VOICE2 Dementia Communication Skills Training: a longitudinal case study evaluation

Final Version 1.1
2ndAugust 2023

Short title: VOICE2 Evaluation

Trial Registration: www.clinicaltrials.gov reference *if appropriate*

ISRCTN: *if appropriate*

IRAS Project ID: 325423

Study Sponsor: University of Nottingham

Sponsor reference: *23035*

Funding Source: National Institute of Health Research

STUDY PERSONNEL AND CONTACT DETAILS

Sponsor:
Contact name

University of Nottingham
Ms Angela Shone
Research and Innovation
E-floor, Yang Fujia Building
Jubilee Campus
Wollaton Road

Nottingham
NG8 1BB
Email: sponsor@nottingham.ac.uk

Chief investigator:

Professor Rowan Harwood
Professor in Palliative and End of Life Care and Consultant Geriatrician
B302, School of Health Sciences
Medical School
University of Nottingham
NG7 2UH
Phone: 0115 8230873
Email: rowan.harwood@nottingham.ac.uk

Add the name and contact details of the medical expert if different to the CI.

Co-investigators:

Professor Sarah Goldberg
Email**:** sarah.goldberg@nottingham.ac.uk

Dr Rebecca O'Brien
Phone: 0115 8230766
Email: rebecca.obrien@nottingham.ac.uk

Professor Alison Pilnick
Phone: 0115 9515237
Email: alison.pilnick@nottingham.ac.uk

Dr Suzanne Beeke
Phone: 020 7679 4215
Email: s.beeke@ucl.ac.uk

Professor Claire Surr
Phone: 0113 8124316
Email: c.a.surr@leedsbeckett.ac.uk

Mrs Kate Sartain
Email: katesartain49@gmail.com

Mrs Morag Whitworth
Email: morag.whitworth@gmail.com

Professor Heather Wharrad
Email: heather.wharrad@nottingham.ac.uk

Professor Aquiline Chivinge
Phone: 0115 9249924
Email: acquiline.chivinge@nuh.nhs.uk

Dr Louise Bramley

Phone: 0115 9249924
Email: louise.bramley@nuh.nhs.uk

Professor Sue Haines
Phone: 0115 9249924
Email: sue.haines@nuh.nhs.uk

Dr Sean Ninan
Email sean.ninan@nhs.net

Dr Sherena Nair
Email: sherenanair@nhs.net

Committees	A study steering committee will be convened. Dr Michele Board, Associate Professor and Deputy Head of Department for Nursing Science, Bournemouth University is the chair.
Study Coordinating Centre	School of Health Sciences; Queen's Medical Centre Nottingham NG7 2HA

SYNOPSIS

Title	VOICE2 Dementia Communication Skills Training: a longitudinal case study evaluation.
Short title	VOICE2 Evaluation
Chief Investigator	Professor Rowan Harwood
Objectives	We aim to give Healthcare Practitioners (HCPs) the communication skills to avoid, de-escalate or resolve distress and challenging behaviours amongst hospital patients who have dementia, in the context of NHS clinical practice. We have developed a 'train the trainers' course to enable hospital clinical in-house skills educators to deliver the VOICE2 course and teach HCPs these communication skills adapted for different clinical contexts and learners' background. Our objectives are to: i) Evaluate the VOICE2 'train the trainers' course ii) Assess the educational impact of the VOICE2 communication skills training course delivered to HCPs in improving educational outcomes (knowledge, confidence, skills/communication behaviours), and identify how the skills improve patient outcomes in practice, using multiple case study methodology iii) Explore and address barriers and facilitators to implementation of the VOICE2 course and use of these skills in clinical practice.
Study Configuration	A longitudinal case study across three to four sites.
Setting	Healthcare of the Older Person wards in general hospitals in England.
Sample size estimate	This is case study research, and a formal sample size calculation is not appropriate.
Number of participants	Anticipated number of participants: Clinical Educators up to 24 Healthcare Practitioners (HCPs) up to 300 Ward managers up to 12 Patients with Dementia up to 60
Eligibility criteria	Clinical Educators: a healthcare professional with a role to provide dementia education to HCPs at the participating site, able and willing to attend the VOICE2 'train the trainers' course and to deliver the VOICE2 training course to HCPs in the participating NHS site. Able and willing to complete all research processes including questionnaires, interviews and to be observed delivering the VOICE2 course. Healthcare Practitioners: employed to deliver healthcare to patients on participating wards. Able and willing to complete all research

