# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparing the effectiveness of a self-management application based on a smartphone on pubertal health in Adolescent Boys

## Protocol summary

**Study aim**
Design, Development, and Evaluation of the Impact of a Smartphone-Based Self-Management Application on Pubertal Health in Adolescent Boys in Urmia in 2025

**Design**
A total of 90 adolescent boys in Urmia will be divided into control and intervention groups. In the first group, 45 individuals will be purposefully and conveniently selected and subjected to pre-test and post-test assessments. In the second group, 45 adolescent boys from Urmia will be assessed randomly. Sampling will be conducted using a multistage cluster sampling method. From the two education districts of Urmia (Districts 1 and 2), one area of public schools with different levels of resources (high-resource, medium-resource, low-resource) will be selected in each district. One school from each area will then be randomly chosen. In total, two schools will be randomly selected for the intervention group and two schools for the control group.

**Settings and conduct**
Public lower secondary schools for boys

**Participants/Inclusion and exclusion criteria**
Adolescent boys with pubertal experience, selected from selected schools in Urmia, and willing to use the application for self-management of pubertal health

**Intervention groups**
Adolescents in the intervention group will use the designed application for 10 to 15 minutes daily for 4 weeks. The control group will receive no intervention

**Main outcome variables**
Awareness of pubertal changes; self-confidence; sexual orientation; mood swings; health-related behaviors

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20250905067127N1**
Registration date: **2025-10-12, 1404/07/20**
Registration timing: **prospective**

Last update: **2025-10-12, 1404/07/20**
Update count: **0**

**Registration date**
2025-10-12, 1404/07/20

**Registrant information**

**Name**
Milad Ghasemi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 44 3384 5525

**Email address**
miladbardiagh@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-01-21, 1404/11/01

**Expected recruitment end date**
2026-08-22, 1405/05/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparing the effectiveness of a self-management application based on a smartphone on pubertal health in Adolescent Boys

**Public title**
Examining the effect of a smartphone-based self-

management application on pubertal health in adolescent boys

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Teenage boys from public schools and experiencing puberty Boys willing to use app for self-management of pubertal health

**Exclusion criteria:**

**Age**
From **10 years** old to **15 years** old

**Gender**
Male

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **90**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Sampling will be done using a multi-stage cluster sampling method, which will select one area of public schools with different levels of access (advantaged, semi-advantaged, under-advantaged) from two education districts of Urmia (districts 1 and 2). In each district, one school will be randomly selected. In total, 2 schools will be randomly selected for the intervention group and 2 schools for the control group.

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committees of Urmia University of Medical Sciences

**Street address**
No. 14, Shekarchi Ave.

**City**
Urmia

**Province**
West Azarbaijan

**Postal code**
5716758537

**Approval date**
2025-08-27, 1404/06/05

**Ethics committee reference number**
IR.UMSU.REC.1404.178

## Health conditions studied

### 1

**Description of health condition studied**
pubertal health

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
pubertal health

**Timepoint**
Assessment of pubertal health at baseline and six months after using the self-management application.

**Method of measurement**
The Adolescent Boys' Pubertal Health Needs Questionnaire developed by Yao et al.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Receiving education through the smartphone-based self-management application for a duration of six months

**Category**
Behavior

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
مدارس دولتی دوره اول متوسطه پسران

**Full name of responsible person**
Milad Ghasemi

**Street address**
Imam Khomeini Hospital, Ershad Blvd.

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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Oroumia University of Medical Sciences
**Full name of responsible person**
صابر قلی زاده
**Street address**
Jihad Street, Urmia University of Medical Sciences
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**Phone**
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**Email**
research@umsu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Research and Technology Deputy
**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
**Full name of responsible person**
Milad Ghasemi
**Position**
Master student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Health Promotion
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No further information is 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**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**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