

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

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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s))**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**  
**King's College London**  
London  
United Kingdom  
SE5 9RW

## **Sponsor information**

**Organisation**  
King's College London (UK)

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

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Dunhill Medical Trust (UK)

**Alternative Name(s)**  
The Dunhill Medical Trust, Dunhill Medical Trust, DunhillMedical, DMT

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
United Kingdom

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

**Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 01/10/2012   |            | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |