

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

Phone

+98 24 3345 9911

Email address

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Recruitment status

Not yet recruiting

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

Afshin Zarghi

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Shahid Beheshti University of Medical Sciences, Arabi Street, Daneshjoo Boulevard, Velenjak, Tehran, Iran

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

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Zahra Valinejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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