

# Xylitol Clinical Studies for Prevention - Xylitol Snack Foods among Adults Study (Gum 3)

<b>Submission date</b> 16/11/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/12/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/08/2009	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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

## Acronym

Gum 3

## Study objectives

Reduction in mutans streptococci by xylitol snack foods is equivalent to xylitol chewing gum among adults

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

University of Washington Internal Review Board - Application#: 05-5945-B 01. Approved 29/03/2005.

## 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

Please note that this trial was stopped during the recruitment phase due to reconsideration of power calculations and insufficient resources. An alternative approach to gaining the information was used and the results have been published in <http://www.ncbi.nlm.nih.gov/pubmed/18267030>.

## Interventions:

Two group design with positive control. Equivalence study, xylitol Gummy Bears (10.4 g/day) compared to xylitol chewing gum (10.3 g/day).

## Intervention Type

Drug

**Phase**

Not Specified

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

Xylitol

**Primary outcome measure**

Reduction in mutans streptococci level in plaque

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

15/05/2005

**Completion date**

01/04/2006

**Reason abandoned (if study stopped)**

Lack of funding/sponsorship

## **Eligibility**

**Key inclusion criteria**

Adult, male & female, with screening plaque mutans streptococci level greater than 10,000 CFU/ml

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

140

**Key exclusion criteria**

1. Gastro-intestinal diseases/problems
2. Phenylalanine intolerant

**Date of first enrolment**

15/05/2005

**Date of final enrolment**

01/04/2006

# Locations

## Countries of recruitment

United States of America

## Study participating centre

### Dental Public Health Sciences

Seattle, Washington

United States of America

98195

# Sponsor information

## Organisation

University of Washington (USA)

## Sponsor details

Carol Zuiches

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## Sponsor type

University/education

## Website

<http://www.washington.edu/research/osp/index.php>

## ROR

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

# Funder(s)

## Funder type

Government

**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