Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the Effectiveness of Psychological Capital Intervention and Cognitive Behavioral Therapy on Psychological Capital and Psychological Well-Being of Patients with Spinal Cord Injury

Protocol summary

Study aim

The present study was conducted with the aim of Comparison of The Effectiveness Psychological Capital Intervention and Cognitive Behavioral Therapy on Psychological Capital and Psychological Well-Being of Patients with Spinal Cord Injury in Isfahan city.

Design

A clinical trial with a control group with parallel groups, purposive sampling and random replacement in two experimental groups and one control group.

Settings and conduct

Hana charity (spinal injury support association of Isfahan province)

Participants/Inclusion and exclusion criteria

The criteria for entering subjects were: 1- Spinal cord injury in paraplegic patients 2- Informed consent of patients 3- Patients not receiving other psychological interventions at the same time 4- having a minimum level of literacy of the patients in terms of reading and writing Also, the subjects' exit criteria were: 1- Absence of more than two patient sessions 2- Aggravation of the disease and deterioration of the patients 3- Lack of necessary cooperation of patients in the process of treatment and doing homework and exercises

Intervention groups

In this research, the sessions of the psychological capital intervention group and the cognitive behavioral therapy group were conducted in 8 weekly sessions of 90 minutes as a group, and the control group did not receive any intervention or treatment.

Main outcome variables

there was a significant difference between the effectiveness of the psychological capital intervention and cognitive behavioral therapy on the psychological capital and psychological well-being of spinal cord injury patients, and the effectiveness of the psychological capital intervention on improving the psychological capital and psychological well-being of spinal cord injury patients was greater than cognitive behavioral therapy ($p<0.05$).

General information

Reason for update

Acronym

PCI, CBT

IRCT registration information

IRCT registration number: **IRCT20240311061252N1**
Registration date: **2024-09-15, 1403/06/25**
Registration timing: **retrospective**

Last update: **2024-09-15, 1403/06/25**
Update count: **0**

Registration date

2024-09-15, 1403/06/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-03-08, 1401/12/17

Actual recruitment start date

2023-02-25, 1401/12/06

Actual recruitment end date

2023-03-13, 1401/12/22

Trial completion date

2023-08-30, 1402/06/08

Scientific title

Comparison the Effectiveness of Psychological Capital Intervention and Cognitive Behavioral Therapy on Psychological Capital and Psychological Well-Being of Patients with Spinal Cord Injury

Public title

Comparison the Effectiveness of Psychological Capital Intervention and Cognitive Behavioral Therapy on Psychological Capital and Psychological Well-Being of Patients with Spinal Cord Injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Spinal Cord Injury

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **51**

Actual sample size reached: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were selected by purposive sampling and randomly divided into two experimental groups and one control group.

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

Research Ethics Committees of Islamic Azad University- Najafaba Branch

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No. 93, Khayam Alley, Taleghani Blvd, Dolatabad, Isfahan

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Approval date

2023-04-06, 1402/01/17

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1402.023

Health conditions studied

1

Description of health condition studied

Spinal Cord Injury

ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

Primary outcomes

1

Description

Psychological capital score of patients with spinal cord injury

Timepoint

Pre-test, post-test, follow-up

Method of measurement

McGee et al.'s Psychological Capital Questionnaire (2011)

Secondary outcomes

1

Description

Psychological Well-being score of Patients with Spinal Cord Injury

Timepoint

Pre-test, post-test, follow-up

Method of measurement

Psychological Well-being Scale by Ryff (1989)

Intervention groups

1

Description

Intervention group: Psychological Capital Intervention. Psychological Capital Intervention is a conceptual and practical sequence of teaching and training principles that focus on the promotion of human capital (who a person is in terms of his knowledge, experience and skills) by recognizing what a person is to achieve further promotion of psychological capital (who is (a person is and what he can be) is centered through the recognition

