

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of acceptance and commitment therapy on the sense of coherence, Locus of Control and post-traumatic growth in patients with spinal cord injury and MS

Protocol summary

Study aim

Determining the Effectiveness of Acceptance and Commitment Therapy on the Sense of coherence, Locus of Control, and Post-Traumatic Growth in Patients with Spinal Cord Injury and Multiple Sclerosis

Design

Clinical trial - has a randomized 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 criteria for entering patients with spinal cord injury - Have ages between 20 and 55 years old. - Have at least a diploma. - live in Tehran. - At least one year from the time of the lesion. - A maximum of five years from the time of the lesion. - Ability to use your upper extremity. Criteria for the withdrawal of patients with spinal cord injury - Their 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 for eight sessions.

Main outcome variables

Sense of coherence, Locus of Control, Post-Traumatic Growth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180710040411N1**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

Javad Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0061

Email address

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

Effectiveness of acceptance and commitment therapy on the sense of coherence, Locus of Control and post-traumatic growth in patients with spinal cord injury and MS

Public title

Effectiveness of acceptance and commitment therapy on the sense of coherence, Locus of Control and post-traumatic growth in patients with spinal cord injury and MS

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

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

Exclusion criteria:

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

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

Random sampling is used to select the samples and random assignment of the subjects to the experimental and control groups is also performed.

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

The sense of coherence: the sense of mental integrity, a general orientation, a penetrating, sustainable and dynamic basis of assurance that the life events to which one is confronted is comprehensible, structured, and explainable, resources to deal with them And these events are meaningful and worthy of engagement

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Antonovsky 's Sense of coherence scale

2

Description

Locus of Control: The concept of Locus of Control refers

to the ability of humans to control environmental conditions and events. On the basis of this concept, people are divided into two categories: one, people with an internal Locus of Control, who perceive themselves to dominate their feelings, behavior, and living conditions, actively seek to modify and reform it, and the successes and They attribute their failures to their intrinsic factors. Second, individuals who have external control, who do not control themselves on their own circumstances and events, attribute their life events to external factors such as the chance, fate, and power of others. Indeed, it seems that these people do not rely on their abilities and efforts

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Julian Rotter's Locus of Control scale

3

Description

Post-traumatic Growth: Post-traumatic Growth As the mental experience of a positive mental change, the individual's struggle with a traumatic event is defined. An increase in the appreciation of life, the new priorities in life, the enhancement of personal self-esteem, the identification of new opportunities, the improvement of intimate relationships or spiritual change are examples of these positive psychological changes.

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Tedeschi & Calhoun post-traumatic traumatic growth scale

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 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

City

Tehran

Province

Tehran

Postal code

ندارد

Phone

+98 21 5515 6450

Email

sa.khanjani@uswr.ac.ir

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

City

Tehran

Province

Tehran

Postal code

ندارد

Phone

+98 21 2220 5326

Email

sa.khanjani@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Mohamad Saeed Khanjani

Street address

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

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 2218 0083

Email

sa.khanjani@uswr.ac.ir

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

5

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

Street address

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

City

Tehran

Province

Tehran

Postal code

65571-37347

Phone

+98 21 2218 0061

Email

kazemi012@gmail.com

Person responsible for scientific 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

Street address

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

City

Tehran

Province

Tehran

Postal code

65571-37347

Phone

+98 21 2218 0061

Email

kazemi012@gmail.com

Person responsible for updating data

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

Street address

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

City

Tehran

Province

Tehran

Postal code

65571-37347

Phone

+98 21 2218 0061

Email

kazemi012@gmail.com

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