

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Orem self care on uremic pruritus in hemodialysis patients

Protocol summary

Summary

Data collection tools: demographic questionnaire, Yosipovitch itch assessment questionnaire and educational need assessment questionnaire based on Orem self-care model. Studied interventions and study time: Researcher intervention was performed in 4 sessions of 30 minutes (at least 2 times a week) initially for three face to face sessions, and then a group meeting based on the common need for patients to solve problems and expressing experiences of each as lecture, questions and answers, pamphlets and booklets up to a month in the intervention group. At the end of each session, the time of next training session was determined due to the patient condition (patient consent and taking into account the physical condition) and educational pamphlets regarding the same session were distributed among samples and the complete booklet was given to the patients at the end of intervention. Primary outcome: Uremic pruritus

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041625852N2**
Registration date: **2016-05-03, 1395/02/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-03, 1395/02/14

Registrant information

Name

Tayebeh Khosravipour

Name of organization / entity

School of Nursing and Midwifery Shahid Beheshti

Country

Iran (Islamic Republic of)

Phone

+98 939 536 8392

Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-02-04, 1394/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Orem self care on uremic pruritus in hemodialysis patients

Public title

The effect of Orem self care program on uremic pruritus in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

1. They must be between 18-60 years old. 2. At least 2 months have passed since their first hemodialysis. 3. They should be dialyzed by bicarbonate solution. 4. They should be dialyzed by using polysulfone filters. 5. Despite intaking anti-itch medication, they still suffer itching. 6. Apart from uremic pruritus, they have no skin problem. 7. They don't suffer liver, active biliary and polycythemia diseases (according to monthly test results of patient and according to the specialist). 8. They should not suffer cognitive problems or debilitating diseases. 9. They should be able to understand conversation in Farsi and communicate.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Shahid Beheshti University of Medical Sciences

Street address

7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin , Tehran, Iran

City

Tehran

Postal code**Approval date**

2015-12-05, 1394/09/14

Ethics committee reference number

sbmu2.REC.1394.16.1

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

uremic pruritus

ICD-10 code

L29.8

ICD-10 code description

Other pruritus

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

Uremic pruritus

Timepoint

Before and after each intervention

Method of measurement

Yosipovitch itch assessment questionnaire

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

Self-care needs

Timepoint

Before intervention

Method of measurement

educational need assessment questionnaire based on Orem self-care model.

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

The control group no received intervention Only in the end, to ethics, to control self-care program was taught during the session Group. And a booklet to provide them and they answered the questions

Category

Other

2**Description**

Researcher intervention was performed in 4 sessions of 30 minutes (at least 2 times a week) initially for three face to face sessions, and then a group meeting based on the common need for patients to solve problems and expressing experiences of each as lecture, questions and answers, pamphlets and booklets up to a month in the intervention group. At the end of each session, the time of next training session was determined due to the patient condition (patient consent and taking into account the physical condition) and educational pamphlets regarding the same session were distributed among samples and the complete booklet was given to the patients at the end of intervention.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali-Asr Hospital in Nourabad Mamasani, ward Hemodialysis

Full name of responsible person**Street address****City**

Nourabad Mamasani

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mahrokh dolatian

Street address

Tehran - Vali Asr intersection and highway Niayesh -
The Rajai cardiac Hospital School of Nursing and
Midwifery - Third Floor Research Department

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tayebeh khosravi pour

Position

Nursing Graduate Student

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

Tehran - Vali Asr intersection and highway Niayesh -
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Person responsible for scientific inquiries

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Ms. Doctor roghayeh esmaeli

Position

PhD in Nursing

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Person responsible for updating data

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Position

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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