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Reducing oral bacteria in those with mild dementia

Submission date
11/05/2016

Recruitment status
No longer recruiting

Registration date
27/05/2016

Overall study status
Completed

Last Edited
19/09/2024

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
18

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≤30ml/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
United Kingdom

England

Study participating centre
The University of Bristol Dental Hospital
Bristol Dental Hospital
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Sponsor information

Organisation
University of Bristol (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

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?
Results article		16/09/2024	19/09/2024	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 6	28/06/2017	08/06/2023	No	No