ISRCTN57204958 https://doi.org/10.1186/ISRCTN57204958

Physiological changes of children with special needs in the application of a papoose board during dental treatment and their caregiver's acceptance

Submission date
13/08/2020

Recruitment status
No longer recruiting

Registration date
27/08/2020

Overall study status
Completed

Last Edited
18/09/2024

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is often a challenge to provide dental treatment for children with disabilities. These patients frequently show high anxiety levels and poor cooperation which form a barrier to dental treatment. Protective stabilization devices such as a Papoose Board® may help with the provision of quality treatment for patients. This study aims to evaluate parental attitude and acceptance of the Papoose Board® in dental treatment for children with special needs and investigate any potential physiological changes that occur during the application of the Papoose Board®. This study may provide evidence for the calming effect of the Papoose Board® in stressful conditions in the dental environment and prove that the application of the Papoose Board® is not harmful. Dental practitioners will consider the use of the Papoose Board® as one of the options for managing uncooperative children and not depending on general anaesthesia. Procedures under general anaesthesia can be reserved for complex dental treatment or severe trauma cases only. When anaesthetic strategies are not appropriate, the Papoose Board® may provide a possible option for the dentists. Therefore, with the use of the Papoose Board®, successful treatment for children with special needs can be achieved.

Who can participate?
Children with special needs aged 16 and below who are undergoing prophylactic (preventative) or restorative dental treatment

What does the study involve?
Participants will receive two treatments (exposures) sequentially over two periods and the order in which treatments are received is randomly allocated. Exposure A is commonly used basic behaviour guidance techniques (tell-show-do, distraction, positive reinforcement) while exposure B is passive immobilization with a Papoose Board. Caregivers will answer a set of questionnaires about their attitudes and acceptance of the use of each exposures before and after application during dental treatment. Physiological changes (blood pressure, heart rate and oxygen levels) will be measured in four distinct phases.

What are the possible benefits and risks of participating?
The parent would be aware of the evidence of using a protective stabilization device during dental treatment. The study may empower parents with children with special needs in receiving dental treatment hence breaking the barriers and challenges for managing children with dental treatment. The child might potentially temporary feel uncomfortable and experience restriction of movement and sweating.

Where is the study run from?
University Teknologi MARA (UiTM) (Malaysia)

When is the study starting and how long is it expected to run for?
June 2020 to June 2022

Who is funding the study?
University Teknologi MARA (UiTM) (Malaysia)

Who is the main contact?
Dr Norsaima Ismail
norsaimaismail6@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Norsaima Ismail

Contact details
Paediatric Dentistry and Orthodontics Department
Faculty of Dentistry
Universiti Teknologi MARA
Sungai Buloh Campus, Selangor Branch
47000, Jln Hospital, Sungai Buloh
Selangor
Sungai Buloh
Malaysia
47000
+60 (0)136422725
norsaimaismail6@gmail.com

Type(s)
Scientific

Contact name
Dr Ilham Wan Mokhtar

ORCID ID
http://orcid.org/0000-0002-6405-9146

Contact details
Center of Comprehensive Care Studies
Faculty of Dentistry
Universiti Teknologi MARA
Sungai Buloh Campus, Selangor Branch
Jln Hospital, Sungai Buloh
Selangor
Sungai Buloh
Malaysia
47000
+60 (0)13 3927229
ilham@uitm.edu.my

Type(s)
Scientific

Contact name
Dr Siti Hajar Hamzah

Contact details
Paediatric Dentistry and Orthodontics Department
Faculty of Dentistry
Universiti Teknologi MARA
Sungai Buloh Campus, Selangor Branch
47000, Jln Hospital, Sungai Buloh
Selangor
Sungai Buloh
Malaysia
47000
+60 (0)133090302
sitihajar1998@uitm.edu.my

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

Physiological changes of children with special needs in the application of a papoose board during dental treatment and their caregiver's acceptance: a non-blinded randomized crossover trial

Study objectives
1. There is a significant difference in caregiver’s acceptance, consent and concern between Papoose Board®, Tell-Show-Do, Distraction and Positive Reinforcement in dental treatment for children with special needs
2. There is a significant difference in caregiver’s attitude, acceptance, consent and concern of Papoose Board® for children with special needs before and after treatment
3. There is a significant difference in physiological measures among children with special needs while receiving dental treatment using Papoose Board, Tell-Show-Do, Distraction and Positive Reinforcement

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2020, UiTM Research Ethics Committee (Research Management Centre, Universiti Teknologi MARA (UiTM), 40450 Shah Alam, Selangor, Malaysia; +60 (0)3 5544 2004; recsecretariat@uitm.edu.my), ref: 600-TNCPI (5/1/6), REC/08/2020 (FB/189)

Study design
Single-centre interventional non-blinded randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

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
Children with special needs while receiving dental treatment

Interventions
Participants will receive two treatments (exposures) sequentially over two periods and the order in which treatments received is randomised (known as the 2×2 or AB/BA design). Exposure A is basic behavioural guidance techniques (BGTs) while exposure B is passive immobilization with a Papoose Board (PB). Basic BGTs adopted in this study are Tell-Show-Do (TSD), Distraction (D) and Positive Reinforcement (PR).