	questionnaires and to be interviewed and observed whilst delivering ward care or during training as part of the study. Ward Managers: working as a ward manager or deputy ward manager on a participating ward. Able and willing to be interviewed. Patients: a diagnosis of dementia recorded in the medical notes, admitted to a participating ward, prone to distress as confirmed by the clinical team, willing to be interviewed and/or observed, capacity to give informed consent or advice from a consultee that they have no reason to believe they would not have wanted to take part. We will exclude patients confirmed by their clinical team to be likely to die within 7 days or judged by the clinical team to be too unwell to participate.
Description of interventions	A dementia communication skills training course for healthcare practitioners working with patients with dementia in the acute hospital (the VOICE2 course). A dementia communications skill 'train the trainer' course for clinical educators to learn how to deliver the VOICE2 training course. The VOICE2 course will include a combination of narrated PowerPoints, group discussions, reflective exercises, case study exercises and video-based simulation exercises.
Duration of study	We will start the study 1st September 2023 with the pilot of the VOICE2 course. The study will end six months after the last HCP is trained on the VOICE2 course – which will be 31st December 2024.
Outcome measures	This is a mixed methods longitudinal case study. Measures include numbers and profession of HCPs attending training, satisfaction with training, confidence in delivering training (for clinical educators), questionnaires to measure changes in knowledge related to training, dementia confidence, barriers and facilitators to putting the learning into practice. Through qualitative interviews we will be understanding the value of the course, the barriers and facilitators to delivering the course and to putting the training into practice and the impact on patient care and patient experience. Observations of care will establish if the VOICE2 trained healthcare practitioners do change their communication behaviours and explore whether the changes have a positive impact on patient care. Observations of the clinical educators delivering the VOICE2 course in their hospital will provide data on how the course is implemented in practice. Ward routine incident reporting will measure changes in incidents of violence or aggression.
Statistical methods	For all quantitative data, we will calculate descriptive statistics (means and standard deviations for normally distributed data and median and interquartile ranges for skewed data), and the mean or median difference between pre and post training quantitative data, together with 95% confidence intervals. All qualitative data will be thematically analysed.

ABBREVIATIONS

AHSN Academic Health Science Networks

ARC Applied Research Collaborations

CA Conversation analysis

CI Chief Investigator overall

CPD Continuing Professional Development

EPIC Enhancing Person Centred Care in Care Homes

GCP Good Clinical Practice

HCP Healthcare Practitioner

HEE Health Education England

HRA Health Research Authority

HS&DR Health Service and Delivery Research

HTA Health Technology Assessment

ICF Informed Consent Form

NHS National Health Service

NIHR National Institute of Health Research

NUH Nottingham University Hospitals NHS Trust

LTHT Leeds Teaching Hospital NHS Trust

PI Principal Investigator at a local centre

PIS Participant Information Sheet

PPI Patient and Public Involvement

REC Research Ethics Committee

R&D Research and Development department

UoN University of Nottingham

ROLE OF STUDY SPONSOR AND FUNDER

NIHR HS&DR funds researcher-initiated studies via a peer-reviewed, competitive process. Comments made by reviewers and the funding panel were incorporated into the final proposal.

The Sponsor provides overall assurance of the ethical conduct and delivery of the research.

Neither has any role in collection or analysis of data. NIHR fund article processing charges to enable open access publication. NIHR requires publication of a funding acknowledgement and a standard disclaimer. NIHR requires prior notification of intention to publish.

TABLE OF CONTENTS

STUDY BACKGROUND INFORMATION AND RATIONALE

Dementia is common and problematic in acute hospitals

Dementia affects 20% of people over 80 years. Prevalence will double over the next 20 years. Dementia is the progressive loss of memory and other thinking abilities due to various brain diseases. Delirium is a worsening of confusion with impaired alertness or attention due to a physical illness, often associated with delusions or hallucinations. Acute physical illness, injury and delirium are commoner in people living with dementia than those without it. Crises, such as these, often lead to hospital admission.

Cognitive disorders are a major problem for acute hospitals [1]. One in three emergency admissions is of a confused older person, including half of those over 70, and half those with a hip fracture [2]. 42% of those over 70 in hospital have dementia [3], although this may be previously undiagnosed. An overlapping one-third have delirium, which exacerbates problems [4].

The scope and scale of the problem of challenging behaviours

We appreciate and respect the sensitivity over the language used to describe the problems we will study. Behaviours indicating distress (also called 'behaviours that challenge', 'neuro-psychiatric symptoms', or 'behavioural and psychological symptoms') are among the most difficult issues for people with dementia, those around them and those who care for them [7,16]. Behaviours may include agitation, aggression, repetitive calling out, exit-seeking, or resistance to personal care or therapy. 20% of people over 70 admitted to hospital as an emergency displayed 'agitation or aggression' on admission [2]. The commonest demographic for reported incidents of 'aggression and violence' in hospitals is men aged 80-90, followed by women of the same age, and the commonest location is general and geriatric medical wards [28]. A recent ethnographic study in five English hospitals identified 'high levels of resistance to care among patients with dementia within acute hospital wards. Every patient observed in hospital *'… resisted care at some point during their admission'*. These instances were managed poorly, often with confrontation or restraint. Care was delegated to the most junior and unskilled staff members, often temporary agency staff [16]. The environment, activity and processes of hospitals can easily provoke or escalate distress amongst ill and confused older people. Despite recent improvements in dementia awareness training, and liaison psychiatry for older people, distress behaviour often leads to frustration and helplessness amongst clinicians [29,30]. Knowledge and skills around de-escalation are highlighted as lacking [19].

There is a direct relationship between relational care (communication, empathy, compassion) and outcomes for people with dementia [20,31]. Improving outcomes requires attention to staff skills and contextual factors, such as leadership, environment and competing priorities [7,10,13-21,31]. Various medical, psychological, and social interventions have been tried in response to the problem of distress [11,27]. Drug interventions are generally ineffective and may be harmful [32]. Psychosocial approaches to understanding and managing distress can be effective but are difficult to enact [11]. Reminiscence therapy, personalised pleasant activities, and training in person-centred care can reduce agitation in care homes [11,18,27]. Person-centred care is a bio-psycho-social theory that aims to promote wellbeing and minimise distress by meeting fundamental physical, psychological and social needs [33]. Delivering person-centred acute care is highly skilled and requires cultural change [7, 19, 34]. Healthcare Practitioners (HCPs; doctors, nurses, therapists and their assistants) are often uncertain what person-centred care means in practice [29, 35].

