

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Assessing the impact of using a self help rehabilitation program on post ICU patient's health status in university hospitals of Kerman University of Medical Sciences.

Protocol summary

Summary

Introduction and aims: Patients in intensive care units experience many physiological and psychological complications that their recovery sometimes takes several years. Life quality of intensive patients after discharge is lower than other internal and surgical patients and physical problems makes a person disable in doing daily activities. This study assesses the effect of using self-help rehabilitation program on the life quality of the patients discharged from Intensive Care Units. Methods: It was a clinical trial study which was done on ninety patients of internal-surgical intensive units of three hospitals in Kerman. This study was done by SIP68 life quality questionnaire with three physical, psychological and social areas and six dimensions in 2012. After patients' discharged from intensive care unit, they were in a general ward in tow case and control groups, data were analyzed by using inferential, descriptive statistical tests and SPSS19 software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110197844N1**

Registration date: **2014-06-11, 1393/03/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-11, 1393/03/21

Registrant information

Name

Mansour Arab

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1320 5179

Email address

marab@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the impact of using a self help rehabilitation program on post ICU patient's health status in university hospitals of Kerman University of Medical Sciences.

Public title

Post intensive care unit patient's recovery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients who stayed in ICU more than 48 hours; were mechanically ventilated ;were eager and able to participate in term of literacy and cognition state; Exclusion criteria: terminally ill patient ;patients with prolonged recovery like those with burn injury ;History of

major psychological disorders as a confounding factor in psychological recovery

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 90

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**

Ethics Committee of Vice chancellor for research,
Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of
Medical Sciences, Jihad Blvd, Somayye Crossroads,
Shariaati St, Kerman

City

Kerman

Postal code

7751123458

Approval date

2011-12-10, 1390/09/19

Ethics committee reference number

326/90/15

Health conditions studied**1****Description of health condition studied**

rehabilitation in intensive care survivors

ICD-10 code

Z50

ICD-10 code description

Care involving use of rehabilitation procedures

Primary outcomes**1****Description**

Quality of life

Timepoint

Before and three months after intervention

Method of measurement

Sickness Impact Profile 68

Secondary outcomes**1****Description**

demographic factors like age, gender, Length of stay and severity of illness score by APACHE ii

Timepoint

Before intervention

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention Group: Intervention was an educational package that consist of weekly programmed manual, exercise training CD and three appointed telephone calls for follow up. This self-help manual guide patients to a better physical and mental situation step by step with a weekly plan. Every two week a phone call was done by researcher to evaluate patients' compliance with the program.patients were persuaded to use the program and probleme solving was done. The manual has three parts. First part is a plan table for exercise and activity of daily living that learn patients how to plan according to their his/ her abilities. Second parts is general recommedations about nutrition, relaxation, smoking abstenation, return to family and social life and so on. Third part is the grading exercising package and its guid for use that is usable with CDs. With appropriate patient's compliance and encourages of the researcher patients get ready within 6 weeks and would be reached an optimal level in term of physical and mental situation.

Category

Rehabilitation

2**Description**

Control Group: This group did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Three educational hospital of Kerman University of Medical

Full name of responsible person

Mansour Arab

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jahad Blvd, Somayye Crossroads, Shariaati St, Kerman

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, kerman University of Medical Sciences

Full name of responsible person

Dr. Malekpour Afshar

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jahad Blvd, Somayye Crossroads, Shariaati St, Kerman

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Kerman

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, kerman 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

Razi Nursing and Midwifery School, Kerman University of Medical Sciences

Full name of responsible person

Mansour Arab

Position

MSN/ Lecturer of Nursing

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty