

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 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

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###### 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**

before of intervention- two months after of intervention

##### **Method of measurement**

Standard questionnaire

### **Secondary outcomes**

#### **1**

##### **Description**

Adaptation

##### **Timepoint**

Before of intervention- two months after of intervention

##### **Method of measurement**

Questionnaire 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**

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## Person responsible for scientific

## inquiries

### Contact

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## Person responsible for updating data

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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*