Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

The Influence of Individualized Education on Learning Needs, Uncertainty in Illness, and Patient Activation among Hemodialysis Patients: A Randomized Controlled Clinical Trial

Protocol summary

Study aim

Determining the Influence of Individualized Education on Learning Needs, Uncertainty in Illness, and Patient Activation among Hemodialysis Patients

Design

A randomized, single-blinded, with a parallel group design of 106 patients, enrolled between December 2023 until May 2024. Random number generation software will be used for randomization.

Settings and conduct

Study Setting: hemodialysis department of Imam Reza hospital of Tabriz (Iran) The educator will be careful that the participants not be aware of their allocation in the intervention or control group. Data collection and pre-test and post-test will be done by the researchers who do not know about the division of participants into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1.Patients with definite diagnosis of end-stage kidney disease 2.Age over 18 years 3.Receiving hemodialysis at least 3 times a week Exclusion Criteria: 1.Patients who have treated by hemodialysis for at least three months 2.Absence of mental disorder 3.Absence of cognitive disorders

Intervention groups

Intervention group: In addition to educational brochures, patients will receive individualized education according to the information obtained in the first session and based on the needs & conditions of each patient. Individualized education sessions will be provided at the bedside of each patient & will vary from 3 to 6 sessions & each session will last 10 to 45 minutes. The educational content will be prepared based on the latest version of the authoritative guidelines of dialysis & will include: 1.the disease 2.diet 3.medications 4.side-effects of hemodialysis. The participants of the control group will only receive the brochures which are routinely provided by the hemodialysis department.

Main outcome variables

Patient learning needs; Uncertainty in illness; Activation

General information

Reason for update

Changing the sampling time due to the preparation of educational content and the training of the trainer in the field of patient education and pilot study. Changing the sample size based on the pilot study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20221031056352N1**
Registration date: **2023-02-16, 1401/11/27**
Registration timing: **prospective**

Last update: **2023-10-03, 1402/07/11**
Update count: **1**

Registration date

2023-02-16, 1401/11/27

Registrant information

Name
Mansour Ghafourifard
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date
2024-05-21, 1403/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Influence of Individualized Education on Learning Needs, Uncertainty in Illness, and Patient Activation among Hemodialysis Patients: A Randomized Controlled Clinical Trial

Public title
The Influence of Individualized Education on Hemodialysis Patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a definitive diagnosis of end-stage kidney disease based on medical records Age over 18 years Receiving hemodialysis at least 3 times a week
Exclusion criteria:
Patients who have been treated by hemodialysis for less than three months. Patients with mental disorder (severe depression and dementia) according to the report of the patient or family or based on the patient's records. Patients with cognitive disorders based on Mini-Mental State Examination (MMSE)
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
The selection of participants will be based on simple random block design with blocks of 4 and 6 and with the ratio of allocation one to one (1:1) for intervention (individualized education) and control groups (educational brochures). In order to the allocation concealment, the method of Using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) will be used. In this way, after creating a random sequence, based on the sample size, a number of opaque letter envelopes will be placed inside the letter envelopes in order to avoid the clarity of the contents of the envelopes. The numbering will be done in the same order. Finally, the lid of the envelopes will be glued and they will be placed in a box in order. At the time of the participation of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes The letter will be opened in order and the assigned group of that participant will be revealed. Blocking and preparation of letter envelopes will be done by someone other than the research team.
Blinding (investigator's opinion)
Single blinded
Blinding description
In order to prevent the Hawthorne effect, the educator will be careful that the participants not aware of their allocation in the intervention or control group. Data collection and pre-test and post-test will be done by the trained researchers and they will not be aware of the division of participants into intervention and control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Golgasht, Tabriz University of Medical Science, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2023-01-23, 1401/11/03
Ethics committee reference number
IR.TBZMED.REC.1401.960

Health conditions studied

1

Description of health condition studied
Hemodialysis Care
ICD-10 code
Z49
ICD-10 code description
Encounter for care involving renal dialysis

Primary outcomes

1

Description
Patient Learning Needs
Timepoint
At the beginning of the study (before the intervention), after the end of the intervention and also 3 months after the last individualized education session.
Method of measurement
Patient Learning Needs Scale (PLNS)

2

Description
Uncertainty in Illness
Timepoint
At the beginning of the study (before the intervention), after the end of the intervention and also 3 months after the last individualized education session.
Method of measurement
Mishel Uncertainty in Illness Scale (MUIS)

