

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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 conducted 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 adherence 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

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 conducted 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 immediately 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

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Lorestan

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6813833946

Phone

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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

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Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Zahra Ahmadifajr

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Enghelab Ave. Razi Ave. 1 Arrasteh Alley. No99

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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

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Postal code

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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

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Person responsible for scientific inquiries

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Position
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Latest degree
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Other areas of specialty/work
Nursery

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Person responsible for updating data

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Other areas of specialty/work
Nursery

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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