

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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)

Phone

+98 51 5241 0300

Email address

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

۷۴۳۳۶ - 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

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Namazi Square, next to Namazi Hospital, Imam Reza Specialized and Sub-Specialized Clinic

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

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

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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