Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 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

Country
Iran (Islamic Republic of)

Phone
+98 81 3826 2756

Email address
hs.hoseini@edu.umsha.ac.ir

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.,

City

Hamadan

Province

Hamadan

Postal code

6517838784

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 Quize 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

Street address
Ekbatan Children's Hospital, Taleghani Street, Jihad Square, Hamadan
City
Hamadan
Province
Hamadan
Postal code
6517838784
Phone
+98 81 3161 0000
Email
hediehhosseini1999@gmail.com
Web page address
https://ekbatan.umsha.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Alireza Soltanian
Street address
Vice Challenger for Research and Technology, Central Headquarters of the Hamadan University of Medical Sciences, Shahid Fahmideh Blvd, Pajoohesh Square, Hamadan
City
Hamadan
Province
Hamadan
Postal code
6517669664
Phone
+98 81 3838 0025
Fax
+98 81 3838 0509
Email
soltanian@umsha.ac.ir
Web page address
https://research.umsha.ac.ir/
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
Street address
No. 19, 2nd Fl., Sadeghiyeh Aly., Shiva Aly., 12-Meter Avicenna St., Taleghani St.
City
Hamedan
Province
Hamadan
Postal code
6515769548
Phone
+98 81 3826 2756
Fax
Email
hs.hoseini@edu.umsha.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Fatemeh Cheraghi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd, Pajoohesh Square, Hamadan
City
Hamadan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۶۹۸
Phone
+98 81 3838 0535
Email
f_cheraghi@yahoo.com

Person responsible for updating data

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
Street address
No. 19, 2nd Fl., Sadeghiyeh Aly., Shiva Aly., 12-Meter Avicenna St., Taleghani St.
City
Hamadan
Province
Hamadan
Postal code
6515769548
Phone
+98 81 3826 2756
Fax
Email
hs.hoseini@edu.umsha.ac.ir

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