

Dental caries prevention program for Cree mothers and infants

Submission date 29/06/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 22/07/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/01/2013	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rosamund Harrison

Contact details
2199 Wesbrook Mall
Vancouver, BC
Canada
V6T 1Z3
+1 604 822 2094
rosha@interchange.ubc.ca

Additional identifiers

Protocol serial number
MCT-67817

Study information

Scientific Title
A clinical trial of the effectiveness of a dental caries prevention program for Cree mothers and their infants

Acronym

Study objectives

Primary question:

Is there any difference in the dental health status of young Cree children whose mothers have participated in a client-centred, one-on-one, preventive counseling intervention, motivational interviewing (MI), and children whose mothers received oral health information in the form of an educational pamphlet? This question will be answered by testing the hypothesis that the prevalence of caries in 30 month old children will be lower in the experimental communities than in the control communities.

Secondary questions:

Are Cree mothers knowledge and beliefs about child dental health issues, their dental health practices, and child feeding and comforting practices altered by participation in a series of motivational interviewing (MI) interventions? This question will be answered by testing the null hypothesis that there will be no difference between the two groups of mothers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of British Columbia (UBC) Behavioural Research Ethics Board (ref: Certificate B04-0295) - this is re-approved annually.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Early childhood caries or tooth decay

Interventions

Primary intervention is behavioural: motivational interviewing (MI)

Experimental group: The first MI session will occur during pregnancy at time of enrolment.

Mothers will participate in at least five more MI sessions that will correspond with well-child immunisation visits between two and 24 months of age. Fluoride varnish will be offered at the 12, 18 and 24 month visits.

Control group: Mothers will receive a pamphlet. Fluoride varnish will be available at local dental clinics.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The prevalence of caries, or percentage of 30 month old children with decayed, extracted and filled surfaces (DEFS) more than zero, in each community will be determined. A child's experience of caries will be determined by recording the DEFS, or number of decayed, extracted or filled primary tooth surfaces.

Key secondary outcome(s)

Data on dental health knowledge, oral home care practices, child-feeding and comforting practices will be collected at 30 months and compared between test and control communities. In addition, data on "caries-related health impacts", for example, history of pain, food avoidance or poor sleeping as a result of dental pain, and dental treatment received as a result of dental caries will be compared.

Completion date

31/03/2010

Eligibility**Key inclusion criteria**

1. 309 Cree mother-child pairs in Eeyou Istchee (Cree territory of northern Quebec)
2. Mothers aged 18 - 49 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

Any pregnant women or woman with a newborn who knows that she will be imminently moving out of the Cree territory.

Date of first enrolment

01/04/2004

Date of final enrolment

31/03/2010

Locations

Countries of recruitment

Canada

Study participating centre

2199 Wesbrook Mall

Vancouver, BC

Canada

V6T 1Z3

Sponsor information

Organisation

Canadian Institutes of Health Research (CIHR) (Canada)

ROR

<https://ror.org/01gavpb45>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-67817)

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	01/11/2012		Yes	No
Protocol article	protocol	13/05/2010		Yes	No