

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Investigating the effect of the augmented reality game of oral health education on the level of oral health knowledge of orthodontic patients 8 to 12 years old : A pilot study

#### Protocol summary

##### Study aim

Determining the effect of augmented reality oral health education game on oral health knowledge of 8-12 year old orthodontic patients

##### Design

The present study is a field trial. Using a simple randomization, 17 children will be in the intervention group (dentist augmented reality game) and 17 children will be in the control group (oral and dental health education in the form of educational pamphlets). The rand function of Excel software was used for randomization.

##### Settings and conduct

The present study will be conducted in a private orthodontic practice in Zanjan city, and patients who are eligible to participate in the study will be used. Blinding of the evaluators and the people who will perform the statistical analysis will be done. And after one week and one month, the level of awareness of children about oral and dental health will be checked using a questionnaire.

##### Participants/Inclusion and exclusion criteria

Children 8 to 12 years old Ability to read and write Having a smart phone An orthodontic patient who has been treated with a orthodontic appliance.

##### Intervention groups

In the intervention group, an educational game designed for children's oral health education is presented, and in the control group, only one oral health educational pamphlet is presented. The augmented reality game is designed based on the snake and ladder game design with practice houses. And the houses are in question. In the intervention group, the link to install the software is provided to the patient, and after installing the software on the mobile phone, the game is launched by placing the mobile phone camera on the game logo.

##### Main outcome variables

new technologies such as augmented reality games can

be used to improve children's knowledge in the field of oral and dental health.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210911052431N2**

Registration date: **2023-12-03, 1402/09/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-03, 1402/09/12**

Update count: **0**

##### Registration date

2023-12-03, 1402/09/12

##### Registrant information

##### Name

Azin Nourian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3314 8100

##### Email address

azin.nourian@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-01, 1402/09/10

##### Expected recruitment end date

2024-01-30, 1402/11/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of the augmented reality game of oral health education on the level of oral health knowledge of orthodontic patients 8 to 12 years old : A pilot study

**Public title**  
Investigating the effect of the augmented reality game of oral health education on the level of oral health knowledge of orthodontic patients 8 to 12 years old

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children 8 to 12 years old Ability to read and write  
Having a smart phone An orthodontic patient who has been treated with orthodontic appliance  
**Exclusion criteria:**  
Non-cooperation of the child or parents and failure to complete the parental informed consent form Children with mental problems and blindness People who have not received orthodontic treatment

**Age**  
From **8 years** old to **12 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**  
Target sample size: **34**

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

**Randomization description**  
simple randomization

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The study is blinded, and the evaluators and the person who performs the data analysis are blinded to the sample allocation. In this study, it is not possible to keep the patient blind because the intervention is in the form of providing an educational game to the patient.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zanzan University of Medical Sciences

##### Street address

Mahdavi Blvd, Zanzan university of medical sciences, Zanzan, Iran

##### City

Zanzan

##### Province

Zanzan

##### Postal code

4513956184

#### Approval date

2023-10-31, 1402/08/09

#### Ethics committee reference number

IR.ZUMS.REC.1402.177

## Health conditions studied

### 1

#### Description of health condition studied

Evaluation of the level of awareness of oral health

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Evaluation of the level of awareness of oral health

#### Timepoint

Time zero, one week and one month after the start of the intervention

#### Method of measurement

Oral health questionnaire will be knowledge, attitude and behavior

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:

#### Category

Other

### 2

#### Description

Intervention group: The intervention group will be presented with how to implement the oral and dental

augmented reality educational game by sending a link and installing the software on the mobile phone. After installing the software on the mobile phone, the game is launched by placing the mobile phone camera on the game logo. This game is as common as Marpleh game, and the dice move in virtual space by throwing dice. Children are asked to play this game every day for a week while their parents watch. In the educational game. In the educational game, there are lessons based on the educational concepts of oral health in children with topics such as: correct brushing methods, flossing, familiarization with healthy food sources, factors leading to oral and dental diseases, recommendations for dental visits, etc. is. The post-test will be taken once after a week and again after a month from the children of both groups. The standard questionnaire of knowledge, attitude and behavior of oral and dental health will be presented to the participants and if they do not receive an answer, they will be contacted. It will be taken to ask them questions and answers verbally, and if the participant does not want to complete the questionnaire, they will be excluded from the study.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Private dental office

**Full name of responsible person**

Azin Nourian

**Street address**

Middle Saadi , in front of Pasargad Bank, corner of Bagheri Street, No. 3, first floor

**City**

Zanajn

**Province**

Zanjan

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4513915315

**Phone**

+98 24 3333 2655

**Email**

azin.nourian@gmail.com

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Azin Nourian

**Street address**

Mahdavi Blvd, Zanjan univeristy of medical sciences, Zanjan, Iran

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info@zums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Azin Nourian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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**Province**

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**Postal code**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Azin Nourian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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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**

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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

It has not been decided on the presentation of personal information of the participants, and if it is presented, it will be anonymous and non-identifiable. Data analysis and informed consent form can be shared.

**When the data will become available and for how long**

The access period will start 6 months after the results are published.

**To whom data/document is available**

It will be available for researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

The relevant request has been sent to the project manager, and if approved, the requested documents will be sent.

**From where data/document is obtainable**

Email Address: a.nourian@zums.ac.ir

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

After studying the researcher's request, an answer will be provided within one to two weeks.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Azin Nourian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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