Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of educational and counseling intervention through smartphone on awareness, sedentary behaviors and fast food consumption in women with high body mass index

Protocol summary

Study aim
Determination the effect of educational and counseling intervention through smartphone on awareness, sedentary behaviors and fast food consumption in women with high body mass index

Design
Experimental, pre-test, post-test in the control and intervention group, based on education and counseling, randomized, with 106 persons

Settings and conduct
Pre-test will be done through a questionnaire in both intervention and control groups. In the intervention group, educational and counseling intervention will be done through the application in the first four weeks. Intermittent messages will then be sent through the app during the study. The user will request counseling through the app whenever he needs. Post-test will be performed in both groups three months after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married women aged 15 to 49 years, Women with a BMI above 25، Consumption fast food at least once a week, Having high sedentary behavior, Exclusion criteria: Getting pregnancy during study , Occurrence of a tragic event in life ، Having a medical problem and Reluctance to continue cooperation

Intervention groups
The application will be installed on the mobile phone in the intervention group.Educational materials related to sedentary behavior will be organized in four sections and in the first week, one day in between one sections will be active for the user. In the first week, an individual consultation will be done with each user twice, and then during the stdy, the user can request a consultation in the application at any time. For fast food, these facilities will be created in the second week.The control group will receive routine training at the health center.

Main outcome variables
Improving awarenes, sedentary behaviors and fast food consumption in women with high body mass index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210722051953N1**
Registration date: **2021-08-04, 1400/05/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-04, 1400/05/13**
Update count: **0**

Registration date
2021-08-04, 1400/05/13

Registrant information
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Sayeh Ebrahimi Gangachin
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Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2021-10-12, 1400/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of educational and counseling intervention through smartphone on awareness, sedentary behaviors and fast food consumption in women with high body mass index

Public title
Effect of education and counseling on sedentary behaviors and fast food consumption
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Married women aged 15 to 49 years Women with a BMI above 25 Consumption fast food at least once a week Having high sedentary behaviors Minimum literacy (fifth grade) Being a resident of Urmia Not participating in any physical activity training program for the past six months Not suffering from diseases related to physical activity Willingness to participate in the study Not having a mental health problem Not having sleep disorder Do not take slimming drugs Non-compliance with a special diet Lack of regular physical activity (walking three times a week for at least 30 minutes) or not participating in sports clubs No specific disease (diabetes, thyroid disorder, pco, cardiovascular, hypertension) Listening and speaking ability Having a mobile phone with Android system
Exclusion criteria:
Getting pregnant during study Occurrence of a tragic event in life (death of loved ones, accidents with disability) Having a medical problem Reluctance to continue cooperation
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done in a simple method, individual randomization unit, using a randomization tool made of stamped envelopes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Specifications of the designed application: Profile (specifications include: age, education, occupation, family income level, number of pregnancies, number of live children, number of abortions), weight and height, fast food educational materials (what is fast food?) Mobility (includes: What is sedentary behavior? What are the disadvantages of sedentary behavior?); And there will be tips, each of which will be shown in the form of an icon.The training content will be uploaded somewhere in the application. Clicking on any of the training icons will open the content on a new page.The "Body Mass Index" icon will also include calculating body mass by writing height in centimeters and weight in kilograms. sedentary behavior training materials will be organized in four sections and in the first week, one day in between sections will be active for the user.So that after reading the contents of the first session, it will be possible to use the contents of the next training.In the first week, an individual consultation will be done with each user twice, and then during the three months that the intervention takes place, the user can request a consultation in the application at any time.For fast food, these facilities will be created in the second week.The researcher calls the user every other day (by phone or WhatsApp) to make sure she is using the APP.During the intervention, by clicking on the consultation icon, samples will be able to perform WhatsApp consultation.From the third week, a short message (notification) in the field of stimulation and consumption of fast food will be sent to the intervention group every day at a specified time.Regarding sedentary behavior at 9, 11, 16, 18, 21 hours, the message "Dear user, it is recommended to be active (get up and walk) will be sent.Regarding the consumption of fast food, every day at 12 noon, 6 pm and 9 pm, the message that "consuming fast food is harmful to health."Eat homemade food instead of fast food" is sent to people.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urzhans Ave , Resalat Blvd
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Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2021-06-23, 1400/04/02
Ethics committee reference number
IR.UMSU.REC.1400.111

Health conditions studied

1

Description of health condition studied
Sedentary behaviors
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Fast food consumption
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Women's awareness of sedentary behaviors
Timepoint
Before and three months after ending of the intervention
Method of measurement
Researcher-made questionnaire

2

Description
Women's awareness of the fast food consumption
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Researcher-made questionnaire

Secondary outcomes

1

Description
Average weight
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Using digital scales (Seca, Germany)

2

Description
sedentary behaviors
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Researcher-made questionnaire

3

Description
fast food consumption
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Researcher-made questionnaire

Intervention groups

1

Description
Intervention group:The modified version of the APP will be installed on the mobile phones of the intervention group in the first briefing session and how to use it will be taught in person and in practice.sedentary behavior training materials will be organized in four sections and in the first week, one day in between sections will be active for the user.So that after reading the contents of the first session, it will be possible to use the contents of the next training.In the first week, an individual consultation will be done with each user twice, and then during the three months that the intervention takes place, the user can request a consultation in the application at any time.For fast food, these facilities will be created in the second week.The researcher calls the user every other day (by phone or WhatsApp) to make sure she is using the APP.In counseling, factors that interfere with healthy eating behaviors and adequate physical activity (when, these behaviors have increased and decreased) and identifying the factors that create resistance to behavior change and how to overcome them through the rain of thoughts, explaining the correct patterns by participants Assessing self-confidence and comparing it with temptation, reviewing goals and motivators, reviewing barriers and facilitators of healthy lifestyle behavioral patterns from participants' perspectives.During the intervention, by clicking on the consultation icon, samples will be able to perform WhatsApp consultation.From the third week, a short message about the mobility and consumption of fast food will be sent to the members of the intervention group every day at the specified time.Regarding sedentary behavior at 9, 11, 16, 18, 21 hours, the message "Dear user, it is recommended to be active (get up and walk) will be sent.Regarding the consumption of fast food, every day at 12 noon, 6 pm and 9 pm, the message that "consuming fast food is harmful to health."Eat homemade food instead of fast food" is sent to people.The members of the intervention group will not be deprived of the routine care of comprehensive health centers.(First week) Educational content on sedentary behavior; Day 1: What is overweight and obesity? What causes obesity? The effect of overweight / obesity on health, fertility and pregnancy and ways to deal with it; Day 3: Definition of physical activity and exercise, the positive effects of physical activity on the body and the prevention and control of non-communicable diseases and the amount and intensity of appropriate physical activity; Day 5: What are sedentary behaviors? What are the disadvantages of sedentary behaviors?; Day 7: What are the strategies to reduce sedentary behavior at

home? What are the strategies to reduce sedentary behaviors at work? Sports activities that can be done while watching TV (Week 2) Educational content about fast food; Day 1: How to get proper nutrition? What is the food pyramid? Introducing food groups; Day 3: Healthy food plate and Iranian dietary guidelines; Day 5: Nutritional recommendations in the prevention of overweight and obesity; Day 7: What is the reduction in fast food consumption? What is fast food? What are the disadvantages of consuming fast food?

Category

Lifestyle

2

Description

Control group:The control group will receive routine training from the Comprehensive Health Service Center.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Islam Abad Comprehensive Health Center

Full name of responsible person

Sayeh Ebrahimi Gangachin

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Recruitment center

Name of recruitment center

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Full name of responsible person

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3

Recruitment center

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4

Recruitment center

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Shoara Comprehensive Health Center

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5

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6

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Sponsors / Funding sources

1

Sponsor
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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
Oroumia 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
Oroumia University of Medical Sciences
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Sayeh Ebrahimi Gangachin
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Master student in midwifery counseling
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Person responsible for scientific inquiries

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Publication of research results in the form of publishing a scientific article

When the data will become available and for how long

The access period starts 6 months after the publication of the article.

To whom data/document is available

All people

Under which criteria data/document could be used

For information and awareness the public about sedentary behaviors and consumption of fast food

From where data/document is obtainable

Dr. Roghayeh Bayrami, Assistant Professor, School of Nursing and Midwifery, Urmia Email :rozabayrami@yahoo.com

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

Enter the site of Urmia University of Medical Sciences and search for thesis title

Comments