The number of people with dementia in the population is increasing, and policy calls for improved care in all settings. Challenging behaviours indicating distress contribute to poor experience and complaints, injuries, poor outcomes, inefficient use of resources and regulatory (CQC) criticism [16]. The problem is under-appreciated and under-researched, especially in acute hospitals [28]. HCPs lack confidence in managing problems, which is a source of stress and dissatisfaction [29].

The role of communication skills

There is limited empirical research on how best to communicate with people with dementia, and the effectiveness of common recommendations [6, 36]. People with dementia often have difficulty with verbal expression and understanding, due to the language impairment which is part of dementia. Behaviours indicating distress are a form of communication, expressing unmet needs [37,38], which may be evident, revealed through skilled assessment, or impossible to interpret [30]. Person-centred care requires specific work from carers to make and maintain relationships, underpinned by dementia-specific communication skills [21,33]. Essential health and personal care tasks may cause distress if staff have difficulties communicating their intentions [16-18,39]. Psychological approaches to challenging behaviours depend on communication skills [24]. Communication breakdowns can cause:

i. Distress from misunderstanding and failure to meet basic needs

ii. Patients declining necessary assessments, care or treatment resulting in poorer outcomes [6,39]

iii. HCPs experiencing stress, contributing to staff sickness and retention difficulties [29,30].

Conversation analysis (CA) is a research method that seeks to uncover and make explicit implicit communication practices. Some people are better than others in how they communicate with people with dementia, but carers do not accurately self-report what they do that works well or less well [24, 36, 40]. CA uses rigorous study of video or audio recordings of naturally occurring interactions to enable the identification of verbal and non-verbal communication practices which would otherwise have remained unconscious (in the sense of inarticulable) to the participants. CA analyses what people actually do when communicating, rather than what they think or say they do, and can be used to reveal what is interactionally successful [41]. It has been used to identify features of successful communication in healthcare and to develop communication skills training in settings such as stroke, acute psychiatry, palliative care and primary care, as well as in dementia [42-47].

We recently completed the conversational analytic VOICE2 study (An observational study of communication skills to manage distress; IRAS 307895; REC 22WA0023). We video or audio recorded 53 naturally occurring healthcare interactions between healthcare practitioners and patients with dementia who were prone to or in distress. We used CA to identify communication approaches that worked to avoid, de-escalate or resolve any distress. We identified the skilful ways in which HCPs deal with the interactional challenges of not being able to meet a patient's need, the patient being in a different reality and HCPs doing unavoidable things to patients that caused them distress (such as giving them an injection or repositioning them in bed). We have used these findings to develop the VOICE2 dementia communication skills training course for HCPs and an associated 'train the trainers' course for clinical educators in NHS trusts to teach the VOICE2 course. We are using a 'train the trainers' model to deliver the course, training clinical educators in NHS acute hospital trusts to deliver the course, to ensure sustainability of the course in the long term.

Evaluation of education and training

Evaluation of training in healthcare, particularly acute hospital care, is more difficult than evaluating clinical interventions. This is because:

a) New knowledge is integrated with previous expertise and experience, therefore establishing realistic control groups is challenging;

b) Acute hospital ward patients stay for only short periods, making prospective studies difficult;

c) Contextual factors, such as illness, mental state, other patients and ward environment impinge on outcomes, so measurable outcomes are influenced by many other factors than the intervention;
d) Evaluation is often affected by the dominance of a few outlier patients;
e) Use of skills has to be flexible and responsive to unpredictable circumstances.

This is sometimes called evaluating an 'open system'. Kirkpatrick proposed evaluation at the levels of reaction, knowledge, behaviour and outcomes [50], but there are few examples of clinical training interventions being evaluated at the level of patient outcomes [9]. A priori, training interventions are likely to be beneficial. Triangulated evidence demonstrating support from multiple different methods can give sufficient certainty of effect. For this reason, multi-method longitudinal case studies are often used [53, 54, 55].

STUDY OBJECTIVES AND PURPOSE

PURPOSE

The overall aim is to give HCPs, through the VOICE2 course, the knowledge, skills and confidence to be able to change their communication behaviour when caring for patients with dementia who are prone to or in distress, in the context of NHS clinical practice. Changes in HCP communication behaviour should decrease observed distress in patients with dementia and increase satisfaction with care reported by people with dementia and their families or friends.

PRIMARY OBJECTIVE

i) To assess the educational impact of the VOICE2 dementia communication skills training courses delivered to HCPs in improving educational outcomes (perceived value of the course, changes in knowledge, confidence, skills/communication behaviours), and explore how the skills improve patient outcomes in practice, using multiple case study methodology

SECONDARY OBJECTIVES

ii) To evaluate the VOICE2 'train-the-trainers' course

iii) To explore and address barriers and facilitators to the implementation of the VOICE2 course and the use of these communication skills in clinical practice.

STUDY DESIGN

STUDY CONFIGURATION

A multi-centre, longitudinal, mixed methods case study design.

STUDY MANAGEMENT

The Chief investigator (CI) will assume overall responsibility for project management, budget, and ethical and scientific rigor of the research, supported by the other senior co-investigators. A project management group (PMG) consisting of all the co-investigators, researchers, and an additional patient and public involvement (PPI) representatives will give oversight to the study. PMG meetings will be held monthly, via Microsoft Office 365 Teams.

