

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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 Zanzan

##### Street address

Emam Khomeini Site, Zanzan

##### City

Zanzan

##### Province

Zanzan

##### 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

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

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**Full name of responsible person**

Soheila Azari

**Position**

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**Latest degree**

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**Phone**

+98 24 3341 1203

**Fax****Email**

soheila.azari@iauz.ac.ir

**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