

# Gum chewing and oral health in older people in the community

<b>Submission date</b> 16/03/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/04/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/01/2013	<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

**Contact name**  
Dr Liana Zoitopoulos

**Contact details**  
King's College London  
Dept. of Community Special Care Dentistry  
Caldecot Road  
London  
United Kingdom  
SE5 9RW  
+44 (0)20 7346 3480  
liana.zoitopoulos@kcl.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

The effect of gum chewing on the oral health and quality of life of older people living in the community: a single blind, randomised controlled study

## Study objectives

The study is investigating whether the daily use of xylitol-containing chewing gum provides oral health benefits for older people living in the community, over and above routine oral care practices and usual dental attendance.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

King's College Hospital Research Ethics Committee gave approval on the 10th February 2006 (ref: 05/Q0703/234)

## Study design

Single blind randomised controlled study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Oral health

## Interventions

Regular use (15 minutes, twice a day) of xylitol chewing gum versus no intervention. The test group is given the chewing gum to take home and use twice a day for 6 months. The follow up is after 6 months. The baseline visit and follow-up last around 45 minutes each. The control group is also seen after six months but are not given any intervention in the meantime.

## Intervention Type

Drug

## Phase

Not Applicable

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

Xylitol-containing chewing gum

**Primary outcome measure**

Improved oral health, determined by:

1. Caries increment (decayed, missing and filled coronal surfaces)
2. Root caries index increment
3. Plaque Index Increment
4. Change in prevalence of soft tissue pathology
5. Denture debris index increment

Collected during the follow-up visit at 6 months.

**Secondary outcome measures**

1. Changes in salivary levels of caries-associated microorganisms (mutans group streptococci, lactobacilli, yeast)
2. Change in stimulated whole salivary flow rate (ml/min)
3. change in oral health related quality of life (OHIP-14)
4. Experience of side-effects and adverse events
5. To ascertain attitudes to chewing gum as an adjunct to oral care

Collected during the follow-up visit at 6 months.

**Overall study start date**

01/11/2006

**Completion date**

20/04/2009

## **Eligibility**

**Key inclusion criteria**

1. Aged 60 years and over, either sex
2. Dentate: with a minimum of 6 natural teeth
3. Living independently in the community

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

200

**Key exclusion criteria**

1. Living in residential care
2. Taken antibiotics during the 4 weeks prior to commencing the trial
3. Not able to understand and give informed consent

**Date of first enrolment**

01/11/2006

**Date of final enrolment**

20/04/2009

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

England

United Kingdom

**Study participating centre**

King's College London

London

United Kingdom

SE5 9RW

**Sponsor information****Organisation**

King's College London (UK)

**Sponsor details**

School of Medicine

First Floor, Hodgkin Building

Guy's Campus

London

England

United Kingdom

SE1 9RT

+44 (0)20 7848 6981

robert.lechler@kcl.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.kcl.ac.uk/>

ROR

<https://ror.org/0220mzb33>

## Funder(s)

### Funder type

Charity

### Funder Name

Dunhill Medical Trust (UK)

### Alternative Name(s)

The Dunhill Medical Trust, DMT

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

## 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	01/10/2012		Yes	No