Weekly meetings, attended by the research fellows, project manager, relevant phase leads and CI, will closely monitor progress.

A Study Steering group of nine independent members including senior academic, clinical, staff training and managerial experience and two PPI representation from user groups will meet with the research team at least six times over the 34-month project to review progress and the achievement of project milestones. Members will also be available to advise the research team on an ad hoc basis.

The data custodian will be the Chief Investigator. A Data Management Plan, including transcription, anonymisation procedures, confidentiality, security and GDPR compliance has been completed using DMPOnline.ac.uk.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: We will start enrolment to this study from 1st September 2023 (for pilot study). Enrolment will continue for up to 12 months.

End of the Study

The end of the study will be the last participant interview or completion of the last participant questionnaire, whichever is later.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Participants will be recruited from acute hospital trust's Healthcare of the Older Person wards, Liaison Psychiatry teams and dementia clinical education teams.

- The initial approach to clinical educators will be from a member of the hospital or ward management team (which may include the investigator) or the research team.

- HCPs will be initially approached by the clinical educators or a member of the ward management team (which may include the investigator).

- Ward managers will be approached by the research team. They will have previously agreed for their ward to be a participating in the study.

- The initial approach to patients will be from a member of the patient's usual care team (which may include the investigator).

Information about the study observations will be on display through posters in the relevant clinical areas. These posters will inform patients, visitors, and hospital staff about the study and that observations are being made on the ward. There will be contact details of researchers for further questions or for individuals to raise concerns about the research.

The investigator or their nominee, e.g. from the research team or a member of the participant's usual care team, will inform the participant or their consultee, of all aspects pertaining to participation in the study. The participant or their consultee will be given firstly, the short version of the information sheet and then offered the full version. They will be given the time to read and consider the information sheet. If needed, the usual hospital interpreter services will be available to assist with discussion of the study, the short participant information sheet and consent forms.

It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care or legal rights will not be affected by their decision. It will also be explained that they can withdraw at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal, it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Inclusion criteria

Clinical Educators

- Employed by the site NHS Trust or an associated trust (for example the mental health trust providing liaison psychiatry services), with a role to provide dementia education to HCPs
- Able and willing to attend the VOICE2 'train the trainers' course and to deliver the training to healthcare practitioners in the participating NHS Trust
- Aged over 18 years old

Healthcare Practitioners

- A healthcare practitioner working on one of the designated wards
- Willing and able to complete all follow-up questionnaires and be interviewed and/or observed
- Aged over 18 years old

Ward Managers

- A ward manager or deputy manager of a participating ward
- Willing and able to be interviewed
- Aged over 18 years old

Patients

- A diagnosis of dementia recorded in the medical notes
- Admitted to a participating healthcare of the older person ward
- Prone to distress as confirmed by clinical team
- Capacity to give informed consent or consultee willing to give agreement on whether the person with dementia would wish to take part
- Willing to be interviewed and/or observed

Exclusion criteria

Clinical Educators

- Unwilling or unable to attend the train the trainers course dates and to complete all parts of the evaluation

Healthcare Practitioners

- unable or unwilling to attend training dates and to complete all parts of the course
- unable or unwilling to be interviewed and observed delivering care

Patients

- Likely to die within the next week (on an end-of-life pathway) or judged by the clinical team to be too unwell to participate
- Lacking capacity to give informed consent and unable to find someone willing to act as consultee

Expected duration of participant participation

Clinical educators will be involved in the study from the time they consent to participate until the three months following the last training course is delivered – approximately one year.

Healthcare practitioners will be involved from the time they consent to participate until their 3 month interview and questionnaire following training – approximately five months.

Ward managers will be involved in the study from the time they consent to participate until the end of their interview.

Patients with dementia will be in the study from the time they consent to participate (or we receive consultee agreement) until they leave the participating ward or the case study ends.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care or legal rights. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants will provide written informed consent or where the patient with dementia lacks capacity to consent, written or recorded verbal consultee advice that the person would wish to take part. The Informed Consent Form will be signed and dated by the participant before they enter the study and before any data is collected. The Investigator or their nominee will explain the details of the study and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. We have followed Health Research Authority (HRA) guidance when developing our participant information sheets. The HRA online guidance (2017; https://www.hra.nhs.uk/documents/283/applying-proportionate-approach-process-seeking-consent_R3gbJKn.pdf) 'Applying a proportionate approach to the process of seeking consent' states *'A proportionate approach to seeking consent, i.e. adopting procedures commensurate with the balance of risk and benefits, should always be adopted so that potential participants are not overwhelmed by unnecessarily lengthy, complex and inaccessible information sheets but instead are provided with succinct, relevant, truthful information in a user-friendly manner that better promotes their autonomy'*.(p5) '*the closer the research is to standard clinical practice, the less need there is to provide patients and service users with detailed and lengthy information about the research.' (p6).* This is a low-risk study, close to routine clinical practice. It involves healthcare practitioners attending a dementia communication skills training course and participants being observed, interviewed, and completing questionnaires. We will recruit busy healthcare practitioners and patients who lack capacity. To ensure all participants understand the study and what they agree to, we have developed a short version of the information sheet. We will follow a layered approach to consent when initially discussing the study, we will show potential participants the short participant information sheet, letting them know there is a full version available. Once they have read the short version and had the opportunity to ask questions, we will offer the potential participant the full information sheet to read. The Investigator will answer any questions that the participant has concerning study participation. If needed participants or their consultees will be given additional time to consider whether they wish to participate. One copy of the consent form or consultee declaration will be kept by the participant or consultee, one will be kept by the Investigator, and a third will be retained in the patient's hospital records (for patient participants).

