

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The Effect of cognitive behavioral therapy on self-esteem and Quality of life in the amputated older patients, hospitalized

Protocol summary

Summary

Objectives: This study aimed to examine the effects of CBT on self-esteem and quality of life of hospitalized amputee elderly patients. A quasi-experimental study with pretest-posttest design was carried out on a sample of 64 amputee elderly patients admitted to the Vascular Surgery unit of the Al-Zahra hospital, Isfahan, Iran. The subjects were selected consecutively and then were randomly assigned into either the experimental or the control groups (32 patients in each group). The intervention group was divided into small subgroups of 3 to 4 patients and each subgroup participated in six sessions of cognitive-behavioral therapy according to the Turkington and Kingdon model. The CBT sessions were held twice a week, in three successive weeks. All the sessions were held in a comfortable room in the surgical ward. The control group received routine care. After the third week, all patients in the both groups were invited to the surgical ward and answered the Rosenberg self-esteem scale and the WHOQoL-short form for the second time. inclusion criteria: The inclusion criteria were: age of 60 years and over, ability to read and write in Farsi language, being conscious and aware of time and place, having no psychological disorder, having no mental, visual and hearing problem. exclusion criteria: The exclusion criteria were confronting with any problem i.e. disability or death that interfere with participating in the study.

General information

Acronym

Do not have

IRCT registration information

IRCT registration number: **IRCT2016092730002N1**

Registration date: **2016-11-09, 1395/08/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-09, 1395/08/19

Registrant information

Name

Mousa Alavi

Name of organization / entity

Department of Psychiatric Nursing, Nursing and Midwifery Care

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2015-09-11, 1394/06/20

Expected recruitment end date

2016-06-09, 1395/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of cognitive behavioral therapy on self-esteem and Quality of life in the amputated older patients, hospitalized

Public title

The Effect of cognitive behavioral therapy on self-esteem and Quality of life

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: The inclusion criteria were: age of 60 years and over; ability to read and write in Farsi language; being conscious and aware of time and place; having no psychological disorder; having no mental, visual and hearing problem. The exclusion criteria were confronting with any problem i.e. disability or death that interfere with participating in the study.

Age

From **60 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

University of Medical Sciences, Hezar Jarib street, Isfahan--

City

Isfahan

Postal code

81745-319

Approval date

2015-08-17, 1394/05/26

Ethics committee reference number

IR.MUI.REC.1394.1.041

Health conditions studied

1

Description of health condition studied

-

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

self-esteem

Timepoint

preintervention/immédiatement postintervention

Method of measurement

Rosenberg self-esteem scale

2

Description

Quality of Life

Timepoint

preintervention/ immédiatement post intervention

Method of measurement

Questionnaire (WHOQoL-short form)

Secondary outcomes

1

Description

do not have

Timepoint

do not have

Method of measurement

do not have

Intervention groups

1

Description

Intervention group : cognitive behavioral therapy
Patients in the intervention group participated in six sessions of cognitive-behavioral therapy. The CBT sessions were held twice a week, in three successive weeks. The control group received routine care. The outline of the CBT sessions : Greeting and introducing the sessions' facilitator and the patients to each other; briefing the patients on the numbers and the structure of the educational sessions; Introducing the cognitive-behavioral intervention; presenting the concepts and the importance of self-esteem and quality of life and provide examples of these concepts; providing some assignments (i.e. identifying instances of self-esteem and quality in him/her life). Greeting, reviewing the content of the previous session and receiving the patients' feedback; presenting the concept of self-knowledge (familiarity with him/her thoughts and how to analysis

them), providing strategies to identify him/her strengths and weaknesses; providing some assignments (i.e. identifying examples of the real strengths and weaknesses of him/herself). Greeting, reviewing the content of the previous session and receiving the patients' feedback; introducing the factors affecting self-esteem and quality of life; teaching the patients about self-control and problem solving; providing some assignments (i.e. identifying instances affecting self-esteem and quality of life of the patients in their real life). Greeting, reviewing the content of the previous session and receiving the patients' feedback; presenting some strategies for cognitive restructuring and how to reorganize his/her thoughts and beliefs; providing some assignments for cognitive restructuring and exercises for reorganizing his/her thoughts and beliefs. Greeting, reviewing the content of the previous session and receiving the patients' feedback; presenting methods for logical behavior analysis, behavior change, relaxation, visual imagery; providing some assignments for behavior change, relaxation, visual imagery by the patients. Greeting, reviewing the content of the earlier sessions and receiving the patients' feedback; presenting some strategies to reinforce positive thoughts and negative behaviors, improvement of coping skills, and providing some assignments to be done at the end of the session.

Category

Behavior

2

Description

Control group:The control group received routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra vsacular surgery ward

Full name of responsible person

Razieh Molavi

Street address

Al-zahra Hospital, Hakim NezamiThree- way, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical Sciences Vice chancellor for research, Isfahan University of

Full name of responsible person

Seid Mohamad Hashemi

Street address

Hezar Jarib street,Chancellor for research of, Isfahan

University of Medical Sciences

City

Isfahan

Grant name

-

Grant code / Reference number

--

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

Yes

Title of funding source

Medical Sciences Vice chancellor for research, Isfahan University of

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Razieh Molavi

Position

MSc in elderly Nursing

Other areas of specialty/work

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Full name of responsible person

Razieh Molavi

Position

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Other areas of specialty/work**Street address**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty