Assessing the effect of self-management program on quality of life in patients with psoriasis

Protocol summary

Summary
This study is a randomized clinical trial and single blind research with a control group, designed to show how a self-management education program is effective on quality of life in patients with psoriasis. The sample size is 110 who are randomly divided into control and intervention groups. The intervention consisted of self-management training program that are held in groups up to 5 patients for 3 sessions of 20 minutes. The training program is provided along with the booklet. 1, 2 and 3 months after discharge, the intervention group received a phone call to possible questions be answered and practicing the instructions be followed. before and 3 months after training Dermatology Life Quality Index and Psoriasis Area and Severity Index are completed research fellow. After collecting the questionnaires scores related to each section of the questionnaire will be calculated and then the raw data and information will be adjusted in original table and will be calculated and compared by using descriptive and inferential statistical methods of SPSS.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2015020220916N1
Registration date: 2015-05-29, 1394/03/08
Registration timing: registered_while_recruiting

Expected recruitment start date
2015-03-21, 1394/01/01
Expected recruitment end date
2015-08-22, 1394/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effect of self-management program on quality of life in patients with psoriasis

Public title
Assessing the effect of self-management program on quality of life in patients with psoriasis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: confirming the diagnosis of psoriasis by doctor; age 18 years old and older; at least 3 months before the study had a history of psoriasis; be at least read and write the language; willingness to participate in the study; was not pregnant. Exclusion criteria: the absence of an intervention group training sessions; readmission samples during sampling in research
environments.

Age
From 18 years old to 100 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 110

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
Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Postal code
1449614535
Approval date
2015-02-10, 1393/11/21
Ethics committee reference number
93/105/5473/

Health conditions studied

1
Description of health condition studied
Psoriasis

ICD-10 code
L40

ICD-10 code description
Psoriasis

Primary outcomes

1
Description
Quality of life

Timepoint
Before and 3 months after intervention

Method of measurement
Dermatology Life Quality Index (DLQI)

Secondary outcomes

1
Description
Severity of disease

Timepoint
Before and 3 months after intervention

Method of measurement
Psoriasis Area and Severity Index (PASI)

Intervention groups

1
Description
Control: the routin training, follow-up after 3 months

Category
N/A

2
Description
Intervention group: self-management training in groups of 5 people at 3 sessions of 20 minutes, then followed up for 3 months.

Category
Lifestyle

Recruitment centers

1
Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Kobra Soltan Dehghan
Street address
Razi Alley, Islamic Unity Square
City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Tahere Najafi Ghezeljeh
Street address
Shahid Hemmat Highway
City
Tehran
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact
Name of organization / entity
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Full name of responsible person
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post graduate nursing student
Other areas of specialty/work
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Web page address
http://fnm.iums.ac.ir/

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