Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Leventhal's Self-Regulatory Model on the Cognitive Emotion Regulation Strategies in Hemodialysis Patients

Protocol summary

Study aim
Determining The Effect of Leventhal's Self-Regulatory Model on the Cognitive Emotion Regulation Strategies in Hemodialysis Patients

Design
In this study, patients will be selected by convenience sampling. Then, individuals will be randomly assigned to the groups using the simple randomization method with balanced blocks. Randomization will be performed using the randomization method with balanced blocks with a block size of 4. 180 participants (90 in each group) will be invited to participate.

Settings and conduct
This will be a randomized controlled clinical trial in patients undergoing hemodialysis at Booali Hospital. The study will involve implementing Leventhal's Model in the intervention group and providing routine care in the control group. Also, we will not have blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in the research and complete the consent form, Full consciousness and the ability to communicate, People over 18 years old, Being literate in reading and writing in the Persian language, Starting, Hemodialysis at least 3 months ago, having access to a phone or mobile for follow-up

Intervention groups
The intervention will consist of 2 sessions, each lasting 30 to 45 minutes. The educational sessions will focus on the cognitive representations discussed in Leventhal's self-regulation model (identity, cause, timeline, consequences, control, and treatment).

Main outcome variables
Cognitive Emotion Regulation Strategies

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240725062542N3**
Registration date: **2024-12-14, 1403/09/24**
Registration timing: **prospective**

Last update: **2024-12-14, 1403/09/24**
Update count: **0**

Registration date
2024-12-14, 1403/09/24

Registrant information

Name
Sima Kazemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3333 6001

Email address
nurse.simakazemi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-21, 1404/01/01

Expected recruitment end date
2025-06-22, 1404/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Leventhal's Self-Regulatory Model on the Cognitive Emotion Regulation Strategies in Hemodialysis Patients

Public title
The Effect of Leventhal's Self-Regulatory Model on the Cognitive Emotion Regulation Strategies in Hemodialysis Patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the research and complete the consent form Full consciousness and the ability to communicate People over 18 years old Being literate in reading and writing in the Persian language Starting Hemodialysis at least 3 months ago Access to a phone or mobile for follow-up
Exclusion criteria:
Diagnosis of a psychiatric disorder and use of psychotropic drugs (as diagnosed by a physician) Experience of spiritual crises in the last 6 months (self-report) Use of alcohol and drugs (self-report)
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Initially, eligible individuals will be selected based on accessibility. Then, for random allocation considering the two-group nature of the study, a randomization method with balanced blocks of size 4 will be employed. To determine the sequence of allocations using the 4-block method, online random allocation software (https://www.sealedenvelope.com/simple-randomiser/v1/lists) will be used. Group identification papers will be placed in sequentially ordered envelopes inside a sealed package to conceal the allocation sequence. This way, the questionnaire with the corresponding code will be assigned to the individual receiving code 1.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Faculty of Nursing and Midwifery, Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code
59811-34197
Approval date
2024-12-11, 1403/09/21
Ethics committee reference number
IR.QUMS.REC.1403.367

Health conditions studied

1

Description of health condition studied
Chronic Kidney Disease
ICD-10 code
N18.9
ICD-10 code description
Chronic kidney disease, unspecified

Primary outcomes

1

Description
This is a score that each participant will receive based on the 18-item Cognitive Emotion Regulation Questionnaire (CERQ-2006).
Timepoint
The Cognitive Emotion Regulation Strategies questionnaire will be administered at three different time points: before the intervention, immediately after the intervention, and three months post-intervention for follow-up.
Method of measurement
This tool (CERQ-2006) measures the cognitive Emotion regulation strategies in response to life-threatening events.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first educational intervention session begins with exploring patients' beliefs about their illness and perceptions of dialysis using simple, clear language without medical jargon, delivered in short sentences. The focus is on addressing misconceptions the patient may have about the illness. In the second

session, after reviewing the previous session's topics, patients are educated on their prognosis, disease duration, treatment methods, complications, and prescribed medications. At the end of each session, a summary of the discussions is reviewed. The content of these sessions is prepared and organized under specialists' supervision, drawing from previous research and medical reference books. In addition to educational sessions, the intervention group will also receive one month of weekly follow-up telephone interventions conducted by the researcher. Call times are determined based on the patient's availability and consent. The content of these calls will focus on encouraging and reinforcing the healthy behaviors taught in the educational sessions, as well as addressing any questions and assessing patient progress within the framework of Leventhal's self-regulation model (identity, cause, timeline, consequences, control, and treatment).

Category

Behavior

2

Description

Control group: In the control group, questionnaires are completed initially, immediately after the intervention, and 3 months post-intervention. At the end, a booklet containing educational points on the disease and points that should be observed during the disease is given to the patient.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali Sina Hospital, Qazvin, Iran

Full name of responsible person

Sima Kazemi

Street address

Faculty of Nursing and Midwifery, Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

59811-34197

Phone

+98 28 3333 6001

Email

nurse.simakazemi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Seyed Mehdi Mirhashmi

Street address

Deputy of Research and Technology, Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

59811-34197

Phone

+98 28 3333 6001

Email

sm.mirhashemi@qums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Sima Kazemi

Position

Faculty Member of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

59811-34197

Phone

+98 28 3333 6001

Email

nurse.simakazemi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Mohammad Ali Soleimani

Position
Professor of Nursing

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Faculty of Nursing and Midwifery, Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
59811-34197

Phone
+98 28 3333 6001

Email
soleimany.msn@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Sima Kazemi

Position
Faculty Member of Nursing

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Faculty of Nursing and Midwifery, Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
59811-34197

Phone
+98 28 3333 6001

Email
nurse.simakazemi@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
All data collected will potentially be shareable after the participants have been de-identified.

When the data will become available and for how long
The data will be available 6 months after the study results have been published.

To whom data/document is available
The data will only be accessible to academic and research institutions researchers.

Under which criteria data/document could be used
Researchers may use this study's results for future studies, provided that they obtain permission from the project coordinators.

From where data/document is obtainable
Executors of the plan: Sima Kazemi (nurse.simakazemi@gmail.com) Mohammad Ali Soleimani (soleimany.msn@gmail.com)

What processes are involved for a request to access data/document
Please contact us via email for further communication.

Comments