Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study Of The Effect Of Smartphone-based Nutrition Education On Biochemistry And Anthropometric Indices Of Ileostomy Subjects

Protocol summary

Study aim

Determination And Comparison Of Biochemical And Anthropometric Indices In Patients With Ileostomy In Both Intervention And Control Groups To Investigate The Effect Of Smart Phone-Based Nutrition Education.

Design

This Is A Quasi-Experimental Clinical Trial With A Control Group. 60 Patients With Ileostomy Were Selected According to Inclusion Criteria And Divided Into Two Groups Of Control (30) And Intervention (30).

Settings and conduct

The First Stage Is Performed In Imam Khomeini Hospital And The Second stage Is Three Weeks After Ileostomy Insertion At Surgical Clinic of Imam Khomeini Hospital. Anthropometric Indices By Researcher And Biochemical Parameters Are Measured By Sending Blood Samples To The Central Laboratory Of Imam Khomeini Hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Not Having A Special Diet Related To Underlying Illness; Having An Android Smartphone; Having At Least Reading And Writing Skills; Ability To Work With Smartphones; Able To Communicate, Initiate Oral Nutrition Before 7 Days After Surgery; Lack Of Known Psychological Illnesses. Exclusion Criteria: Unwilling To Participate In The Study; Lack Of Cooperation In The Study; Not Attending A Training Session; Readmission; Longer Hospitalization Time Due to Problems Caused During Surgery; Starting Chemotherapy Before The Third Week After The Implantation of Postoperative Ileostomy In Patients.

Intervention groups

For Both Control And Intervention Groups, The First Step Is To Complete The Demographic Questionnaire And Anthropometric And Biochemical Studies In Two Stages, The Control Group Is Trained By The Staff In Routine And In The Intervention Group, Nutrition Education Is Smartphone-Based.

Main outcome variables

It Is Hoped That Smart Nutrition Education Will Help Reduce The Changes In Biochemical And Anthropometric Indices In These Center, If The Research Results Are Positive.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180615040106N1**
Registration date: **2018-08-26, 1397/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-26, 1397/06/04**
Update count: **0**

Registration date

2018-08-26, 1397/06/04

Registrant information

Name

Ghazaleh Akhoondian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1000

Email address

akhondian.gh@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-05, 1397/05/14

Expected recruitment end date

2018-09-05, 1397/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study Of The Effect Of Smartphone-based Nutrition Education On Biochemistry And Anthropometric Indices Of Ileostomy Subjects

Public title

"The Effect Of Nutrition Education In Ileostomy Patients With Smartphone"

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Not Having A Particular Diet Related To Underlying Disease, Including Diabetics, Low Salt And Low Fat, And ... Owning A Smartphone With Android OS Have At Least Reading And Writing Skills. Ability To Work With Smartphone. Mighty To Communicate. Starting Oral Nutrition Before 7 Days After Surgery. Lack Of Known Psychological Diseases.

Exclusion criteria:

Unwilling To Participate In The Study. Lack Of Cooperation In The Study. Not Attending A Training Session. Readmission (Due to: Non-nutritional Items, Including: Wound Infection, Stomach Hernia, etc.) Longer Hospitalization Time Due to Problems Caused During Surgery. Starting Chemotherapy Before The Third Week After The Implantation of Postoperative Ileostomy In Patients.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

School of Nursing & Midwifery, Rashid Yasemi st., Valiasr St., Tehran, 1996713883, IRAN

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۷۱۳۸۸۳

Approval date

2017-10-26, 1396/08/04

Ethics committee reference number

IR.IUMS.FMD.REC1396.9413686001

Health conditions studied

1

Description of health condition studied

People With Ileostomy

ICD-10 code

Z43.2

ICD-10 code description

Encounter for attention to ileostomy

Primary outcomes

1

Description

The number Of Lymphocytes

Timepoint

This Is Done In Two Steps: The First Stage, The Day Before The Surgery, Which Was Considered In The Pre-intervention Stage, And The Second Stage, Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Method of measurement

Complete Blood Count Test Kit

2

Description

Hemoglobin Index

Timepoint

This Is Done In Two Steps: The First Stage, The Day Before The Surgery, Which Was Considered In The Pre-intervention Stage, And The Second Stage, Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Method of measurement

Complete Blood Count Test Kit

3

Description

Albumin Index

Timepoint

This Is Done In Two Steps: The First Stage, The Day

Before The Surgery, Which Was Considered In The Pre-intervention Stage, And The Second Stage, Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Method of measurement

