

Living with dentures - Participant Information Sheet

1. Research Project Title:

Living with dentures: quality of life.

2. Invitation paragraph

You are being invited to take part in a research project. Before you decide whether or not to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

3. What is the project's purpose?

The project aims to understand the effects of dentures on everyday life. The first objective of the project is to explore the journey of individuals with their first dentures, including the overall impact of the loss of teeth and subsequent replacement by denture, as well as the impact of the denture on everyday life. Based on responses from the interviews a new quality of life measure will be developed. The project is scheduled to last 17 months (until December 2022), and we anticipate that the interview stage of this process, and the analysis of this, will take around 5 months to complete. This research is part of a project funded by GlaxoSmithKline.

4. Why have I been chosen?

You have been chosen as you have met the criteria we set out in the recruitment email you responded to (i.e. having had your first denture fitted in the past 5 years). In total we expect to recruit around 20 participants who meet these criteria.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form) and you can still withdraw at any time without any negative consequences. You do not have to give a reason. If you wish to withdraw from the research, please contact rpdstudy@sheffield.ac.uk. There will be a point at which it will not be possible for your data to be withdrawn from the research. You can still withdraw from any ongoing or future data collection, but any data you do provide cannot be removed from the study beyond December 12th 2022.

Please note that by choosing to participate in this research, this will not create a legally binding agreement, nor is it intended to create an employment relationship between you and the University of Sheffield.

6. What will happen to me if I take part? What do I have to do?

Participation in this research will be based on a one-time interview with a project researcher, which will form part of the larger research project that is due to run for 17 months (September 2021 – December 2022). We anticipate the interview will last between 60-90 minutes, and will be arranged at a mutually suitable time and place. This may be face-to-face, or via other means (videoconferencing, social media, telephone) depending on what is most suitable. Regardless of where interviews are conducted, recordings will always be made using a Zoom recording device (<https://zoomcorp.com/en/us/handheld-recorders/> - or a similar voice recording device), and never using the facilities or software in which the interview is being conducted (i.e. videoconferencing or social media).

We are looking to gather information on the journeys of individuals with their dentures, and associated impacts on everyday life. This information is important for the project as it will give greater insight into the most important factors related to adapting to dentures. This in turn will allow for the development of a tool to measure similar experiences in the future. Topics that will be covered in the interview include your personal history of your denture, reactions to the denture, the impact of the denture on your daily life, and any adaptation or coping strategies you may have. The interviews will be conducted in an open-ended style, meaning that participants can discuss issues in depth and in a flexible manner. All we ask of you is to be ready to discuss your experiences with your denture (no work is required beforehand).

Travel expenses will be reimbursed, and everyone who attends an interview will be given a £20 honorarium (in the form of a Love to Shop voucher) to thank you for your time. We may also contact you again at a later date to ask if you are interested in helping us to panel test our new questionnaire. We will ask for your consent to be contacted about this.

7. What are the possible disadvantages and risks of taking part?

Some participants may find discussing their dentures and related issues uncomfortable or perhaps upsetting at times. If you consider any of the questions inappropriate you may decline to answer and are free to stop your contribution. Beyond this, we do not anticipate any other foreseeable discomforts, disadvantages or risks through participation in this research. Should any arise during the research, these will be brought to the attention of the principal investigator (Professor Barry Gibson).

8. What are the possible benefits of taking part?

Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will add to the understanding of dentures and quality of life, and aid in the creation of a measure that will help to identify impacts of dentures for use in clinical trials and other health-related projects. We will also be using the findings of this research to better inform dentists and dental students about what it is like to live with a denture in everyday life. This means they should be better prepared to look after your oral health and denture use in the future.

9. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team. Transcripts will be anonymised, and you will not be able to be identified in any reports or publications unless you have given your explicit consent for this. If you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included unless you explicitly request this. All data will be completely anonymised at this point and you will not be identifiable.

10. What is the legal basis for processing my personal data?

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

As we will be collecting some data that is defined in the legislation as more sensitive (information about health), we also need to let you know that we are applying the following condition in law: that the use of your data is necessary 'for archiving purposes in the public interest, scientific research purposes or statistical purposes' (9(2)(j)).

11. Will I be recorded, and how will the recorded media be used?

The audio recordings of your activities made during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.

12. What will happen to the data collected, and the results of the research project?

Once an interview has been conducted the recording will be sent to be transcribed by a data processor (The Transcription Centre). This transcription will be conducted as close to the interview date as possible, and data will be anonymised as part of this process. As part of this process we will also ask if you would like to see your transcript, and if you would like any other information removed. Once the interview has been transcribed the recording will be kept in a secure online repository (Google Drive provided by the University of Sheffield) for a period of 2 years. The research team at the University of Sheffield will then have access to the transcribed data, in order to further analyse its content. The project funder will also receive a copy of the transcripts.

The results of the research will be used to create a quality of life measure related to dentures. The results are likely to be published after the study has concluded (in December 2022). Your data will not be identifiable in these peer-reviewed publications, which may be publicly available depending on the journal the research papers are submitted to. Separate reports of the results will also be produced for GlaxoSmithKline after the project has concluded. These reports will not contain names of participants.

The transcribed data (in anonymised form) will be stored beyond the end of the project in a secure online University repository (Google Drive provided by the University), as well as in a University archive, as due to the nature of this research it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will also use the data for the future training of our students as well as presentations at research conferences. The data will be embargoed for a period of 5 years as part of our agreement with GlaxoSmithKline. After this period anyone wishing to access the data will have to submit a request and agree to a user agreement. We will ask for your explicit consent for your data to be shared in this way.

13. Who is organising and funding the research?

The research is being organised by members of the research team in the School of Clinical Dentistry at the University of Sheffield. The research is funded by GlaxoSmithKline. The funders will be updated on progress, and will receive a report at the end of the project, but will not be involved in the design of the research.

14. Who is the Data Controller?

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

15. Who has ethically reviewed the project?

This project has been ethically approved via the University of Sheffield's Ethics Review Procedure, as administered by the School of Clinical Dentistry (Application 043367).

16. What if something goes wrong and I wish to complain about the research or report a concern or incident?

If you are dissatisfied with any aspect of the research and wish to make a complaint, please contact Professor Barry Gibson (b.j.gibson@sheffield.ac.uk) in the first instance. If you feel your complaint has not been handled in a satisfactory way you can contact the Dean of the School of Clinical Dentistry, Professor Chris Deery (c.deery@sheffield.ac.uk). If the complaint relates to how your personal data has been handled, you can find information about how to raise a complaint in the University's Privacy Notice: <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

If you wish to make a report of a concern or incident relating to potential exploitation, abuse or harm resulting from your involvement in this project, please contact the project's Designated Safeguarding Contact Professor Barry Gibson (b.j.gibson@sheffield.ac.uk). If the concern or incident relates to the Designated Safeguarding Contact, or if you feel a report you have made to this Contact has not been handled in a satisfactory way, please contact the Dean of the School of Clinical Dentistry, Professor Chris



Deery (c.deery@sheffield.ac.uk) and/or the University's Research Ethics & Integrity Manager (Lindsay Unwin; l.v.unwin@sheffield.ac.uk).

17. Contact for further information

Should you wish to obtain any further information about the project, please contact the research team using the study email address - rpdstudy@sheffield.ac.uk.

Participants will be given a copy of the information sheet and, if appropriate, a signed consent form to keep.

Thank you for considering taking part in this project.