Patient participants in this study will be cognitively impaired. Most (or all) will lack mental capacity to give informed consent. If this is the case, their inclusion will be based on consultee

advice, under the Mental Capacity Act (2005), Sections 30-34. Inclusion of participants who lack mental capacity is essential, as it is this patient group who are most likely to become distressed whilst being cared for on an acute hospital ward. This is also the patient group for whom healthcare practitioners say they would value more training in dementia communication skills to improve the quality of care they deliver. We would not be able to do this research on patients who have capacity.

The capacity of the patient will be initially determined by their usual care team at point of requesting verbal consent from the potential participant to make introductions to the researcher. Where they are deemed to have or potentially have capacity to decide to speak to the researcher, a further capacity assessment regarding participation in the research will be made when the researcher takes consent/speaks to the patient about the research. Capacity will be assumed unless there is an indication the person may lack capacity. To have capacity, the patient must understand the information given to them, retain that information long enough to be able to make the decision, weigh up the information available to make the decision, and communicate their decision.

If the person has mental capacity, we will ask their agreement to take part and ask them to complete a consent form. We will also ask their permission to inform a family member/supporter about their participation. All patient participants in this study will be vulnerable and most will be cared for by family or friends. Involving family ensures that we are acting transparently and will alleviate any concerns family might have about their relative or friend being involved in research. If the patient does not want us to inform their family, we will respect that. If the patient lacks mental capacity, we will follow the procedures set out in Section 32 of the Mental Capacity Act (2005). We will try to identify a family member or friend and ask if they are willing to act as a personal consultee. If they are willing, we will ask if they know of any reason why the person would not want to be involved in the research, and to complete a written or verbal declaration form. Previous research has shown that 9% of patients with dementia being cared for on hospital wards have no family or friends [2]. To include these patients in the study, we will use a nominated consultee who will be a senior healthcare professional on the ward, who is not involved in the research.

It will be explained to the potential participant and/or their consultee that entry into the study is entirely voluntary and that their treatment, care, and legal rights will not be affected by their decision. It will also be explained that they can withdraw at any time.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent Form which will be signed by the participant.

Patient participants are only in this study for the duration of their hospital stay. It is unlikely that their capacity will change during this time. If they do regain mental capacity (for example, due to resolution of delirium), we will seek their consent. There is a small possibility that a patient participant with capacity at the time of taking consent will experience an acute event such as a stroke causing a significant worsening of their cognitive impairment. In this situation, if the participant still meets the inclusion criteria, we will seek consultee agreement to continue to include them in the study.

STUDY INTERVENTION

VOICE2 Pilot

We will pilot the VOICE2 dementia communication skills training course (from here on referred to as the VOICE2 course) and our course evaluation research processes. The VOICE2 course will be delivered by clinicians and academics working on the VOICE2 study. The HCPs attending the course will be healthcare practitioners from one site, who will have the experience to offer constructive advice on how we can improve the training. We will pilot the evaluation questionnaires before and after the course. We will hold a focus group to identify any changes needed to the course or research questionnaires. The focus group discussion will last for one hour, be audio recorded, transcribed verbatim by a researcher or an approved University of Nottingham transcriber and thematically analysed.

Train the Trainers Course

We will recruit up to 24 dementia clinical educators from up to four participating NHS Trusts. The clinical educators will be identified by the participating site management team or through our clinical contacts (RH is a consultant geriatrician and ROB is a senior speech and language therapist).

The clinical educator participants will attend the one-day VOICE2 course, followed by the one-day VOICE2 train the trainer's course. Mentoring and support will be provided to the

clinical educators after the train the trainers course until they have delivered all training at their site.

VOICE2 Course

Healthcare practitioners will be recruited from two study wards at each site, with the aim to train at least 50% of healthcare practitioners from each participating ward.

Evaluation

We will follow Kirkpatrick's four levels of evaluation: level 1 -Reaction (has the HCP or clinical educator found the training relevant and useful to their role); level 2-learning (has the HCP or clinical educator acquired the new knowledge, skills and confidence following the training); level 3-behaviour (has the HCP changed their behaviour following the course); level 4-results (has the training improved patient care). [50]

All questionnaire data will be collected remotely via *Jisc OnLine Surveys* www.onlinesurveys.ac.uk/:

Evaluation of Train the Trainers Course

Pre- and post-course questionnaires will be sent and completed online and will take approximately 30 minutes to complete in total, at each timepoint. Table 1 provides information on the data collected at each timepoint. They include:

Reaction:

- Post-course questionnaire on satisfaction and usefulness of the VOICE2 course and Train the Trainers course [5].

Learning:

- a communication knowledge in dementia test developed for the VOICE2 course based on the learning outcomes of the course. We have developed similar questionnaires for the VOICE1 communication course [5,49].
- the Confidence in Dementia Scale (9-item scale assessing self-efficacy, measured on a 5-point Likert scale [76]).
- A confidence in training questionnaire, piloted during the VOICE1 'train the trainers course'.

