Participant Information Sheet

Designing Inclusive Health Communication for Digital Parkinson's Care.

1. Invitation

You are being invited to take part as a Patient and Public Involvement (PPI) contributor in a study to improve written health information for people with Parkinson's. Before you decide, it is important for [you] to understand what the project involves and what your involvement would mean. 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 if [you] wish to take part or wish to decline to take part.

2. What is the purpose of the study?

Remote monitoring technology allows people with Parkinson's to track their symptoms at home using a wearable device, without needing to visit a clinic. The information collected is sent to their care team and summarised in a written report. Some of the content in these reports can be hard to understand, it is too long, uses medical terms, or may not feel relevant to everyone who reads it. We want to [rewrite this content], so it works for everyone, whatever their age, background, or experience with medical information. We need your help to do this.

3. Why have I been chosen?

You have been chosen because you are living with Parkinson's, or because you care for someone who is. You do not need any experience of remote monitoring or wearable technology to take part. We will explain everything you need to know before we begin.

4. Do I have to take part?

[No]. It is up to you to decide whether to take part, you can decline to take part. If you decide to take part, you will be asked to sign a consent form to confirm that you understand what is involved when taking part. [If you decide to take part, [you are free to leave the study at any time and without giving a reason]. If you withdraw, unless you object, we will keep records relating to the data collected from you as this is valuable. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

5. What will happen to me if I take part?

You will have an [initial telephone call] with a member of the research team, who will discuss the study further with you, and can answer any questions you may have. If you then wish to take part, they will record your verbal consent over the telephone. We plan to recruit approximately 10-15 people with Parkinson's or carers. If you are selected to take part, you will be invited to 3 **focus-group workshops**, described below. **We offer a £100 amazon voucher as a thank you for taking part in the (3) workshop sessions.**

Workshop sessions.

All the workshops will be carried out by video call, each lasting approximately 90 minutes with a 5-minute break in-between. We will send you materials to read in advance by email before the first workshop. You will share your views as part of a group of participants. All sessions will be recorded. No photographs will be taken. The recordings will remain confidential and stored securely. Details are provided in section 7 of this information sheet.

Workshop 1: Information Hierarchy

Next you will have a date and time booked for a researcher to meet you and carry out a workshop with you and others taking part. The researcher will meet you online. At this visit they will confirm you still consent to take part, answer any further questions, then once you are satisfied, we will begin the activities.

For the first workshop will be based around examples of the current symptom advice text from a remote monitoring report given to real patients. Using simple rating activities and digital sticky notes, you will tell us what is unclear, too long, or difficult to understand. We will also ask specific questions about the wording, message, and value of the text, but the conversation will also be led by your answers. **This workshop will be audio-recorded and video-recorded** by the researcher so that an accurate anonymised written transcript can be created. Direct quotes might be used in some cases. Please note, **no photographs will be taken on any workshop.**

Workshop 2: Translation into Digital App

1 week after the first workshop, you will be invited to take part in a second workshop. This will be done online.

During the workshop, using your feedback from Workshop 1, we will prepare a draft revised version of the text and share it with you 3 days before the workshop. In the workshop, you will compare the original and revised versions side by side, suggest further changes, and help rewrite sections in your own words. The researcher will facilitate the discussion with questions**. The workshop will again be audio recorded and video-recorded** by the researcher so that it can be accurately transcribed. Direct quotes might be used in some cases. The Workshop will take approximately 90 minutes with a 5-minute break in-between.

Workshop 3: Review of Digital Prototype

A further 1 week after the second workshop, you will be invited to take part in the final workshop. **This will be carried out online and will be audio recorded and video-recorded.** This will be very straight-forward and would be similar to the earlier workshop sessions and will be approximately 90 minutes. We will share the finalised revised text and a short plain language

guide for how to write this kind of information. You will give your final feedback and confirm you are happy with the materials before they are completed.
End of Study: The study comes to an end on the date of the last workshop.

