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Enabling Aboriginal dental assistants to apply fluoride varnish to the teeth of school-children in communities with a high Aboriginal population in New South Wales

Submission date
30/06/2018

Recruitment status
No longer recruiting

Registration date
03/07/2018

Overall study status
Completed

Last Edited
01/03/2021

Condition category
Oral Health

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

Plain English Summary

Background and study aims
Australian Aboriginal children have more tooth decay than non-Aboriginal children. High strength fluoride varnishes have been shown to prevent tooth decay, especially if put on to the teeth 2-4 times per year. In New South Wales, Australia, only medical doctors and dentists can put on the varnish. This increases the risk of Aboriginal children living in rural and remote areas having tooth decay as there is a shortage of dentists in these areas. This means that Aboriginal children have less access to preventive dental services. Other countries have started to allow dental assistants to put on the varnish, this is not yet the case in Australia. This study aims to test the use of Aboriginal dental assistants to put on fluoride varnish for Aboriginal school children.

Who can participate?
Aboriginal dental assistants who have completed the minimum Australian training requirement to become a dental assistant will be able to participate. This is a Certificate III in Dental Assisting from a registered training organisation.
Aboriginal children aged 5–12 years enrolled in six schools across New South Wales will be able to participate in the study.

What does the study involve?
The study involves training six Aboriginal dental assistants to put on fluoride varnish. Six schools across New South Wales will be chosen which enroll a large amount of Aboriginal children. The dental assistants will work with the school to schedule 4 days over 12 months. Each of these days, the dental assistant will come into the school and put on the fluoride varnish on the teeth of Aboriginal school children who have consented to be part of the study.

What are the possible benefits and risks of participating?
The possible benefit for children in this is study is that the fluoride varnish can prevent tooth decay. The possible risk is that if children swallow too much fluoride, they can experience effects such as vomiting or discolouring of their teeth.

Where is the study run from?
The study is run from six schools in New South Wales.

When is the study starting and how long is it expected to run for?
The study started in October 2017 and is expected to run for 12 months.

Who is funding the study?
The University of Sydney (Australia)

Who is the main contact?
Yvonne Dimitropoulos
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Enabling Aboriginal dental assistants to apply fluoride varnish for school-children in communities with a high Aboriginal population in New South Wales, Australia: A study protocol

Study hypothesis

In New South Wales (NSW), Australia, the application of fluoride varnish is restricted to dental and medical professionals. This is problematic in communities with a high Aboriginal population and limited access to oral health services. This study will test the use of Aboriginal dental assistants to apply fluoride varnish to Aboriginal school-children in communities with a high Aboriginal population. A qualified Aboriginal dental assistant workforce in NSW (or Australia) legally approved to apply fluoride varnish may increase the sustainability and scalability of fluoride varnish programs and improve the oral health of Aboriginal children in Australia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NSW Aboriginal Health and Medical Research Council, 28/08/2017, 1281/17
2. NSW State Education Research Application Process, SERAP2017353

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
See additional files

Condition
Dental caries prevention

Interventions
Six schools across NSW that enroll at least 12% Aboriginal children will be invited to participate in the 12-month study. Aboriginal children aged 5–12 years enrolled in these schools will be eligible to be enrolled in the study. Parents and/or guardians will be asked to complete a medical history questionnaire along with the consent form to ascertain each child's asthma and allergy status. A caries risk assessment will be completed by an Oral Health Therapist before including each eligible child into the study. Six Aboriginal dental assistants will undertake training to apply fluoride varnish. Fluoride varnish (Duraphat) will be applied at 3-month intervals by the dental assistants to the occlusal surfaces of posterior teeth and buccal surfaces of maxillary anterior teeth using a small brush.

Intervention Type
Supplement

Primary outcome measure

1. Number of Aboriginal dental assistants and supervising oral health therapists participating in the study throughout the 12 months
2. Proportion of children who received one, two, three or four fluoride varnish applications over the study period assessed by reviewing clinical records at 3-month intervals and at the end of the study

Secondary outcome measures
1. Readiness to change of dental assistants and oral health therapists through questionnaires before and after the 2-day training
2. Cost analysis to determine the overall cost effectiveness of using dental assistants to apply fluoride varnish four times per year to school-children compared to oral health therapists based on hourly rates of pay assessed at the end of the study
3. Satisfaction of key stakeholders assessed by a questionnaire at the end of the study

Overall study start date
08/04/2017

Overall study end date
09/01/2019

Eligibility

Participant inclusion criteria
Children:
1. Aboriginal children
2. Aged 5-12 years
3. Non-Aboriginal children at the school's request
4. 'At risk' of developing caries

Dental assistants:
5. Aboriginal
6. Minimum training requirement: Certificate III in dental assisting from a registered training organisation

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
500

Participant exclusion criteria

Children:
1. Uncontrolled asthma
2. History of allergy to resins
3. Not 'at risk' of developing caries

Dental assistants:
4. Non-Aboriginal descent
5. No minimum qualification in dental assisting

Recruitment start date
01/10/2017

Recruitment end date
31/12/2018

Locations

Countries of recruitment
Australia

Study participating centre
Poche Centre for Indigenous Health
Room 224 Edward Ford Building
The University of Sydney
Australia
2006

Sponsor information

Organisation
Poche Centre for Indigenous Health

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

Sponsor type
University/education

ROR
https://ror.org/01kpzv902

Funder(s)

Funder type
Not defined

Funder Name
University of Sydney

Alternative Name(s)
The University of Sydney, Sydney University, University of Sydney - Australia, University of Sydney, Australia, Universitas Sidneiense, USYD, Sydney Uni

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

Results and Publications

Publication and dissemination plan
Results will be reported back to local Aboriginal communities that participate in this study. The results will also be published in publication journals and may be presented at Australian or international conferences.

Intention to publish date
08/01/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		03/07/2018	02/04/2019	No	Yes
Protocol article	protocol	22/01/2019	01/03/2021	Yes	No