Table 1: Clinical Educator training data collection

Timepoint	Pre VOICE2 training	Immediately Post VOICE2 training	Immediately post VOICE2 training-the-trainers	Immediately post first VOICE2 training course	One- three month post last VOICE2 course
Demographics	X				
Communication knowledge test	X	X			
Confidence in Dementia Scale	X	X			
Course evaluation questionnaire		X			
Confidence in training questionnaire	X		X		X
Semi-structured interview				X	X

The Kirkpatrick 'behaviour' and 'results' levels of evaluation for the train-the-trainers course are the effective delivery of training to HCPs by the clinical educators. These will be assessed by:

1. Recording the number of training sessions delivered and number, profession and grade of HCPs trained

2. Observing training delivery sessions (in person or remotely on MS Teams) using an observational framework based on one used in the What Works? Study [9]. This will enable the observers to keep notes as training proceeds, under headings of: Training content and delivery, learners' reactions, evidence of learning, learners' intentions in relation to changes in their future practice and the way they thought this might impact on quality of care; observed barriers and facilitators to learning. Observations will be made by a member of the study team.

Evaluation of the VOICE2 Course

Pre- and post-course questionnaires will be sent and completed online and will take approximately 30 minutes to complete in total, at each timepoint. Table 2 provides information on the data collected at each timepoint. They include:

1. Reaction: Post-course evaluation questionnaire on satisfaction and usefulness of the VOICE2 course [5].

2. Learning: assessing knowledge, attitudes, and confidence. Pre- and post-course questionnaires:

- The communication knowledge in dementia test
- the Confidence in Dementia Scale (9-item scale assessing self-efficacy, measured on a 5-point Likert scale [76]).

3. Behaviour:

i) We will undertake 2 observations on each participating ward, one before and one 3-4 months after training). We will identify participant HCPs on a ward and 1 or more patients identified by ward staff as liable to get distressed, and the times and contexts when this occurs, and observe their interactions with the HCPs for up to two hours. For each interaction, we will observe and rate communication. The aim will be to evaluate whether approaches learned during training are implemented in practice, that is, changes in communication behaviour (Kirkpatrick level 3). We will use a checklist of the communication skills taught on the course similar to that developed for VOICE1 [5,49]. The unit of analysis will be the interaction. Qualitative field notes will be recorded to provide the context of the data recorded, such as descriptions of care practices, behaviours, or interactions. All directly observed patients will have provided informed consent or consultee agreement before the observation starts. We will publicise the occurrence of observations by posters in clinical area.

ii) We will collect data pre training and 1-3 months post training on the perceived barriers and facilitators for HCPs putting their learning into practice using the validated 23-item 'Influences on Patient Safety Behaviours Questionnaire' [77] adapted to the VOICE2 training (we have called this the 'Putting VOICE2 dementia communication skills learning into practice questionnaire'). This questionnaire is based on the Theoretical Domains Framework of behaviour change, an evidence-based framework drawn from implementation science. HCPs will be asked to indicate their agreement with each statement on a 5-point Likert scale from Strongly Agree to Strongly Disagree [77].

As an inconvenience allowance, we will give all HCP participants a £10 gift voucher on completion of baseline and immediately post training questionnaires and a further £10 voucher on completion of three month follow up questionnaires.

Table 2 Healthcare Practitioner Data Collection

Data Collected	Pre training	Immediately post training	1-3 months post training
Demographics	X		

Course evaluation Questionnaire		X	X
Communication knowledge in dementia test	X	X	X
Confidence in Dementia Scale	X	X	X
'Putting VOICE2 dementia communication skills learning into practice' questionnaire	X		X
Semi structured interviews			X
Structured and unstructured observations	X		X
Focus group (pilot study)		X	

Observations

4. Training impact (Results):

We will use the Cohen-Mansfield Agitation Inventory [51], observational version (CMAI-O), and the Pittsburgh Agitation Scale [78] during the direct ward observation periods and observed interactions. The CMAI-O consists of 29 items forming 4 sub-scales: physically aggressive behaviour (e.g., hitting others), physically non-aggressive behaviour (e.g., pacing), verbally aggressive (e.g., swearing) and verbally non-aggressive behaviours (e.g., repetitive sentences). The CMAI-O incorporates both the frequency and severity of behaviours associated with agitation and allows the quantification of agitated behaviours into a continuous measure. The Pittsburgh scale measures intensity of agitation on four domains; aberrant vocalization, motor agitation, aggressiveness, and resisting care, each scored on a 5-point Likert scale. These were successfully used together in the NIHR HTA EPIC trial [79].

Interviews

i) We will undertake semi-structured interviews with all the clinical educators after they attend the 'train the trainers' course and again 3 months later. Interviews will be conducted either face to face or remotely via Microsoft teams. Interviews are expected to last 30 minutes each. They will be video or audio recorded and transcribed verbatim. The interviews will cover the clinical educator's experiences

of the 'train-the-trainer' course, how well it prepared them to deliver, their plans for and actual delivery of training within the hospital, adaptions to how materials have been delivered and any barriers and facilitators.

ii) We will interview a sample of up to 5 HCP participants from each participating ward 1-3 months post-training. Interviews will last approximately 30 minutes. We will include representatives of the roles and across the different sites and participating wards. We will ascertain how they have cared for patients in distress, perceptions of the usefulness of the communication skills taught, if and how they are using the skills, how they fit in with their prior experience, skills, and knowledge, and if and how the communication skills were benefiting patients or staff. We will ask about barriers to implementation, including ideas about 'critical mass'. Interviews will be aided by a topic guide, specific for each group interviewed.

