Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the influence of Mobile-Based dietary program education on Constipation Management and quality of life of Peritoneal dialysis patients

Protocol summary

Study aim
Determining the effect of mobile-based diet plan training on constipation management and quality of life of peritoneal dialysis patients

Design
Phase 3 randomized clinical trial on 30 patients, two arms with active control, Single-blind. Block randomization with random sequence generation software

Settings and conduct
The present study is a double-blind clinical trial that has been compiled using the criteria of the 2010 concert checklist. This study will be performed as a pre-test and post-test with an intervention and control group in Shiraz University of Medical Sciences Peritoneal Dialysis Centers in 2021. physicians, evaluators, educators, statistical analyzers are blinded in this study.

Participants/Inclusion and exclusion criteria
inclusion criteria: 30 patients (+18 y) with symptoms of constipation at the time of screening and scoring 1 and 2 on the Bristol chart. Exclusion criteria: current use of Constipation-Causing Medications, pregnancy or lactation, history of alcohol use or drug abuse, history of thyroid disease in oneself and family, dementia, colitis, irritable bowel syndrome.

Intervention groups
Intervention group for 4 weeks, mobile diet training + placebo; C-Lax placebo, administered twice daily 5 Session 10-minute In the form of Meetings in absentia (WhatsApp software), on days 1-5. Educational content: Definition of peritoneal dialysis, constipation, the importance of constipation and its complications in patients undergoing peritoneal dialysis, the diet of patients undergoing peritoneal dialysis (fruits, vegetables, and water), and appropriate activities to relieve constipation.

Main outcome variables
Constipation status before and after the intervention, assessment with PAC-SYM questionnaire and Bristol chart; Quality of life before and after the interventions, assessment with the PAC-QOL questionnaire.

General information

Reason for update
Writing problems

Acronym

IRCT registration information
IRCT registration number: **IRCT20200707048035N1**
Registration date: **2021-07-02, 1400/04/11**
Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**
Update count: **1**

Registration date
2021-07-02, 1400/04/11

Registrant information

Name
Javad Rajab Zadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 5241 0300

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javadrajabzade888@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-11, 1400/04/20

Expected recruitment end date
2021-08-11, 1400/05/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the influence of Mobile-Based dietary program education on Constipation Management and quality of life of Peritoneal dialysis patients

Public title
Mobile-Based dietary program education on Constipation Management and quality of life
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 18 years, treated with peritoneal dialysis in Shiraz University of Medical Sciences Peritoneal Dialysis Centers in 2021 Ability to read and write Access telecommunications facilities such as telephones or cell phones. Get a score of 1 and 2 on the Bristol chart. Informed consent to enter the study. Patients with symptoms of constipation at the time of screening (average <3 spontaneous bowel movements per week + symptoms related to constipation in at least 25% of bowel movements).
Exclusion criteria:
Current use of medications known to have constipation effects (such as narcotics, calcium channel blockers, tricyclic antidepressants, and anti-parasympathetic drugs), pregnancy or lactation, history of alcohol or drug abuse, and no history of thyroid disease And family; and other significant or uncontrolled illnesses (patients with one of the following conditions: dementia, colitis, irritable bowel syndrome). If the patient undergoes a kidney transplant during the intervention, or does not want to continue participating in the study, he will be excluded from the study.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the block randomization method. Random sequence generation software is also used for randomization. After obtaining written consent, patients will be randomly assigned to blocks of 6 (including 3 participants in the diet + placebo group and 3 participants in the standard treatment group) at a ratio of 1: 1. For concealment, we use random allocation concealment, so that the assigned group is not known before the individual is assigned.
Blinding (investigator's opinion)
Single blinded
Blinding description
C-lax and placebo tablets made by Shiraz School of Pharmacy with similar appearance will be packed in medicine boxes with a similar appearance and will be delivered with the Researcher's assistance. Patients who meet the inclusion criteria from the physician's point of view are selected for inclusion in the study with the help of the Researcher's assistance, And based on the specified random sequence, they are divided into two groups made in WhatsApp software and will receive the bottle with the symbol A or B. Patient education is performed by the principal investigator, patient assessment by the treating physician, and data collection is performed by the Researcher's assistance. All of these people, plus the person performing the statistical analysis, will be unaware of whether A or B is related to the drug or placebo until the end of the study and data analysis. Patients are treated at home and will not be unaware of the allocation of study groups due to their training, but will be unaware of whether A or B is related to medication or placebo until the end of the study. Peritoneal dialysis is performed at home and diet training in the intervention group will be individual.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Fars Province, Shiraz, Zand
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Approval date
2021-04-20, 1400/01/31
Ethics committee reference number
IR.SUMS.REC.1400.050

Health conditions studied

1

Description of health condition studied
constipation
ICD-10 code
K59.0
ICD-10 code description
Constipation

Primary outcomes

1

Description
Severe constipation on the Bristol chart and , Patient Assessment of Constipation and Symptoms
Timepoint
Before and after the intervention
Method of measurement
Bristol chart, Patient Assessment of Constipation and Symptoms

2

Description
Quality of life score in the Constipation Patient Quality of Life Assessment Questionnaire
Timepoint
Before and after the intervention
Method of measurement
Patient Assessment of Constipation-Quality of Life

Secondary outcomes

1

Description
The amount of fiber in the diet
Timepoint
Before and after the intervention
Method of measurement
24-hour food recall questionnaire

Intervention groups

1

Description
The intervention group will be held for 4 weeks by holding training sessions in absentia and through the membership of group members in groups formed in WhatsApp software via mobile. Training sessions for the case group will include 5-10 minute sessions that will take place on days 5-1. Educational content will include the definition of peritoneal dialysis, constipation, the importance of constipation and its complications in patients undergoing peritoneal dialysis, the diet of patients undergoing peritoneal dialysis (fruits, vegetables, and water), and appropriate activities to relieve constipation. Questions and answers, group discussions, and educational videos will be provided through WhatsApp software. Patients will then be reviewed and followed up for 3 weeks in terms of adherence to the educational content provided, diet consumed and how to consume the recommended items and the current situation, and appropriate feedback will be provided if needed. In addition to training, the case group will be given a placebo. The above-mentioned placebo is two corn starch tablets (after preparation by Shiraz University of Medical Sciences Pharmaceutical Company) with the brand name C-Lax, which patients will receive twice a day, similar to the control group. The placebo will be similar in color, shape, and weight to the C-Lax tablet made by the Dineh Iran company.
Category
Behavior

2

Description
Standard treatment group: This group will be treated twice a day as usual with C-Lax made by Dineh Iran Company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza (AS) Specialized Independent Specialized and Sub-Specialized Clinic
Full name of responsible person
Dr. Mani Ramzi
Street address
Namazi Square, next to Namazi Hospital, Imam Reza Specialized and Sub-Specialized Clinic
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Abbas Rezaeianzadeh
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Email
info@sums.ac.ir
Web page address
https://www.sums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
javad rajab zadeh
Position
University student
Latest degree
Bachelor
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Person responsible for updating data

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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 is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published.

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The results of the study can be used to complete the research of academic researchers on dialysis patients and patients with constipation.

From where data/document is obtainable

In order to access the results of the studies, it is possible to contact Mr. Javad Rajabzadeh (listed in the Iranian Clinical Trial Registration Center) through various communication channels. Email address: javadrajabzade888@gmail.com

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

Six months after the publication of the results, the applicant can send a request for the use of data and documents through the communication channels listed in the Iranian Clinical Trial Registration, and an appropriate response will be provided to their request at least three months from the date of application.

Comments