6. What are the possible benefits of taking part?

We cannot promise the project will benefit you directly. However, your involvement will directly shape how symptom information is written and communicated in remote monitoring reports making them clearer and more accessible for people with Parkinson's in the future. Your contribution will be acknowledged in any publications or outputs from this work.

7. Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. If you consent to take part in this study, the records obtained while you are in this study will always remain strictly confidential. We will need to use information for this study. This information will include your

- Name
- Contact details.

We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

The information you provide will be held securely on paper and electronically in accordance with GDPR guidance and the provisions of the 2018 Data Protection Act. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Any identifiable data that we keep during the study will be held securely, and only members of the research team will have access to it. Electronic data collected will be password protected and only accessible to members of the research team. Your name and contact details (which we will need to contact you) will be stored separately from the other information you supply during the study so that you cannot be identified from your study records.

The workshops will be recorded digitally. The recordings will be used to make a written record of your contribution linked to your unique code number. At the end of the study, we will save some of the data [in case we need to check it] **AND/OR** [for future research]. We will make sure no-one can work out who you are from the reports we write. These will be stored securely for 5 years after the end of the study. We will keep all information about you safe and secure.

Your records will be available to people authorised to work on the study but may also need to be made available to people authorised by the Study Sponsor (Newcastle University), which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Study Sponsor (Newcastle University) during the study. By signing the consent form, you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

If you withdraw consent from further study activities, your data will remain on file and will be included in the final study analysis.

Privacy Notice for Participants

Newcastle University is the sponsor for this study based in the United Kingdom. We will be using information from you to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Newcastle University will keep identifiable information about you for a minimum of 10 years after the study has finished in our secure University archive.

We need to manage your 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. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. To safeguard your rights, we will use the minimum personally identifiable information possible.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

The Data Protection Officer can be contacted at:

Data Protection Officer
Executive Office
Newcastle University
Newcastle upon Tyne
NE1 7RU

E-mail: rec-man@ncl.ac.uk

For more information about research and about general use of patient information go to https://www.hra.nhs.uk/information-about-patients/

8. What will happen if I don't want to carry on with the study?

If you decide you do not want to carry on with the study you may withdraw at any time and without giving a reason (although we may ask you for a reason, to help us design better studies for the future, it is up to you whether you are happy to supply a reason or not). If you withdraw, we will keep records of any workshops already carried out, as this is valuable to the study. In the case, that a participant loses capacity to consent, they will be withdrawn from the study but study data already collected will be retained. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

9. Will the study information help with other research projects?

It is important that good quality data can be shared with others to advance clinical research and to benefit patients in the future. After the end of the study, anonymised information collected during the study may be made available to other researchers under an appropriate data sharing agreement, but it will not be possible to identify you personally from any information shared.

10. What will happen to the results of this study?

The study team will prepare a summary of the study to send out to all participants once the study is completed. The results will also be shared through publication in a medical journal or presentation at a scientific conference. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication.

11. Who is organising and funding this study?

This study is being organised and funded by Newcastle University.

12. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favorable opinion by the Health Research Authority, the appropriate Research Ethics Committee and the Research Development and Innovation team at Newcastle University.

13. Contact Details

Study Coordinator

Name: Hannah Kim

Tel. Number: **0191 208 1281**

Chief Investigator

Name: Dr. Precious Onyeachu

Tel.Number:**07780029537,**
Precious.Onyeachu@newcastle.ac.uk

14. Contact for further information

You are encouraged to ask any questions you wish, before, during or after the study. If you have any questions about the study, please speak to any member of the research team, who will be able to provide you with further information. If you require any further information or have any concerns while taking part in the study, please contact a member of the research team.

If you have concerns while on the study

Whilst it is something we hope will not happen, if you have concerns about any aspect of research, please speak to the researchers using the contact details you will have been provided with.

If you decide you would like to take part, then please read and sign and date the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records, and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.