Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of care plan based on “Roy’s adaptation model” on coping strategies of war veterans with lower limb amputees

Protocol summary

Summary

Background: Amputation in veterans have been affected several aspects of their lives. According to the importance of adaptation and coping in chronic disease management, the present study was designed to determine the effectiveness of care plan based on “Roy’s adaptation model” on coping strategies of war veterans with lower limb amputees. Material and Method: This study is clinical trial and was performed in Kosar Orthotics and Prosthetics Center in Tehran in 2013-2014. Lower limb amputee veterans using convenience sampling method were recruited and were allocated randomly into experimental and control groups. The research instruments included the demographic questionnaire, the Roy Adaptation Questionnaire and the coping strategies questionnaire of Lazarus and Folkman. Face and content validity of Roy’s Adaptation Questionnaire was evaluated with content validity index and ratio. The reliability of questionnaire also was examined and approved. Questionnaires completed by the subjects in the pre-test phase and the care plan based on the Roy’s Adaptation Model in the experimental group were designed and conducted. Then, two months after, the questionnaires were completed by both groups. The data were analyzed by descriptive and analytic statistics and by SPSS 19 version with p<0/05 significance level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081118763N1**
Registration date: **2014-09-26, 1393/07/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-26, 1393/07/04

Registrant information

Name

Somayeh Azarmi

Name of organization / entity

AJA University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 7750 0201

Email address

s.azarmi@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

AJA University of Medical Science

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-07-21, 1392/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of care plan based on “Roy’s adaptation model” on coping strategies of war veterans with lower limb amputees

Public title

The effect of “Roy’s adaptation model” on coping strategies

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The ability of reading and writing, age below 65 years, not having a known mental illness, lack of spinal cord injury, not be Chemical veterans. Exclusion Criteria: Unwillingness to pursuit of the study process.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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

AJA University of Medical Science

Street address

The next of Emam Reza hospital, Tehran

City

Tehran

Postal code

18151-16139

Approval date

2013-06-20, 1392/03/30

Ethics committee reference number

9203

Health conditions studied

1

Description of health condition studied

Lower limb amputee

ICD-10 code

T93.6

ICD-10 code description

Sequelae of crushing injury and traumatic amputation of lower limb

Primary outcomes

1

Description

Coping Strategies

Timepoint

befor of intervention- two months after of intervention

Method of measurement

Standard questionnaire

Secondary outcomes

1

Description

Adaptation

Timepoint

Befor of intervention- two months after of intervention

Method of measurement

Questionnair that is made by researcher

Intervention groups

1

Description

In experimental group: Intervention included care plan and education of adaptation strategies based on Roy’s Adaptation Model in four dimensions at two sessions with two- hour in two week with 30 minute Question and respond at the end of sessions. Also, training manual Contains a summary of the training were given to subjects. Telephone follow-up was conducted over 2 months.

Category

Rehabilitation

2

Description

In control group: Without intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Orthotics and Prosthetics Center

Full name of responsible person

Mr Kabiri

Street address

Edge of Boostane Dahom, Banyhashem Street, Resalat Highway

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
AJA University of Medical Science
Full name of responsible person
Mrs Heiranipour
Street address
The next of Emam Reza hospital, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
AJA University of Medical Science
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
AJA University of Medical Science
Full name of responsible person
Somayeh Azarmi
Position
MSc
Other areas of specialty/work
Street address
Shareati Street, Faculty of Nursing, AJA University of Medical Sciences, Tehran
City
Tehran
Postal code
Phone
+98 21 7750 0201
Fax
Email
azarmi1363@yahoo.comazarmi1363@gmail.coms.azarmi@ajaums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing, AJA University of Medical Sciences
Full name of responsible person
Somayeh Azarmi
Position
MSc
Other areas of specialty/work
Street address
Shareati Street, Faculty of Nursing, AJA University of Medical Sciences
City
Tehran
Postal code
Phone
+98 21 7750 0201
Fax
Email
azarmi1363@yahoo.comazarmi1363@gmail.coms.azarmi@ajaums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
+98 21 7750 0201
Fax
Email
azarmi1363@yahoo.comazarmi1363@gmail.coms.azarmi@ajaums.ac.ir
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