

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

Submission date 02/02/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/03/2024	Condition category 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?

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Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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).

Secondary outcome measures

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).

Overall study start date

15/01/2019

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

Age group

Child

Lower age limit

6 Years

Upper age limit

8 Years

Sex

Both

Target number of participants

88

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

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Sponsor information**Organisation**

King Saud University

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Sponsor type

Government

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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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

09/02/2022

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?
Results article		01/03/2022	04/04/2022	Yes	No
Results article		22/08/2022	06/03/2024	Yes	No