

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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 implement the 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 were 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**  
9717853577  
**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**

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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**

9717803077

**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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**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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hosseinrahimi92@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Hossein Rahimi

**Position**

Instructor, Faculty Member

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**Phone**

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**Email**

hosseinrahimi92@yahoo.com

## 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