of what he can be. In Psychological Capital Intervention, emphasis on the upgradable nature of the components of psychological capitals (self-efficacy, optimism, hope and resilience) and as a result of the improvement of its central structure, after the combination of these components has been promoted. This intervention was implemented on the patients during 8 90-minute group sessions and weekly by the therapist based on the concepts and educational plan of Luthans, Yossef and Avolio. The first sessionIn: this meeting, in order to get familiar with the concepts and expectations from the intervention, as well as hope and despair and the characteristics of hopeful, optimism, real pessimism and unrealistic optimism and the difference between them, the concept of self-efficacy and the concept of resilience were defined and about the characteristics of people Self-efficacy and characteristics of resilient people were discussed. Next, the relaxation technique was taught. At the end of the session, self-sedation exercises were presented and explained, and then the session was summarized and feedback was received from the patients. The second session: At the beginning of the session, the previous session was reviewed. In the following, the goals, paths and motivating factors of the patients were determined and the obstacles to achieving them were investigated, also the concept of learned desperation and its role in optimism and pessimism was taught and the role of learned desperation in reducing self-efficacy was discussed. Problem-oriented and emotion-oriented solutions were presented to deal with tension. In the next step, patients were taught mindfulness. At the end of the session, the practice of examining one's abilities, the practice of remembering three good things, and the practice of mindfulness were presented and explained to the patients. The third session: At the beginning of the meeting, the tasks of the previous meeting were reviewed. In the following, materials were presented to familiarize with the role of goals in creating and increasing hope, familiarization with the documentation process and the concept of source of control, examining the relationship between motivation, will and self-confidence with self-efficacy, and in the next step, the use of expression feedback technique and definitions of the concept. Stubbornness and the introduction of its components (commitment, challenge and restraint) were presented. At the end of the muttering of positive pleasures exercise, the gratitude exercise was presented and explained to the patients. The fourth session: At the beginning of the meeting, the tasks of the previous meeting were reviewed. In the following, materials were presented to learn how to achieve clear and attainable goals, learn about positive emotions, learn about internal, external, general, specific, stable and unstable documents and the role of each in optimism, and how to increase self-confidence. And the self-efficacy of investigation and the use of positive feedback technique was expressed Also, explanations were given about focusing on the commitment component, focusing on the challenge component, how to turn problems into challenges and increase the willingness to face them for patients. At the end of the positive feedback exercise session, the exercise of struggling with pessimistic thoughts and beliefs was presented and explained to the patients, and the preparation of a list of important life goals was also emphasized. The fifth session: At the beginning of the meeting, the tasks of the previous meeting were reviewed. In the following, how to divide a big goal into smaller goals in order to increase the probability of their realization was taught, as well as materials to get familiar with the role of documents in optimism, and in the next step, the upward arrow was taught, and together with the patients, they tried to focus. He became a moderator on the component; In the following, there was a discussion about how to increase the sense of control over life. At the end of the open door and closed door exercise session, mental imagery exercise in order to create positive experiences and strengthen it, and the upward arrow exercise were presented and explained to the patients, and then the patients' feedback from the session was examined. The sixth session: At the beginning of the meeting, the tasks of the previous meeting were reviewed. In the following, materials related to how to formulate clear and objective goals, knowledge of scientific methods of problem solving and their practical role in increasing the level of self-efficacy were presented, as well as training on how to create and expand internal positive documents and training on visualization and persuasion. It was spoken. Emphasis was also placed on the use of the substitution strengthening technique through the presentation of examples in order to become more familiar with problem-oriented and emotion-oriented strategies. At the end of the session, the analysis of unpleasant events was presented and explained to the patients, and the contents expressed in the meeting were summarized. The seventh session: At the beginning of the meeting, the tasks of the previous meeting were reviewed. In the following, in order to learn about the role of setting daily goals in the realization of big goals and how to do it, to learn about how to use multiple paths in the realization of the goal, materials were presented. Also, explanations were given regarding the use of direct reinforcement and substitution through the discussion of previous successes in order to increase self-efficacy, and the role of the inhibitory place in stubbornness was discussed, as well as emphasizing more familiarity with problem-oriented strategies and encouraging patients to use them more. It was one of these strategies. At the end of the verbal persuasion training session, the practice of positive self-talk to increase the level of resilience was presented and explained to the patients. The eighth session: In this final meeting, the contents of the previous meetings were reviewed and more familiar with how to use multiple crossings and motivational methods to achieve the goal and practical training in order to increase the level of hope. Also, the contents of the previous sessions and attention and focus on individual and environmental talents and abilities and practical exercises were reviewed in order to increase the level of optimism. In the next step, the contents of the previous sessions and more familiarity with the techniques of increasing self-efficacy and practical exercises in order to increase The level of self-efficacy was reviewed, and finally, the

contents of previous sessions and practical exercises were reviewed and reviewed in order to increase the level of resilience. At the end of the practice session, the assignments presented in the intervention sessions were reviewed and explained to the patients, and the feedback of the sessions was also received from the patients.

