

# Xylitol clinical studies for prevention: In-school xylitol gummy bear snack study

<b>Submission date</b> 07/02/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/07/2008	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
U54 DE14254

# Study information

## Scientific Title

School-based xylitol gummy bears snacks: a randomized controlled trial

## Study objectives

Consumption of xylitol gummy snacks reduces *S. mutans* and *Lactobacillus* spp. levels

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

University of Washington Internal Review Board. Date of approval: 27 March 2007 (ref: HS # 07-4857-B 01)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied

Dental caries

## Interventions

Randomisation was carried out at the level of individuals. Gummy bear snacks were packaged by the unit-dose and labeled specific to the students ID number which corresponded with the individual randomization.

Three-group design:

Group 1: Xylitol gummy bears, 11.7 g/day xylitol

Group 2: Xylitol gummy bears, 15.6 g/day xylitol

Group 3: Maltitol gummy bear (control)

All groups consumed gummy bears 3 times/day for 6 weeks in the classroom during school hours only.

## Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

xylitol

**Primary outcome measure**

S. mutans and Lactobacillus spp. levels in plaque samples at enrollment (baseline) and 6 weeks (end of study).

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/04/2007

**Completion date**

01/06/2007

**Eligibility****Key inclusion criteria**

Children attending First through Fifth grade at two elementary schools in rural Washington State, USA

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Both

**Target number of participants**

153

**Key exclusion criteria**

Children with gastrointestinal problems

**Date of first enrolment**

01/04/2007

**Date of final enrolment**

01/06/2007

**Locations****Countries of recruitment**

United States of America

**Study participating centre**  
**Dental Public Health Sciences**  
Seattle  
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## Sponsor information

**Organisation**  
University of Washington (USA)

**Sponsor details**  
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**Sponsor type**  
University/education

**Website**  
<http://www.washington.edu/research/osp>

**ROR**  
<https://ror.org/00cvxb145>

## Funder(s)

**Funder type**  
Research organisation

**Funder Name**  
National Institute of Dental and Cranio-facial Research (NIDCR, USA; ref: U54 DE14254)

# Results and Publications

Publication and dissemination plan  
Not provided at time of registration

Intention to publish date

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?
<a href="#">Results article</a>	Results	25/07/2008		Yes	No