Qualitative Protocol Development Tool

This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY

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

The feasibility of digitally scanning dentures for residents in care homes to provide a person centred solution to lost or broken dentures compared with conventional denture construction methods

SHORT STUDY TITLE / ACRONYM

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

PROTOCOL VERSION NUMBER AND DATE: Version 2 dated 29/09/2021year

RESEARCH REFERENCE NUMBERS

IRAS Number:	296809
SPONSORS Number:	N/A
FUNDERS Number:	N/A

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:
.....

Date:
...../...../.....

Name (please print): Natalie McCarthy

Position: Head of Research, Surrey and Sussex Healthcare NHS Trust

Chief Investigator:

Signature:
.....

Date:…./…./…..

Name: Daniel Gillway, Surrey and Sussex Healthcare NHS Trust

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Daniel Gillway Dental Officer Surrey and Sussex Healthcare NHS Trust East Surrey Hospital Redhill RH1 5RH daniel.gillway@nhs.net
Supervisor/Co-Investigator	Mili Doshi Consultant in Special Care Dentistry Maxillofacial Department Surrey and Sussex Healthcare NHS Trust East Surrey Hospital Redhill RH1 5RH Mili.Doshi@nhs.net
Study Co-ordinator	• Daniel Gillway • Mili Doshi
Sponsor	Surrey and Sussex NHS Healthcare Trust East Surrey Hospital Trust Headquarters Canada Avenue Redhill, RH1 5RH
Funder(s)	FDS RCSEng - British Society of Gerodontology grant Faculty of Dental Surgery The Royal College of Surgeons of England 35–43 Lincoln's Inn Fields London WC2A 3PE Den-Tech (Registered Charity Number 1172889) www.den-tech.org 16 Tudor Street Sutton-In-Ashfield NG175AN K2 Ceramic Studio Limited (Company number 09566540) Glyn Wylfa House Castle Road Chirk Wrexham LL145BS
Key Protocol Contributors	Mili Doshi and Daniel Gillway, Surrey and Sussex Healthcare NHS Trust Sami Stagnell, Andrea Johnson, Peter Harling: Den-Tech digital denture scanning working group

STUDY SUMMARY

Study Title	Digital denture scanning and 3D printing for residents in care homes – an innovative solution for managing denture loss/breakage
Internal ref. no. (or short title)	Digital denture scanning and 3D printing for residents in care homes
Study Design	Prospective qualitative feasibility study
Study Participants	Residents living in care homes
Planned Size of Sample (if applicable)	Minimum 10 dentures scanned and replicated
Follow up duration (if applicable)	N/A
Planned Study Period	8 months (July 2021- March 2022)
Research Question/Aim(s)	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.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Royal College of Surgeons of England /British Society of Gerodontology	£9,270.00
Den-Tech, Charitable Incorporated Organisation	Providing scanner
K2 Ceramic Studio Limited	3D printing of the dentures

ROLE OF STUDY SPONSOR AND FUNDER

Surrey and Sussex Health NHS Health Care Trust will be responsible for the initiation and management of the study.

The Royal College of Surgeons and the British Society of Gerodontology are providing a joint grant.

Den-Tech, a charitable organisation is sourcing a 3D scanner to loan during this research and K2 Cermaic Studio is printing the replicate dentures.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Groups