Albumin Assay Kit

4

Description

Transferring Index

Timepoint

This Is Done In Two Steps: The First Stage, The Day Before The Surgery, Which Was Considered In The Pre-intervention Stage, And The Second Stage, Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Method of measurement

Transferrin Assay Kit

5

Description

C Reactive Protein

Timepoint

This Is Done In Two Steps: The First Stage, The Day Before The Surgery, Which Was Considered In The Pre-intervention Stage, And The Second Stage, Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Method of measurement

C Reactive Protein Elisa Kit

6

Description

Body Mass Index

Timepoint

This Is Done In Two Steps: The First Stage, The Day Before The Surgery, Which Was Considered In The Pre-intervention Stage, And The Second Stage, Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Method of measurement

Calculation Of Height Based On Meter And Weight In Kilograms And Placing In The Formula Of Division Of Weight Into Squared Height

7

Description

Midarm circumference

Timepoint

This Is Done In Two Steps: The First Stage, The Day Before The Surgery, Which Was Considered In The Pre-intervention Stage, And The Second Stage, Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Method of measurement

Measure with Cloth Meter

8

Description

Tricuspid skin fold thickness

Timepoint

This Is Done In Two Steps: The First Stage, The Day Before The Surgery, Which Was Considered In The Pre-intervention Stage, And The Second Stage, Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Method of measurement

Measure With Caliper

9

Description

Waist circumference

Timepoint

This Is Done In Two Steps: The First Stage, The Day Before The Surgery, Which Was Considered In The Pre-intervention Stage, And The Second Stage, Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Method of measurement

Measure With Cloth Meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Smartphone Training Is Based On Two Sessions Of Instruction For The Installation And Use Of The App, Which Includes Nutrition And Diet, After The Surgery, Before The Patient Is Discharged. The First Session Will Include Introducing The App And Installing A Training Program On The Patient's Or His Family's Smartphone, And In The Second Session You Will Learn How To Use The App And Answer Questions Related To The App. Anthropometric Analyzes (Including Measurements Of Body Mass Index, Median Arm Circumference, Skin Thickness In The Trunk Head And Waist Profile) And Biochemical (Including: Hemoglobin, Albumin, Transferrin, Reactive Protein C, Number Of Lymphocytes) In Order To See The Result Of Training In Nutritional Indices In Patients With Ileostomy, It Is Done In Two Steps. The First Stage, The Day Before The Surgery, Is Considered In The Pre-Intervention Phase, And The Second Stage Is Three Weeks After The Surgery And The Insertion Of The Ileostomy.

Category

Lifestyle

2

Description

Control Group: Applying Appropriate Nutrition and Nutrition Training is Done by The Relevant Department Staff, Based on The Routine Section That Includes The Presentation of Pamphlets and Face-to-Face Training. Anthropometric Examinations (Including Measurements of Body Mass Index, Midarm Circumference, Tricuspid Skin Fold Thickness and Waist Circumference) and Biochemical (Including: Hemoglobin, Albumin, Transferrin, Reactive Protein C, Number of lymphocytes), To See The Result of Training in Nutritional Indices in Patients With Ileostomy, in Two Stages Gets The First Stage, The Day Before The Surgery, is Considered in The

Pre-intervention Phase, and The Second Stage is Three Weeks After The Surgery and The Insertion of The Ileostomy.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mehrdad Salehi

Street address

Imam Khomeini Hospital Complex,Dr Gharib st, End of Keshavarz Blvd

City

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Postal code

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Phone

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Email

Imamhospital@tums.ac.ir

Web page address

http://ikhc2.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Deputy Director of Researche And Technology University of Iran

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

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Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

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Email

adminsite@iums.ac.ir

Web page address

http://iums.ac.ir/index.php?sid=1

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Ghazaleh Akhoondian

Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Ghazaleh Akhoondian

Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Ghazaleh Akhoondian
Position
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Latest degree
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Postal code
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Phone
+98 21 4365 1000
Email
akhondian.gh@tak.iums.ac.ir
Web page address
http://fnm.iums.ac.ir/fa?sid=31

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
Total Non-identifiable Data, The Potentialof The People Sharing
When the data will become available and for how long
Start Access 2018/8
To whom data/document is available
Professors and Students
Under which criteria data/document could be used
-
From where data/document is obtainable
-akhondian.gh@tak.iums.ac.ir
What processes are involved for a request to access data/document
Request Via E-mail and Respond by E-mail Within one Week to DO.
Comments