Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of psychoeducation on depression and anxiety symptoms among dialysis patients

Protocol summary

Summary

The aim of this study was to investigate the effect of psychoeducation on depression and anxiety symptoms among dialysis patients. A total of 60 hemodialysis patients with the depression or anxiety HADS score ≥8 were assigned into investigation and waiting groups, after matching for the important risk factors (sex, marital status, educational level, time and frequency of dialysis). Three an-hour sessions about the kidney anatomy and physiopathology, treatments of ESRD, the mechanism of dialysis, adjustment steps in human, problem solving, stress management and relaxation training were held for the investigation group. The HADS inventory was completed for both group before and a week after the educational session.

General information

Acronym

non

IRCT registration information

IRCT registration number: **IRCT138805282353N1**

Registration date: **2012-05-17, 1391/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-17, 1391/02/28

Registrant information

Name

Arefeh Bigom Shafaat

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 15 1325 2955

Email address

ashafaat@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2008-07-22, 1387/05/01

Expected recruitment end date

2010-01-20, 1388/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of psychoeducation on depression and anxiety symptoms among dialysis patients

Public title

Effect of psychoeducation on depression and anxiety symptoms among dialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: depression or anxiety scores greater or equal to 8 scale HADS patients with renal failure being treated with hemodialysis Exclusion criteria: 1. Experiencing new stressful events during the time of study based on Holmz-Rahe list of stressful life events 2. Any change in the dialysis schedule 3. Starting any other psychiatric treatment during the period of study 4. A known history of previous psychiatric disorder 5. Having a new stressor during previous 6 months except for those related to kidney disease 6. Failure to attend in all educational sessions

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

non

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for Research of Mazandaran University of Medical Sciences and Health Services

Street address

Moallem square

City

Sari

Postal code

Approval date

2008-06-23, 1387/04/03

Ethics committee reference number

24-85

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Organic anxiety disorder

2

Description of health condition studied

depression

ICD-10 code

F33

ICD-10 code description

Recurrent depressive disorder

Primary outcomes

1

Description

Depression

Timepoint

before and 1 week after intervention

Method of measurement

HADS Questionnaire

2

Description

Anxiety

Timepoint

before and 1 week after intervention

Method of measurement

HADS Questionnaire

Secondary outcomes

1

Description

non

Timepoint

non

Method of measurement

non

Intervention groups

1

Description

Three an-hour group education, by a nephrologist and psychiatrist. Content of educational sessions include: 1. Describing the anatomy and pathophysiology, all causes of kidney failure, the advantages and disadvantages of various treatments for renal failure, mechanism of function of dialysis, care needed in dialysis patients, 2. The adaptive response in human learning and problem solving skills 3. Stress management training and muscle relaxation

Category

Behavior

2

Description

psychoeducation

Category

Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hospital
Full name of responsible person
Street address
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Ahmad Ali Enayati
Street address
Moallem Square
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
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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*