

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

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##### Province

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##### Postal code

1439955991

##### Phone

+98 21 8163 3686

#### Fax

#### Email

[vcr@tums.ac.ir](mailto: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

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School of dentistry TUMS, North karegar St., Tehran

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##### Province

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##### Postal code

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##### Phone

+98 21 4279 4000

##### Email

[a1001heidari@gmail.com](mailto: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

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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 address**No. 102, zerehpoush 18th st., North karegar st.,  
Tehran**City**

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**Province**

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**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 &amp; 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**