Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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. inclusioncriteria: 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

+98 31 3792 7588

Email address

m_alavi@nm.mui.ac.ir

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 vscualar 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

Street address

Home Karimi, Abdullahi deadlock, Alley martyr Eshaghi, South malek street,Isfahan

City

Isfahan

Postal code

8154739111

Phone

+98 31 3264 7292

Fax

+98 31 4583 7934

Email

raziehmolavi@yahoo.com

Web page address

Person responsible for scientific 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

Street address

Home Karimi, Abdullahi Deadlock, AlleyMartyr Eshaghi, South malek street,Isfahan

City

Isfahan

Postal code

8154739111

Phone

+98 31 3264 7292

Fax

+98 31 4583 7934

Email

raziehmolavi@yahoo.com

Web page address

Person responsible for updating data

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

Street address

Home Karimi, Abdullahi Deadlock, Alley Martyr Eshaghi, South malek street,Isfahan

City

Isfahan

Postal code

8154739111

Phone

+98 31 3264 7292

Fax

+98 31 4583 7934

Email

raziehmolavi@yahoo.com

Web page address

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