Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

effectivness of integation in coupelthrapy

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

quesstioner

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

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Jalaei poor_ Tarasht _ Emam khomeini hospitial

Full name of responsible person
Dr.efatosadat merghati khoei

Street address
Gharib

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2210

Email
zsalmani@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr.efatosadat merghati khoei

Street address
gharib

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2210

Email
effat_mer@razi.tums.ac.ir

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
Academic

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

Street address
gharib

City
tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2210

Email
zsalmani@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
zahra salmani

Position
resedent

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
gharib

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2210

Email
zsalmani@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
zahra salmani

Position
reseadent
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Gharib
City
tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2210
Email
zsalmani@razi.tums.ac.ir

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