

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Impact Orem's self-care nursing model on the quality of life in patients with migraine

Protocol summary

Summary

Aim: This study was performed to determine the Impact Training of Orem's self-care program on the quality of life in patients with migraine. Design: This study is a randomized controlled clinical trial as before and after. Inclusion criteria: Diagnosis of migraine based on International headache indices by a physician, Age 55-18 years. Exclusion criteria: Lack of proper implementation of intervention and unwillingness to cooperate in any phase of the study. Population and sample size: In this 83 patients with migraine were divided into two groups by random allocation: 43 of patients in experimental group and 40 patients in control group. Intervention: Self care Program were held as four 30-45 minutes training sessions based on their self care needs in Orem model for experimental group. The Check lists were used to monitor and follow-up self care programs Intervention time: the subjects were asked to apply self-care program for 3 months. Data collection tools were demographic questionnaire, Short Form SF36 and Orem cognition form and self care checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302023023N7**

Registration date: **2013-07-14, 1392/04/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-14, 1392/04/23

Registrant information

Name

Fatemeh MahmoudzadehZarandi

Name of organization / entity

Birjand University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Baqiatallah University of Medical Sciences

Expected recruitment start date

2009-11-11, 1388/08/20

Expected recruitment end date

2010-02-04, 1388/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact Orem's self-care nursing model on the quality of life in patients with migraine

Public title

Impact Orem's self-care nursing model on the quality of life in patients with migraine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of migraine based on International headache indices by a physician, Age 55-20 years Exclusion criteria: Pregnancy, menopause, History of cardiovascular diseases, hypertension.

Age

From **20 years** old to **55 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 83

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Baqiatallah University of Medical Sciences

Street address
Mollasadra street, Vanak Square

City
Tehran

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
21

Health conditions studied

1

Description of health condition studied
migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
quality of life

Timepoint
baseline, three months later

Method of measurement
SF36 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group: Implementation Orem's self-care nursing model in Nutrition, exercise and relaxation dimensions for three months

Category
Lifestyle

2

Description
The Control group: no action

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Medical Neurology Clinic of Baqiatallah Hospital

Full name of responsible person
Fatemeh MahmoudzadehZarandi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Baqiatallah University of Medical Sciences

Full name of responsible person
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Baqiatallah University of Medical Sciences, Araj Three ways, Aqdasiyeh

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Baqiatallah 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

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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