

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Designing and Developing an Oral Health Educational Game and Evaluating its Effect on 8-12-year-old Children's Oral Health

Protocol summary

Study aim

Designing and Developing an Oral Health Educational Game and Evaluating its Effect on 8-12-year-old Children's Oral Health

Design

Clinical experimental study with parallel groups, without blindness of participants but blindness of researcher was done, randomized, was used on 40 patients.

Settings and conduct

The study will be conducted in a private dental office and since the educational game will be presented in the intervention group, it is not possible to blind the participants, but the evaluator was blind to the assignment of the groups.

Participants/Inclusion and exclusion criteria

participants: patients aged 8-12 years referring to a private dental clinic
Inclusion criteria: children aged 8-12 years
exclusion criteria: Children who were beyond the range of age 8-12 years, have mental disabilities, are illiterate in reading and writing, are unfamiliar with the Persian language, are treated with antimicrobial mouthwash or use fixed orthodontic appliances

Intervention groups

The experimental group received game-based training. In the experimental group, the children and their parents took part in an introduction session and received some explanations about the game. In the waiting room, the child was shown how to play a game with the healthcare provider (researcher) acting as a facilitator. It took about 30 minutes to complete the game. The game was then given to the children for home practice and repetition, with a focus on parental supervision and parents playing with their children. Only oral hygiene advice was provided to the control group.

Main outcome variables

Oral health is assessed using the Simplified Oral Hygiene Index (OHIS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210911052431N1**

Registration date: **2021-09-12, 1400/06/21**

Registration timing: **prospective**

Last update: **2021-09-12, 1400/06/21**

Update count: **0**

Registration date

2021-09-12, 1400/06/21

Registrant information

Name

Azin Nourian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

azin.nourian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

2021-09-23, 1400/07/01

Actual recruitment end date

2021-10-23, 1400/08/01

Trial completion date

2021-10-23, 1400/08/01

Scientific title

2

Control group: Only oral hygiene advice was provided to the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Private dental clinic

Full name of responsible person

Azin Nourian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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Web page address

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

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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

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

Information about the main outcome can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

It is possible to use it if you get a valid license from academic and scientific centers.

From where data/document is obtainable

Zanjan Dental School, Orthodontic department, Dr Azin Nourian

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

After reviewing the valid license of academic and scientific centers, it is possible to submit.

Comments