Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of application-based education on preventive behaviors against pediculosis infection in students

Protocol summary

Study aim

The aim of the study was to investigate the effect of app-based education on pediculosis preventive behaviors in students. In this study, knowledge, health beliefs, and preventive behaviors were compared between two groups at three times (before, immediately, and three months after education).

Design

Cluster randomized clinical trial with 90 students in four Aliabad Katul schools; two intervention schools (app-based education) and two control schools (usual education); randomization with Excel; data assessor was blinded.

Settings and conduct

The study was conducted in Aliabad Katul girls' elementary schools. Two schools were selected from the east and two schools from the west and were randomly assigned to the intervention (app-based training) and control (usual training) groups. Data collection was conducted before, immediately, and three months after the training. The data assessor was blinded to the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female students in grades 4-6 in Aliabad Katul with their own and parents' consent, access to a phone or tablet, no chronic illness or recent pediculosis. Exclusion criteria: Withdrawal or non-cooperation, non-use of the app, illness or school change, and absence or non-response to post-tests.

Intervention groups

In this study, the intervention group received education on pediculosis prevention through an educational application based on the health belief model. The content of the application included multimedia education (text, images, videos, and interactive games) about ways to prevent and care for lice. The control group received regular school education on personal hygiene as usual without using the application.

Main outcome variables

Awareness; Perceived susceptibility; Perceived severity; Perceived benefits; Perceived barriers; Self-efficacy; Pediculosis preventive behaviors.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251108067908N1**
Registration date: **2025-11-15, 1404/08/24**
Registration timing: **prospective**

Last update: **2025-11-15, 1404/08/24**
Update count: **0**

Registration date

2025-11-15, 1404/08/24

Registrant information

Name
mehdi zaheriniko
Name of organization / entity
Tarbiat Modares University
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Iran (Islamic Republic of)
Phone
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-06, 1404/09/15

Expected recruitment end date

2025-12-16, 1404/09/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of application-based education on preventive behaviors against pediculosis infection in students

Public title
Investigating the effect of application-based education on preventive behaviors against pediculosis infection in students
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Female students in grades four to six of elementary school in Aliabad Katul County Written consent from the student and parents to participate in the research Access to a mobile phone or tablet to use the educational app (with parental supervision) Not having chronic diseases or specific physical conditions that prevent participation in training No history of pediculosis or active treatment within one month prior to the start of the study.
Exclusion criteria:
Lack of written consent from students and parents to participate in the research Having chronic illnesses or specific physical conditions that prevent participation in training Having a history of pediculosis or active treatment within one month prior to the start of the study Lack of access to a mobile phone or tablet to use an educational app (with parental supervision) Female students other than fourth to sixth graders of primary school in Aliabad Katul County
Age
From **10 years** old to **12 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, stratified cluster randomization was used. The school was considered the unit of randomization to prevent the transfer and exchange of information between students of different groups. For this purpose, first, a list of primary girls' schools in Aliabad Katul city was received from the Education Department. Then, the schools were divided into two classes, east and west of the city, based on geographical location, to ensure a balanced geographical distribution of the samples. In each class, two schools that had similar conditions in terms of the number of students, socio-economic level, and willingness to cooperate with the research were selected; a total of four schools were included in the study. In each class (east and west), schools were randomly assigned to the intervention and control groups. For this purpose, Excel software and the RAND function were used to generate random numbers. Each school was assigned a random number, and the school with the smaller number was designated as the intervention group (app-based education) and the other school as the control group (regular school education). The random sequence generation process was performed by a research associate who was unaware of the purpose of the study and the nature of the groups. The file containing the random sequence was stored in encrypted form and was unchangeable after finalization. To maintain allocation concealment, the randomization results were kept in sealed, coded envelopes. Until the pretest was completed at each school, none of the research team members were aware of the school allocation type. After the pretest was completed, the envelope for each school was opened and the group type was determined. This process helped maintain impartiality in data collection and prevent allocation bias.
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 Committee of Tarbiat Modares University
Street address
Intersection of Jalal Al-Ahmad and Chamran Highways, Tarbiat Modares University
City
Tehran
Province
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Postal code
۱۴۱۱۷۱۳۱۱۶
Approval date
2025-11-15, 1404/08/24
Ethics committee reference number
IR.MODARES.REC.1404.121

Health conditions studied

1

Description of health condition studied
Pediculosis

ICD-10 code
B85.0
ICD-10 code description
Pediculosis due to Pediculus humanus capitis

