

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of the Tiny Dentist game on 4 - 10 years old children's anxiety compared with Tell-Show-Do method

Protocol summary

Study aim

Main aim: comparison of the Tell-Show-Do method effect on 4-10 years old children anxiety during dental treatment with use of the Tiny Dentist computer game. Specific aim: comparison of Tell-Show-Do method with the Tiny Dentist computer game on children's anxiety due to Venham-Frankel anxiety index; Minor aims: comparison of Tell-Show-Do method with the Tiny Dentist computer game on children's heart rate during treatment; comparison of Tell-Show-Do method with the Tiny dentist computer game on children's encountered pain due to Wong-Baker pain index; applicable aim: wide use of the Tiny Dentist computer game to control children's anxiety during treatment in Dental clinics if there is a significant difference beside Tell-Show-Do method.

Design

Clinical Trial with control group - parallel - double blinded - randomized

Settings and conduct

Double blinded study held in School of Dentistry, Tehran University of Medical Sciences. Tell-Show-Do for control & Tiny Dentist for intervention.

Participants/Inclusion and exclusion criteria

Study entry criteria: age 4-10 years of old; no history of dental or medical treatment; treatment plan: Oral hygiene education, brushing, infiltration anesthesia, Class II amalgam filling or pulpotomy. Study exit criteria: systemic diseases, psychic disorders, physical or mental retardation; teeth pain at visit; children having mobile phones or personal tablets; history of playing with the Tiny Dentist application.

Intervention groups

After examination & profile completion & before treatment, the procedure will be explained to intervention group by the Tiny Dentist application & they will play with it for 5 minutes.

Main outcome variables

Venham-Frankel Index; heart rate; Wong-Baker Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190720044281N1**

Registration date: **2019-12-07, 1398/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**

Update count: **0**

Registration date

2019-12-07, 1398/09/16

Registrant information

Name

Amirreza Tahersoltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 3942

Email address

a.reza.t.soltani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the Tiny Dentist game on 4 - 10 years old children's anxiety compared with Tell-Show-Do method

Public title

Effect of computer game on children's anxiety

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 4-10 years old; No dental or medical history; Treatment plan: Oral hygiene education, brushing, infiltration anesthesia, Class II amalgam filling or pulpotomy

Exclusion criteria:

Systemic diseases, psychic disorders, physical or mental retardation Teeth pain at visit Children having mobile phone or personal tablets History of playing with the Tiny Dentist application

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Allocation - Flip coin method

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding of the Outcome Evaluator: Given that the anxiety control method is not included in the evaluation documents (Patient profile, Recorded film of treatment procedure and evaluation paper), the evaluators are unaware of the anxiety control method in each patient. Blinding of Data Analyzer: Considering that the control & intervention groups are distinguished from the each other by number & they are not named, then the analyst is also unaware of which group is control or intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics in research committee, School of Dentistry, Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, School of dentistry, North karegar Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2019-06-01, 1398/03/11

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1398.041

Health conditions studied**1****Description of health condition studied**

Dental Anxiety (This condition is not a disease)

ICD-10 code

F41

ICD-10 code description

Anxiety

Primary outcomes**1****Description**

Anxiety

Timepoint

During Treatment

Method of measurement

Venham-Frankel Anxiety Index

Secondary outcomes**1****Description**

Heart Rate

Timepoint

Before & after anesthesia, before & after intervention, during treatment

Method of measurement

Pulse-oximeter Device

2**Description**

Encountered pain

Timepoint

During treatment

Method of measurement

Wong-Baker index

Intervention groups

1

Description

Intervention group: Use of the Tiny Dentist application

Category

Treatment - Other

2

Description

Control group: Tell-Show-Do method

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Alireza Heydari

Street address

School of Dentistry TUMS, North karegar st., Tehran

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 4279 4000

Email

a1001heidari@gmail.com

Web page address

<http://dentistry.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amirali Sohrabpour

Street address

Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8163 3686

Fax

Email

vcr@tums.ac.ir

Web page address

<http://vcr.tums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Alireza Heydari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

School of dentistry TUMS, North karegar St., Tehran

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 4279 4000

Email

a1001heidari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sara Ghadimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

School of Dentistry TUMS, North Karegar st., Tehran

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 4279 4000

Email

sghadimi@tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Amirreza Tahersoltani

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street addressNo. 102, zerehpoush 18th st., North karegar st.,
Tehran**City**

Tehran

Province

Tehran

Postal code

1438835884

Phone

+98 21 8801 3942

Email

a.reza.t.soltani@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is still no base for data publishing regarding information privacy.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Age & gender Heart rate Venham-Frankel index Wong-Baker index

When the data will become available and for how long

After publishing the letter

To whom data/document is available

Researchers Journal authorities

Under which criteria data/document could be used

Systematic Review performers

From where data/document is obtainable

Study General Author/PI

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

Contacting General Author

Comments