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Imperial College London

UNIVERSITY OF OXFORD

UNIVERSITY OF PLYMOUTH

Autonomous telephone follow-up after cataract surgery
PARTICIPANT INFORMATION SHEET

Integrated Research Application System (IRAS) Reference: 297548

We would like to invite you to take part in this research project. You should only take part if you want to; choosing not to take part will not disadvantage you in any way. Before you decide if you wish to take part, you need to understand why the research is being done and what taking part will involve.

Please take up to one week to read the following information carefully and talk it through with others to decide if you would like to participate or not. Please contact us at the above email if there is anything that is not clear or if you would like more information.

1. Why is this research being conducted?

The aim of the study is to evaluate the quality and safety of Ufonia's automated telephone follow-up system for patients after cataract surgery. This study will develop evidence on how often Ufonia's technology agrees with a clinician on symptoms and overall management plan decisions. The study will determine if patients can successfully interact with this technology and what views patients have about interacting with an automated telephone system for surgery follow up.

2. Who is conducting the project?

The study is being led by Dr Eduardo Normando in a consortium led by Imperial College London and including the University of Plymouth and the University of Oxford. The Imperial College Healthcare NHS Trust and the Oxford University Hospitals NHS Foundation Trust are conducting all clinical activity.

3. Why have I been invited to participate?

Increasingly hospitals are providing follow up after routine cataract surgery by telephone conducted by a member of the clinical team. Ufonia Ltd has developed an automated system called **DORA**. This system is a computer which can conduct telephone follow up. The aim of this study is to see if this system is safe and that **DORA** makes the same recommendations as a clinician. We are evaluating this for 1014 patients who have surgery on certain operating lists which is why you are being asked if you would like to take part.

The study is being conducted as a collaboration between The Imperial College Healthcare NHS Trust and the Oxford University Hospitals NHS Foundation Trust.

4. **Do I have to take part?**

No, taking part is entirely voluntary. 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 or provide consent verbally (where your consent will be recorded on your behalf on a consent form). If you decide to take part, you are still free to withdraw at any time and without giving a reason.

5. **What will happen to me if I take part in the research?**

If you choose to take part, you will be called at a time and day selected by you three weeks after your surgery by **DORA**, the automated service. **DORA** will ask you some questions about how you are doing after your surgery and plan the next step in your care as well as what you think of the automated service. This will be overseen by a clinician (Imperial College Healthcare NHS Trust: Dr Eduardo Normando, Clinical Senior Lecturer and Consultant Ophthalmologist; Dr Ernest Lim, Specialty Registrar in Ophthalmology. Oxford University Hospitals NHS Foundation Trust: Dr Kanmin Xue, Honorary Consultant Ophthalmologist; Dr Aisling Higham, Specialty Registrar in Ophthalmology) and if you are not in agreement with the plan you can ask for this to be reviewed. This call will not replace any direct contact with a clinician or routine clinical care that you should receive.

After your call with **DORA**, you will be provided with a paper or online survey about your experiences using **DORA**. This survey will also ask some optional demographics questions. One week after your call with **DORA**, you may also be invited to take part in a telephone interview for 40-60 minutes, where you will be asked questions about your experience with **DORA**. The interviews will be held privately between you and a researcher. The sessions shall be recorded, subject to your permission, and transcribed by a third-party supplier of the University of Plymouth.

6. **Are there any potential risks in taking part?**

Potential disadvantages are that this is a new system so has not been demonstrated to be effective - this is why the system is currently overseen by a clinician.

7. **Are there any benefits to taking part?**

This post surgery review completed as part of this project is additional to the usual standard of care at the two sites where the study is being conducted. The process may be overseen by a clinician and the system is designed to provide a thorough assessment every time. This study may also benefit future patients through a more convenient follow-up service.

8. What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator, Dr Eduardo Normando at e.normando@imperial.ac.uk or 02033123206. The normal National Health Service complaints mechanisms are also available to you.

9. How will we use information about you?

Imperial College London is the sponsor for this study and will be the data controller. The University of Plymouth, The University of Oxford and Ufonia will act as data processors for this study. This means that all research partners are responsible for looking after your information, using it properly and will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.
- 10 years after the study has completed for the purpose of contacting you about possible related follow-up studies.

10. **What happens to the data provided?**

The information you provide during the study is known as the **research data**.

Any research data from where you can be identified or is linked to you is known as **personal data**. This data will be accessed via your digital interactions with

DORA and stored on an EEA hosted server and on secure university network drives. These digital interactions will be transferred from **DORA** to your clinical record using secure electronic file transfer protocols. Audio recordings will be created from interview sessions via a digital recorder. This data will be directly transferred from the device to a secured drive and transcribed by Prestige Network Limited, York House, 68 - 70 London Road, Newbury, Berkshire, United Kingdom, RG14 1LA. Once the transcription is completed, the original interview audio interview files will be destroyed.

Other research data (including consent forms) will be stored for ten years after publication or public release of the research and stored on a secure university network drives at Imperial College and the University of Plymouth. Dr Normando and Dr Meinert and their research teams will have access to the research data. Responsible members of Imperial College London, the University of Plymouth and the University of Oxford may be given access to data for monitoring and/or audit of the research.

All data will be stored on a password-protected network drive within the Imperial College London's and University of Plymouth's network. Access to these files will be limited to the study research team. Electronic data shall be coded using a process where fictitious information will be linked to participant numbers to prevent the identification of individuals. Physical copies of consent forms will be stored in a locked folder at Dr Meinert's office in the University of Plymouth at 6 Kirkby Place, Room 2.

We would like your permission to use direct quotes with a fictitious name in any research outputs.

We would like your permission to use anonymised data in future studies and to share data with other researchers. All personal information that could identify you will be removed or changed before the information is shared with other researchers or results are made public.

If you consent to take part in the research, any information you provide may be inspected and used by administrators of the study. Each participant's identity will be hidden by replacing identifying information with a unique identifier to maintain confidentiality, and all data will be securely stored and managed according to University of Plymouth rules and expected practices. Raw, un-anonymised audio data will be securely stored separately from the anonymisation key and deleted when it is no longer needed. The non-identified transcripts will be securely stored according to Imperial College London's and the University of Plymouth protocols and regulations.

11. Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using patient data, they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

12. Will what I say be kept confidential?

All information provided during interviews will be labelled with a unique ID (not with your personal details), kept strictly confidential and not attributed to you. Participants will be allocated a study ID number and any information collected will only be seen by the study team. The voice data derived from conversations with DORA will be stored and used by Ufonia, Ltd, the manufacturer of DORA, for up to 10 years to train and improve its system. This data will be stored using a unique ID and will not include your name.

13. What will happen to the results of the project?

The results of this evaluation study will be used for the purpose of deciding whether the system is safe to provide autonomous telephone follow-up after cataract surgery without oversight from a clinician. We will publish findings from the study in a medical journal.

14. Who has reviewed the project?

The study has been reviewed and given a favourable approval by the London-Chelsea Research Ethics Committee. The University of Plymouth, The University of Oxford and Imperial College London have reviewed this project and provided approval.

15.Legal Basis

As universities we use personally identifiable information to conduct research to improve health, care and services. As publicly funded organisations, we have to ensure that this work is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

16.International transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

17.Sharing your information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other Imperial College London employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

- The following Research Collaborators / Partners in the study:
  - The University of Plymouth – The University of Plymouth will access research and personal data for the purpose of completing an evaluation of **DORA.**
  - The University of Oxford – The University of Oxford will access research and personal data for the purpose of completing an evaluation of **DORA**.
  - Ufonia, Ltd. – Ufonia, Ltd. will access personal data for the processing of conversations with **DORA** and using these conversations to train and improve **DORA**'s ability to conduct automated telephone follow-up.

18.Complaints

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

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 ICO does recommend that you seek to resolve matters with the data controller first before involving the regulator.

19.**What should I do if I want to take part?**

If you agree to take part, you will be asked to sign a consent form or provide consent verbally and will be given a date to expect a call from **DORA**.

Contact for further information:

- Dr Eduardo Normando – e.normando@imperial.ac.uk
- Dr Kanmin Xue – kanmin.xue@ouh.nhs.uk
- Dr Edward Meinert – edward.meinert@plymouth.ac.uk