Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Acceptance and Commitment Therapy on Cognitive Flexibility and Emotional Regulation of Patients with Spinal Cord Injury and MS Patients

Protocol summary

Study aim
Determining the effectiveness of acceptance and commitment therapy on psychological flexibility and emotional regulation in patients with spinal cord injury and multiple sclerosis

Design
Clinical trial, randomized, with control group

Settings and conduct
This research is done on the psychological problems of patients with spinal cord and multiple sclerosis in Tehran.

Participants/Inclusion and exclusion criteria
The inclusion criteria for patients with spinal cord injury: - age between 20 and 55 years. - education at least diploma. - live in Tehran. - At least one year after lesion. - A maximum of five years from the time of the lesion. - Ability to use upper extremity. Exclusion criteria for patients with spinal cord injury: - cervical spinal cord injury. - Have alcohol or drugs. - Simultaneously undergo another psychological treatment. - have more than two absentee sessions. - Have brain damage. The criteria for the entry of MS patients - Have ages between 20 and 55 years old. - Have at least a diploma. - live in Tehran. - At least one year from the time of illness. - A maximum of five years from the end of the illness. - Based on the ICF index, they have the ability to use the upper limb. MS patient exit criteria - Multiple sclerosis is benign. - Have alcohol or drugs. - Simultaneously undergo another psychological treatment. - have more than two absentee sessions. - have memory problems.

Intervention groups
The intervention group included 15 patients with spinal cord injury and 15 patients with multiple sclerosis who received acceptance and commitment treatment for eight sessions.

Main outcome variables
Psychological flexibility and emotional regulation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180710040411N3**
Registration date: **2018-11-24, 1397/09/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-24, 1397/09/03**
Update count: **0**

Registration date
2018-11-24, 1397/09/03

Registrant information

Name
Javad Kazemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2218 0061

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sa.khanjani@uswr.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2018-12-21, 1397/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effectiveness of Acceptance and Commitment Therapy on Cognitive Flexibility and Emotional Regulation of Patients with Spinal Cord Injury and MS Patients

Public title
The Effectiveness of Acceptance and Commitment Therapy on Cognitive Flexibility and Emotional Regulation of Patients with Spinal Cord Injury and MS Patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria for sci have at least a diploma education reside in Tehran Aged between 20 and 55 years old At least one year has passed since the time of the lesion. Maximum five years from the time of the lesion. Inclusion criteria for MS have at least a diploma education reside in Tehran Aged between 20 and 55 years old at least one year pass from the end of the illness maximum five years passed from the illness Based on the ICF indicator, the ability to Use of upper limbs

Exclusion criteria:
Exclusion criteria for sci Have cervical spinal cord injury Simultaneously undergo another psychological treatment Have alcohol or drugs use. Have brain damage have more than two absentee sessions Exclusion criteria for MS Multiple sclerosis is benign Using alcohol or drugs have more than two absent sessions have memory problems Simultaneously undergo another psychological treatment

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to select the samples in the experimental and control groups, simple random method with Using random numbers, was used. Randomizing unit was individually. Therefore, according to the inclusion and exclusion criteria among the patients with spinal cord and MS which were referred to the center of the SCI in Shahid Jalayipoor in Tehran and the MS Society of Iran in 2018, 60 patients (30 patients with sci and 30 MS patients) were selected.

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
The Ethics Committee of of the Educational Deputy of the University of Welfare and Rehabilitation Sc

Street address
No.1, javadi ally., Mazandaran st., Emam Hossin sq., Tehran

City
Tehran

Province
Tehran

Postal code
1481886593

Approval date
2018-07-04, 1397/04/13

Ethics committee reference number
IR.USWR.REC.1397.019

Health conditions studied

1

Description of health condition studied
Spinal cord injury

ICD-10 code
T91.3

ICD-10 code description
Sequelae of injury of spinal cord

2

Description of health condition studied
multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Cognitive Flexibility: Cognitive Flexibility refers to the ability of individuals to focus on the present situation and to take advantage of opportunities to position them in pursuit of intrinsic goals and values, despite the presence of challenging or unwanted psychological events (for example, thoughts, feelings , Physiological emotions, mental images and memories).

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Questionnaire

2

Description

The emotional setting is a unique process that modifies the emotional experience to achieve social acceptance and relates to physical and psychological states in response to internal or external demands.

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 15 patients with SCI receiving 8 sessions of acceptance and commitment therapy. This treatment is a type of third wave of cognitive therapy that, instead of changing the thoughts works on responses to thoughts, allows them to accept them. By accepting emotions and changing the response to Thoughts in this therapy are a form of flexibility in the individual, and this flexibility makes one committed to act in its original and intrinsic values.

Category

Rehabilitation

2

Description

Intervention group: intervention group 2: consists of 15 patients with MS who receive 8 sessions of acceptance and commitment therapy. This treatment is a type of third wave of cognitive therapy that, instead of changing the thoughts works on responses to thoughts, allows them to accept them. By accepting emotions and changing the response to Thoughts in this therapy are a form of flexibility in the individual, and this flexibility makes one committed to act in its original and intrinsic values.

Category

Rehabilitation

3

Description

Control group: Control group 1: has 15 patients with spinal cord injury who do not receive treatment.

Category

N/A

4

Description

Control group: Control group 2: consists of 15 patients with MS who do not receive treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Jalaypour's Spinal Cord Injury Center

Full name of responsible person

Ali Zarabi

Street address

Shaheed Jalayipour spinal cord center., behind Shaheed Akbar Abadi Hospital., Mowlavi street.,Tehran

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ندارد

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2

Recruitment center

Name of recruitment center

Rofeideh Hospital

Full name of responsible person

Mohammad Saeed Khanjani

Street address

Rofeideh Rehabilitation Hospital., Nemati Alley., Soleimani St., Ghaytrieh.,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Mohamad Saeed Khanjani

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University of Social Welfare and Rehabilitation Sciences., Khodakyar Alley., Student street.,Shahid Shahriyari Square.,Tehran
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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
University of social welfare and rehabilitation sciences

Proportion provided by this source
0

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
University of social welfare and rehabilitation sciences
Full name of responsible person
Javad Kazemi
Position
PHD student
Latest degree
Master
Other areas of specialty/work
Psychology
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University of Social Welfare and Rehabilitation Sciences., Khodakyar Alley., Student street., Shahid Shahriyari Square., Tehran
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results will be published without mentioning the names of the participants

When the data will become available and for how long

10 months

To whom data/document is available

Supervisors-Researchers - Journalists

Under which criteria data/document could be used

The data will be published without mentioning the names of individuals for presentation in research journals.

From where data/document is obtainable

Will be consulted by the University's Ethics Committee

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

About three months after the completion of the project, the results of the research will be received by the applicant.

Comments