3

Description
Patient Activation
Timepoint
At the beginning of the study (before the intervention), after the end of the intervention and also 3 months after the last individualized education session.
Method of measurement
Patient Activation Measure (PAM)

Secondary outcomes

1

Description
Intra Dialysis Weight Gain (IDWG)
Timepoint
At the beginning of the study (before the intervention), after the end of the intervention and also 3 months after the last individualized education session.
Method of measurement
Scale

2

Description
hemodialysis adequacy
Timepoint
At the beginning of the study (before the intervention), after the end of the intervention and also 3 months after the last individualized education session.
Method of measurement
Blood Test

3

Description
Urea & creatinine levels
Timepoint
At the beginning of the study (before the intervention), after the end of the intervention and also 3 months after the last individualized education session.
Method of measurement
Blood Test

Intervention groups

1

Description
The patients will be asked to determine their goals on diet, physical activity and proper weight gain, taking medications and managing complications related to the disease. In order to set goals, participants will be motivated and will be supported in setting goals for their disease management. In order to motivation, examples of patients who play an active role in managing their disease and experience fewer hemodialysis complications will be mentioned. The first session will last about up to 60 minutes. In the next sessions, according to the information obtained in the first session and based on the needs, conditions, education level, age and cognitive status of each patient, individualized education will be provided. In order to prevent distraction and disruption in the education session, the education will be provided mainly at the beginning of the hemodialysis sessions and after connecting to the hemodialysis machine. The education will be provided at the bedside of each patient by a master of science Medical- Surgical nursing student, who has a certificate of hemodialysis nursing skill course. The duration of the sessions will be individualized and will vary from 10 to 45 minutes & it will continue until the patient does not feel tired, cooperates and does not have complications such as hypotension. In addition, the education will be in the favorite language of each patient (Persian or Turkish). In addition, in the presentation of educational materials, simple and understandable sentences will be used for each patient, and the use of specialized and incomprehensible terms for the patient will be avoided. The educational content will be prepared based on the latest version of the authoritative guidelines of dialysis (Kidney Disease Outcomes Quality Initiative (KDOQI)) (5-8). Also, the content validity of the individualized education program will be evaluated by a specialized group that includes a nephrology subspecialist, nursing teachers, a hemodialysis supervisor, and an experienced hemodialysis nurse. The educational content will be presented in 4 steps: In the first step, about the nature of the disease, symptoms, complications, warning signs, follow-up (time to see a doctor), prognosis and other alternative treatments, individualized education will be presented. In the second step, individualized education will be provided about proper diet, water, salt, protein, vitamins, physical activity, and proper weight. In the third step, about the medications that each patient takes (application, possible side effects, warning signs, prohibitions on the use of medicines) will be discussed. In the fourth step, the management of complications related to the disease in each patient (skin care and Access, skin edema and itching, constipation, anemia, etc.) will be discussed. The educational content will be

presented orally and face-to-face based on the patient's condition. At the end of each session, the patient will be encouraged to ask his questions. If specialized questions are raised, the patient's nephrologist will be consulted and the appropriate answer will be provided to the patient. If the patient's problems are outside the expertise of the research team (for example, having problems and questions about orthopedics, infectious diseases, etc.), they will be referred to the relevant specialist doctor and the follow-up will be done for the patient's referral. Also, in order to ensure the patient's understanding of the educational materials presented, feedback will be obtained from each patient at the end of each educational session. Also, at the beginning of each session, the materials presented in the previous sessions will be reviewed and some questions will be asked. If the patient cannot remember the material presented in the previous sessions, that material will be repeated. Also, the patient will be asked about the application of the provided educational materials. If the participant is successful in achieving the goals, strategies such as positive support, effective feedback, and encouragement will be implemented in order to maintain successful behavior. If the participant is not successful in using the educational materials, the obstacles will be checked and the appropriate solution will be provided in partnership with each patient. The educational sessions will continue until the patient is able to express the content correctly and answer the researcher's questions correctly. Individualized education sessions will vary from 3 to 6 sessions. In order to maintain continuity in education and prevent forgetting educational materials, at least one educational session will be held for each participant every week. Also, patients can ask their questions by phone or by sending SMS and receive answers to their questions in this way.

Category
Other

2

Description
Control group: The participants of the control group will only receive the educational brochures which are routinely provided by the hemodialysis department of the hospital.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza hospital of Tabriz

Full name of responsible person
Mojtaba Mohammadzade Lame

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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https://ethics.research.ac.ir/EthicsProposalView.php?&code=IR.TBZMED.REC.1401.960

Grant name
.

Grant code / Reference number
.

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available