

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of performance and non-performance Peplau,s interpersonal relationship theory on stress , depression and anxiety in hemodialysis patients in two groups

Protocol summary

Summary

This study is implemented with the aim of determining the effects of Peplau's theory of interpersonal relationship on stress and anxiety and depression in patients undergoing hemodialysis. The study participants are 66 hemodialysis patients aged 30 to 60 years, who are able to communicate. Patients stopping dialysis treatment will be excluded from the study. First, a stress, anxiety and depression questionnaire will be filled out by the patient. Then the patients will be divided into two groups and Peplau's nursing pattern will be applied to the intervention group. The questionnaire will be completed by the patients again after the intervention. The evaluation will be based on a comparison of questionnaire results before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051217059N8**

Registration date: **2016-07-10, 1395/04/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-10, 1395/04/20

Registrant information

Name

Masoume Hemmati Maslakkpak

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

hemmati_m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of performance and non-performance Peplau,s interpersonal relationship theory on stress , depression and anxiety in hemodialysis patients in two groups

Public title

The impact of relationship therapy on stress and anxiety and depression in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 30 to 60 years; Lack of chronic mental and physical illness and also cognitive, hearing and vision disorders based on the patient record; Being fluent in Turkish or Persian language; Non-member of Medicine Department; written consent by participants to participate in the study. Exclusion criteria: Death during the study period; Kidney or Renal transplantation during the study period; Catching other diseases and exiting from the dialysis program; Dissatisfaction with

continuing to participate in the study.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Use of a sealed bag containing the names of patients and chance choose intervention group

Secondary Ids

empty

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

Ethics committee of Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd, Urmia

City

urmia

Postal code

5714783734

Approval date

2016-02-09, 1394/11/20

Ethics committee reference number

ir.umsu.rec.1394.340

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

Hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Dialysis (renal) NOS

2**Description of health condition studied**

Depression

ICD-10 code

F32.9

ICD-10 code description

Depression NOS Depressive disorder NOS

3**Description of health condition studied**

Stress

ICD-10 code

Z63.7

ICD-10 code description

Anxiety (normal) about sick person in family Health problems within family Ill or disturbed family member Isolated family

4**Description of health condition studied**

Anxiety

ICD-10 code

F06.4

ICD-10 code description

A disorder characterized by the essential descriptive features of a generalized anxiety disorder (F41.1), a panic disorder (F41.0), or a combination of both, but arising as a consequence of an organic disorder

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

Stress

Timepoint

before and after intervention

Method of measurement

DASS-21 Stress and Anxiety and Depression Scale

2**Description**

Anxiety

Timepoint

before and after intervention

Method of measurement

DASS-21 Stress and Anxiety and Depression Scale

3**Description**

Depression

Timepoint

before and after intervention

Method of measurement

DASS-21 Stress and Anxiety and Depression Scale

Secondary outcomes

empty

Intervention groups

1

Description

Implementation of peplau interpersonal relationship during 7 to 8 sessions with each patient on three stages , including 1- orientation 2- work phase including identify and exploit and 3- finishing stage

Category

Behavior

2

Description

The impact of non-performance Peplau interpersonal relationship on control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Iraj Mohebi

Street address

Shahr chayi, Kashani street

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Urmia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebi

Street address

Orjhans Street, Resalat Blvd, Urmia

City

Urmia

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, Urmia 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Masoume Hemmati Maslarpak

Position

PhD in Nursing, Associate Professor, Educational Assistant School of Nursing and Midwifery

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Babak Alishahi

Position

Master student Medical Surgical Nursing

Other areas of specialty/work

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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