Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of group hope therapy on anxiety and medication adherence of hemodialysis patients

Protocol summary

Study aim
Examine the effect of group hope therapy on anxiety and medication adherence of hemodialysis patients
Design
Randomized clinical trials without control group and blinding
Settings and conduct
Group therapy on hemodialysis patients without blinding in a semi-experimental study before and after (without independent control group). In shahid rahimey and shohadaey asheir khoramabaf
Participants/Inclusion and exclusion criteria
The patients are within the age limit of 18-65. The patient should be interested in the research and in participating in the training sessions. The patient has undergone hemodialysis for one month. The patient should not suffer from mental disorders. The patient has not taken Psychiatric medicines. Patients' anxiety score that is higher than the anxiety level should be trivial Lack of patients' interest in continuing the research. The use of anxiety-reducing medicines or other therapies for anxiety . Having severe anxiety disorders such as phobia and panic attack during dialysis .Patient death. Patient emigration. Having visual, hearing, and speech impairment
Intervention groups
This study doesn't have a control group. It will be conducted with one group of hemodialysis patients. Group hope therapy will be conducted with five hemodialysis patients in each group. The contents of the hope therapy sessions are based on hope therapy protocol. The hope therapy is conduced weekly in 8 sessions, each lasting 60 minutes. Then, the effects of group hope therapy on state and trait anxiety and follow-up treatment will be examined one month and then three months later.
Main outcome variables
Determining the effect of treatment on apparent and hidden anxiety and compliance with the treatment of hemodialysis patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180628040273N1**
Registration date: **2018-10-31, 1397/08/09**
Registration timing: **retrospective**

Last update: **2018-10-31, 1397/08/09**
Update count: **0**
Registration date
2018-10-31, 1397/08/09

Registrant information
Name
Zahra Ahmadi fajr
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 66 3320 4517
Email address
zhraahmdy669@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-05, 1396/11/16
Expected recruitment end date
2018-09-16, 1397/06/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The effect of group hope therapy on anxiety and medication adherence of hemodialysis patients

Public title
The effect of group hope therapy on anxiety and medication adherence of hemodialysis patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The patients are within the age limit of 18-65 The patient should be interested in the research and in participating in the training sessions. The patients have undergone hemodialysis for one month. The patients should undergo hemodialysis 3 times a week. A doctor should introduce the patient to participate in the study The patient should not suffer from mental disorders The patients have not taken Psychiatric medicines The patients should promise not to use other methods for decreasing anxiety during the hope therapy. The patients should be able to participate in all of the group hope therapy sessions Patients' anxiety score that is higher than the anxiety level should be trivial
Exclusion criteria:
Lack of patients' interest in continuing the research The use of anxiety-reducing medicines or other therapies for anxiety Having chronic and debilitating diseases based on doctor's diagnosis Having severe anxiety disorders such as phobia and panic attack during dialysis Patient death Patient emigration Having visual, hearing, and speech impairment Patients not being in good physical condition Being absent for sessions Not being able to participate in hope therapy sessions during the research Changing the treatment approach(kidney transplant, peritoneal dialysis) Severe family and social crises (the death of a member of the immediate family, job, divorce, dropout) Participating and following other training programs which affects anxiety.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Lorestan Univercity Medical Sience
Street address
Moalem ave.Anooshirvan rezaei str.
City
Khoramabad
Province
Lorestan
Postal code
6813833649
Approval date
2018-01-15, 1396/10/25
Ethics committee reference number
IR.LUMS.REC.1396.356

Health conditions studied

1

Description of health condition studied
hemodialysis -patient
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
score anxiety the hidden and on the basis of a questionnaire, anxiety eshpilberger
Timepoint
Before the start of the intervention, immediately after the intervention and one months after the interventiond and three months after the intervention
Method of measurement
Scale obtained from Spielberger's revealing and hidden anxiety questionnaire

Secondary outcomes

1

Description
The score of medication adherance in the hemodialysis patients to the questioneria ESRD-AQ
Timepoint
Before the start of the intervention, immediately after the intervention and one month after the intervention and three months after the intervention
Method of measurement
the result of the questionnaire was to follow the treatment of hemodialysis patients according to the

questionnaire - ESRD-AQ

Intervention groups

1

Description

This study doesn’t have a control group. It will be conducted with one group of hemodialysis patients. Group hope therapy will be conducted with five hemodialysis patients in each group. The contents of the hope therapy sessions are based on hope therapy protocol. The hope therapy is conduced weekly in 8 sessions, each lasting 60 minutes. Then, the effects of group hope therapy on state and trait anxiety and follow-up treatment will be examinedimmediatly after intervention and one month and then three months later.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis centers of the martyrs hospital in Khorramabad city

Full name of responsible person

Zahra Ahmadi Fajr

Street address

Ave Enghelab Shohada ashayer Hospital

City

Khoramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3323 6404

Email

Zhraahmdy669@gmail.com

2

Recruitment center

Name of recruitment center

Hemodialysis Center of Shahid Rahimi Hospital in Khorramabad

Full name of responsible person

Zahra Ahmadi Fajr

Street address

Ave Mojahedin, Azadi square

City

Khoramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3333 6150

Email

Zhraahmdy669@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Zahra Ahmadifajr

Street address

Enghelab Ave.Razi Ave. 1Arrasteh Alley. No99

City

Khoramabad

Province

Lorestan

Postal code

۶۸۱۶۸۴۹۴۴۹

Phone

+98 66 3320 4517

Email

Zhraahmdy669@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Khoram-Abad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

2

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Tolabi Tahere

Street address

Khorramabad University of Medical Sciences . Km 5 Khorramabad .Complex Campus

City

Khoramabad

Province

Lorestan

Postal code

۶۸۱۳۸-۳۳۹۴۶

Phone

+98 66 3312 0138

Fax

+98 66 3312 0140

Email
pr@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad University of Medical Sciences
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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Zahra Ahmadi Fajr
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No99, 1 Arahsteh Alley, Razi Ave, Enghelab Ave
City
Khoramabad
Province
Lorestan
Postal code
6816849449
Phone
+98 66 3320 4517
Email
Zhraahmdy669@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Zahra Ahmadi Fajr
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No99, 1 Arasteh Alley,Razi Ave,Enghslab Ave
City
Khoramabad
Province
Lorestan
Postal code
6816849449
Phone
+98 33204517
Email
zhraahmdy669@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Zahra Ahmadi Fajr
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No99, 1 Arahsteh Alley, Razi Ave, Enghelab Ave
City
Khoramabad
Province
Lorestan
Postal code
6816849449
Phone
+98 66 3320 4517
Email
Zhraahmdy669@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information related to the main outcome and final result of the impact of therapeutic intervention on variables shared
When the data will become available and for how long
The start of the course access 3moonnth after printing results

To whom data/document is available

Researchers working in academic institutions, and scientific

Under which criteria data/document could be used

If you have a confirmation of the direction of the Run of the Protocol therapy of the scientific institutions

From where data/document is obtainable

Zahra ahmadifajr Zhraahmdy@gmail.com 09384580853

What processes are involved for a request to access data/document

Ask the person the applicant until finally a week later from the knowledge of its authenticity for them to be sent

Comments