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Digital denture scanning and 3D printing for residents in care homes

Submission date
21/10/2021

Recruitment status
No longer recruiting

Registration date
24/03/2022

Overall study status
Completed

Last Edited
05/02/2024

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
For any individual, losing or breaking a denture (false teeth) can have a detrimental effect on their overall well-being, impacting on nutrition, communication, and dignity and it is not always possible to remake them. Dentures take on average five dental appointments over eight weeks to remake. Often people in care homes may be frail or have a cognitive condition such as dementia and are unable to cooperate with the invasive denture making process. Making dentures via digital scanning and 3D printing is well established in the private dental sector and provides a non-invasive, person-centred solution to replacing dentures for people living in care homes.

The aim of the study is to explore the possibility of digitally scanning dentures for residents living in care homes. To examine if scanning and 3D printing provide a better solution to lost or broken dentures compared with conventional methods of remaking a denture.

Who can participate?
Care home residents who wear dentures.

What does the study involve?
Residents will be provided with the printed replicate dentures which will then be assessed for function and appearance. Brief semi-structured interviews will be conducted with a number of residents to evaluate their experience and acceptability of the replicate dentures.

What are the possible benefits and risks of participating?
Benefits of participating is to contribute to research that aims to reduce the impact of denture loss in vulnerable groups. Residents will have a spare 3D printed denture and oral health assessment.
We do not foresee any risks associated with this study. It is designed around the standard of care that is provided to care home residents.

Where is the study run from?
East Surrey Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2021 to June 2022.

Who is funding the study?
1. Royal College of Surgeons of England
2. British Society of Gerodontology

Who is the main contact?
Mr Daniel Gillway, daniel.gillway@nhs.net

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
296809

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 296809, CPMS 51913

Study information

Scientific Title
Digital denture scanning and 3D printing for residents in care homes – an innovative solution for managing denture loss/breakage

Study objectives
To examine the feasibility of digitally scanning dentures for residents living in care homes. To examine if scanning and 3D printing provides a better solution to lost or broken dentures compared with conventional methods of remaking a denture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/10/2021, London – Brighton and Sussex REC (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8137; brightonandsussex.rec@hra.nhs.uk), ref: 21/LO/0601

Study design
Observational qualitative feasibility study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Dentures for care home residents

Interventions
The aim is to scan a minimum of 10 dentures at the care home. Residents will be provided with the printed replicate dentures which will then be assessed for function and appearance. Brief semi-structured interviews will be conducted with a number of residents to evaluate their experience and acceptability of the replicate dentures.

This study is a prospective qualitative feasibility study to be carried out in the care home setting with residents. Once the care home resident has had the opportunity to wear the replicated denture, semi-structured interviews will be carried out with the resident.

Interviews will take place in a quiet, private room provided by the care home with the research team (chief investigator and supervisor), and the resident. The research team is trained in supporting residents who require help with communication and each individual will be assessed separately for this. Interviews will be short and semi-structured, they would not be expected to last longer than 30 minutes and will be guided by the research team. They will be audio recorded using basic .mp3 laptop software and transcribed verbatim using Microsoft office. Field notes will be made by the research team. Any personal identifiable data such as names that might be

collected during the interview will not be included in the transcripts, no participant in the study will be able to be identified from the transcripts.

Data analysis will be conducted by the Chief Investigator and supervisor.

Intervention Type
Other

Primary outcome measure
Thematic analysis of semi-structured interviews from the care home residents into their opinions on denture loss and the feasibility of 3D scanning and printing dentures in care homes. Interviews will take place at a single time point.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2021

Completion date
01/06/2022

Eligibility

Key inclusion criteria
1. Adult (over 18 years) care home resident
2. Denture wearer, either full denture or one with significant function (i.e. it replaces more than 5 teeth) or where there is an aesthetic benefit (it replaces front teeth)
3. If the resident does not speak English as a first language we will liaise with their key worker on how they communicate with the resident (member of staff, communication app or translator) and use this method.
4. Adults who are assessed as having the capacity to consent to take part in this study

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Total final enrolment
8

Key exclusion criteria
1. Residents who do not wear full/partial denture
2. Residents who have declined consent to participate
3. Residents with dentures that are not worn or cannot be 3D printed/scanned
4. Residents where best interests decision is against oral health assessment or dentures scanning due to distress or otherwise
5. Residents who are assessed as not having the capacity to consent

Date of first enrolment
15/10/2021

Date of final enrolment
27/01/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East Surrey Hospital
Surrey and Sussex Healthcare NHS Trust
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Sponsor information

Organisation
Surrey and Sussex Healthcare NHS Trust

Sponsor details
East Surrey Hospital
Canada Avenue
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+44 (0)1737 768511
sash.research.office@nhs.net

Sponsor type

Hospital/treatment centre

Website
https://www.surreyandsussex.nhs.uk/

ROR
https://ror.org/0480vrj36

Funder(s)

Funder type
Research council

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
British Society of Gerodontology

Results and Publications

Publication and dissemination plan
BSG conference presentation and publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	29/09/2021	24/03/2022	No	Yes
Protocol file	version 2	29/09/2021	24/03/2022	No	No
HRA research summary			28/06/2023	No	No
Plain English results			05/02/2024	No	Yes
Results article		29/10/2023	05/02/2024	Yes	No