

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of a Behavioral Self-Regulation Education on Weight Changes in Hemodialysis Patients

Protocol summary

Study aim

The effect of self-regulation training on weight change in patients treated by hemodialysis

Design

A clinical trial study that is easy and convenient sampling and randomization in groups

Settings and conduct

It was a clinical trials study. The research population of hemodialysis patients referring to Shahid Hasheminejad Hospital will be divided into two groups: test and comparison. Research environment: Hemodialysis section of Shahid Hasheminejad Hospital

Participants/Inclusion and exclusion criteria

Entry criterion: more than 18 years, have studying and writing skill, should be hemodialyzed for at least 3 months. The average weight gain of 6 sessions of dialysis is more than 2.5 kg, Non-participation in the study or training in relation to compliance with fluid restriction simultaneously with the impact of self-regulation training, no kidney transplant history and no psychological problems, awareness of time, place and person. Exit criteria: have no desire to attend in the study, be hospitalized, Participants in the study died, do not attend in 2 sessions of training

Intervention groups

Chronic renal patients who treated by hemodialysis and do not observe the limitations of fluid intake.

Main outcome variables

Self-regulation, Adherence with fluid-intake restriction, Body Weight changes, hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180627040254N1**

Registration date: **2018-11-30, 1397/09/09**

Registration timing: **retrospective**

Last update: **2018-11-30, 1397/09/09**

Update count: **0**

Registration date

2018-11-30, 1397/09/09

Registrant information

Name

Zeinab Afshar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5585 7741

Email address

zeinabafshar94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-22, 1397/04/31

Expected recruitment end date

2018-09-20, 1397/06/29

Actual recruitment start date

2018-07-31, 1397/05/09

Actual recruitment end date

2018-10-01, 1397/07/09

Trial completion date

2018-10-11, 1397/07/19

Scientific title

Effect of a Behavioral Self-Regulation Education on Weight Changes in Hemodialysis Patients

Public title

Effect of a Behavioral Self-Regulation Education on Weight Changes in Hemodialysis Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

More than 18 years Have studying and writing skill
Should be hemodialized for at least 3 months The
average weight gain of 6 sessions of dialysis is more
than 2.5 kg Non-participation in the study or training in
relation to compliance with fluid restriction
simultaneously with the impact of Self-regulation training
No kidney transplant history and no psychological
problems Awareness of time, place and person

Exclusion criteria:

Have no desire to attend in the study Be hospitalized
Participants in the study died Do not attend in 2 sessions
of training

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

An easy and accessible sampling method was used.
Therefore people who come to the dialysis unit will be
selected and by completing the weighing table two
weeks before the intervention and average calculating
for 6 consecutive dialysis sessions, identified peoples
who are not following the limitations of fluid intake and if
have the criteria for entering the study, the informed
consent form and the form of the demographic
information will be completed by samples. Qualified
persons will be placed in two groups randomly (odd or
even days). By coin tossing the test and comparison
groups (test group with letter A and comparison group
with letter B) will be specified.

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 Iran University of Medical
Sciences

Street address

Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-08-10, 1396/05/19

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9411449001

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18.9

ICD-10 code description

Chronic kidney disease

Primary outcomes

1

Description

Weight Changes of undergoing hemodialysis patients

Timepoint

Two weeks before the intervention, 2 weeks and 3
months after the intervention

Method of measurement

Weight was measured by calibrated digital weighing
scales

Secondary outcomes

empty

Intervention groups

1

Description

In the experimental group, self-regulatory behavior
training based on the Kanfer framework included self-
observation, self-assessment, and self-enhancement of a
target behavior. In the form of face-to-face training, with
the presence of a researcher and a psychologist of
behavioral science for 7 weeks, each week, an hour of
meeting with the subjects will be performed. Trainings
are more about discussing people's problems and
leading to solving problems. The content of each session
will be determined by the progress of each session and
the individual's requirements. First session: introduction
of self-regulation practices and its relationship with the
regime of dialysis treatment. Brief overview of fluids and
long-term complications and noncompliance will be done.
Second session: An overview of the relationship between
self-regulatory processes of behavior (eg self-
observation, self-assessment, self-esteem) and goal
behavior. Session 3: Self-reflection will be reviewed and

discussed. Session Four: Self-monitoring skills and the beginning of night-time assignments include their own monitoring of daily fluid intake, mood, and behaviors that lead to over-consumption of fluid in the setting of fluid intake and people will set goals for fluid intake. Fifth Session: Finding you're Strengthening Strategies. Sixth Session: Learning about controlling stimulus behaviors. Seventh session: review and evaluation of experiences Group.

Category

Prevention

2**Description**

Comparison Group: In the comparison group, with the collaboration of a nursing staff member of the Shahid Hasheminejad Hospital's Dialysis Hospital, (Training routine will be repeated) regular training will be provided for 7 weeks, each meeting will receive an appointment with a nurse for one hour. It includes: The first session will be a public discussion of how hemodialysis will be treated. Second Session: Why behavior change (including fluid intake) is important for success and quality of life. Third Session: How the disease affects family members and relatives. Fourth Session: The importance of active participation in Dialysis Sessions. Fifth Session: The importance of patient's interaction and dialysis providers to provide dialysis schedules to set dialysis programs. Sixth Session: logistical problems related to dialysis (for example: patients who are traveling). Seventh session: Completion of the meeting will be discussed with an overview of the discussions.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Hasheminejad Hospital Tehran

Full name of responsible person

Kazem Malakoti

Street address

Valinezhad St. Vali-e-Asr Ave.

City

Tehran

Province

Tehran

Postal code

1969714713

Phone

+98 21 2501 5080

Email

PR@iums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Kazem Malakoti

Street address

Hemmat High way

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

PR@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Zeinab Afshar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Rashid Yasemi st. Vale asr Aven.

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 8820 1978

Fax**Email**

zeinabafshar94@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Jaleh mohammad- aliha

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Rashid Yasemi St. Valeasr Ave

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 8820 1978

Email

mohammadaliha.j@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Zeinab Afshar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Rashid Yasemi St. Valeaser Ave

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 8820 1978

Fax

Email

zeinabafshar94@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 the potential data can be shared after unidentifiable people

When the data will become available and for how long

After paper publication that is taken from article

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Academic research that mentioned to cite this article

From where data/document is obtainable

E-mail responsible for the general response to the trial

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

A month after the receipt of the email will be sent

Comments