

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effectiveness of group therapy based on acceptance and commitment to reduce anxiety and improve the quality of life in patients with dialysis and kidney transplant

Protocol summary

Study aim

The comparative evaluation of the effectiveness of group therapy based on acceptance and commitment to reduce anxiety and improve the quality of life in patients with dialysis and kidney transplant.

Design

The study population will be included all patients with dialysis and kidney transplant from 5 to 15 years old. The sample size will be 60 patients. Intervention will be included: the first group treatment of hemodialysis patients based on acceptance and commitment, the second group Treatment of kidney transplant patients based on acceptance and commitment and third group patients without acceptance and commitment therapy (control).

Settings and conduct

The study is designed to reduce the anxiety and improve the quality of life of patients undergoing dialysis and kidney transplantation. The location of the study is Zanjan health centers. The study is interventional.

Participants/Inclusion and exclusion criteria

Inclusion criteria will be included: the maximum age 50 years; having literacy; hemodialysis and kidney transplant and no problem in writing and listening. Exclusion criteria will be included: the presence of psychiatric disorders requiring to the emergency treatment such as psychosis symptoms and suicide; under treatment with anti-anxiety and anti-depressant drugs and severe physical inability.

Intervention groups

Intervention will be included: the first group treatment of hemodialysis patients based on acceptance and commitment, the second group Treatment of kidney transplant patients based on acceptance and commitment and third group patients without acceptance and commitment therapy (control). Intervention time will be six weeks (one session a week).

Main outcome variables

The primary outcome variables will be included: quality of life (physical health, psychological health, social and environmental relationships), Beck anxiety, acceptance and commitment.

General information

Reason for update

Acronym

ACT

IRCT registration information

IRCT registration number: **IRCT20171104037210N1**

Registration date: **2017-12-26, 1396/10/05**

Registration timing: **retrospective**

Last update: **2017-12-26, 1396/10/05**

Update count: **0**

Registration date

2017-12-26, 1396/10/05

Registrant information

Name

Soheila Azari

Name of organization / entity

Islamic Azad University of Zanjan

Country

Iran (Islamic Republic of)

Phone

+98 24 3333 0443

Email address

soheila.azari@iauz.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University of Zanjan

Expected recruitment start date

2017-09-23, 1396/07/01
Expected recruitment end date
 2017-10-23, 1396/08/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The effectiveness of group therapy based on acceptance and commitment to reduce anxiety and improve the quality of life in patients with dialysis and kidney transplant

Public title
 Group therapy based on acceptance and commitment in patients with dialysis and kidney transplant

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 The maximum age 50 years Having literacy; hemodialysis and kidney transplant no problem in writing and listening
Exclusion criteria:
 The presence of psychiatric disorders requiring to the emergency treatment such as psychosis symptoms and suicide Under treatment with anti-anxiety and anti-depressant drugs Severe physical inability

Age
 From **15 years** old to **50 years** old

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
 Simple randomization using random numbers table.

Blinding (investigator's opinion)
 Not blinded

Blinding description
Placebo
 Not used

Assignment
 Parallel

Other design features
 Does not have.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University of Zanjan

Street address

Emam Khomeini Site, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515658145

Approval date

2017-07-31, 1396/05/09

Ethics committee reference number

IR.IAU.Z.REC.1396,63

Health conditions studied

1

Description of health condition studied

Kidney transplant

ICD-10 code

Z94.0

ICD-10 code description

Kidney transplant status

2

Description of health condition studied

Renal dialysis

ICD-10 code

Z99.2

ICD-10 code description

Dependence on renal dialysis

Primary outcomes

1

Description

Quality of life

Timepoint

Six month

Method of measurement

WHO quality of life

2

Description

Anxiety

Timepoint

Six month

Method of measurement

Beck anxiety

3

Description

Acceptance

Timepoint

Six month
Method of measurement
ACT acceptance criteria

4

Description
Commitment

Timepoint
Six month

Method of measurement
ACT commitment criteria

Secondary outcomes

empty

Intervention groups

1

Description
Treatment of hemodialysis patients based on acceptance and commitment

Category
Prevention

2

Description
Treatment of kidney transplant patients based on acceptance and commitment

Category
Prevention

3

Description
Control

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kidney Foundation of Zanzan
Full name of responsible person
Soheila Azari
Street address
Farvardin St., Azadegan Town, Zanzan
City
Zanzan
Province
Zanzan
Postal code
4571964186
Phone
+98 24 3341 1203
Fax
+98 24 3341 1205

Email
soheila.azari@iauz.ac.ir
Web page address
<http://zanzankf.org>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University of Zanzan
Full name of responsible person
Ahmad Taqiloo
Street address
Emam Khomeini Site, Zanzan
City
Zanzan
Province
Zanzan
Postal code
4515658145
Phone
+98 24 3342 1001
Fax
+98 24 3342 1007
Email
Amoozesh@iauz.ac.ir
Web page address
<http://www.iauz.ac.ir/>
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University of Zanzan
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kidney Foundation of Zanzan
Full name of responsible person
Soheila Azari
Position
M.Sc. Clinical Psychology
Latest degree
Master
Other areas of specialty/work
Psychology

Street address

Farvardi St., Azadegan Town

City

Zanjan

Province

Zanjan

Postal code

4513733678

Phone

+98 24 3341 1203

Fax**Email**

soheila.azari@iauz.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kidney foundation of Zanjan

Full name of responsible person

Soheila Azari

Position

M.Sc. Clinical Psychology

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Master

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Psychology

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Fax**Email**

soheila.azari@iauz.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Not allowed from the University viewpoint

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable