Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy of a family-centered physical activity intervention at the level of sedentary behavior: Study protocol for a population-based intervention

Protocol summary

Study aim

Our study focuses on the 'Family-Centered Physical Activity ' program, designed to encourage lifestyle modifications that reduces sedentary behaviour.

Design

A two-arm, parallel-group, randomized controlled trial with blinded outcome assessment. The study involves 76 participants, with centralized computerized randomization and allocation concealment. It will be conducted as a single-center trial at Tehran University of Medical Sciences.

Settings and conduct

The trial will be conducted at the Tehran University of Medical Sciences. It employs a single-blind design where participants are blinded to their group assignments. Independent researchers perform assessments to ensure unbiased data collection.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women aged 18 to 65 years. Minimum literacy level (reading and writing skills). Access to a mobile phone capable of receiving text messages. Voluntary consent to participate in the study. Exclusion Criteria: Uncontrolled high blood pressure, heart failure, or heart valve disease. Advanced pulmonary disease or history of heart/stroke events in the past 6 months. Severe weight loss (over 10% body weight) in the past 6 months without dietary management. Pregnancy or positive response to any item in the Physical Activity Readiness Questionnaire (PARQ). Orthopedic problems that may limit physical activity.

Intervention groups

This intervention involves a series of sessions aimed at promoting regular physical activity and reducing sedentary behaviour via simple and available exercises. Also behavior change sessions are included.

Main outcome variables

The primary outcomes are changes in physical activity levels, reductions in sedentary behavior, and improvements in functional fitness. These will be measured using the Global Physical Activity Questionnaire (GPAQ), transtheoretical model questionnaire, and functional tests.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180129038545N2**
Registration date: **2024-11-24, 1403/09/04**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-24, 1403/09/04**
Update count: **0**

Registration date

2024-11-24, 1403/09/04

Registrant information

Name

Maryam Selk Ghaffari

Name of organization / entity

Sports Medicine Research Center Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-18, 1403/05/28

Expected recruitment end date
2026-08-19, 1405/05/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of a family-centered physical activity intervention at the level of sedentary behavior: Study protocol for a population-based intervention

Public title
evaluation of the effectiveness of family-centered physical activity intervention in immobility
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18 to 65 years A minimum level of literacy(reading and writing skills) Access to a mobile phone capable of receiving text messages Voluntary consent to participate in the study
Exclusion criteria:
Uncontrolled high blood pressure Heart failure Heart valve disease Advanced pulmonary disease History of heart or Stroke events in the past 6 months Severe weight loss (more than 10% of body weight) in the past 6 months without dietary management Pregnancy positive response to one or more items inthe Physical Activity Readiness Questionnaire (PARQ) orthopedic problems that may limit physical activity
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of Randomization: The study utilized a simple randomization method to allocate participants into either the intervention group or the control group. Simple randomization was chosen to ensure each participant had an equal chance of being assigned to any of the study groups, thereby minimizing selection bias. Unit of Randomization: The unit of randomization was the individual. Each participant was independently randomized into one of the two groups without considering clusters, ensuring that the effects measured are attributable to the individual-level intervention. Randomization Strata: No stratified randomization was applied in this study. Participants were randomized without prior stratification based on any baseline characteristics. This approach was selected due to the homogeneity of the study population, which consisted of women aged 18 to 65 years from Tehran University of Medical Sciences employees. Tools Used in Randomization: Randomization was conducted using computerized software. This method was selected for its efficiency and ability to generate a random sequence without human intervention, thus ensuring the integrity of the randomization process. How the Random Sequence was Built: The random sequence was generated using a computerized algorithm designed to produce a random allocation sequence. Participants meeting the inclusion and exclusion criteria were entered into the software, which then randomly assigned them to either the intervention or control group in a 1:1 ratio. The algorithm used ensured that each assignment was independent of the previous ones. Allocation Concealment: Allocation concealment was strictly maintained throughout the study to prevent selection bias. The randomization sequence was concealed from the investigators and participants until assignments were made. An independent researcher, who was not involved in the recruitment or assessment processes, handled the allocation. The sequence was kept in a secure, password-protected database, accessible only to the independent researcher responsible for allocation. This process ensured that neither the participants nor the investigators could predict or influence group assignments.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding: This study implemented single-blind blinding, meaning that the participants were unaware of their group assignments (intervention or control). However, due to the nature of the intervention, complete blinding of the participants was not feasible. Blinded Assessments: To minimize bias, an independent researcher who was blinded to group assignments conducted all baseline and post-intervention assessments. This included administering the Global Physical Activity Questionnaire (GPAQ), the transtheoretical model questionnaire, and performing the functional tests such as the 30-second chair stand test and the single leg stand test for balance. The researcher responsible for data analysis was also blinded to the group assignments to ensure objective and unbiased statistical evaluation. Ensuring Blinding Integrity: Throughout the study, efforts were made to maintain the integrity of the blinding process. The independent researcher handling the randomization and allocation was separate from those conducting the assessments and intervention sessions. Participants were instructed not to disclose their group allocation to the assessors, and the intervention materials provided to participants were neutral in appearance, without any indication of group assignment.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
16th Azar St., Enghelab Sq., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417466191

