

An assessment of strategies to control dental caries in Aboriginal children living in rural and remote communities in New South Wales, Australia

Submission date 07/06/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/09/2019	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In 2014, Aboriginal Elders in Central Northern NSW identified three Aboriginal communities that had extremely limited access to dental services and needed preventive oral health care programs. The Poche Centre for Indigenous was invited to work in partnership with the local Aboriginal community to introduce sustainable preventive oral health care programs for Aboriginal people in the region. The Precede-Proceed model was used to inform and develop a preventive oral health program. The baseline data collected as part of Stage 1 data provided valuable planning information. Following baseline data collection, four risk factors were found to be associated with an increased risk of developing dental caries: low levels of toothbrush ownership, infrequent daily toothbrushing with a fluoride toothpaste, frequent sugar consumption, and high intake of sugar-sweetened beverages rather than drinking tap water. Following subsequent consultation with the community, a program was developed to address these risk factors. The aim of the program is to improve the oral health of Aboriginal children by promoting daily toothbrushing using fluoride toothpaste, increasing oral health knowledge and encouraging the consumption of water to reduce the reliance on sugar-sweetened beverages.

Who can participate?

Children enrolled in schools in rural NSW in the selected communities, and school staff and parents/guardians from these schools

What does the study involve?

The proposed program includes four components: daily in-school toothbrushing; distribution of free fluoride toothpaste and toothbrushes; in-school and community dental health education; and the installation of refrigerated and chilled water fountains to supply a school water bottle program. Primary school children are given toothbrushing kits to be kept at school to facilitate daily brushing using a fluoride toothpaste under the supervision of trained teachers and/or Oral Health Aides. School children, parents and guardians are given free fluoride toothpaste and toothbrushes for home use at three-monthly intervals. Four dental health education sessions are

delivered to children at each school and parents/guardians at local community health centres over the 12-month study. Dental education is delivered by an Oral Health Therapist and local Aboriginal Dental Assistant. The program also facilitates the installation of refrigerated and filtered water fountain to ensure cold and filtered water is available at schools. A structured school water bottle program encourages the consumption of water. The efficiency, feasibility and effectiveness of the program are assessed.

What are the possible benefits and risks of participating?

Possible benefits include improved oral health, improved general health (reduction in sugar-sweetened beverage consumption and increased consumption of water), and increased oral health knowledge. Possible risks include ingestion of fluoride toothpaste.

Where is the study run from?

Poche Centre for Indigenous Health (Australia)

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

November 2014 to December 2018

Who is funding the study?

Poche Centre for Indigenous Health (Australia)

Who is the main contact?

Mrs Yvonne Dimitropoulos

Contact information

Type(s)

Public

Contact name

Mrs Yvonne Dimitropoulos

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

An assessment of strategies to control dental caries in Aboriginal children living in rural and remote communities in New South Wales, Australia

Study objectives

This study hypothesises that community-led strategies including: in-school toothbrushing, distribution of free oral hygiene resources, refrigerated and filtered water fountains and dental health education will promote daily toothbrushing using fluoride toothpaste, increase oral health knowledge and encourage the consumption of water to reduce the reliance on sugar-sweetened beverages in Aboriginal children and families in order to control dental caries in Aboriginal children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Australian NSW Aboriginal Health and Medical Research Council, 17/11/2017, ref: 1281/17

Study design

Interventional single-group study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Oral health

Interventions

Primary school children will be issued toothbrushing kits to be kept at school to facilitate daily brushing using a fluoride toothpaste under the supervision of trained teachers and/or Oral Health Aides. School children, parents and guardians will be issued free fluoride toothpaste and toothbrushes for home use at three-monthly intervals. Four dental health education sessions will be delivered to children at each school and parents/guardians at local community health

centres over the 12-month pilot. Dental education will be delivered by an Oral Health Therapist and local Aboriginal Dental Assistant. The program will also facilitate the installation of refrigerated and filtered water fountains to ensure cold and filtered water is available at schools. A structured school water bottle program will encourage the consumption of water. A process evaluation will be undertaken to assess the efficiency, feasibility and effectiveness of the pilot program.

Intervention Type

Mixed

Primary outcome measure

The following outcomes will be used during the process evaluation to measure the reach and efficiency of daily in-school toothbrushing:

1. At least 70% of Aboriginal children enrolled in the school have consented to participate in the program
2. 90% of children with consent to participate will brush their teeth at least 170 out of the 200 school days
3. 80% of children with consent to participate are continuing to brush their teeth each day at school after six months
4. Teacher support for the program both at the time of commencement and six months later is positive

The following outcomes will be used during the process evaluation to measure the impact of dental health education and the provision of free oral toothbrushes and toothpaste:

1. 90% of Aboriginal children have a toothbrush and toothpaste at home
2. 90% of Aboriginal children brushed their teeth in the last 24 hours
3. 70% of parents and/or guardians are satisfied with the toothbrushing program
4. 70% of parents and/or guardians assist their children to brush their teeth each night
5. A 70% increase in dental health knowledge specifically relating to the importance of the primary dentition, prevention of tooth decay and the effects of giving a baby a bottle of milk to bed

The following outcomes will be used during the process evaluation to measure the impact and effectiveness of refrigerated and filtered water fountains:

1. 70% of children drink water from the fountain every day
2. 90% of children drink tap water daily
3. 70% reduction of consumption of sugar-sweetened beverages on a daily basis in children aged 5-12 years
4. The use of the water fountain by the children will be recorded by a researcher on two randomly chosen days over the 12-month pilot
5. 70% of teacher support for the water fountain and water bottle program is positive
6. Attitudes of children towards water consumption over that of sugar-sweetened beverages
7. A record of maintenance issues for water fountains installed

All outcomes will be measured using an interviewer assisted questionnaire at 10 months.

Secondary outcome measures

Community satisfaction with the programs, measured using an interviewer assisted questionnaire at 10 months

Overall study start date

10/11/2014

Completion date

18/12/2018

Eligibility

Key inclusion criteria

1. Children enrolled in schools in rural NSW in the selected communities
2. School staff and parents/guardians from these schools

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

Approximately 100 children

Key exclusion criteria

Children who do not have a signed valid consent form

Date of first enrolment

01/02/2017

Date of final enrolment

02/02/2018

Locations

Countries of recruitment

Australia

Study participating centre

Poche Centre for Indigenous Health

Australia

2006

Sponsor information

Organisation

Poche Centre for Indigenous Health

Sponsor details

Room 224 Edward Ford Building
The University of Sydney
Sydney
Australia
2006

Sponsor type

University/education

ROR

<https://ror.org/01kpzv902>

Funder(s)

Funder type

University/education

Funder Name

Poche Centre for Indigenous Health

Results and Publications

Publication and dissemination plan

The protocol will be submitted for publication in June 2018. It can be provided once accepted for publication. This study will be submitted for publication and presented at State and potentially International conferences. Results will also be reported back to the communities which participated in this study.

Intention to publish date

01/06/2018

Individual participant data (IPD) sharing plan

The data set will not be made available as it is the property of local Aboriginal Community Controlled Health Services in Central Northern NSW where this study took place. This is in accordance with the ethics approval which states data on Aboriginal people is owned by the local Aboriginal people.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Protocol article](#)

protocol

29/10/2018

12/09/2019

Yes

No