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)

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+98 35 3224 3027

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardakan University
Full name of responsible person
Yasser Rezapour-Mirsaleh
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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
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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 tare 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