Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Impact of Orem Self- Care Program on Self-Efficacy and Quality of Life in Patients with Burn Referred to Ghotbedin shirazi Burn Clinic Shiraz-Iran , 2012

Protocol summary

Summary

Objective: Determining the effect of orem self-care program on self-efficacy and quality of life 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)confirmation of mental illness and mental retardation and other chronic diseases. Main exclusion criteria: 1)patients deaths 2)a stressful event during the study except burns 3)participate in any training or consulting other parallel to it. 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 experimental group and their fellows and program adherence Followed with a phone calling every 15 days and checklist to eight weeks. Study outcomes: Primary outcomes was self-efficacy and quality of life Patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042112129N1**
Registration date: **2013-06-03, 1392/03/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-03, 1392/03/13

Registrant information

Name

Fatemeh Rahimi dolatabad

Name of organization / entity

Shiraz University of Medical Sciences

Country

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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 Self-Efficacy and Quality of Life in Patients with Burn Referred to Ghotbedin shirazi Burn Clinic Shiraz-Iran , 2012

Public title

The Impact of Orem Self- Care Program on Self-Efficacy and Quality of Life in Patients with Burn

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being in the age range 18-60; Willing to engage in research; Persian literate enough to read and

write; Confirmation of mental illness and mental retardation and other chronic diseases (according to doctor 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; a stressful event during the study (except burns); Participate in any training or consulting other parallel initiatives.

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commitee of Shiraz University of Medical Sciences

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

City
Shiraz

Postal code
1978-71345

Approval date
2012-10-07, 1391/07/16

Ethics committee reference number
CT-91-6263

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
Self-Efficacy

Timepoint
Before intervention, 1 month and 2 month after intervention

Method of measurement
Questionnaire

2

Description
Quality of Life

Timepoint
Before intervention ,1 month and 2 month after intervention

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 Ghotbedinshirazi Hospital

Full name of responsible person
Dr Mahdi Ayaz
Street address
Ghotbedin 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
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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