

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Effectiveness of Self-Transcendence Based Intervention on Self-Coherence and Loneliness of Individuals with Spinal Cord Injury: A Clinical Randomized Trial

Protocol summary

Study aim

Determining the effect of self-transcendence intervention on self-cohesion and loneliness in people with spinal cord injury+

Design

A clinical trial with a control group, one-way blind, randomized, on 44 patients with spinal cord injury

Settings and conduct

A clinical randomized control trial design with waiting list control group was used. A total of 44 men with SCI selected by purposeful sampling and were assigned randomly in experimental and control groups. The participants of experimental group received 8 sessions of self-transcendence based intervention and control group was on the waiting list. All participants answered to the sense of coherence and loneliness scales as dependent variables at 3 time points (pre, post and 2-month follow-up test).

Participants/Inclusion and exclusion criteria

Criteria for inclusion in the study were as follow: 1- Inclination to participate in the study 2- has at least school education, and 3- age between 40-50 years; Criteria for exclusion were included having a specific mental disorders and receiving other psychological treatments.

Intervention groups

The intervention program was based on Frankel's theory of existence and Reed's theory of transcendence. The sessions were conducted by a third author who had previously received training in the transcendental approach. The waiting list control group did not receive any intervention during the experimental period. The control group, as placebo, received explanations of the psychological consequences of spinal cord injury in three sessions. The control group was placed on a waiting list and after the end of the study, due to ethical issues, received all the interventions of the experimental group.

Main outcome variables

Self-Coherence, Loneliness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044798N1**

Registration date: **2022-07-20, 1401/04/29**

Registration timing: **retrospective**

Last update: **2022-07-20, 1401/04/29**

Update count: **0**

Registration date

2022-07-20, 1401/04/29

Registrant information

Name

Yasser Rezapour-Mirsaleh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3224 3027

Email address

y.rezapour@ardakan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-27, 1398/08/05

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

2022-02-20, 1400/12/01

Actual recruitment end date

2022-04-19, 1401/01/30

Trial completion date
2022-04-19, 1401/01/30

Scientific title
The Effectiveness of Self-Transcendence Based Intervention on Self-Coherence and Loneliness of Individuals with Spinal Cord Injury: A Clinical Randomized Trial

Public title
The Effectiveness of Self-Transcendence Based Intervention

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Inclination to participate in the study has at least school education age between 40-50 years
Exclusion criteria:
Having a specific mental disorders Receiving other psychological treatments

Age
From **40 years** old to **50 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **56**
Actual sample size reached: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Among individuals with spinal cord injury referring to rehabilitation centers of Abadeh City (Iran), a total of 44 male patients were selected by purposeful sampling; Then they were randomly assigned to control and experimental groups. Simple randomization by a table of random numbers was used to assigned the participants in the experimental and control groups; In order to use the table of random numbers, it was first decided to read the numbers from the top of the table. The numbers 01-22 were selected for the experimental group and the numbers 23-44 were selected for the control group. Allocation concealment was also used to ensure that the randomization sequence was performed without knowing which patient received which treatment. In the implementation of the randomization process, the researcher who was involved in creating the randomization plan was different from the researcher who was involved in enrolling the participants. We tried to eliminate the bias that can be created by the awareness of the researcher who creating the random sequence.

Blinding (investigator's opinion)
Single blinded

Blinding description
Because the participants in the control group also

participated in several sessions about psychological consequences of spinal cord injury as a placebo, none of the participants in the experimental and control groups were aware of how the study groups were assigned.

Placebo
Used

Assignment
Parallel

Other design features
Parallel groups were chosen because the participants of control group received a placebo intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
دانشگاه آزاد یزد
Street address
Shohadaye Gomnam Blv
City
Yazd
Province
Yazd
Postal code
8916871967

Approval date
2020-01-27, 1398/11/07
Ethics committee reference number
IR.IAU.YAZD.REC.1398.057

Health conditions studied

1

Description of health condition studied
آسیب نخاعی
ICD-10 code
S14.10
ICD-10 code description
Unspecified injury of cervical spinal cord

Primary outcomes

1

Description
Level of loneliness feeling score

Timepoint
All participants answered to the UCLA loneliness scale as dependent variable at 3 time points (pre, post and 2-month follow-up test).

Method of measurement
Loneliness was measured using a standardized questionnaire entitled "the UCLA Loneliness Scale", the validity and reliability of its Persian version has been confirmed in an Iranian sample.

2

Description

Level of self-cohesion score

Timepoint

All participants responded to the Sense of Self Coherence (SOS) scale to measure self-cohesion as the dependent variable at 3 time points (pre-test, post-test, and 2-month follow-up test).

Method of measurement

Self-cohesion was measured using a standardized questionnaire entitled "Sense of Self Coherence (SOS) scale" which has been provided by Antonovsky (1987); the validity and reliability of the its Persian version has been confirmed in an Iranian sample.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants of experimental group received 8 sessions of self-transcendence based intervention. The duration of each session was approximately 90 minutes. Intervention protocol was based on Frankl's existential theory and reed's self-transcendence theory. According to self-transcendence theories, a self-transcendent person seeks to understand the nature of the world, herself or himself values and meaning of life; he/she looks at life and relates with humans and the world in a transcendent manner. Therefore, in intervention sessions, concepts such as self-awareness, self-worth and spirituality were discussed; how to interact with others, hope in life, acceptance of problems, life events and death with a self-transcendence manner were taught. The sessions were conducted by one of the authors who had previously received necessary training in self-transcendence approach.

Category

Rehabilitation

2

Description

Control group: The control group was on the waiting list but received three placebo sessions including general descriptions of the characteristics of spinal cord injury

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emami occupational therapy

Full name of responsible person

Elham Emami

Street address

Jomhour

City

Abadeh

Province

Fars

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7391154198

Phone

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Email

elham.emami@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardakan University

Full name of responsible person

Yasser Rezapour-Mirsaleh

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Ayatollah Khatami Blv.

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Phone

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Email

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Grant name

Grant code / Reference number

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

No

Title of funding source

Ardakan University

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

Ardakan university

Full name of responsible person

Yasser Rezapour-Mirsaleh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardakan University

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Ardakan University

Full name of responsible person

Yasser Rezapour-Mirsaleh

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The output of statistical software can be shared after identifying individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers of academic institutions

Under which criteria data/document could be used

The data are available from the corresponding author upon reasonable request

From where data/document is obtainable

Corresponding Author (Yasser Rezapour-Mirsaleh)

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

Send email to correspondence author

Comments