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Local Letterhead to be added

Patient Participant Information Sheet
(Final version 1.1: 2nd August 2023)

IRAS Project ID: 325423

Title of Study: VOICE2 Evaluation

Name of Chief Investigator: Professor Rowan Harwood
Local Researcher(s):

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

Hospital staff such as nurses, doctors, therapists and healthcare assistants often find it difficult to communicate effectively with patients with dementia when the patient is distressed. The patient might show their distress as agitation, aggression or repetitive calling out. There is little hard evidence on what communication strategies work to avoid, de-escalate or resolve patient distress. We have video and audio recorded conversations between healthcare practitioners and patients with dementia and studied them to identify which communication strategies are most effective when the patient is distressed. Using this information, we have developed a communication skills training course for hospital staff and a 'train the trainers' course for hospital clinical educators to learn how to deliver this course. We want to test whether the communications skills the staff learn on this course, does have a positive impact on patient care.

Why have I been invited?

You are being invited to take part because you are a person with dementia, who at times becomes distressed, being cared for on an older person ward. We are inviting up to 60 people with dementia from 3 hospitals, like you to take part.

Do I have to take part?

No, it is up to you to decide whether 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. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your healthcare.

What will happen to me if I take part?

If you take part, we will look at your medical notes to confirm you have a diagnosis of dementia. We will watch and make notes of the care you receive from the members of staff we have trained. There will be no changes to the care you receive, we will only be watching routine care being given to you. We might, also talk to you, for about 10 minutes, about the care given to you and how well staff treated you when you felt distressed. We will record this using a recording device called a Dictaphone, if you are happy with this. This is to help us remember what you have said. You will also be asked to complete a survey card on your satisfaction with ward care. This will take about 5 minutes to complete.

You will be involved in this research for the time you are a patient on the ward.

What are the possible disadvantages and risks of taking part?

We are only watching the ward staff delivering the usual care to you and talking to you about the care you have received. There is very little risk of harm. You might find that talking about the care you received when you were distressed makes you feel more distressed. Our researchers are skilled at talking to patients who are distressed and will be able to support you.

What are the possible benefits of taking part?

We cannot promise the study will help you directly. We hope that the information we get will help staff to care better for people in a similar situation to you in the future.

What happens when the research study stops?

The information you give us will be used to understand whether the communication skills training course we have developed does improve patient care. We will write up the results of the study in medical journals and share the results with hospital staff, people with dementia and their family members and friends. If the course is shown to be of benefit, we will aim to roll it out nationally.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting Professor Rowan Harwood who is leading the research, and his contact details are given at the end of this information sheet. You can also contact the hospital Patient Advice and Liaison Service (PALS) [contact details of local PALS].

If something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham, but you may have to pay your

legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham and at [site]. Under United Kingdom Data Protection laws, the University is the Data Controller (legally responsible for the data security), and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible, information about you which leaves the [site] will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however, to make the observations and conduct the interview we will need to know your name and the ward you are working on. By signing the consent form, you agree to the above.

Your contact information will be kept by the University of Nottingham for 6 months after the end of the study so that we are able to contact you about the findings of the study and follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time, your data will be disposed of securely. During this time, all precautions will be taken by all those involved to maintain your

confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's, and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information, we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the United Kingdom and how we will protect your confidentiality.

Although what you say to us is confidential, should you disclose anything to us or if we observe anything which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

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

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw, we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally identifiable information possible.

What will happen to the results of the research study?

The results of this study will be discussed at medical research meetings and written about in research and clinical journals. You will not be identified in any publication.

We will send a newsletter to all patients recruited to the study updating them on the results.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the National Institute of Health Research.

Who has reviewed the study?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Health and Care Research Ethics Committee Wales REC4.

Further information and contact details

If you have any additional questions, please contact one of the research team at the University of Nottingham or Nottingham University Hospitals. You can contact the project administrator Kasia Kowalewska who will direct you to the most appropriate person email: katarzyna.kowalewska@nottingham.ac.uk or the Chief Investigator Professor Rowan Harwood by phone 0115 8230873, or on email: rowan.harwood@nuh.nhs.uk.

Thank you for reading this and considering taking part in the study.