

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison the effect of infographic and pamphlet on laboratory indices and weight in patients under hemodialysis

Protocol summary

Study aim

Comparison of the effect of education through pamphlets and mapping information on laboratory indicators and weight of patients undergoing

Design

Educational intervention, two-way blind and parallel and on 234 people. Randomized, three groups, randomization by random block method

Settings and conduct

Before starting the educational program (sodium, potassium, calcium, phosphorus) and the weight of the patients during the last month will be recorded by the researcher. The patients will be randomly divided into three groups at the Hami dialysis center and the intervention will begin. 2 and 6 weeks After the intervention, weight and (sodium, potassium, calcium, phosphorus) are measured again. The participant, clinical caregiver, data analyst, and outcome assessor are blinded.

Participants/Inclusion and exclusion criteria

Inclusion: Verbal communication skills, the desire to participate in the current study, At least 3 months of dialysis history with at least two dialysis sessions per week, not participating in other educational sessions related to therapeutic nutrition in the last year, ability to read exclusion: Long-term transfer/admission to other medical centers, visual and hearing problem

Intervention groups

In the infographic, information will be presented to the patients in 2 training sessions for 20-30 minutes and in groups of 4-6 people, face to face and one week apart. In the first session, how to use the infographic, and the second session will be dedicated to solving the ambiguity and answering the patients' questions. In the pamphlet group, the training sessions in terms of content, number of sessions, and presentation duration are similar to the infographic group, but in the form of a pamphlet. During this time, control group samples will simply receive routine care as before.

Main outcome variables

Weight, sodium, potassium, phosphorus, calcium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220521054937N1**

Registration date: **2022-08-05, 1401/05/14**

Registration timing: **prospective**

Last update: **2022-08-05, 1401/05/14**

Update count: **0**

Registration date

2022-08-05, 1401/05/14

Registrant information

Name

Zakieh Aliyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of infographic and pamphlet on laboratory indices and weight in patients under hemodialysis

Public title

Comparison of the effect of infographic and pamphlets on hemodialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Ability to communicate verbally Willingness to cooperate in the study Perform at least two dialysis sessions per week Have at least 3 months of dialysis history lack of participation other nutrition-related training classes in the past year Ability to read

Exclusion criteria:

Vision and hearing problems Long-term referral to other medical centers in order to follow up and continue the treatment process

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **234**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, patients will be selected by census method and will be assigned to three groups (infographic, pamphlet, control) in a block random manner. Before block randomization, the letter A will be assigned to the Infographic group, the letter B will be assigned to the pamphlet group, and the letter C will be assigned to the control group And in this way, after the randomization, the names of the patients will be written in alphabetical order, and in the opposite column, the letters B, A, and C will be randomly placed in front of the names of each patient. In the block randomization method, each person has an equal chance to be placed in each of the three groups. (Although in this study, all patients will participate in a census, however, for more certainty, according to the analysis of the respected professor of statistics, 40 people will be included in each group)

Blinding (investigator's opinion)

Double blinded

Blinding description

In each shift, in coordination with the patients and the

head of the center, in order to prevent information leakage during the presentation of educational content between patients in different groups, the infographic group will be placed in the first floor, the pamphlet group will be placed on the ground floor, and the control group will be placed on the basement floor. In order to prevent the leakage of information between different groups, as much as possible, groups that are related by family will be in separate groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Arak University of Medical Sciences

Street address

Vice-Chancellor for Research, Arak University of Medical Sciences, Basij Square, Sardasht, Arak

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Province

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Postal code

6941738481

Approval date

2022-05-01, 1401/02/11

Ethics committee reference number

IR.ARAKMU.REC.1401.035

Health conditions studied**1****Description of health condition studied**

Hemodialysis patients

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The amount of laboratory indicators calcium

Timepoint

Before the study, 2 weeks after the start of the intervention and 6 weeks after the intervention

Method of measurement

Calcium measurement using blood sampling

2

Description

The amount of phosphorus laboratory index

Timepoint

Before the study, 2 weeks after the start of the intervention and 6 weeks after the intervention

Method of measurement

Phosphorus measurement using blood sampling

3

Description

The amount of sodium laboratory index

Timepoint

Before the study, 2 weeks after the start of the intervention and 6 weeks after the intervention

Method of measurement

Sodium measurement using blood sampling

4

Description

The amount of potassium laboratory index

Timepoint

Before the study, 2 weeks after the start of the intervention and 6 weeks after the intervention

Method of measurement

Potassium measurement using blood sampling

5

Description

Weight

Timepoint

Before the study, 2 weeks after the start of the intervention and 6 weeks after the intervention

Method of measurement

Weight measurement using a standard scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, topics such as: tips to prevent thirst, side effects of increasing fluids in the body, the role of potassium, phosphorus, sodium and calcium in the body and the side effects of increasing and decreasing them on the body, solutions to improve the amount of phosphorus and sodium and Calcium and potassium in the body are presented to patients in the form of infographic.

Category

Other

2

Description

Intervention group 2: In this group, topics such as: tips to prevent thirst, side effects of increasing fluids in the body, the role of potassium, phosphorus, sodium and calcium in the body and the side effects of increasing and decreasing them on the body, solutions to improve the amount of phosphorus and sodium, calcium and potassium. It is presented to patients in the form of pamphlets.

Category

Other

3

Description

Control group: During this period, the samples of the control group will receive routine care as before and will not receive training from the researcher

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hami Hemodialysis Center

Full name of responsible person

Zakiah Aliyari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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
 Arak 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
 Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
 Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available	One year after the publication of the article and if the corresponding author agrees, the access request will be reviewed.
Clinical Study Report	To whom data/document is available
Yes - There is a plan to make this available	All applicants can access the information.
Analytic Code	Under which criteria data/document could be used
Not applicable	nothing
Data Dictionary	From where data/document is obtainable
Not applicable	Koresh Rezaei; ir.ac.arakmu@rezaei.K; University of Medical Sciences Arak, 00989183677622.
Title and more details about the data/document	What processes are involved for a request to access data/document
After the request is received and reviewed by the research team, the cooperation will be done.	Two weeks after the request of the applicant.
When the data will become available and for how long	Comments