Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the Impact of Application-Based Sexual Empowerment with Lecture on Sexual Satisfaction of patient with Spinal Cord injury.

Protocol summary

Study aim
The comparison of the Impact of App-Based Sexual Empowerment with Lecture on Sexual Satisfaction among spinal cord injured patients

Design
A randomized controlled clinical trial with parallel groups, single blind

Settings and conduct
this study was conducted in Birjand. The duration of the intervention was two months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: injury from T8 to L2, 20 to 60 years old,being married,at least 6 months disability, reading and writing ability, smart phone and Internet access,hearing and vision health. Exclusion Criteria :Unwillingness to continue to participate in research and divorce.

Intervention groups
Application-based group:the required content was prepared using valid sources.the content was designed as an Android app.The educational content in the app was included in the form of audiovisual. The app was provided to the app-based group for 2 months.The main topics prepared in this application were marital relations, anatomy of genital systems and sexual behaviors, unrealistic beliefs about sexual issues in sexual intimacy . Lecture-based empowerment group:In order to implementation of intervention in the lecture-based group, a content similar to one provided for the application-based group was provided by the researcher. The content was provided using whiteboard and projector. This intervention was supervised by a South Khorasan Welfare Organization education expert. Based on the educational level, the participants in the lecture-based group was divided into three groups. Each group included 10 participants. Each session lasted about half to 1.5 hours.Intervention was given to the three groups in three separate days per week. The intervention lasted two months.Six weeks after the intervention, the questionnaires were completed

Main outcome variables
Sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190515043601N2**
Registration date: **2019-12-08, 1398/09/17**
Registration timing: **retrospective**

Last update: **2019-12-08, 1398/09/17**
Update count: **0**

Registration date
2019-12-08, 1398/09/17

Registrant information

Name
Hossein Rahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 56 3238 1427

Email address
hosseinrahimi92@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-01-22, 1397/11/02

Actual recruitment start date
2019-01-21, 1397/11/01

Actual recruitment end date

2019-01-22, 1397/11/02

Trial completion date

2019-06-25, 1398/04/04

Scientific title

Comparison the Impact of Application-Based Sexual Empowerment with Lecture on Sexual Satisfaction of patient with Spinal Cord injury.

Public title

Comparison the Impact of Application-Based Sexual Empowerment with Lecture on Sexual Satisfaction of patient with Spinal Cord injury.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Spinal cord injury from T8 to L2 20 to 60 years old being married at least 6 months disability reading and writing ability access to smart phones and the Internet visual and hearing health

Exclusion criteria:

Received systematic sex education from other institutions.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting 60 participants, they were divided into intervention and control groups using coin toss.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyzer in the study was unaware of the type of intervention performed for each group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

ayatollah Ghafari Blvd

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۵۷۷

Approval date

2018-11-20, 1397/08/29

Ethics committee reference number

IR.BUMS.REC.1397.235

Health conditions studied

1

Description of health condition studied

Sexual satisfaction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Larson Sexual Satisfaction Questionnaire scores

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Larson Sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Application-based group: the required content was prepared using valid sources. the content was designed as an Android app. The educational content in the app was included in the form of audiovisual. The app was provided to the app-based group for 2 months. The main topics prepared in this application were marital relations, anatomy of genital systems and sexual behaviors, unrealistic beliefs about sexual issues in sexual intimacy .

Category

Rehabilitation

2

Description

Control group: Lecture-based empowerment group: In order to implementation of intervention in the lecture-based group, a content similar to one provided for the

application-based group was provided by the researcher. The content was provided using whiteboard and projector. This intervention was supervised by a South Khorasan Welfare Organization education expert. Based on the educational level, the participants in the lecture-based group was divided into three groups. Each group included 10 participants. Each session lasted about half to 1.5 hours. Intervention was given to the three groups in three separate days per week. The intervention lasted two months. Six weeks after the intervention, the questionnaires were completed

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Welfare Organization of South Khorasan Province-Birjand

Full name of responsible person

Ali Arabnejad

Street address

End of Sanat and madan Street, Masoumieh

City

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Province

South Khorasan

Postal code

9717698751

Phone

+98 56 3240 0550

Email

Aliarabnejad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Tuba Kazemi

Street address

Ayatollah Ghafari Blvd

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۵۷۷

Phone

+98 56 3244 0260

Email

drtooba.kazemi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Hossein Rahimi

Position

Instructor, Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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hosseinrahimi92@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Hossein Rahimi

Position

Instructor,Faculty member

Latest degree

Master

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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Once unrecognizable, all information is shared

When the data will become available and for how long

The access period will start in winter 1399

To whom data/document is available

All information will only be available to researchers working in academia

Under which criteria data/document could be used

After sending the request by email, the information will be sent within one month

From where data/document is obtainable

Researchers can submit their request to Hosseinrahimi92@yahoo.com. Only requests sent by email will be answered.

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

After submitting the request by email, the applicant's identity will be requested from the relevant organization within one week.Upon verification, the information will be provided in an email

Comments