exclusion criteria

Age over 18 years old, at least one incomplete or complete spinal cord injury for one year or more, satisfaction Moderate and less sexually, no history of chronic psychological and physical illness except lesion S

Intervention groups

sci couple

Main outcome variables

sexual satisfaction

General information

Reason for update

Acronym

RCT

IRCT registration information

IRCT registration number: **IRCT20180430039484N1**

Registration date: **2018-05-18, 1397/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-18, 1397/02/28**

Update count: **0**

Registration date

2018-05-18, 1397/02/28

Registrant information

Name

Zahra Salmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2210

Email address

zsalmani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty
Scientific title
A Comparative Study of the Effectiveness of a Combined Therapeutic Model with a Sexual Therapeutic-counselling Model on level of Sexual Satisfaction and Sexual Interactions of Couples with Spinal Cord Injury

Public title
effectiveness of integration in couple therapy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
age over 18 years old sexual satisfaction moderate and lover at least one year of marriage at least cyclical agree
Exclusion criteria:

Age
From 18 years old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: 56
Randomization (investigator's opinion)
Randomized

Randomization description
Randomization allocation After determining the total sample size, randomly, a set of them was allocated to the test group and the remainder to the control group

Blinding (investigator's opinion)
Single blinded
Blinding description
Participants were blinded in this study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
medical University Tehran
Street address
gharib
City
Tehran
Province

Tehran
Postal code
1419733141
Approval date
2017-07-23, 1396/05/01
Ethics committee reference number
IR.Tums.REC.1394.1963

Health conditions studied

1
Description of health condition studied
Sexual problems of couples
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
Increased sexual satisfaction
Timepoint
At the beginning of the intervention and six weeks after the intervention
Method of measurement
questioner

Secondary outcomes

empty

Intervention groups

1
Description
For the experimental group, the intervention therapy (8 sessions and 2 sessions for the pre-test and post-test, once a week) and for the control group, the routine treatment (general education for one session for couples jointly) will be done. If the individual Sexually only has physiological problems and only needs medical treatment, but it is kept in research if there is a problem in interactions and a sexual problem. If the couples need referrals to a psychiatrist or psychologist and an orrologist, reference is made and this is possible for everyone. After a referral session, treatment will continue. During the intervention, couples who have undergone a premature and post-traumatic disorder have not participated in the medical or test sessions or for any reason desire to leave the study will be excluded from the study. Using the standard sexual satisfaction questionnaire Marital satisfaction, sexual knowledge, intimacy, marital adjustment, and the level of sexual performance before and after the intervention, the effect of treatment on couples and control will be investigated and compared between the two groups. Data were analyzed using SPSS 16 using paired t-test, t-test, Wilcoxon, Mann-Whitney, ANCOVA, and two-way ANOVA.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Jalaei poor_ Tarasht_ Emam khomeini hospital

Full name of responsible person

Dr.efatosadat merghati khoei

Street address

Gharib

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

zahra salmani

Position

resident

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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