Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 reasercher 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
+98 24 3314 8100

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

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

Public title
Effect of Oral Health Educational Game on Children’s Oral Health
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
8-12-year-old Children
Exclusion criteria:
Children who were beyond the range of age 8-12 years Children with mental disabilities Children who are illiterate in reading and writing Children who are unfamiliar with the Persian language Children who are treated with antimicrobial mouthwash Children who use fixed orthodontic appliances
Age
From **8 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted block randomization was used to allocate two study groups to intervention and control groups. six permutations were utilized with blocks of size of four including ABAB, AABB, ABBA, BAAB, BABA and BBAA (A: intervention group, B: control group).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In this study, due to the educational game provided to patients, it was not possible to blind the participants, but the evaluator who was blinded to the group’s allocation, in all stages.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
mahdavi Bolvar, Zanjan University of Medical Sciences
City
Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2020-02-05, 1398/11/16
Ethics committee reference number
IR.ZUMS.REC.1398.451

Health conditions studied

1

Description of health condition studied
Oral hygiene index
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Simplified Oral hygiene index(OHI-S)
Timepoint
Measurement of simplified oral hygiene index before intervention, one week and one month after intervention
Method of measurement
Observation with dental mirror and explorer is done and checklist of Simplified oral hygiene index is completed.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 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.
Category
N/A

2

Description

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

Street address

Saadi Bolvar, Bagheri Avenue, No 307

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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

Master of Science in Medical Education

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Person responsible for updating data

Contact

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Full name of responsible person
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Latest degree
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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