Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the Effect of an Educational Intervention Based on the Theory of Planned Behavior on the Prevention of Hypothyroidism in Rural Adolescent Girls: A Randomized Controlled Field Trial

Protocol summary

Study aim

Investigation the impact of an educational intervention based on the Theory of Planned Behavior on preventing hypothyroidism in rural adolescent girls.

Design

A randomized, controlled, parallel group trial with 326 participants (153 intervention, 173 control). Randomization is done using computer-generated. The intervention includes two face-to-face sessions and two weeks of SMS education, followed by a 3-month follow-up. Conducted in 2023-2024.

Settings and conduct

The trial was conducted in Karkheh, Iran, in 2023-2024. Participants were selected from local high schools. The intervention group received two face-to-face sessions and daily SMS messages. The control group received standard education. Data were collected at baseline and three months later.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Informed consent No hypothyroidism Enrolled in a rural secondary school Owns a smartphone Resides in the study village Exclusion Criteria: Missing two sessions Relocated or inaccessible Incomplete questionnaire responses

Intervention groups

This study include an intervention and a control group. The intervention group receives two 30-minute sessions and daily SMS messages for two weeks on hypothyroidism prevention. The control group receives routine care without additional education.

Main outcome variables

Awareness: Knowledge of hypothyroidism and prevention before and after the intervention. Attitude: Participants' beliefs about hypothyroidism prevention. Subjective Norms: Perceived social pressure regarding prevention. Perceived Behavioral Control: Self-perception of ability to prevent hypothyroidism.Behavioral Intentions: Intent to adopt preventive behaviors. Actual Behavior: Changes in behavior related to prevention after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250327065163N1**
Registration date: **2025-06-08, 1404/03/18**
Registration timing: **retrospective**

Last update: **2025-06-08, 1404/03/18**
Update count: **0**

Registration date

2025-06-08, 1404/03/18

Registrant information

Name

Sharifeh Khasraji

Name of organization / entity

Country

Iran (Islamic Republic of)

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khasraji.sh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

2023-10-23, 1402/08/01

Actual recruitment end date

2024-03-19, 1402/12/29

Trial completion date

2024-03-19, 1402/12/29

Scientific title

Investigating the Effect of an Educational Intervention Based on the Theory of Planned Behavior on the Prevention of Hypothyroidism in Rural Adolescent Girls: A Randomized Controlled Field Trial

Public title

How Can Education Help Prevent Hypothyroidism in Rural Teenage Girls?

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to Participate in the Study Absence of hypothyroidism according to the student's health record Studying at a rural secondary school Not Participation in a Similar Educational Program Having a Smartphone

Exclusion criteria:

Inability to communicate in Persian or Arabic Not residing in the village where the student is studying

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **353**

Actual sample size reached: **326**

Randomization (investigator's opinion)

Randomized

Randomization description

his study is a randomized controlled educational intervention with a pre-and-post test approach.The schools were coded with numbers from 1 to 6. Using the RAND function in Excel, a random number is assigned to each school, and the schools were then sorted based on these numbers. The three schools with the highest random numbers were assigned to the intervention group, and the other three schools were assigned to the control group. In this study, no sampling was performed. All students who met the inclusion criteria and whose parents and themselves provided informed consent were included in the research process.st approach.

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 Ahvaz Jundishapur University of Medical Sciences

Street address

No. 23, Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2023-05-27, 1402/03/06

Ethics committee reference number

IR.AJUMS.REC.1402.128

Health conditions studied

1

Description of health condition studied

Hypothyroidism and its prevention in teenager students

ICD-10 code

E03

ICD-10 code description

Other hypothyroidism

Primary outcomes

1

Description

change in the behavior scores about hypothyroidism prevention measured before and three months after the intervention

Timepoint

At baseline (before intervention) and 3 months after the intervention

Method of measurement

Researcher-developed structured questionnaire on hypothyroidism behavior

2

Description

change in the attitude scores about hypothyroidism prevention measured before and three months after the intervention

Timepoint

At baseline (before intervention) and 3 months after the intervention

Method of measurement

Researcher-developed structured questionnaire on hypothyroidism attitude

3

Description
change in the subjective norm scores about hypothyroidism prevention measured before and three months after the intervention
Timepoint
At baseline (before intervention) and 3 months after the intervention
Method of measurement
Researcher-developed structured questionnaire on hypothyroidism subjective norm

4

Description
change in the perceived behavioral control scores about hypothyroidism prevention measured before and three months after the intervention
Timepoint
At baseline (before intervention) and 3 months after the intervention
Method of measurement
Researcher-developed structured questionnaire on hypothyroidism perceived behavioral control

5

Description
change in the behavioral intention scores about hypothyroidism prevention measured before and three months after the intervention
Timepoint
At baseline (before intervention) and 3 months after the intervention
Method of measurement
Researcher-developed structured questionnaire on hypothyroidism behavioral intention

6

Description
change in knowledge score about hypothyroidism prevention measured before and three monthe after the intervention
Timepoint
At baseline (before intervention) and 3 months after the intervention
Method of measurement
Researcher-developed structured questionnaire on hypothyroidism knowledge

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Received an educational program including two 30-minute in-person sessions and two weeks of daily SMS messages. The content focused on awareness, prevention, and healthy behaviors related to hypothyroidism. Sessions were conducted at school during regular hours.
Category
Behavior

2

Description
Control group: during the course of the study, no educational interventions were conducted for the control group, and they only received routine training.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Rural High Schools of Karkheh County
Full name of responsible person
Sharifeh Khasraji
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Iran, Khouzestan, Karkheh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Grant name
research and technology deputy of ahvaz jundishapur university of medical sciences

Grant code / Reference number

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

Title of funding source
Ahvaz University of Medical Sciences

Proportion provided by this source
1

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
Ahvaz University of Medical Sciences

Full name of responsible person
Sharifeh Khasraji

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Public Health

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Person responsible for scientific inquiries

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Position
Professor

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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
Title: De-identified Participant-Level Dataset and Data Dictionary Details: Includes all collected de-identified individual participant data related to primary and secondary outcomes, alongside a comprehensive data dictionary explaining variables, coding schemes, and units.

When the data will become available and for how long
The data will be available starting 6 months after publication of the main study results and will remain

accessible for a minimum of 5 years thereafter.

To whom data/document is available

De-identified data and documentation will be available to qualified researchers affiliated with academic institutions, research organizations, or relevant industry partners who submit a justified request.

Under which criteria data/document could be used

ata may be used for meta-analyses, secondary analyses, or other ethically approved research purposes. Requests will be reviewed by the study’s data access committee. Approval depends on scientific merit, ethical considerations, and compliance with data use agreements.

From where data/document is obtainable

By contacting Sharifeh Khasraji sh.khasraji@gmail.com Khasraji.sh@ajmus.ac.ir

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

Submit a formal request with a brief proposal Review by data access committee (within 4 weeks) Sign a data-sharing agreement Data delivery via secure platform

Comments