

# The use of a dental storybook for reduction of dental anxiety among children

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<b>Registration date</b> 04/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/03/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Dental anxiety is fear, anxiety or stress associated with a dental setting. Dental anxiety is one of the major challenges in child dentistry that may result in the avoidance of dental treatment and affect the overall treatment quality.

**Aim:** To evaluate the effectiveness of a specially-designed dental storybook in reducing dental anxiety among children.

### Who can participate?

Children aged 6-8 years old due to have dental treatment

### What does the study involve?

Children were randomly divided into two groups: the intervention group (received the storybook) and the control group. Three dental visits (screening, examination and cleaning, and treatment) were provided for each child. Anxiety and behavior were assessed following each visit.

### What are the possible benefits and risks of participating?

**Benefits:** children benefited from having the storybooks, fluoride application, and dental cavities treatment

**Risks:** there are no potential risks expected

### Where is the study run from?

Dental University Hospital, King Saud University (Saudi Arabia)

### When is the study starting and how long is it expected to run for?

January 2019 to March 2020

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr. Alrouh Alsaadoon, alrouhms@gmail.com

## Contact information

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Public

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

IRB E-18-3190, CDRC (No. PR 0104).

## Study information

### Scientific Title

The use of a dental storybook as a dental anxiety reduction medium among pediatric patients: A randomized controlled clinical trial

### Study objectives

Children who receive the dental storybook will show a reduction of dental anxiety levels compared to those who will not receive it.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 20/03/2019, Institutional Review Board (IRB) at the College of Medicine, King Saud University (P.O.Box, 7805 Riyadh 11472 DEM 65, Saudi Arabia; +966 114691531; irb.medksu@hotmail.com), ref: PR 0104

### **Study design**

Multicenter interventional double-blinded randomized clinical trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Dental anxiety in children

### **Interventions**

Eighty-eight children (6–8 years old) were randomly divided into two groups: the intervention group (received the storybook) and the control group (did not receive the storybook). Three dental visits (screening, examination and cleaning, and treatment) were provided for each child. Anxiety was assessed following each visit using the Children's Fear Survey Schedule-Dental Subscale (CFSS-DS) and the Venham clinical anxiety scale (VCAS). The behavior was assessed using Frankl's scale.

All the eligible children were randomized to one of the two groups using the block randomization method: an intervention group (who received the storybook) and a control group (who did not receive the storybook). The required sample size of 105 was divided into seven blocks with 15 subjects in each block. A block of 15 two-digit random numbers was generated from which odd/even random numbers were allotted to the intervention and control groups. An independent trial investigator performed allocation concealment with sequentially numbered, opaque, and sealed envelopes (not measuring the study's outcomes). The allocation ratio was intended to be equal. The main investigator (outcome assessor AR. S) was blinded to the group allocations.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Dental anxiety is measured using the self-report 15-items Arabic Version of Children's Fear Survey Schedule-Dental Subscale (CFSS-DS) questionnaires, and Venham clinical anxiety scale (VCAS) at screening visit, examination visit, and treatment visit (with a one-week interval between each visit).

**Key secondary outcome(s)**

Behavior was assessed using Frankl's behavior rating scale at screening visit, examination visit, and treatment visit (with a one-week interval between each visit).

**Completion date**

22/03/2020

**Eligibility****Key inclusion criteria**

1. Children aged 6-8 years old
2. Medically fit children with ASA I (a normal healthy patient) according to the American Society of Anesthesiologists Classification
3. Children/parents who can read and understand Arabic
4. The need for restorative treatment (occlusal fillings) that required local anesthesia in the upper arch

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

8 years

**Sex**

All

**Total final enrolment**

88

**Key exclusion criteria**

1. Children with special needs
2. Children who have a complete audio-visual impairment
3. Children with learning difficulties or mental retardation
4. Children of non-Arabic speakers
5. Previous treatment with nitrous, sedation, or general anesthesia
6. Conditions requiring emergency dental treatment (abscess, draining sinus, cellulitis)
7. The need for pharmacological management to cooperate; and known dental phobia

**Date of first enrolment**

21/03/2019

**Date of final enrolment**

10/03/2020

## Locations

**Countries of recruitment**

Saudi Arabia

**Study participating centre****King Saud University**

Dental University Hospital

P.O BOX 60169

Riyadh

Saudi Arabia

12372

## Sponsor information

**Organisation**

King Saud University

**ROR**

<https://ror.org/02f81g417>

## Funder(s)

**Funder type**

University/education

**Funder Name**

College of Dentistry, King Saud University

**Alternative Name(s)****Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Saudi Arabia

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/03/2022	04/04/2022	Yes	No
<a href="#">Results article</a>		22/08/2022	06/03/2024	Yes	No