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

Submission date	Recruitment status	[_] Prospectively registered
02/02/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/02/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/03/2024	Oral Health	

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

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Public

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Additional identifiers

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

Primary study design
Interventional

Study design
Multicenter interventional double-blinded randomized clinical trial

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