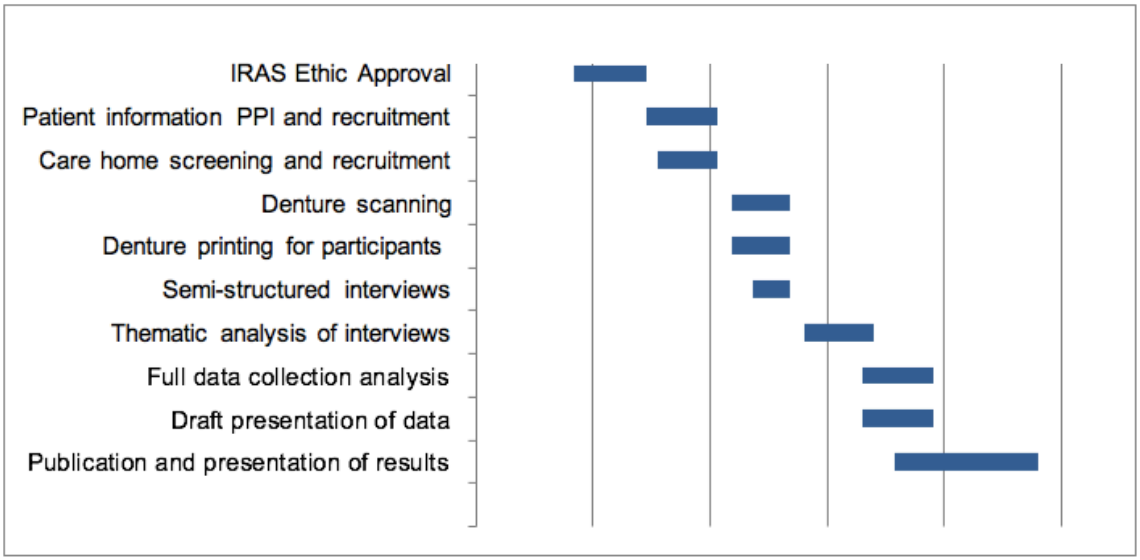
1. Denture Scanning Working Group – group made up of a clinical entrepreneur, clinical dental technicians and experts in special care dentistry was established in 2020 to discuss the potential of scanning dentures as part of a strategy to reduce inequalities for people living in care homes. The group will work on the manuscript writing and dissemination of results with the Chief Investigator.
2. Care homes forums –a local Surrey and Sussex forum that is made up of care home mangers, local general medical practitioners and geriatricians. The aim of this group is to discuss the reasons why dentures are lost and input into the design of the study and disseminate information.
3. Study steering group - group made up of the Chief investigator, supervisor, community older people's team and care home managers, families and residents. The aim of this group is to input into the design of the study. We will invite appropriate representatives to form a virtual steering group including care home residents, care home staff and family members who have a resident in the care home to collaborate on the development at each stage of this project including the study information and interview schedules, data analysis, reporting and dissemination of findings. We will recruit representatives through our local care home forums. We will also consult forums such as INVOLVE and local Healthwatch to support us with patient and public engagement.

PROTOCOL CONTRIBUTORS

- Daniel Gillway, Chief Investigator, Surrey and Sussex Healthcare NHS Trust. Dental Officer who provides domiciliary dental care and will carry out the protocol activity in the participating care homes.
- Mili Doshi, Surrey and Sussex Healthcare NHS Trust. Consultant in Special Care Dentistry who will work alongside Chief Investigator and provide supervisory support.
- Andrea Johnson, Dental Technician/Chair of Den-Tech who will input into the study design.
- Sami Stagnell, Primary Care Specialist Oral Surgeon /Trustee of Den-Tech who will input into the study design and consult on clinical scanning equipment.
- Peter Harling, Director of K2 Ceramic Studio Limited who will be responsible for printing the dentures.
- All contributors will work on the manuscript writing and dissemination of results led by the Chief Investigator.

KEY WORDS: Lost dentures, broken dentures, oral health , care homes, domiciliary dental care

STUDY FLOW CHART



STUDY PROTOCOL

The main aim of this project is to examine the feasibility of digitally scanning and producing 3D replacement dentures for residents living in care homes and whether this provides a better solution to lost or broken dentures compared with conventional methods.

1 BACKGROUND

For any individual, losing a denture can have a detrimental effect on their overall well-being, but for someone in a residential setting who is vulnerable it can be devastating by impacting on nutrition, communication, and dignity. Research in Kent, Surrey and Sussex (KSS) has found that dentures are often lost during a hospital admission (1). There is less data on denture loss in care homes but it is the experience of local dental teams that denture loss/breakage is also a significant issue nationally. Accessing dental services to remake dentures is a problem as identified by the Care Quality Care (CQC) report 'Smiling Matters' (2018) (2). The report highlighted that access to dental care, especially domiciliary care, is a significant problem for people living in care homes. A survey in 2019 by the study investigators of care home managers in Surrey found 80% reported barriers to their residents accessing dental care and only 20% had policies and arrangements in place to refer residents if needed. A study found 51% of care home residents in the UK (mean age 80) had a denture (3) so this is a significant issue. Dentures take on average five dental appointments over six to eight weeks to remake using conventional methods. Often people in care homes may be frail or have a cognitive condition such as dementia and are unable to cooperate with having impressions (mould of the mouth taken as part of the denture making process). The longer the time an individual is not wearing a denture the greater the risk that they will be unable to wear a denture in the future (4).

