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Gum chewing and oral health in older people in the community

Submission date	Recruitment status	[_] Prospectively registered
16/03/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/01/2013	Oral Health	

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
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
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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?
Results article	results	01/10/2012		Yes	No