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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/10/2021		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
24/03/2022		[X] Results		
Last Edited 05/02/2024	Condition category Oral Health	[] 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

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

296809

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s))

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

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

United Kingdom

England

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

ROR

https://ror.org/0480vrj36

Funder(s)

Funder type

Research council

Funder Name

Royal College of Surgeons of England

Alternative Name(s)

RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

British Society of Gerodontology

Results and Publications

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?
Results article		29/10/2023	05/02/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2	29/09/2021	24/03/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			05/02/2024	No	Yes
Protocol file	version 2	29/09/2021	24/03/2022	No	No