

Reducing oral bacteria in those with mild dementia

Submission date 11/05/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/09/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study is to see whether we can improve the oral health of people with gum disease (periodontitis) who are in the early stages of dementia. If we can show that it is possible to do that then we can apply for more funding for a larger study.

Who can participate?

Patients with mild dementia and gum disease

What does the study involve?

All patients follow a routine programme designed to reduce dental plaque and oral bacteria levels over a 2 year period. We hope to collect information on patient compliance, drop-out rate, and the success of the treatment. We measure the improvement in the patients' gum health and also any change in cognition. The patient's carer/friend is asked to support the patient, including reminding and aiding the patient in appointment attendances, home-care routine and compliance.

What are the possible benefits and risks of participating?

Participants may benefit from improved periodontal health, which should reduce dental discomfort and future tooth loss. We are hoping that this may also reduce the rate of cognitive decline. Participants will be asked to attend the dental hospital on a number of occasions. This will be fully explained to them during the informed consent process and some money is available to cover travel expenses. Antibiotics may be used to treat periodontitis if necessary but will only be prescribed where there is a clear indication. As with use of any antibiotics, there may be a risk of *Clostridium difficile* associated disease. This will be discussed and participants and project partners will be informed about possible symptoms and advised how to access medical care if necessary. Plaque control agents used in the protocols are commercially available. If any side effects occur a suitable mouthwash alternative will be sourced for the participant to use. A routine dental examination including X-rays has good clinical justification and would be required for dental diagnosis and treatment planning. All X-ray exposures will be kept as low as reasonably practicable.

Where is the study run from?
The University of Bristol Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2016 to February 2020

Who is funding the study?
Bristol Research into Alzheimer's and Care of the Elderly (BRACE) (UK)

Who is the main contact?
1. Dr Shelley Allen
2. Nicola Hellin (dental-clinical-trials@bristol.ac.uk)
3. Maria Davies (Maria.Davies@bristol.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Dr Shelley Allen

ORCID ID
<http://orcid.org/0000-0001-7870-740X>

Contact details
Level 2
Learning & Research Building
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Type(s)
Public

Contact name
Miss Nicola Hellin

Contact details
Bristol Dental Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY
+44 (0)117 928 4314 (Dental Hospital)
dental-clinical-trials@bristol.ac.uk

Type(s)
Scientific

Contact name

Dr Maria Davies

Contact details

Clinical Trials Unit
Bristol Dental School and Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY
+44 (0)117 342 9503
Maria.Davies@bristol.ac.uk

Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

CT1975/RG2538

Study information**Scientific Title**

Feasibility study to reduce oral bacteria and improve periodontal health in those living with mild dementia

Acronym

HGHD (Healthy Gums to Help Dementia)

Study objectives

We hypothesise that, by compliance with a professional and homecare routine designed to improve periodontal health, patients with mild/early dementia will be able to reduce their number of pathogenic oral bacteria during the course of this study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southwest Frenchay Ethics Committee, Bristol UK, 22/01/2016, REC ref: 15/SW/0343

Study design

Interventional single-centre open study with no controls

Primary study design

Interventional

Secondary study design

Open feasibility study with no placebo and no controls

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet. Email dental-clinical-trials@bristol.ac.uk

Health condition(s) or problem(s) studied

Periodontitis (gum disease) in people living with mild dementia

Interventions

Carried out by dentists:

1. Standard dental health protocols for periodontitis
2. Periodontal monitoring

Carried out by clinical psychologist:

3. Cognitive assessment and assessment of daily living

Intervention Type

Procedure/Surgery

Primary outcome measure

Measured on day 0, 6 months, 1 year and 2 years. Additional appointments will be required for periodontal stabilisation during the 2 years (exact timepoints cannot be specified).

