Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 trail,50 patient will be selected and Will be placed randomly in both intervention and control groups. At First, maladaptive behaviors will be determined by interview. Trainingl 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
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

vice chancellor for research of Gonabad University of Medical Sciencess.

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 haspital 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
City
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
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Position
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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Phone
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Fax
Email
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