iii) We will interview the ward managers from each participating wards (up to 12) for their perceptions of the accessibility of training, staff ability to implement learning into practice and the impact this has had on staff communication and patient outcomes such as occurrence of distress. Interviews will last approximately 30 minutes.

iv) We will have ten-minute unstructured conversational interviews with patient participants or family members, friends and informal carers of patient participants (n=up to 60) who have been present with the patient participant and observed care delivered. The interviews will be about quality of care and management of distress, during the observation periods before and after training. Field notes will be made immediately after the conversation, and subsequently typed for analysis. No personal details will be collected about the family member or friend, who will be providing proxy information on care quality, where the patient, because of their cognitive impairment, is unable to give this information themselves.

v) For 1 month before, and 1 month after, training, we will make available on the wards, and invite completion of, survey cards for patients with dementia and visiting family members or friends. These cards will be modelled on the NHS Family and Friends Test and invite the participant to respond to each of 4 questions on 6-point Likert scales, and to make free text comments. The cards take 2 minutes to complete. It will be made clear on the card that by completing the card, the patient, family member or friend is consenting to their responses being included in the research [53]. Patients

and carers completing the survey cards will be asked if they would like a 10 minute 'chat' about their views on care quality. This will be either face to face on the ward or via telephone.

Other Data Collection

i) We will collect recorded incidents of challenging behaviour on participating wards on the Datix reporting system, for 3 months before, and up to 6 months after, training.

Criteria for terminating study

There are no criteria for terminating this study.

ANALYSIS

Methods

Analysis involves the following sequential steps [53,73,74]. Each case will be the participating NHS site, with the individual wards being cases within the case:

i) Analysis of each data source/type (set out above).

ii) Integration of data by case, to produce individual cases drawing on multiple data sources, describing mechanisms and processes that appear to be significant contributors to implementation and use of skills.

iii) Comparison and integration across cases, to produce summaries describing mechanisms and processes that appear to be common or unique barriers or facilitators across cases.

Steps i) and ii) will be considered in the context of a logic model (see appendix) [81]. We recognise the complex range of factors that are likely to influence outcomes, particularly at Kirkpatrick levels 3 and 4, since these are 'distal' from the training itself. We will consider if and how these wider factors may influence outcomes in our evaluation of barriers and facilitators to training implementation. Caution will be exercised in the analysis not to assume attribution of direct causality between any of the patient outcomes and individual HCP completion of the training programme. By triangulating evidence from all sources, however, we can determine whether it is likely that the training had a role in achieving better outcomes, if these are seen. If no positive outcomes are observed, the training itself, its delivery, reach or its implementation may not have been optimal. The aim of communication skills education

and training is to facilitate good quality care for people with dementia. In view of this, adopting a longitudinal, mixed methods, multiple case study design offers a robust approach for understanding the impact of training within complex organisational systems. Others have successfully used this approach [52,53,54].

QUESTIONNAIRE AND OBSERVATIONAL CHECKLIST DATA

Stata software will be used for the storage and analysis of numerical data. We will calculate descriptive statistics, and simple pre-post comparisons of quantitative data (mean or medians, 95%CI for differences). We will summarise staff views of reactions to training, levels of dementia knowledge (communication knowledge test), self-efficacy (Confidence in Dementia Scale), demonstration of taught communication skills, agitation questionnaires (Cohen-Mansfield Agitation Inventory Observational Version and Pittsburgh Agitation Scale), 'putting VOICE2 dementia communication skills into practice' questionnaire, family carer survey cards and clinical incidents. Analysis will be supported by Professor Rowan Harwood and an in-house statistician (Dr Andrea Venn).

INTERVIEW, OBSERVATION AND FOCUS GROUP DATA

Audio and video-recordings of interviews and the focus group will be professionally transcribed by a University of Nottingham approved supplier with a duty of confidentiality. A confidentiality agreement between the University of Nottingham and the supplier will be in place. Potentially identifying information about participants will be anonymised or removed before uploading to QSR NVivo version 12 to facilitate analysis.

The transcripts will be subject to thematic analysis, using a combination of 'top-down' and 'bottom-up' coding [61, 82, 83]. The pre-set top-down thematic headings will reflect the evaluative approaches used, and will include:

i) Context
ii) Training materials design, planning and facilitation
iii) Learners' satisfaction (Kirkpatrick level 1)
iv) Learners' knowledge, confidence, or skills because of training (Kirkpatrick level 2)
v) Learners' behaviour in practice (Kirkpatrick level 3)
vi) Quality of care experienced by people living with dementia (Kirkpatrick level 4)
vii) Barriers and facilitators to effective dementia education and training.

To develop the full coding framework, the project team and two trained PPI members will analyse a small number of transcripts. Two researchers will read and re-read the transcripts

and assign inductive codes. The codes will be placed under the thematic heading that best captures their meaning. Looking across the inductive codes under each thematic heading, the researcher will group codes into sub-themes. The research team including the PPI members will meet collectively to compare emergent codes and sub-theme headings. This process will be iterative with two rounds of coding and two meetings to refine the subtheme headings. This approach will help identify patterned meaning in the data. Using a realist lens, the analytic focus will be on assumed reality that is evident in the data, and testing and developing the hypotheses of intervention impact and pathways, or barriers to this, within the logic model.