1. Compliance:

- 1.1. Attendance of visits
- 1.2. Short questionnaire about ease of following the oral hygiene regime

2. Stabilisation of periodontitis: periodontal assessment to include:

- 2.1. Tooth mobility
- 2.2. Bone loss
- 2.3. Bleeding on probing
- 2.4. Presence of pus
- 2.5. Periodontal pocket depth
- 2.6. Plaque assessment as determined by Turesky plaque index
- 2.7. Saliva sample for bacterial load determination

Secondary outcome measures

Measured on day 0, 6 months, 1 year and 2 years. Additional appointments will be required for periodontal stabilisation during the 2 years (exact timepoints cannot be specified).

Cognitive improvement:

1. Addenbrooke's Cognitive Examination III
2. Alzheimer's disease quality of life assessment (DEMQOL)
3. Bristol Activities of Daily Living (BADLS)

Overall study start date

01/04/2016

Completion date

05/02/2020

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 29/05/2019:

1. Adults with mild dementia, such as sporadic early-stage AD, mild early stage familial AD, mixed dementia (most commonly AD and vascular dementia) and vascular dementia associated with cerebral amyloid angiopathy, mild cognitive impairment (MCI)
2. Cognitive scores that demonstrate the patient is likely to have the capacity to consent
3. Moderate to severe periodontitis
4. ≥ 2 sextants score 4 on Basic Periodontal Examination (BPE)
5. Minimum of 6 remaining teeth
6. A project partner (commonly a carer or friend) who will consent to take part in the study in this capacity and attend appointments with the participant

Previous participant inclusion criteria:

1. Adults with mild dementia, such as sporadic early-stage AD, mild early stage familial AD, mixed dementia (most commonly AD and vascular dementia) and vascular dementia associated with cerebral amyloid angiopathy
2. Cognitive scores that demonstrate the patient is likely to have the capacity to consent
3. Moderate to severe periodontitis
4. ≥ 2 sextants score 4 on Basic Periodontal Examination (BPE)
5. Minimum of 6 remaining teeth
6. A project partner (commonly a carer or friend) who will consent to take part in the study in this capacity and attend appointments with the participant

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

20

Total final enrolment

Key exclusion criteria

1. Insufficient capacity to consent
2. Previously fitted pacemaker
3. Allergy to essential oil mouthwash
4. Tobacco smoking
5. Uncontrolled systemic disease
6. Uncontrolled dental disease other than periodontitis
7. Pregnancy or breastfeeding
8. Severe renal impairment ($GFR \leq 30 \text{ ml/min}$)
9. Those scoring ≥ 3 on the American Society of Anaesthesiologists (ASA) Physical Status Classification System
10. Those currently enrolled in another study whose inclusion/exclusion criteria state that while on the study they cannot enrol in new studies, such as the Oral Health Study

Date of first enrolment

27/07/2016

Date of final enrolment

31/12/2018

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

The University of Bristol Dental Hospital

Bristol Dental Hospital

Lower Maudlin Street

Bristol

United Kingdom

BS1 2LY

Sponsor information**Organisation**

University of Bristol (UK)

Sponsor details

Senate House

Tyndall Avenue

Bristol

England
United Kingdom
BS8 1TH
+44 (0)117 928 9000
Birgit.whitman@bristol.ac.uk

Sponsor type

University/education

Website

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

ROR

<https://ror.org/0524sp257>

Funder(s)

Funder type

Charity

Funder Name

Bristol Research into Alzheimer's and Care of the Elderly (BRACE) (UK)

Results and Publications

Publication and dissemination plan

We hope that any trial data will have been assessed by June 2019. Participants are invited to contact us if they want to know any general results of the trial.

Intention to publish date

30/04/2024

Individual participant data (IPD) sharing plan

The microbial datasets generated and/or analysed during the current study will be included in the subsequent results publication. Other data generated during the current study are not expected to be made available as participants were not asked to consent for the sharing of their data.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 6	28/06/2017	08/06/2023	No	No

HRA research summary		28/06/2023	No	No
Results article	16/09/2024	19/09/2024	Yes	No