

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of mobile-based APP education on sexual adjustment sexual satisfaction, marital adjustment and marital satisfaction of men with spinal cord injury

Protocol summary

Study aim

The effect of mobile-based educational intervention on sexual adjustment, sexual satisfaction, marital adjustment and marital satisfaction with spinal cord injury

Design

This study was a randomized controlled trial (RCT) with a parallel control group.

Settings and conduct

The application is designed to be installed on the smartphone of the intervention group and its use is explained. The intervention consists of three phases of pre-test, content training, and post-test. The app is designed to allow active training content to be immediately integrated into the intervention group after completing the pre-test form, and the group will have access to educational content for up to 8 weeks at any time and place on their mobile phone. After completing the training, the first test will be activated, and at the end of the first test, a message will be sent to the individual who will read the next 4 weeks to complete the second test. After loading and installing the application, the control group can only access the pre-test section on their mobile phone. Educational content is disabled for this group. 4 and 8 weeks after the end of the intervention, the post-test section is activated for the control group. At the end of the intervention, the control group will have access to educational content.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Man with spinal cord injury Having aged over 18 years old Ability to speak Persian, Interested in participating in the study, having a mobile phone with Android system, Exclusion Criteria Chronic psychological diseases, History of drug abuse.

Intervention groups

Will receive intervention about Sexual Adjustment and Marital Adjustment Relationships via SAMAR Mobile

based-App

Main outcome variables

Sexual Adjustment and Marital Adjustment Relationships

General information

Reason for update

End of data collection

Acronym

IRCT registration information

IRCT registration number: **IRCT20181205041861N2**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **prospective**

Last update: **2020-01-11, 1398/10/21**

Update count: **1**

Registration date

2019-07-08, 1398/04/17

Registrant information

Name

Sara Kazemi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8882 4546

Email address

sara.kazemi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-10, 1398/04/19

Expected recruitment end date

2019-11-10, 1398/08/19

Actual recruitment start date

2019-07-10, 1398/04/19

Actual recruitment end date

2019-11-10, 1398/08/19

Trial completion date

2019-11-10, 1398/08/19

Scientific title

The effect of mobile-based APP education on sexual adjustment sexual satisfaction, marital adjustment and marital satisfaction of men with spinal cord injury

Public title

Mobile Phone Applications Education In SCI

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The mere man's involvement in spinal cord injury Type of incomplete or complete traumatic spinal cord injury Duration of damage for one year or more Having aged over 18 years old Ability to speak Persian, Interested in participating in the study At least one year of life in common marriage Not attending couples' training classes before the study Having a minimum level of literacy Having a mobile phone with Android system The age difference of couples is less than or equal to 10 years Not having a history of infertility

Exclusion criteria:

People whose spinal cord injury is due to other diseases or non-traumatic causes. History of or chronic psychological disorders such as depression and anxiety History of physical problems other than spinal cord injury Excessive brain damage leading to cognitive problems History of drug abuse and history of using psychiatric drugs in the last six months

AgeFrom **18 years** old**Gender**

Male

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70**Actual sample size reached: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

Individuals were randomly assigned to two groups of Intervention and control.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran, Keshavarz Blvd., Ghodss St., Central Office, Tehran University of Medical Sciences, Seventh Floor, Educational Assistant

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2016-02-22, 1394/12/03

Ethics committee reference number

IR.TUMS.REC.1394.2049

Health conditions studied**1****Description of health condition studied**

Sexual adjusment

ICD-10 code

Z70.0

ICD-10 code description

Counselling related to sexual attitude

Primary outcomes**1****Description**

Sexual adjustment

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Hospital Anxiety and Depression Scale(SAQ)

2**Description**

Sexual Satisfaction

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Sexual adjustment questionnaire Larson's

3

Description

Marital adjustment

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Spinner's Marital adjustment

4

Description

Sexual-Satisfaction

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Sexual-Satisfaction scale

Secondary outcomes

1

Description

Mean score of Sexual Adjustment

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Via Hospital Anxiety and Depression Scale (SAQ)

2

Description

Mean score of Sexual satisfaction

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Larson's Sexual-Satisfaction scale

3

Description

Mean score of Marital adjustment

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Spinner's' Marital adjustment questionnaire

4

Description

Mean score of Marital satisfaction

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Via Marital Satisfaction ENRICH

Intervention groups

1

Description

Intervention group: The application is designed to be installed on the smartphone of the intervention group eg ; Men with spinal cord injury and its use is explained. The intervention consists of three phases of pre-test, content training, and post-test. The app is designed to allow active training content to be immediately integrated into the intervention group after completing the pre-test form, and the group will have access to educational content for up to 8 weeks at any time and place on their mobile phone. After completing the training, the first test will be activated, and at the end of the first test, a message will be sent to the individual who will read the next 4 weeks to complete the second test.

Category

Behavior

2

Description

Control group: After loading and installing the application, the control group can only access the pre-test section on their mobile phone. Educational content is disabled for this group. 4 and 8 weeks after the end of the intervention, the post-test section is activated for the control group. At the end of the intervention, the control group will have access to educational content.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Veterans Center of the Martyr Foundation and Affairs

Full name of responsible person

Dr Raziye Masoomi

Street address

Taleghani Street - next to the Revolution Hotel - the central building of the Martyr Foundation and the affairs of the emperors

City

Tehran

Province

Tehran

Postal code

1234567890

Phone

+98 21 8894 7618

Email

issar@gmail.com

Sponsors / Funding sources

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohamadali Sahraeiyan

Street address

Tehran Province, Tehran, District 6, Nosrat St

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6692 7171

Email

ncrc.iums@gmail.com

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**

Tarbiat Modares University

Full name of responsible person

Fatemeh Zarei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Tehran, Jalal Ale Ahmad ,Nasr.Tarbiat Modares University

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 4546

Email**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Fatemeh Zarei

Position

Assistant professor

Latest degree

Ph.D.

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Health Promotion

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City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 4546

Email

f.zarei@modares.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Fatemeh Zarei

Position

Assistant Professor

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Email

f.zarei@modares.ac.ir

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic information is confidential, but information about the outcome of the participant's behavior is shareable.

When the data will become available and for how**long**

A week after receiving the request via email to the corresponding researcher

To whom data/document is available

Researchers in academic institutions

Under which criteria data/document could be used

Deputies of health in Medical Universities

From where data/document is obtainable

Contact with Dr.Fatemeh Zarei as the corresponding researcher via email: f.zarei@modares.ac.ir

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

A week after receiving the request via email the corresponding researcher

Comments