

Effectiveness of supervised toothbrushing on prevention of childish dental caries

Submission date 03/11/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 11/12/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/03/2011	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
06/51300-0

Study information

Scientific Title
Cost-effectiveness of supervised toothbrushing on prevention of dental caries in permanent molar first

Study objectives
To compare two techniques of direct supervised toothbrushing with fluoridated dentifrice on occurrence of caries lesions in permanent molar first.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Research Ethical Committee from Catholic University of Santos on the 20th November 2005.

Primary study design

Interventional

Study design

An interventional community-randomised controlled single-centre trial will be conducted in six preschools with 5 - 6 year-old children.

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Caries lesion on surface of permanent molar first

Interventions

Intervention group:

A modified technique of direct supervised toothbrushing with fluoridated dentifrice will be carried out in eligible children every 45 days in three randomly selected preschools (test-units). The modified technique includes professional toothbrushing on occlusal surfaces of permanent molar first carried out by trained auxiliary personnel.

Control group:

A conventional technique of direct supervised toothbrushing with same fluoridated dentifrice will be carried out in eligible children every 90 days in three preschools (control-units).

Total duration of intervention and follow-up is the same: twenty-four months

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Enamel caries measured by visual exam with aid of a ball point instrument recommended by World Health Organization. The outcomes will be measured at first, 6th, 12th and 18th month.

Key secondary outcome(s)

Dentine caries measured by visual exam with aid of a ball-point instrument recommended by World Health Organization. The outcomes will be measured at first, 6th, 12th and 18th month.

Completion date

02/05/2009

Eligibility

Key inclusion criteria

Eligible subjects with one or more sound erupted permanent molar first.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Infants with condition or disease that increase caries risk.

Date of first enrolment

02/04/2007

Date of final enrolment

02/05/2009

Locations

Countries of recruitment

Brazil

Study participating centre

Rua Carvalho de Mendonca 144 - 4th floor

Santos

Brazil

11070906

Sponsor information

Organisation

Catholic University of Santos (Universidade Catolica de Santos) (Brazil)

ROR

<https://ror.org/00vcyhn10>

Funder(s)

Funder type

Government

Funder Name

State of Sao Paulo Research Foundation (Fundacao de Amparo a Pesquisa do Estado de Sao Paulo [FAPESP]) (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/03/2011		Yes	No