

Gum chewing and oral health in older people in the community

Submission date 16/03/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/04/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/01/2013	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 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

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)

Primary study design

Interventional

Study design

Single blind randomised controlled study

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?
Results article	results	01/10/2012		Yes	No