

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The Impact of Orem Self- Care Program on General Health in Patients with Burn

Protocol summary

Summary

Objective: Determining the effect of orem self-care program on general health in patients with burn. Main inclusion criteria: 1) having at least 10% body surface area burns 2) after discharge from the hospital to complete rehabilitation 3) no record of certified mental illness and mental retardation, and other chronic diseases. Main exclusion criteria: 1) patients deaths 2) incidence of stressful incident during the research besides the burn 3) participation in any other training or counseling program parallel to the current program. Method: Randomized clinical trial with intervention and control. groups population: Patients with burn referred to burn clinic shiraz university of medical sciences. Sample: 110 Patients (56 of Patients in intervention group and 54 Patients in control group). Intervention: self-care program were held as five 75-90 minutes training sessions based on their self care needs for experiment group and their fellows and program adherence Followed with a phone calling every 15 days and checklist to eight weeks. Study outcome: Primary outcome was general health of the Patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122612129N2**

Registration date: **2014-01-10, 1392/10/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-10, 1392/10/20

Registrant information

Name

Fatemeh Rahimi dolatabad

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology of Shiraz university of medical sciences

Expected recruitment start date

2012-09-25, 1391/07/04

Expected recruitment end date

2012-12-24, 1391/10/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Orem Self- Care Program on General Health in Patients with Burn

Public title

The Impact of Orem Self- Care Program on General Health in Patients with Burn

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being in the age range 18-60 years; willingness to participate in the research; Persian literacy of reading and writing; no record of certified mental illness and mental retardation, and other chronic diseases (according to doctors records); access to a

telephone for follow-up training by the researcher; having at least 10% body surface area burns; after discharge from the hospital to complete rehabilitation; participate in all training sessions Exclusion criteria: patients' deaths; incidence of stressful incident during the research (besides the burn); participation in any other training or counseling program parallel to the current program.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Participants in the study will randomly be divided into two groups of intervention and control using the table of random numbers and the questionnaires serial numbers. The study will be double blind. The patient and the clinician are unaware of the type of the treatment that has been used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Seventh floor, Shiraz University of Medical Sciences and Health Services, Next to Red Crescent Organization, Zand blvd

City

Shiraz

Postal code

71345-1978

Approval date

2013-12-16, 1392/09/25

Ethics committee reference number

CT-92-6812

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T31

ICD-10 code description

Burns classified according to extent of body surface involved

Primary outcomes

1

Description

General Health

Timepoint

Before, one and two months after the end of study

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: self-care program was set based on the training needs of patients within 75 to 90 minutes 5 times a week in groups of 3-5 people in a group discussion, presentation slides, training manual and ... Was administered to patients and their family members with a phone call every 15 days, and the check list for eight weeks of following the plan were followed.

Category

Rehabilitation

2

Description

Control group: routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Burn Clinic of Ghotb-al-Din-e-Shirazi Hospital

Full name of responsible person

Dr. Mahdi Ayaz

Street address

Ghotb-al-Din-e-Shirazi Burn Hospital

City

shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Seventh floor, Shiraz University of Medical Sciences and Health Services, Zand blvd

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

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**

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Hashemi

Position

MS in nursing

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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