University of Nottingham
UK | CHINA | MALAYSIA

Local Letterhead to be added

Healthcare Practitioner 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?

Healthcare practitioners working in hospital 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 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 healthcare practitioners. The course is a full day. We want to assess the practicality, acceptability, and impact of the course.

Why have I been invited?

You are being invited to take part because you are a healthcare practitioner working on an older person ward in one of the participating hospitals. We are inviting up to 300 potential participants 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 will not affect your legal rights.

What will happen to me if I take part?

If you take part, you will:

- Might be observed for up to 2 hours before the course and then 1-3 months after the course delivering routine care to your patients with dementia who are prone to distress. A researcher will make notes during these observations.
- Complete questionnaires before, immediately after and 3 months after attending the VOICE2 course on your knowledge of, and confidence in, communicating with patients with dementia. These questionnaires will take you about 15 minutes to complete in total.
- Attend a one-day dementia communication skills training course. This course will be delivered by clinical educators working in your Trust.
- Complete a questionnaire on the usefulness and acceptability of the training course both immediately after the VOICE2 training course and 1-3 months after the training course. This questionnaire will take 10 minute to complete.
- Complete a questionnaire on how you found putting the dementia communication skills learnt into practice. This questionnaire will take 5 minutes to complete.
- All questionnaires will be completed online, with the link emailed to your work email address.
- We may invite you to a 30minute interview on the communications skills training course. The interview will each last approximately 30 minutes and will be either in person in a private room at your hospital or at the University of Nottingham, via telephone or via video call depending on your preference. All in person and telephone interviews will be audio recorded, interviews via Microsoft Teams will be video recorded, all interviews will be transcribed by a researcher or an approved University of Nottingham transcriber with a confidentiality agreement in place.
- We may invite you to a focus group on the VOICE2 course. The focus group will be audio recorded and transcribed as above.

You will be involved in this research for three-four months following attending the course.

The course is free.

Expenses and payments

You will be given a £10 voucher once you have completed questionnaires immediately following the training course and another £10 voucher once you have completed questionnaires 3 months after the training course.

What are the possible disadvantages and risks of taking part?

This is a training course for healthcare practitioners. Risk of harm is very low.

We will be talking about delivering care to patients with dementia who are in distress. You might find reflecting on this important aspect of clinical care distressing. The trainers are clinical educators who will be experienced at delivering this type of training.

What are the possible benefits of taking part?

You may enjoy the training course and learn better communication skills needed for good care of patients with dementia. Attending the course can be used for your professional revalidation. If the course is shown to be beneficial, we hope to roll it out Nationally.

What happens when the research study stops?

The information you give us will be used to understand the benefits of the training to healthcare practitioners and patients with dementia. We will also understand what helps support or hinders healthcare practitioners using these communication skills in clinical practice.

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 you should then contact the Faculty of Medical and Health Sciences Senior Administrator, Louise Sabir; Email: fmhs-researchethics@nottingham.ac.uk to complain formally.

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 or 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 work 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 healthcare practitioners recruited to the study updating them on the results. We will also hold an event for healthcare practitioners to provide the results of the study.

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 the Health and Social 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.