

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of nursing intervention based on "Roy" adaptation model on adaptation modes in patients with pemphigus vulgaris

Protocol summary

Summary

The purpose of this study is to examine the effect of nursing intervention based on "Roy" adaptation model on adaptation of self-concept, role function and interdependence in pemphigus vulgaris patients. Inclusion criteria include: The age between 30 and 50 years; a definitive diagnosis of the disease; willingness to participate in study; at least 6 months passed diagnosis and being Under treatment with oral steroids. Exclusion criteria include: Not attending in training sessions regularly; no follow-up; the patient's own request; change of residence area. In this clinical trial, 50 patients will be selected and will be placed randomly in both intervention and control groups. At first, maladaptive behaviors will be determined by interview. Training content based on maladaptive behaviors in 8 sessions of 60 minutes during 8 weeks with method of lecture will be provided. Monitoring will be done for 1 month after intervention. Then, rate of adaptation in two groups will be measured. The main variable is implementation of nursing intervention based on "Roy" adaptation model that its effect will be evaluated on three dimensions of self-concept, role function and interdependence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041921855N1**
Registration date: **2015-08-24, 1394/06/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-24, 1394/06/02

Registrant information

Name

Tahereh Ashtab

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

ashtab.t@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research of Gonabad University of Medical Sciences.

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nursing intervention based on "Roy" adaptation model on adaptation modes in patients with pemphigus vulgaris

Public title

The effect of nursing care on adaptation in patients with pemphigus vulgaris

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The age between 30 and 50 years; A definitive diagnosis of the disease; Willingness to

participate in study; At least 6 months passed diagnosis ;
Being Under treatment with oral steroids. Exclusion
criteria: Not attending in training sessions regularly; No
follow-up or the patient's own request; Change of
residence area.

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

education and follow- up of patients

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to
Asian Road- Gonabad

City

Gonabad

Postal code**Approval date**

2015-03-11, 1393/12/20

Ethics committee reference number

gmu.rec.1393.135

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

Pemphigus vulgaris

ICD-10 code

L10.0

ICD-10 code description

pemphigus neonatorum (L00)

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

Self concept mode

Timepoint

Before and after intervention

Method of measurement

Questioner and interview

2**Description**

Role function mode

Timepoint

Before and after intervention

Method of measurement

Questioner and interview

3**Description**

Interdependence mode

Timepoint

Before and after intervention

Method of measurement

Questioner and interview

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

Adaptation strategies

Timepoint

Before and after intervention

Method of measurement

Questioner

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

In intervention group, after determining maladaptive
behaviors and codificationeducational plan, training
content in 8 session of 60 minutes and during 8 weeks
with method of lecture will be provided.

Category

Other

2**Description**

Control group will not receive any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital of Tehran University of Medical Sciences

Full name of responsible person

Tahereh Ashtab

Street address

Razi hospital- Vahdat Eslami Avenue- Vahdat Eslami Square- Tehran- Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of Gonabad University of Medical Sciences

Full name of responsible person

Ali Mohamadpur

Street address

Gonabad University of Medical Sciences, Next to Asian Road- Gonabad

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Gonabad

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 of Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Tahere Ashtab

Position

MSc. student in nursing education

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

doctor Musa Sajjadi

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PhD of nursing

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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