Approval date
2021-06-01, 1400/03/11

Ethics committee reference number
IR.TUMS.NI.REC.1400.014

Health conditions studied

1

Description of health condition studied
Healthy Individuals

ICD-10 code
Z00.0

ICD-10 code description
Encounter for general adult medical examination

Primary outcomes

1

Description
Physical Activity Level: Changes in physical activity levels will be measured using the Global Physical Activity Questionnaire (GPAQ). This questionnaire assesses the intensity, duration, and domain of physical activity.

Timepoint
Primary outcomes will be measured at the following time intervals:Before Intervention:Baseline measurements. Two Months After Intervention. Six Months After Intervention:Follow-up measurements.

Method of measurement
Physical Activity Level:The primary outcome of physical activity level will be measured using the Global Physical Activity Questionnaire. This tool evaluates the intensity, duration, and domain of physical activity through a structured questionnaire.

2

Description
Reduction in Sedentary Behavior: Reduction in sedentary behaviors will be measured through participants' self-reports. This variable includes a decrease in the time spent sitting, reclining, and other sedentary activities throughout the day

Timepoint
Primary outcomes will be measured at the following time intervals:Before Intervention:Baseline measurements. Two Months After Intervention. Six Months After Intervention:Follow-up measurements.

Method of measurement
Reduction in Sedentary Behavior: Sedentary behavior will be measured through self-reported data using a detailed questionnaire. Participants will log their daily activities, specifying the duration of sitting, reclining, and other sedentary behaviors.

3

Description
Improvement in Functional Fitness: Improvement in functional fitness will be measured using functional tests such as the 30-second chair stand test and the single-leg stand test for balance. These tests provide quantitative insights into participants' muscular strength and balance.

Timepoint
Primary outcomes will be measured at the following time intervals:Before Intervention:Baseline measurements. Two Months After Intervention. Six Months After Intervention:Follow-up measurements.

Method of measurement
Improvement in Functional Fitness:Functional fitness will be measured using the 30-second chair stand test and the single-leg stand test for balance. The 30-second chair stand test assesses lower body strength by counting the number of times a participant can stand from a seated position in 30 seconds. The single-leg stand test evaluates balance by timing how long a participant can stand on one leg without support.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This intervention involves a series of sessions aimed at promoting regular physical activity and reducing sedentary behaviour via simple and available exercises. Also behavior change sessions are included. Behavior change sessions are designed to educate, motivate, and facilitate behavior change in order to establish a routine of physical activity. The approach encompasses several key components, including simple exercises, education, goal setting, regular reminders, and family involvement, all aimed at enhancing participants' commitment to a more active lifestyle. Family-Centered Physical Activity " program consists of fun, easy, accessible, and effective exercises and behavior change education.

Category
Prevention

2

Description
Control group: Participants in the control group will receive only general information on physical activity recommended duration of the first session. Unlike the intervention group, participants in the control group will not receive weekly reminder text messages.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sports medicine research center Tehran university of medical sciences
Full name of responsible person
Maryam Selk Ghaffari
Street address
No.7,Jalal Al Ahmad Ave., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Selk Ghaffari
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Sports Medicine Research Center, Jalal-ale-ahmad street
City
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Province
Tehran
Postal code
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Phone
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Email
sportsmed@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Maryam Selk Ghaffari
Position
Sports medicine specialist
Latest degree
Specialist
Other areas of specialty/work
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Latest degree
Specialist
Other areas of specialty/work
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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 collected deidentified IPD
When the data will become available and for how long
starting as soon as the publication
To whom data/document is available
will be available for people working in academic institutions or people working in businesses
Under which criteria data/document could be used
Documents without mentioning the names of the participants can be shared by the researchers after a reasonable request, as well as if there is a need to perform other analyzes after the request and determine the type of analysis and the type of data use with the permission of the authors of the work and the main authors of the final article without is an obstacle
From where data/document is obtainable
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What processes are involved for a request to access data/document
After the approval of each of the owners and authors of the work and study, the applicant will be notified by email and will be informed how to access it. It will take approximately 1 to 2 months to submit the documents.
Comments