Primary outcomes

1

Description
In this study, the pediculosis preventive behaviors score was considered as the primary outcome variable. This variable was measured using the Pediculosis Prevention Behaviors Questionnaire in three stages (before, immediately, and three months after the intervention) and was used as the basis for determining the study sample size.
Timepoint
The primary outcome variable (prevention behavior score) is measured at three time points:Pretest — before the intervention begins (before training).Immediate posttest — immediately after the end of the training program (up to one week after the end of the intervention).Three-month follow-up — three months after the end of the intervention (approximately 90 days after the end).Each measurement is made with the same prevention behavior questionnaire and is used to analyze changes between these time points.
Method of measurement
The primary outcome variable, the pediculosis preventive behaviors score, was measured using the Pediculosis Prevention Behaviors Questionnaire. This questionnaire includes a set of standard items about health behaviors related to pediculosis prevention and was completed by students at all three time points.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Students in this group received training based on the pediculosis educational app. The content of the app included: short educational videos infographics health tips, preventive behaviors and early detection methods interactive activities and questions. Students used the app with their parents for a specific period of time and had full access to all educational sections. No pharmaceuticals or therapeutic interventions were provided and only structured e-learning was implemented.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Aliabad Katul Girls' Elementary Schools
Full name of responsible person
Mehdi Zaheri Niko
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ayat
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
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Phone
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mjavan@modares.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares University
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
Tarbiat Modares University

Full name of responsible person
Fadlallah Ghafranipour

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

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Position
Associate Professor

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Health Promotion

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Person responsible for updating data

Contact

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Full name of responsible person
mehdi zaheri niko

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Health Promotion

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Phone
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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
Not applicable

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
In this study, individual participant data files including knowledge scores, health model constructs, and preventive behaviors were collected at three time points. These data are available for sharing after removing any identifiable information (fully de-identified). Sharing will only include data related to the main study outcomes and will not release identifying information, school details, or any other sensitive data.

When the data will become available and for how long
De-identified study data will be available 6 months after the publication of the final research results. The data access period will continue for at least three years after the date of publication of the results.

To whom data/document is available
De-identified study data will be available to researchers and university faculty members. Applicants must have a valid institutional affiliation and provide a clear research objective. Data will not be available to individuals outside of academic and research settings—including industry.

Under which criteria data/document could be used
The conditions for use and access to de-identified data are as follows: Submission of a formal request including the title of the research, the purpose of using the data, and the type of analyses desired. Use only for research

and non-commercial purposes; any commercial or promotional use is prohibited. Permitted analyses are limited to statistical analyses related to the scientific purposes specified in the request; analyses that lead to the inference of the identity of individuals are strictly prohibited. No re-sharing of data with other individuals or organizations without written permission. Use of data in accordance with the principles of research ethics and with full confidentiality. Appropriate citation to the original study in any scientific output (article, thesis, report, etc.).

From where data/document is obtainable

Applicants can apply for de-identified data or study documentation through the following channels: 1. Email contact (mehdizaheriyotub@gmail.com Name of the responsible person: Mehdi Zaheri Niko (Principal Investigator) Email: [mehdizaheriyotub@gmail.com 2. Postal correspondence (second priority) Address: Tehran, Intersection of Jalal Al-Ahmad and Chamran Highways, Tarbiat Modares University, Postal Code: 1411713116, P.O. Box: 111-1 3. Telephone call (third priority) Contact number: [09051436545] In the submitted request, the following information must be provided: Research title, purpose of data use, proposed type of analysis, applicant's organizational affiliation, and confidentiality agreement.

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

The process of receiving data is step-by-step and transparent as follows: Submitting a formal request The applicant must send their request along with the title of the study, purpose of use, type of analysis, and an institutional introduction via the principal investigator’s email. Time required: 1–2 days to register the request. Reviewing the request The request is reviewed by the principal investigator to ensure that the use of the data is consistent with ethical principles and study conditions. Time required: approximately 7–10 business days. Sending a confidentiality undertaking In case of initial approval, the applicant will be sent a confidentiality and non-sharing undertaking form that must be completed and signed. Time required: 3–5 days (depending on the speed of return of the form). Final approval and data preparation After receiving the signed undertaking, the de-identified data are prepared and reviewed for final review. Time required: 5–7 business days. Sending data to the applicant Files will be provided to the applicant via email or secure storage. Estimated total time to receive data: Approximately 2-4 weeks from the time of initial request to final delivery of data.

Comments