Most recently, the Covid-19 pandemic has also increased inequalities faced by older people with dementia living in care homes including dental access and this research could potentially positively impact on their overall care (5). 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 (6, 7). The benefits of a functioning dentition are well known, however the impact of denture loss on nutrition, ability to communicate and quality of life (8, 9) is often under reported. Data from East Surrey Hospital after trust-wide implementation of methods to reduce loss still found 91 incidents reported relating to loss of dentures in between 2014-2019. The British Dental Association (BDA) estimates that around 9,500 dentures are lost (10) in NHS hospitals in England every year, costing the NHS in the region of one million pounds. There is limited published data on denture loss in care homes, but many of those who do lose a denture in hospital will be a care home resident.

Dental care is provided to care homes residents through general dental services, community dental services and specialist hospital dental services. The research team is made up of clinicians based in East Surrey Hospital (Surrey and Sussex Healthcare NHS Trust) who provide treatment for people living in care homes on referral from general dental services and are also established as a domiciliary dental care service. Referrals can be taken directly from care home staff or allied health professionals. The research team have established links with local care homes and are trained to provide this specialist service including dental care for residents who may lack capacity. The research team will assess the feasibility of incorporating digital denture scanning into routine care and if dentures can be replicated from the 3D scan in a care home setting. Oral health assessment on admission to a care home should be mandatory practice as per NICE guidance, often this population will be frail, elderly and have cognitive impairment.

2 RATIONALE

Losing or breaking a denture is a significant problem for people living in care homes, impacting on nutrition, quality of life and dignity. Denture loss is underreported and access to dental care for care home residents is poor. The conventional process for remaking a denture can often takes nearly two months. The longer the length of time a person is without a denture the greater the risk they will not tolerate wearing a new set. Unfortunately, denture loss is very common especially when residents require hospital admission. 70% of residents living in care homes have dementia (12). Access to dental services for care home residents has been found to be problematic, this will have been further confounded by the COVID-19 pandemic.

In KSS the Mouth Care Matters (MCM) programme found an average spend of £51,096 per Trust for denture loss over 6 years but also that it was significantly under reported. Methods to reduce loss have been implemented with some success however the issue remains a source of morbidity and financial burden. Interventions to replace dentures in a timely manner are needed. Prior to COVID the researchers attended a local care home engagement event with 31 care home managers in Surrey which provided an open forum to discuss dental care that included the impact of denture loss. Care home managers were keen to know more about accessing appropriate dental services especially domiciliary care. In a survey carried out at the event 80% reported barriers in accessing dental care. We have looked at the 45 patient complaints about denture loss reported at East Surrey Hospital over five years and the main themes were difficulties in accessing dental care, cost and the impact on eating and increased frailty. Denture lost is an under-reported issue in hospitals and care homes especially for people who are unable to advocate for themselves. This often means that people who lose or break a denture cannot have them replaced. At a virtual care home oral health training session March 2021 with carers the concept of denture scanning was discussed and was welcomed with much

positivity. We have collected qualitative information on the difficulties replacing dentures for people with dementia from online carer forums including Alzheimer's society/ Carers UK. Denture loss searches on social media have highlighted that denture loss is a very emotive topic that is discussed frequently. The data from forums and engagement event have highlighted that there are long waiting lists for domiciliary dental care appointments. This will be incorporated into the project protocol. Covid-19 has been found to increase waiting times for dental care especially for those residents in care homes.

This is a feasibility study with the aim to preliminary demonstrate that digitally scanning dentures for residents living in care homes could potentially address this issue. This established intervention used in the private sector would be applied to the target population to allow duplicate dentures to be remade within days rather than months without the need for clinical impressions. The scanned dentures would be the same shape as their existing denture but might vary in terms of colour. This project could be scaled up nationally which could lead to changes in practice with the hope of improving residents quality of life and reduce the cost to the responsible health or social care system.

3 THEORETICAL FRAMEWORK

The supervisor has published research on denture loss identifying the financial costs to the NHS (1). MCM introduced ways to reduce denture loss in hospitals including the use of denture containers, symbols, oral health assessments and pathways for reporting loss. Data collected after MCM implementation at the pilot Trust found the numbers of reported lost dentures increased 5 fold due to increased awareness of reporting pathways.

'Smiling Matters' a 2018 CQC report identified residents in care homes face barriers to accessing dental care and this will impact on residents with dementia having dentures remade (2). Many of these residential need homes visits but domiciliary dental care but levels of commission this service are low; a key recommendations from the Royal College of Surgeons in England report in 2017 included all care homes having pathways for denture loss (13). Although denture labelling is often cited as a solution finding from MCM are that dentures are rarely found. Dentures in people with dementia has been found to improve quality of life (14).

Making dentures via digital scanning and 3D printing is well established in the private dental sector (5) and provides a non-invasive person centred solution to replacing dentures for people with dementia living in care homes. There also may be financial benefits as digitally reproducing dentures can be cheaper than traditional methods (15).

4 RESEARCH QUESTION/AIM(S)

The main aim of this project is to examine the feasibility of digitally scanning dentures for residents living in care homes and whether scanning and 3D printing could provide a better solution to lost or broken dentures compared with conventional methods of remaking a denture.

The project also aims to demonstrate that the dentures can be replicated to an acceptable standard for this vulnerable group, where denture loss has a detrimental impact on the quality of life and is difficult to remedy.

4.1 Objectives

The objectives are to:

1. Establish a pathway to replicate dentures through scanning and 3D printing for care home residents
2. Assess the feasibility of this pathway
3. Explore the use of digital scanning technology
4. Demonstrate that dentures can be replicated to an acceptable standard
5. Assess whether study participants are satisfied with denture replacements and the process
6. Explore barriers to having dentures remade through digital scanning and 3D printing for people in care homes

4.2 Outcome

In this feasibility study we hope to show that scanning and reproducing 3D dentures is an acceptable, practical solution for denture replacement. This could lead to a larger scale study.

5 STUDY DESIGN, METHODS of DATA COLLECTION and DATA ANALYSIS

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. Please see Appendix 11.2 for the interview questions.

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 are 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.

6 STUDY SETTING

The study will take place in local care homes in East Surrey and South West London who have met the five CQC care home quality standards and are not 'at risk'. The care homes have been chosen by the research team from the Surrey and Sussex care home forum or homes with an established link with the research team.

Care home managers who expressed an interest in being involved in research have been invited to take part in the study by the research team. The care homes have confirmed they can support the study and that they have residents who wear dentures.

As per routine health screening all residents in the participating care homes will be invited to have an oral assessment in their care homes to check the health of their mouth, identify whether they wear a denture. and assess the fitting of their denture. The oral assessment will use the NICE oral health assessment tool recommended by NICE guidance (NG48) and the CQC report 'smiling matters'.

For the individuals identified as wearing a denture, care home managers will provide study information, developed by the research team, to residents, and families via information leaflets, notice board posters and a video.

The research team will visit the care home on two occasions over the course of this study.

Visit 1

At this visit the routine oral assessments and capacity assessment to take part in the research will be carried out by the research team who provide routine domiciliary care and have specialist training in providing dental services to vulnerable people including those who lack capacity.

The oral health assessment will be undertaken in treatment rooms provided by care homes. The research team will assess, remove and clean the resident's current dentures and if any remedial work is needed to improve the fit this will be undertaken at the care home as per routine care. If dental issues are identified during the screening onward referrals can be made for treatment and signposting to dental services.

Residents who wear a full denture or partial denture with significant functional or aesthetic use will be identified, confirmation of consent to have their dentures scanned will be sought.

Where there is a cognitive impairment a capacity assessment will be undertaken with the resident and their key worker from the care home and if they do not have the capacity to consent to be involved in

this study they will be excluded. If there are any concerns about their oral health, they will be referred to appropriate services.

For consented participants, their dentures will be removed from the mouth and after cleaning they will be scanned using a portable digital dental scanner, the participant will be without their denture for approximately 20 minutes during this process.

The scan data will be stored in a secure encrypted computer and will be pseudonymised with a unique study number that does not contain any participant identifiable information. The pseudonymised scan data will be sent securely to K2 dental lab via encrypted software or email and the dentures will then be replicated using the 3D printing technology in a high quality tooth coloured acrylic material which will be posted securely back to the researchers at the Trust.

Visit 2 (anticipated 2 weeks after visit 1)

The research team will attend the care home to provide the study participants with the printed replicate dentures which will then be assessed for function and appearance by the researchers and the residents/carers. The resident will be asked to wear the denture for at least 30 minutes. If they feel the denture is uncomfortable and do not want to wear it, it will be removed. The research team will then conduct semi-structured interviews with the participants to evaluate their experience and acceptability of the replicate dentures. Interviews will be recorded, transcribed verbatim and analysed using thematic analysis (11). The residents will be invited to keep their replacement dentures.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Resident in a care home that are wearing a full or functional denture and have undergone an initial oral health assessment. Sample size calculation to be considered and at least 10 resident's dentures scanned and replicated.

7.1.1 Inclusion criteria

- Adult (over 18) care home resident
- 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)
- 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.
- Adults who are assessed as having the capacity to consent to take part in this study

7.1.2 Exclusion criteria

- Residents who do not wear full/partial denture
- Residents who have declined consent to participate

Residents who are assessed as not having the capacity to consent

Residents with dentures that are not worn or cannot be 3D printed/scanned

- Residents where best interests decision is against oral health assessment or dentures scanning due to distress or otherwise

7.2 Sampling

7.2.1 Size of sample

The aim is to scan a minimum of 10 dentures. Discussions have been had with a research statistician who has advised a minimum of 10 would be sufficient for this feasibility study to test the pathway. The study will not examine in microscopic detail the differences between the original and duplicate denture. Residents from two care homes will be recruited initially to incorporate sufficient consenting residents and allow for any withdrawals.

7.2.2 Sampling technique

All residents in the care home who fulfil the inclusion criteria will be invited to have their dentures scanned.

7.3 Recruitment

The participating care homes will be sent an information pack about the study in advance. All residents in the participating care homes will be invited to have an oral assessment in their care homes to check the health of their mouth and assess whether they wear a denture. Potential participants will be identified as per the eligibility criteria explained above. Care home managers will provide HRA and REC approved participant study information, developed by the research team, about the study to residents via information leaflet, poster and a video.

7.3.1 Sample identification

The research team as part of routine care will liaise with the care homes and invite all residents in the participating care homes to have an oral assessment in their care homes to check the health of their

mouth . The oral assessment will be the NICE oral health assessment tool recommended by NICE guidance and the CQC report smiling.

For those residents who wear dentures the care home managers will provide participant study information, developed by the research team, to residents via information leaflets, poster and a video.

The oral health assessment will help identify residents that meet the eligibility criteria to take part in the study.

7.3.2 Consent

Informed consent for the study will be obtained from all participants.

Care home staff will identify residents for oral health assessment and those wearing dentures and will introduce the study to residents. A video produced to explain the study and information leaflets will be distributed by the care home. Oral health assessments should be carried out for all residents as per NICE guidelines and so specific consent is not needed.

The research team will work with the care home staff when assessing the capacity of each participant. The care home staff will be able to inform the research team if the resident has an impairment that may affect their capacity

The research team will attend the care home and carry out an oral assessment with care homes staff present. A capacity assessment will be undertaken by the researchers to participate in the study (researchers routinely carry out capacity assessments as part of their daily practice).

If the resident has the capacity to consent they will be asked complete a written consent form. If the resident does not have capacity to consent to be involved in this study they will be excluded.

As part of the consent process the research team will provide a study information sheet in easy read format for residents. The research team will assess their ability to understand why we want to scan their dentures and will explain that a spare set of dentures will be made that we hope will be very similar in shape to their existing denture but may look different, and that we will want to ask them some questions about how they feel about the process afterwards. There will be an opportunity for participants to ask questions. Written consent will be provided in line with research standards using HRA templates and patient information leaflets have been produced in easy read format.. We will explain that all data will be anonymised and depersonalised and not shared with anyone.

. No individuals will participate in the study without signed, written consent from themselves

participants are free to withdraw from the study at any time without giving reasons and without prejudicing further care or treatment.

8 ETHICAL AND REGULATORY CONSIDERATIONS

Risks

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.

We recognise that resident may become distressed during routine oral assessment. In this scenario we will stop the assessment. We will ask a member of the care home that knows the resident will to be present and attempt to minimise any intrusion.

Some residents may be very private about wearing dentures and may not want to disclose this to the research team. We will be sensitive to their needs. Where there is cognitive impairment this may be a confusing pathway to explain and we will be mindful to avoid jargon in information leaflets.

Reassurance will be given regarding confidentiality and strict data storage confidentiality procedures including anonymising the scan data.

Some residents may be worried about having their dentures removed - we will reassure them that we will give them back after 20 minutes after also being thoroughly cleaned and assessed. We will make sure all this information is given prior to the study.

Potential risks and burdens will be described in the participant information sheet in such a way that potential participants can clearly understand what is involved if they consent to take part.

The participant can choose to withdraw from the study at any point without obligation and this will not compromise their care.

Benefits

The participants will have a ‘spare denture’

Opportunity to focus on safe denture care in care homes.

Patients will have an oral health assessment which is a mandatory part of care as per NICE guidance and will be referred for dental care in needed. ‘Smiling Matters’ a Care Quality Care (CQC) report released in 2018 identified that the oral health of people living in care homes to be very poor requiring improvement. The report highlighted that access to dental care especially domiciliary care is a significant problem for people living in residential care. As a result of this study oral health for residents in care homes may improve.

Improved links between care homes and dental services and focus on oral health promotion.

8.1 Assessment and management of risk

Risks

When carrying out an oral assessment the researches may notice that the participant needs further dental treatment or has oral pathology that requires further investigation. In this scenario the patient will be referred to the appropriate local dental team for treatment

If oral hygiene or denture hygiene is found to be suboptimal for a participant that requires support with mouth care. In this scenario this will be discussed with care home manager and oral health training provided.

For any safeguarding issues, we will follow local governance and raise concerns as we would do if carryout out a domiciliary dental visit.

For studies such as this which are not clinical trials of investigational medicinal products (non-CTIMP), only serious adverse events that are considered by the Chief Investigator (CI) to be (a) related to the study (i.e. they resulted from administration of any of the research procedures) **and** (b) are unexpected (i.e. not listed in the protocol as an expected occurrence) will be notified to REC.
Safety reporting will be in accordance with Trust policy.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from the NHS Research Ethics Committee (REC) service and the HRA. Substantial amendments that require review by REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC will be retained.

It is the Chief Investigator's responsibility to produce annual reports as required. An annual progress report will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

The Chief Investigator will notify the REC of the end of the study.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Amendments

The Chief Investigator will be responsible for any amendments that need to be made to the protocol in consultation with the sponsor.

Amendments will be discussed and agreed at the study steering group.

The Chief Investigator will be responsible for the decision to amend the protocol or supporting documents and for deciding whether an amendment is substantial or non-substantial

The amendment history will be tracked through appropriate labelling of subsequent versions of the protocol document and its being made available to the sponsor.

8.3 Peer review

As part of the grant application the study has undergone a process where two experts from the British society of Gerodontology have passed the protocol and it has gone through an official committee with the Royal College of Surgeons.

The protocol had been reviewed by Professor Ken Eaton who is a visiting Professor, University College London. The review was positive and supportive.

8.4 Patient & Public Involvement

We have invited appropriate representatives to the steering group including residents, care home staff and family members who have a resident in the care home where they will assist with the development of the study information and interview schedules, data analysis, reporting and dissemination of findings.

Summary of care homes forum virtual talk 10th March 2021

Is denture loss a problem: All care home representative acknowledged denture loss is an issue and some have had significant problems, one care home manager explained issues with complaints and lost dentures between hospital transfer, all agreed transfers are main source of denture loss

Do they have access issues for dental care for residents: Main issues all agree are for those who are house bound / bed bound, and the patients who are the most vulnerable? Commented that dental care can be costly and waiting times for most vulnerable patients. Other residents are able to leave for an appointment

Do they think scanning would help and who should store the scans: Home would be happy and able to store the scans, would pay for scans if under £50 or so, could keep with resident's digital record and potentially GP care record. Otherwise cloud based would be acceptable. Homes are research friendly and happy for this.

Feedback from the British Society of Geriatrics National Conference

At this conference we discussed the issue of denture loss and possible solutions. There were over a hundred delegates who via an online poll all agreed that denture loss was a significant problem for older people, They said that this was an issue for people with dementia and often people never have dentures remade due to poor links with dental services. They were very keen on looking at innovative ways to present denture loss such as labelling, microchips and QR codes. When the potential of 3D scanning was discussed there were lots of positive comments.

8.5 Protocol compliance

Accidental protocol deviations will be documented and reported to the Chief investigator and sponsor. There will follow a discussion amongst the research team about how future similar breaches can be avoided and an action plan documented.

8.6 Data protection and patient confidentiality

All information for this study will be held securely and treated as strictly confidential according to NHS policies. No directly identifiable personal data will be stored outside the hospital either in paper or electronic format.

The Chief Investigator and supervisor will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

There is no personal data being collected for this study.

All study information will be kept secure on a Trust encrypted computer.

Each study participant will be assigned a study number (a random combination of letters and numbers), and this will be linked to their name on a linked list which will be stored on a Trust secure server in a project file accessible only to the Chief Investigator and supervisor (and sponsor representatives in line with sponsor monitoring requirements)

Each denture scan will be coded with the participant study number and the Chief Investigator will keep the code details on a Trust encrypted trust computer.

Scanned image will be transferred via an encrypted server (https:wetransfer.com) to K2 (the 3D printer company) using the study number only.

No participant personal identifiable data is entered into or kept on the scanner device.

The interviews will be recorded via software and transcriptions stored on the encrypted laptop, no personal information will be collected. Direct quotes may be used in the final report/results but it will not be possible to identify individuals from the transcripts in the published results.

The original consent forms which will detail participant names will be stored at the Trust in a lockable cabinet/office.

The study data, anonymous transcripts and consent forms will be stored for a maximum of 12 months and destroyed once the final study report has been published.

Mili Doshi (supervisor) will be the data custodian.

8.6 Indemnity

The researchers have crown and personal indemnity that already covers them for providing all dental services in care homes.

Indemnity to meet the potential legal liability of the Investigators/collaborators for the harm of participants arising from the management and design of the research is provided by NHS indemnity scheme.
Participating care home managers will be asked to check with their insurance and indemnity provider regarding undertaking research within their care home with their residents and whether they have adequate cover prior to any research activity.

Den-tech charity will insure the scanner and it will be serviced according to manufacturer's instruction.

K2 hold insurance/indemnity for any 3D product they produce

8.8 Access to the final study dataset

The data from this study is owned by Surrey and Sussex Healthcare NHS Trust

The Chief Investigator and Supervisor will have full access to the study dataset during the study and for the time the data is stored.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

On completion of the study a final report will be prepared for the Royal College of Surgeons of England and the British Society of Gerodontology, this will include data that is analysed.

The study will be published on the British Society of Gerontology website. The Chief Investigator will lead on publishing the study in a peer reviewed journal. As part of the funding a requisite is that a presentation of this study is undertaken at a national conference for the British Society of Gerodontology.

Outcomes of the study will be shared with the PPI group and the study participants via a newsletter and the care home forum. The finding will be shared will all stakeholders.

The study and results will be registered on the ISRCTN database.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The Chief Investigator will be the primary author on the final study report and the denture scanning group will be the co-authors.

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11. APPENDICIES

11.1 Appendix 1 – Schedule of Procedures

Activity	Who	Requirements			
		Visit 1	Visit 2		
Participant identification	care home staff	X			n/a
Provide information on the study to residents Obtain initial – verbal consent	care home staff	X			n/a
Routine oral health assessment and eligibility check	Chief Investigator, supervisor	X			Private room required for oral health assessments
Assess capacity of residents	Chief Investigator, supervisor, care home staff	x	x		Private room required
Informed consent for research study with resident	Chief Investigator, supervisor	X			Private room required
Ongoing informed consent process	Chief Investigator, supervisor	X	x		n/a
Denture removed and scanned	Chief Investigator, supervisor	X			Private room required (20 minutes per denture scan)
Provide scanned denture for participant to wear	Chief Investigator, supervisor		x		Aim is for participant to wear denture for at least 30 minutes
Semi structured	Chief Investigator,		x		Private/quiet room

interviews with participant	supervisor				required for up to 1 hour per participant interview

11.2 Appendix 2 - Semi-structured Interviews

Topic	Guiding question	Follow up questions
Replacement denture	How do you feel about the new set of dentures	Are they comfortable? Can you speak clearly? Have you been able to eat with them? Are you happy with how they look?
Existing denture	Do you wear your dentures every day?	Do you eat wearing your dentures? Do you find dentures help with your speech? Do you like to wear dentures when you have visitors or are speaking to staff or other people in the care home?
Denture replacement process	How did you feel about having your dentures scanned?	Were you worried about the denture being lost or damaged? Were you pleased to have them scanned so that they you could have a spare set made?
Losing or breaking a denture	How would you feel if your dentures were lost or broken?	Would you be worried about how long it would take to replace them? Would you worry about having new dentures that looked or fitted differently?
Dental visits	Do you regularly visit the dentist?	Does the dentist visit you at home? Do you go to a dentist?

Summary	Thank you for taking the time to speak with me today. Is there anything else you would like to add or discuss about dentures or your dental health?	

11.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made