Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the Effect of a Multicomponent Healthy Lifestyle Education Program Based on Persian Medicine in Schools on the Quality of Life of Elementary School Students and Parental Self-Efficacy: A Pilot Study

Protocol summary

Study aim

To determine the effect of a multi-component healthy lifestyle education program based on ITM in schools on the quality of life of primary school students and their parents' self-efficacy.

Design

A pilot cluster-randomized controlled trial with intervention and control groups, investigating an Iranian traditional medicine-based lifestyle education intervention among 60 parents of primary school students

Settings and conduct

This study will be conducted in public primary schools in Tehran by randomly selecting two schools from one district and allocating them as clusters to the intervention and control groups. In the intervention group, the students' parents will receive a healthy lifestyle education program based on ITM over a 3-month period (initial in-person training followed by 3 months of virtual education). The control group will receive only routine education. Study outcomes will be evaluated at the end of the 3-month period. Blinding will not be performed in this study

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Students in grades one to three of primary school Obtaining informed written consent from a parent Minimum literacy level (ability to read and write) for the participating parent The participating parent's access to the internet and a smartphone Exclusion Criteria: Students with chronic underlying medical conditions Students living in a single-parent household (due to death or divorce) At least one parent currently undergoing treatment for mental health conditions

Intervention groups

Intervention group: Parents of students who participate in the multi-component healthy lifestyle education program based on Iranian traditional medicine (including educational sessions). Control group: Parents of students who receive routine education not related to ITM.

Main outcome variables

Quality of life of primary school students Parental self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260621069908N1**
Registration date: **2026-07-18, 1405/04/27**
Registration timing: **prospective**

Last update: **2026-07-18, 1405/04/27**
Update count: **0**

Registration date

2026-07-18, 1405/04/27

Registrant information

Name

Zahra Valinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2026-11-21, 1405/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of a Multicomponent Healthy Lifestyle Education Program Based on Persian Medicine in Schools on the Quality of Life of Elementary School Students and Parental Self-Efficacy: A Pilot Study

Public title

Investigating the Effect of Healthy Lifestyle Education Based on Iranian Traditional Medicine in Schools on the Quality of Life of Primary School Students and Parental Empowerment

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Students in grades one to three of primary school (first stage of primary education) Written informed consent obtained from a parent (father or mother) Minimum literacy level (ability to read and write) for the participating parent Access to the internet and a smartphone for the participating parent

Exclusion criteria:

Students with chronic underlying medical conditions (e.g., seizures, diabetes, epilepsy, cancer, hypothyroidism, morbid obesity or underweight, autism, ADHD, etc.) Students living in single-parent households (due to bereavement or divorce) Parents who are currently undergoing treatment for psychiatric or mental health disorders (e.g., severe anger, aggression, depression, etc.)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

First, one district will be selected by simple random sampling from the educational districts. Then, two public primary schools from that district will be randomly selected. Finally, one of these schools will be randomly assigned to the intervention group and the other to the control group. The unit of randomization in this study is the ‘school’ (cluster).

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Shahid Arabi Street, Daneshjoo Boulevard, Valanjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2026-01-25, 1404/11/05

Ethics committee reference number

IR.SBMU.RETECH.REC.1404.997

Health conditions studied

1

Description of health condition studied

Promotion of a healthy lifestyle and health-promoting behaviors, quality of life of primary school students, and parental self-efficacy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean score of children’s health-promoting behaviors based on a researcher-made checklist (Persian Medicine-based)

Timepoint

before, immediately after, and 3 months after the intervention

Method of measurement

A Persian Medicine-based questionnaire/checklist for assessing children’s health-promoting behaviors, completed by the parents

2

Description

Quality of life of primary school students: The mean

score obtained based on the questionnaire.

Timepoint

Before the intervention, immediately after the intervention, and 3 months after the intervention

Method of measurement

Pediatric Quality of Life Inventory (PedsQL), completed by parents

3

Description

Parental self-efficacy: Mean score obtained from the Parenting Self-Agency Measure (PSAM)

Timepoint

Before the intervention, immediately after the intervention, and 3 months after the intervention

Method of measurement

Parenting Self-Agency Measure (PSAM), completed by parents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Parents of primary school students who participate in the multi-component healthy lifestyle education program based on Iranian Traditional Medicine (including educational sessions) and receive the related training

Category

Lifestyle

2

Description

Control group: Parents of students who receive only the routine school education and do not participate in the healthy lifestyle education program based on Iranian Traditional Medicine provided in this study

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected primary schools in one district of Tehran, Iran

Full name of responsible person

Reihane Alipour

Street address

No. 8, Shams Alley, Opposite Tavanir, Valiasr St., Shahid Beheshti School of Traditional Medicine, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Valinejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work
Traditional Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available