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Comparing inhaled nitrous oxide gas with cognitive behavioral therapy to reduce anxiety in children undergoing dental treatment

Submission date
30/11/2018

Registration date
07/01/2019

Last Edited
11/09/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people become anxious when they have dental treatment. This can put them off going to the dentist regularly, which might result in teeth being in a worse condition and needing more invasive treatment. Often the anxiety stems from a stressful experience at the dentist in childhood. This study aims to compare two methods of calming children during dental treatment. Nitrous oxide can be mixed with air and inhaled through a nose mask. It reduces anxiety, pain and the gag reflex. It is safe and the effects start and wear off quickly, so the amount breathed in can be easily adjusted if the patient is in pain or feeling too woozy. Cognitive behavioural therapy (CBT) is a talking therapy that help people understand and deal with distressing feelings.

Who can participate?
Children aged 5 to 12 years who have dental anxiety and need pulp treatment in at least one molar tooth in the lower jaw.

What does the study involve?
Participants will be randomly allocated to receive nitrous oxide or CBT during the dental appointment. They will describe their anxiety levels by selecting from a set of faces before and after the dental treatment. They will also provide saliva samples before and after treatment so that levels of the stress hormone cortisol can be measured.

What are the possible benefits and risks of participating?
Patients will receive a complete dental treatment and oral health promotion as a benefit of participating in the study. All participants may leave the study any time and are informed about all the procedures that will be conducted. Nitrous oxide inhalation may provoke side effects, such as nausea or vomiting, but these effects are reversed quickly if the inhalation mask is removed.

Where is the study run from?
Universidad Austral de Chile (Chile)

When is the study starting and how long is it expected to run for?
January 2018 to December 2018

Who is funding the study?
Universidad Austral de Chile (Chile)

Who is the main contact?
1. Mrs Bruna Benso (scientific contact), bruna.benso@uc.cl
2. Mrs Claudia Mautz (public contact), cpazmautz@gmail.com

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Protocol serial number
2017-30

Study information

Scientific Title
Comparison of nitrous oxide inhalation and cognitive behavioral therapy for anxiety in pediatric dental patients in Chile

Study objectives
The current study aimed to verify the safety and effectiveness of inhalation sedation with nitrous oxide when compared to cognitive behavioral therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité de Bioética en Investigación en Humanos, Universidad Austral de Chile, 19/06/2018, ref: 007/2018

Study design
Randomised parallel-arm trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety associated with dental treatment

Interventions
Patients who accepted the invitation were randomly allocated to the intervention A or control group B using a closed envelope technique and a block assignment of two patients. Group A received dental treatment under pharmacological sedation with a mixture of nitrous oxide in oxygen delivered by mask inhalation. Gas concentrations ranged from 30% to 70%, accordingly to patients needs. Group B received dental treatment under cognitive behavioral therapy. The cognitive behavioral therapy was a verbal 'tell–show–do' explanation of dental procedures provided before and during treatment. This is a non-pharmacological technique that allows a link to be established between the child and the dentist. All communication was constructed in phrases appropriate to the development level of the patient. Each treatment session was performed in 30-40 minutes. The total number was defined depending on their needs and according to the DMFT (decayed missing and filled teeth) caries index. All efforts were made to obtain a 1- to 2-week follow-up.

Intervention Type
Mixed

Primary outcome(s)
Completion of planned treatment

Key secondary outcome(s))
1. Anxiety levels assessed using a facial image scale (FIS) immediately before the start of dental treatment and after the end of procedure
2. Stress assessed by measuring saliva cortisol levels immediately before the start of dental treatment and after the end of procedure

Completion date

12/12/2018

Eligibility

Key inclusion criteria
1. Aged 5 to 12 years
2. Moderate to severe dental anxiety
3. Parents' consent to participate in sampling process and two sessions of dental treatment
4. At least one mandibular primary molar needing pulp treatment
5. Previous history of dental treatment

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
12 years

Sex
All

Total final enrolment
49

Key exclusion criteria
1. Chronic obstructive pulmonary diseases
2. Acute otitis media
3. Current medications
4. Chronologically immaturity that may interfere with the ability to understand verbal communication
5. Systemic or congenital disorders
6. Mental retardation

Date of first enrolment
01/07/2018

Date of final enrolment
01/12/2018

Locations

Countries of recruitment

Chile

Study participating centre
Universidad Austral de Chile
Rudloff 1640, Valdivia, Región de los Ríos
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5090000

Sponsor information

Organisation
Universidad Austral de Chile

ROR
https://ror.org/029ycp228

Funder(s)

Funder type
Government

Funder Name
Dirección de Investigación, Universidad Austral de Chile

Alternative Name(s)
DID, UACH

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available upon request from Claudia Mautz, claudiamautz@uach.cl

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes