

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of gamification mobile health application based on Pender's health promotion model on medication adherence in adolescents with epilepsy

Protocol summary

Study aim

Determine the effect of gamification mobile health application based on Pender's health promotion model on medication adherence in adolescents with epilepsy

Design

A randomized controlled clinical trial was conducted with intervention and control groups, involving 92 patients. Simple randomization was performed using the RAND function in Excel.

Settings and conduct

This study will be conducted at the Ekbatan Hospital, Hamadan, Iran. Due to the nature of the intervention, blinding of investigators is not feasible. The statistician who will analyze the data will be blinded to the intervention and control groups

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adolescents aged 11 to 20 years with epilepsy with medium to poor medication adherence. Willingness to participate and cooperate in the study. Ability to use their own smartphone and access to the Internet. Exclusion Criteria: Use of medications that affect the nervous system. Presence of developmental, psychological, or comorbid medical conditions.

Intervention groups

In the Intervention Group: a gamification app designed will be installed on adolescents' mobile phones and will be used as an intervention over a one-month period. The content was developed based on the constructs of the Pender model, and the program included five icons: Education, Quiz, Reminder, Forgetfulness, and Chat. After earning badges, points, and level upgrades, participants will complete the questionnaires at the end of the intervention period. In the Control Group: During the intervention period, on the related virtual channel, only questionnaires and notifications to complete them will be provided. The Control Group will continue to receive usual care and routine visits. At the end of the

study, to meet ethical considerations, the gamification content will also be provided to them

Main outcome variables

medication adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250901067065N1**

Registration date: **2025-10-03, 1404/07/11**

Registration timing: **registered_while_recruiting**

Last update: **2025-10-03, 1404/07/11**

Update count: **0**

Registration date

2025-10-03, 1404/07/11

Registrant information

Name

Hedieh Sadat Hosseini

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-09, 1404/06/18

Expected recruitment end date

2025-10-22, 1404/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of gamification mobile health application based on Pender's health promotion model on medication adherence in adolescents with epilepsy

Public title
The effect of gamification mobile health application on medication adherence

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Definitive diagnosis of epilepsy based on medical record
 Minimum of 6 months elapsed since definitive epilepsy diagnosis, as documented in the medical record
 Uniform medication regimen according to the medical record
 Age range: 11 to 20 years
 Medication adherence: poor to moderate, assessed by adherence questionnaire
 Willingness of the adolescent and the legal guardian to participate and cooperate in the study
 Ability to use the participant's own smartphone (Android OS) for study procedures
 Access to the Internet
Exclusion criteria:
 Use of medications that affect the nervous system, excluding antiseizure medication regimen
 Presence of a significant developmental disorder (e.g., autism spectrum disorders or intellectual disability)
 Presence of comorbidity (e.g., diabetes, etc.)
 Presence of serious psychiatric disorders (e.g., depression, anxiety disorders, attention deficit hyperactivity disorder) with confirmation by a psychiatrist
 History of acute incidents leading to physical or psychological problems within the past month

Age
From **11 years** old to **20 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
A random number will be generated for each participant using the RAND function in Excel, and participants will be sorted in ascending order based on these numbers. A simple lottery will then be conducted to determine which group (intervention or control) will be allocated to the first half of the list. Accordingly, the first 46 participants will be assigned to the selected group, and the remaining 46 to the other group. The allocation will be performed after all participants have been enrolled in the study to ensure allocation concealment.

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 Hamadan University of Medical Sciences

Street address

Deputy of Research and Technolog, Central Headquarters, Hamadan University of Medical Sciences, 4th Fl., Shahid Fahmideh Blvd., Hamadan, Iran.,

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Approval date

2025-08-30, 1404/06/08

Ethics committee reference number

IR.UMSHA.REC.1404.410

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

Medication adherence score on the Pediatrics Medication Adherence Scale (PMAS) by Bayraktar

Timepoint

Baseline (pre-intervention) and at 1 and 2 months after the initiation of gamification

Method of measurement

Pediatrics Medication Adherence Scale (PMAS) by Bayraktar

Secondary outcomes

1

Description

Medication beliefs score on the Beliefs about medication questionnaire-Specific (BMQ-Specific) by Horne

Timepoint

Baseline (pre-intervention) and at 1 and 2 months after the initiation of gamification

Method of measurement

Beliefs about medication questionnaire-Specific (BMQ-Specific) by Horne

2

Description

Medication barriers score on the Adolescent Medication Barriers Scales (AMBS) by Simons

Timepoint

Baseline (pre-intervention) and at 1 and 2 months after the initiation of gamification

Method of measurement

Adolescent Medication Barriers Scales (AMBS) by Simons

3

Description

Self-efficacy score for appropriate medication use on the Self-Efficacy for Appropriate Medication Use Scale (SEAMS) by Risser

Timepoint

Baseline (pre-intervention) and at 1 and 2 months after the initiation of gamification

Method of measurement

Self-Efficacy for Appropriate Medication Use Scale (SEAMS) by Risser

Intervention groups

1

Description

Intervention group: The designed gamification application, along with installation instructions and user guidelines, will be provided in the form of educational content via a virtual channel. Adolescents will be asked to install the application on their smartphones and use it in their daily routine for a period of one month (the intervention duration). The gamification content was developed based on the determinants of medication adherence and according to the constructs of Pender's Health Promotion Model. The application consists of five icons: Education, Quiz, Reminder, Forgetfulness, and Chat. Education and Quiz section: Includes educational videos related to medication adherence. Adolescents are required to watch these videos every other day and participate in the related quiz embedded in the Quiz section. Successful completion of each quiz will unlock the next level in the game. Participants are allowed unlimited attempts until they pass the quiz. Each quiz contains several questions with a pre-defined and limited

response time. Upon passing each quiz, the adolescent receives a "badge" within the game. Reminder section: Medication reminder alarms will be set for each participant by the researcher via the server, based on the physician's prescription. After each reminder is activated, the adolescent has 60 seconds to take the medication and confirm intake through the notification system. Each confirmation of medication intake is rewarded with one coin as a game "point". Forgetfulness section: Displays a forgetfulness log, where the number of missed doses (i.e., failure to confirm medication intake after an alarm) is automatically recorded, providing a visual overview of the adolescent's medication-taking behavior. Chat section: Allows adolescents to share their forgetfulness logs with peers and communicate directly with the researcher via a chat box to ask questions or report problems. At the end of the intervention, prizes will be awarded to the top three adolescents who earn the highest number of badges and points. All user activities within the application will be monitored and controlled by the researcher through the server. It should be noted that none of the gamification features interfere with adolescents' school, sleep, or daily activities. During the intervention period, the experimental group will also continue to receive routine care and medical visits. Parents will have access to the virtual channel and the application and sufficient opportunity to supervise their child's participation. participants completed the questionnaires at the end of the intervention period.

Category

Behavior

2

Description

Control group: During the intervention period, in the related virtual channel, simultaneously with the Intervention Group, only questionnaires will be provided for completion, along with information on how to complete them and reminder notifications to complete the questionnaires. Data will be recorded and collected on the investigators' server. The Control Group, during the intervention period, will continue to receive usual care and routine visits. At the end of the study, to adhere to ethical considerations, the gamification content, together with installation and usage instructions, will be uploaded to their related virtual channel and responses to their questions will be provided. The duration and method of implementing gamification will be the same as for the Intervention Group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ekbatan Children's Hospital

Full name of responsible person

Hedieh Sadat Hosseini

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan 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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Hedieh Sadat Hosseini

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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