Category

Behavior

2

Description

Intervention group: Cognitive Behavioral Therapy.Cognitive behavioral therapy is a theoretical model related to how thoughts, behavior and emotions are related. Most people believe that situations create their emotions. The cognitive model challenges this subjective experience and suggests instead that it is thoughts about the situation that cause emotions. In explaining the cognitive elements of cognitive behavioral therapy, the therapist teaches patients certain skills that help them improve their mood and change their behavior by adjusting their way of thinking. This therapy was performed on the patients during 8 90-minute group sessions and weekly by the therapist according to the protocol of cognitive behavioral therapy sessions from Sochting training package. The first session: After getting to know each other and establishing a therapeutic alliance, as well as getting to know the goals and expectations of the patient from the treatment, getting to know the number of sessions and rules of the group, and gaining the clients' trust, the relationship between cognition, emotion, behavior, and physical reactions in the context of the environment was examined and determined. In this way, how thoughts create feelings, as well as the ability to recognize the difference between thoughts and facts were expressed. In the following, the introduction of the cognitive behavioral therapy model was investigated and the logic of the treatment was presented using an example and gaining the patient's trust. In the next step, treatment goals were determined in such a way that joint efforts were made with the patient in determining objective and operational goals and selecting goals and objectives for immediate intervention. At the end of the meeting, homework including identification and arrangement of recent events based on the A-B-C pattern was presented and explained, and the meeting contents were summarized and feedback was received from the patients. The second session: At the beginning of this meeting, the previous meeting was reviewed and feedback received from it, and the agenda of the meeting was determined and agreed upon with the patients. Then the homework was reviewed and the results were evaluated and possible obstacles and problems were investigated. In the following, familiarization with the hierarchies of thinking, including spontaneous thoughts (it was determined by asking this question, "What thought came to your mind now?"), mental images, underlying rules and assumptions, and central beliefs, and then familiarization It was done with cognitive distortions and challenging them. At the end of the meeting, homework including daily notes of events, thoughts and feelings and identification of cognitive distortions were presented and explained, and finally, the contents of the meeting were summarized and feedback was received from the patients. The third session: At the beginning of this session, the previous session was reviewed and its feedback was received from the patients, as well as homework was reviewed and checked. In the following, with the cooperation of patients, to elicit and examine negative spontaneous thoughts using direct questions, Socratic questions (guided exploration), cognitive reconstruction by providing alternative explanations for events, identifying cognitive distortions, de-catastrophizing and re-documenting, and cognitive reconstruction. Ineffective thoughts were addressed. At the end of the session, the homework including recording positive and ineffective thoughts was presented and explained, and the session contents were summarized and feedback was received from the patients. The fourth session: At the beginning of the session, feedback was received from the previous session and homework was reviewed. In the following, the concepts of behavioral activation include teaching the skills of combining, looking at the results and not giving up; trigger, response and avoidance pattern; Triggers, response and alternative coping were introduced, and functional analysis strategies, avoiding avoidance and strengthening effective practices were presented to patients. In the next step, familiarization with the concept of documents was done and the causes of misunderstandings and teaching how to change documents (teaching beliefs based on the dimension of continuity: "sometimes" against "always"; inclusiveness: "specific" against "general" and personal) Being: "Internal" versus "external" was discussed. At the end of the session, homework including using the mentioned skills and identifying the documents about the bitter events of life was explained and an attempt was made to change the incorrect documents and then to summarize the contents of the session. and received feedback from patients. The fifth session: At the beginning of the session, review of the previous session and receiving feedback from the previous session was done and homework was checked. In the following, problem solving skills were taught to the patients, including defining the problem and presenting different solutions and evaluating them. At the end of the session, homework including problem-solving skill practice was presented and explained, and the session contents were summarized and feedback from the patients was discussed. The sixth session: At the beginning of the session, the previous session was reviewed and its feedback was received from the patients and the patients' homework was checked. In the continuation of communication and its elements, the definition and effective communication skills such as eye contact, body language, etc. were presented to patients. At the end of the session, the homework including effective communication practice was presented and explained, and the contents of the session were summarized and feedback was received from the patients. The seventh session: At the beginning of the session, the previous

session was reviewed and its feedback was received from the patients and the patients' homework was checked. In the continuation of familiarization with external reality and internal mental reality, the ways of changing the objective world by doing enjoyable activities, social communication and courageous relationship were done and explained to the patients. At the end of the session, the homework including the practice of enjoyable activities and the practice of bold behavior skills were presented and explained, and then the contents of the session were summarized and feedback was received from the patients. The eighth session: In this session, which was the final session, the contents of the previous sessions were reviewed and the skills taught were reviewed in general, strategies to prevent relapse were also taught to the patients, and the assignments presented in the treatment sessions were generally practiced.

Category

Behavior

3

Description

Control group: no intervention or treatment. Patients of the control group did not receive any intervention and treatment and only participated in the pre-test, post-test and follow-up.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hana charity (spinal injury support association of Isfahan province)

Full name of responsible person

Ramin Sadeghi dolatabadi

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Hana Charity, Shahidan Teimori Ave, Atashgah Blvd, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Hana charity (spinal injury support association of Isfahan province)

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Aad University, Najafabad Branch

Full name of responsible person

Ramin Sadeghi dolatabadi

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Unwillingness of the subjects to publish the data and maintain the confidentiality of the data

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable