

Participant Information Sheet

Study Title: Digital Denture Scanning and 3D Printing for Residents in Care Homes

Part 1

We would like to invite you to take part in a research study which will help us understand if it is possible to replace a denture by scanning it and 3D printing a copy for residents in care homes. Before you decide we would like you to understand why the research is being done and what it will involve for you.

Please take time to read the following carefully and discuss it with others if you wish. We will go through the information sheet with you and answer any questions you have.

What is the purpose of the study?

When dentures are lost, it can take 6-8 weeks and many appointments to make a replacement set. There is evidence to show denture loss is an issue for people in hospitals and care homes.

We know dentures can be made by 3D printing in the private sector; however we are aiming to study if they can be made from a 3D scan taken in a care home. This scan could be kept and if the dentures were lost or broken they could be remade.

Currently we do not know if this scanning and 3D printing process would be possible in a care home and if they could be produced to a satisfactory standard.

Why have I been invited?

You have been invited to participate in the study because:

- You are a care home resident
- You are a denture wearer
- You are currently using your denture and it is not broken

In total we plan to recruit at least ten participants to the study.

Do I have to take part?

No, you do not have to take part in the study, it is entirely voluntary. We will describe the study and go through this information sheet with you.

If you do decide to participate, you will be given this information sheet to keep and asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or not take part will not affect the standard of care you receive.

What will happen to me if I take part?

If you decide to take part in the study during your routine dental health check in your care home, we will ask you to remove your denture and we will then scan your denture using a 3D scanner. This process should take no longer than 20 minutes; your denture will be cleaned and given back.

The scan will be used to print a replacement denture at a dental laboratory. Once the replica dentures are made we will ask you to wear them for a short period of time. We will ask for your opinion on the process and the feel of the replacement denture during a discussion lasting about 30 minutes. With your permission we will audio record the discussion.

The replacement denture will be yours to keep and use if you would like.

What are the possible disadvantages and risks of taking part?

We do not expect you to be disadvantaged in any way by participating in the study and we do not believe there are any risks.

We understand that removing your denture and being without it for a period of time can be worrying; the researchers are trained dentists and will respect your dignity at all times. Your dentures will be kept safe and returned to you once scanned.

The replacement dentures may feel and look different to your own dentures and if you wear them it is possible you may feel some discomfort but you can remove them at any time.

What are the possible benefits of taking part?

There may be no direct benefit to you from taking part in the study but your participation may provide information on whether scanning and 3D printing dentures for residents in care homes is possible.

You will have a replacement set of dentures to use which you may find useful.

What happens when the research study stops?

Once you have received and worn your replica denture you can decide to keep it or we can dispose of it for you. Your routine dental care will continue in the same way, whether you participate in this study or not.

Will my taking part in the study be kept confidential?

Yes. We will follow the law (Data Protection Act 2018) by making sure your information is kept private and secure.

If you consent to take part in the study, the study research records may be looked at by a member of the research team, sponsor or a regulatory authority. All information which is collected about you during the course of the research will be kept strictly confidential and kept in a locked cabinet at Surrey & Sussex Healthcare NHS Trust, East Surrey Hospital.

Participants will not be identified in any report or publication that arises as a result of the study. Data will be kept for a maximum of 12 months following completion of the study.

This completes Part 1. *If the information in Part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.*

Part 2

What will happen if I don't want to carry on with this study?

If you wish to stop involvement in the study you may do so at any stage. Your routine dental care will not be affected in any way.

What if there is a problem?

We will take any complaint about the way you have been dealt with during the study very seriously. If you wish to complain about any aspect of the way you have been approached or treated during this study, in the first instance please contact the Chief Investigator (the person leading the study):

Dr Daniel Gillway, Dental Officer, Surrey & Sussex Healthcare NHS Trust, East Surrey Hospital, Redhill RH1 5RH

Telephone number 01737 768511 Ext 1650, e-mail Daniel.gillway@nhs.net

If you would prefer to speak with someone who is not part of the research team, you can contact the hospital's Patient Advice & Liaison Service (PALS) at **01737 231958/** sash.pals@nhs.net

What will happen to my information?

We will have your name on a consent form which will be stored in a locked cabinet at the hospital.

In order to match you to your scan and replica denture we will allocate you a code number for the study. We will keep this code list secure in an electronic study folder using a secure password protected hospital laptop.

With your permission we will audio record the group discussions using a secure password protected hospital laptop. We will keep these recordings until we have written the study report then they will be destroyed. We may use your direct quotes in our report but

these will be anonymised so it will not be possible to identify you.

Surrey and Sussex Healthcare NHS Trust will keep identifiable information about you from this study for a maximum of 12 months after the study has finished. All information will be stored securely. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason.

We need to manage your research records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ and www.hra.nhs.uk/patientdataandresearch, or by asking one of the research team who can direct you to the hospital's Data Protection Officer.

What will happen to the scan of my denture?

The scans will be labelled with a non-identifiable coding system specific to each participant. The scan will then be transferred to a dental laboratory for processing. The dental laboratory will print the replica dentures and transfer them to the research team who will bring them to you in the care home. The dental laboratory will not keep a copy of the scan; it will be deleted once the replicate denture has been made.

The dental laboratory is called K2 Ceramic studio and specialises in dental work (<https://k2ceramicstudio.co.uk>). They have agreed to

print the replica dentures free of charge for the study. Please ask the research team if you would like any further information.

What will happen to the results of the research study?

We will present the study results at the British Society of Gerodontology conference. We also plan to publish the results of the study in a peer-reviewed medical journal.

You as an individual will not be identified in any report or publication.

Who is organising and funding the research?

The study is sponsored by Surrey & Sussex Healthcare NHS Trust.

Funding for the study is confirmed by the British Society of Gerodontology Royal College of surgeons pump-prime grant award.

The doctors organising the research are not being paid for their involvement.

Who has reviewed the study?

All NHS research is reviewed by an independent group of people, called a Research Ethics Committee, to protect the interests, rights and wellbeing of patients and their family members who participate in research. **The xxxxx Research Ethics Committee** has reviewed this study and given it a favourable opinion

Thank you for taking the time to read this information sheet, it is yours to keep.