

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

Submission date 30/11/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/09/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised parallel 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

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 measure

Completion of planned treatment

Secondary outcome measures

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

Overall study start date

01/01/2018

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

Age group

Child

Lower age limit

5 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

25 patients in each of the two groups

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

Valdivia

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5090000

Sponsor information**Organisation**

Universidad Austral de Chile

Sponsor details

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Sponsor type

University/education

Website

<http://medicina.uach.cl/institutos/odontoestomatologia/>

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

Publication and dissemination plan

We plan to submit a results article to a peer-reviewed journal on 01/01/2019.

2019 results presented at the Chilean Division Meeting of the International Association for Dental Research (IADR) in <https://iadr.abstractarchives.com/abstract/chilean-iadr2019-3264757/nitrous-oxide-sedation-reduce-sessions-and-cortisol-levels-in-children>

Intention to publish date

30/06/2019

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