Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

comparison of the effect of family-centered empowerment model based lifestyle modification on quality of life of female patients with Pemphigus Vulgaris and active family member in the intervention group with no implementation of the model in patients and active family member in the control group.

Protocol summary

Study aim
Health services

Design
matched controlled clinical trial study; parallel group; No blinding; Simple randomization using lottery.

Settings and conduct
This matched controlled clinical trial study was conducted by Purposive sampling 72 female patients with Pemphigus Vulgaris and 72 active family members and through random allocation was divided into two groups: intervention and control. Data were collected by demographic, specialty instrument of empowerment of patients and specialty instrument of active family members questionnaires, Lifestyle (HPLP II) and SF-36 for patients and active family members , dermatology life quality index, the family Dermatology life quality index (FDLQI) questionnaires. FCEM implemented in steps (perceived threat, self-efficacy, self-esteem and evaluations) for the intervention group. Usual care was done for control group. After 6 weeks, was compared with the control. Data was analyzed by statistical software SPSS V.24, and rate (P <0.05) was considered significant.

Participants/Inclusion and exclusion criteria
Inclusion criteria: register Pemphigus Vulgaris in the health case; Patients' and active family member's satisfaction ; Ability to communicate; No mental illness or other acute or chronic illness; Not a member of health team and having at least literacy. Exclusion criteria: the patient and active family member's unwillingness to continue; patient has an acute or chronic illness; the patient has a mental illness; Patient or active family member death.

Intervention groups
female patients with Pemphigus Vulgaris and active family member in two groups of intervention and control.

Main outcome variables
Quality of public and Exclusive life of female patients with Pemphigus Vulgaris and active family member.

General information

Reason for update
Add primary and secondary outcome variable

Acronym
-

IRCT registration information
IRCT registration number: **IRCT2017061934632N1**
Registration date: **2017-08-16, 1396/05/25**
Registration timing: **retrospective**

Last update: **2022-08-07, 1401/05/16**
Update count: **1**

Registration date
2017-08-16, 1396/05/25

Registrant information

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Recruitment status
Recruitment complete

Funding source
Tarbiat Modares University

Expected recruitment start date
2017-06-22, 1396/04/01
Expected recruitment end date
2017-08-23, 1396/06/01
Actual recruitment start date
2017-06-22, 1396/04/01
Actual recruitment end date
2017-07-23, 1396/05/01
Trial completion date
2017-09-23, 1396/07/01

Scientific title
comparison of the effect of family-centered empowerment model based lifestyle modification on quality of life of female patients with Pemphigus Vulgaris and active family member in the intervention group with no implementation of the model in patients and active family member in the control group.

Public title
Family-centered empowerment model for enhance quality of life of female patients with Pemphigus Vulgaris and active family member.
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
register Pemphigus Vulgaris according to the doctor's diagnosis in the health case women aged 30-60 years Patients' and active family member's desire and satisfaction to participate in the research; Ability to communicate verbally ; provide information and collaborate with the researcher No mental illness or other acute or chronic illness Not a member of the health team having at least literacy to complete the Questionnaire
Exclusion criteria:
the patient and active family member's unwillingness to continue to participate in research the patient has an acute or chronic illness the patient has a mental illness Patient or active family member death
Age
From **30 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **144**
Actual sample size reached: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the research samples were selected by the researcher using the purposeful sampling method by studying the patients' files to reach the qualified patients more precisely, according to the entry criteria and after assimilation by one of the nurses based on the criteria of age, type of disease, severity of the disease and duration of the disease, the block was randomly assigned and then, using the Minimization method, the samples were homogenized by SPSS software and by using lottery and randomly, the research samples were placed in one of the control or intervention groups.
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 Tarbiat Modares University
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1411713116, No.7, Tarbiat Modares University, Jalal All Ahmad Street, Tehran, IR. Iran
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Approval date
2016-11-09, 1395/08/19
Ethics committee reference number
IR.TMU.REC.1395.404

Health conditions studied

1

Description of health condition studied
Pemphigus Vulgaris
ICD-10 code
L10.0
ICD-10 code description
Pemphigus vulgaris

Primary outcomes

1

Description
lifestyle
Timepoint
Before intervention- two months after the end of the intervention
Method of measurement

Walker- Pender health-promoting Lifestyle Questionnaire

Lifestyle

Secondary outcomes

1

Description
Quality of public life of female patients with Pemphigus Vulgaris and active family member
Timepoint
Before intervention; two months after the end of the intervention
Method of measurement
SF-36 quality of life Questionnaire

2

Description
Quality of Exclusive life of female patients with Pemphigus Vulgaris
Timepoint
Before intervention; two months after the end of the intervention
Method of measurement
Iranian version dermatology life quality index (DLQI)

3

Description
Quality of exclusive life of active family member.
Timepoint
Before intervention; two months after the end of the intervention.
Method of measurement
The family dermatology life quality index (FDLQI).

Intervention groups

1

Description
After analyzing the data before the intervention, which led to the identification of the resources, limitations, needs and strengths of the patient and his active family member in different fields, Changes were made in the previously designed empowerment program for these patients, so that the implementation of the empowerment model fits the needs and demands of the research samples. After the pre-test, the intervention phase began and since this study was conducted as an intervention and control; The intervention phase was performed only for the intervention group and the control group did not receive any intervention. In the intervention group, the family-centered empowerment model in executive steps (understanding the threat, internalizing the axis of control, self-efficacy, self-belief, self-control, follow-up and evaluation) for 8 sessions by group problem solving method and using educational participation method and adult educational theory for The intervention group was implemented and after 6 weeks, were compared with the control group.
Category

2

Description
Conducting the pre-test by completing the demographic information questionnaire, the Iranian version of the quality of life index questionnaire for skin patients (DLQQI), the quality of life questionnaire (SF-36), the family specific questionnaire of skin patients (FDLQQI), the Iranian version of the Walker and Pender lifestyle questionnaire, Questionnaire for measuring the patient's ability and questionnaire for measuring the ability of the active family member by the patient and the active family member and conducting post-test 6 weeks after the completion of the intervention in the intervention group by re-completing the main tools for measuring lifestyle and quality of life by the patient and active family member.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
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Sponsors / Funding sources

1

Sponsor
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Grant name
121000
Grant code / Reference number
528712/د
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tarbiat Modares University
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available