Block randomization will be applied to allocate a sequencing group for the eligible subjects. Caregivers will select an envelope, which are evenly divided into two types of sequencing groups: 45 AB exposure sequence and 45 BA exposure sequence.

Treatment intentions: Dental prophylaxis or/and Class 1 restoration using a slow-speed handpiece.

Physiological changes will be recorded by a designated Dental Surgery Assistant (DSA): the child' s blood pressure, heart rate and SPO2 will be measured using a Welch Allyn Connex® Vital Signs Monitor in four different phases which are baseline, pre-treatment, treatment and post-treatment.

After completion of the treatment, caregivers will be asked to complete a post-intervention questionnaire using the same set of paper-based questionnaires.

Prior to the second stage of the study, the patient will be placed in a washout period for 1-2 months to diminish the impact of the carryover effect. The child will repeat the same procedure as in the first stage of the study for Exposure B. The exposure sequence will be vice versa.

The questionnaire will undergo face validation with 10 parents (not included in the present study) to ensure the clarity of the questions. Implementation of selected BMT and dental treatments on each child will be carried out by the primary investigator (NSI), under the supervision of expert supervisors (IWM and SHH). Training on papoose board placement will be given by an expert supervisor (IWM) prior to commencement of the study.

Intervention Type
Behavioural

Primary outcome measure
Caregiver's acceptance, concern and consent measured using 5-point Likert's Scale questionnaire before and after the intervention

Secondary outcome measures
Physiological changes recorded by a designated Dental Surgery Assistant (DSA): child's blood pressure, heart rate and SpO_2 will be measured by using a Welch Allyn Connex® Vital Signs Monitor in four different phases:
Baseline: child in the waiting room/surgery room sitting on a chair
Pre-Treatment: child lying down on the dental chair and proposed BGT (Exposure A) or wrap in PB (Exposure B) will be applied for 1-2 minutes
Treatment: chosen treatment, either prophylaxis or caries removal (using slow-speed handpiece inside the oral cavity for 1-2 minutes
Post Treatment: child remains lying on the dental chair without Exposure A or Exposure B which lasts 1-2 minutes

Overall study start date
09/06/2020

Completion date
09/06/2022

Eligibility

Key inclusion criteria
Child:
1. All children with special needs aged 16 years old and below who are willing to sit in the dental chair without excessive physical persuasion
2. Children with special needs who will be subjected to either prophylaxis treatment (using a bristle brush with a slow speed handpiece) or simple composite restorative treatment (class I) (using a round burr with a slow handpiece for anterior/posterior teeth)
3. No previous history of Papoose board experience
4. No previous trauma to the fingers of the hand (to enable electrode use in that hand)

Caregiver:
Caregiver can read and understand the language of conduct (Bahasa Malaysia/English)

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
90 participants (45 patient for each group)

Total final enrolment
88

Key exclusion criteria
Child:
1. Medically compromised child with any kind of underlying heart disease that may affect the heart rate variability measurement
2. Child who requires any prophylaxis or restorative treatment in conjunction with the usage of local anaesthesia or inhalation sedation
3. Child who are taken any medication or caffeinated drink on the day of the treatment /intervention
4. Child with episode of asthma and seizure attack, or restrictions in circulation over the past 3 months

Caregiver:
1. Caregiver cannot read and understand the language of conduct (Bahasa Malaysia/English)
2. Caregiver refuses to give consent for their child and themselves to participate in this study

Date of first enrolment
01/10/2020

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
University Teknologi MARA (UiTM)
Special Care Dentistry (Paediatric) and Paediatric Dentistry Clinic
Faculty of Dentistry
Sungai Buloh Campus
Jalan Hospital
Selangor
Malaysia
47000

Sponsor information

Organisation
Universiti Teknologi MARA

Sponsor details
Institute of Graduate Studies
Block 8
INTEKMA Convention Centre
Persiaran Raja Muda
Section 7
Shah Alam
Malaysia
40000
+60 (0)5522 5244
ipsis@uitm.edu.my

Sponsor type
University/education

Website
http://www.uitm.edu.my/index.php/en

ROR
https://ror.org/05n8tts92

Funder(s)

Funder type
University/education

Funder Name
Universiti Teknologi MARA

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethics obligation and confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			05/09/2020	No	No
Results article		05/10/2022	19/12/2022	Yes	No
Results article		01/11/2023	18/09/2024	Yes	No