Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
+98 86 3369 0389
Email address
it@arakmu.ac.ir

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

City
Arak

Province
Markazi

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
Street address
Hami Dialysis Center, Shahrak Gardo
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3524
Fax
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Email
pr_valiasr@arakmu.ac.ir
Web page address
https://arakmu.ac.ir/file/download/page/1611645357-marakez-dyaliz.pdf

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Nursing school, Payambar Azam Complex, Basij Square, Sardasht Arak
City
Arak
Province

Markazi
Postal code
3848176941
Phone
+98 86 3417 3639
Fax
+98 86 3417 3645
Email
research@arakmu.ac.ir
Web page address
https://research.arakmu.ac.ir/fa
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

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Zakieh Aliyari
Position
Master Of Medical_surgical Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Markazi
Postal code
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Email
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Zakiah Aliyari
Position
Master Of Medical_surgical Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
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Province
Markazi
Postal code
3848176341
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Fax
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Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Zakieh Aliyari
Position
Master Of Medical_surgical Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Hedayat 6, Moalem town
City
Arak
Province
Markazi
Postal code
3818759335
Phone
+98 86 3369 0389
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Email
it@arakmu.ac.ir

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After the request is received and reviewed by the research team, the cooperation will be done.

When the data will become available and for how long

One year after the publication of the article and if the corresponding author agrees, the access request will be reviewed.

To whom data/document is available

All applicants can access the information.

Under which criteria data/document could be used

nothing

From where data/document is obtainable

Koresh Rezaei; ir.ac.arakmu@rezaei.K; University of Medical Sciences Arak, 00989183677622.

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

Two weeks after the request of the applicant.

Comments