INTEGRATION BY SITE

We will integrate data from all sources to provide case studies at site (and ward) level, including all sub-themes from each data source, turning thematic and statistical material into text descriptions, supported by a selection of the most pertinent illustrative examples and statistics. This will involve a process of data reduction, from the full sets of codes, examples, and statistics to a more streamlined set. The resulting descriptive integrated text will be organised under the framework headings described above. The research team will collectively read the ward level case studies to check for plausibility of sub-themes and that they were adequately supported by the data.

INTEGRATION BY AND ACROSS SETTINGS

To add to understanding of what leads to effective communication training, convergence coding [84], will be used to achieve triangulation across the different case studies, establishing if there were points of agreement, partial agreement, silence, and dissonance at setting level. The themes about elements contributing to effective training will be compared with those derived from the What Works? Audit checklist [9].

We have constructed a draft logic model for the training course (see appendix). We will use this as a framework to test hypotheses within it from the dataset and will revise the logic model as needed [83].

Sample size and justification

This is a mixed methods longitudinal case study, and a sample size calculation is not appropriate. We aim to train up to 24 dementia clinical educators from 3-4 sites as VOICE2 trainers and up to 300 healthcare practitioners across the sites.

Definition of populations analysed

All HCP participants, who receive VOICE2 training, and all clinical educators recruited as trainers will be included in the analysis, together with all patient observations and ward manager, patient, and carer interviews and datix information collected.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, informed consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA). Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible, and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent or consultee agreement will be in accordance with the REC guidance, Good Clinical Practice (GCP) and the Mental Capacity Act (2005) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant or their consultee shall both sign and date the Informed Consent Form or Consultee Declaration Form before the person can participate in the study (or for consultee declaration, occasionally, this will be soon after we have collected

observational data). Where necessary, we will take verbal consultee declaration. This will be via telephone or Microsoft teams and will be recorded.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study Master File. A second copy will be filed in the participant's medical notes (for the patient) and a signed and dated note made in the notes that informed consent or consultee agreement was obtained for the study.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasise to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, loss of benefits to which the participant is otherwise entitled or legal rights. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Study Forms

Each participant will be assigned a study identity code number for use on study forms or other study documents and the electronic database. The documents and database will also use this number. The identity code will be made up of an identifier of whether the participant is a clinical educator, HCP, ward manager or patient (or their proxy); an identifier for the participating site and ward; a study number; and the initials (of first and last names separated by a hyphen or a middle name initial when available).

Study forms will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, age, ward, hospital, phone number and email address and Participant Study Number (the Study Recruitment Log), to permit identification of all participants enrolled in the study, in

accordance with regulatory requirements and for follow-up as required. Study forms shall be restricted to those personnel approved by the Chief or local Principal Investigator and recorded on the 'Study Delegation Log.'

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled, and dated.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, interview transcriptions and audio records, current medical records, and study forms. A study form may also completely serve as its own source data. Only study staff as listed on the Delegation Log shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The study forms and all source documents shall be made available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The study forms will only collect the minimum required information for the purposes of the study. Study forms will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and relevant regulatory authorities. Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (at least encrypted using a one way encryption method).
Information about the study in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance of claims made by research participants. University staff from other collaborating sites will be covered by their indemnity and insurance arrangements.

STUDY CONDUCT

Study conduct may be subject to systems audit of the Study Master File for inclusion of essential documents; permissions to conduct the study; Study Delegation Log; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits); and reporting; accountability of study materials and equipment calibration logs.

The Study Coordinator, or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made to the Study Steering Committee.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Study data and evidence of monitoring and systems audits will be made available for inspection by REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. Pseudo-anonymised data will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility. Personal data will be destroyed 6 months after the end of the study.

The Study Master File and study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the Study Steering Committee as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Our ambition is to have a nationally important and utilised communication skills training course, to change the narrative about how skilled intervention can be used to manage distress, and to be internationally influential. Our research outputs will be disseminated to hospital leaders, clinical educators, HCPs, people living with dementia and their carers, academic experts in dementia, training and linguistics and CA.

We will work with the NIHR Applied Research Collaborations (ARC) East Midlands implementation hub to achieve this. This will provide access to implementation, cultural competency and community engagement expertise; advice on ethnicity implications; assistance in making outputs 'product ready'; dissemination support, via pathways to ARC regional partners and other topic-specific dissemination pathways; communications support; dissemination to the other 15 ARCs and onward dissemination across their areas; sharing with the national ARC Mental Health Network; flagging as an area of interest, and work to build the required information that would be needed by the Academic Health Science Networks (AHSN) to consider their involvement in future adoption and spread activities.

Our research outputs will be disseminated through:

• Best practice guides for healthcare practitioners

• Conference presentations

• Peer reviewed journals and healthcare publications.

All publications will be made open access.

We will disseminate our reports, papers, and guides and the VOICE2 training course through our contacts in practitioner societies (for example, the British Geriatric Society, Royal College of Nursing, Royal College of Speech and Language therapists); the Academic Health Science Network (AHSN); NIHR ARC-East Midlands and twitter (via the established twitter account @voice_study). We will use the UoN press office to attract media interest into our research.

To disseminate our VOICE2 train-the-trainers' course, we will work collaboratively with ARC-EM and the Integrated Care Systems in the 3 areas participating in the study, and then we will engage with other Integrated Care Systems across England. Established groups such as the Nursing, Midwifery and Allied Health Professionals cabinet, chaired by co-applicant Sue Haines, are planning education and workforce educational needs. This group can help

to identify where this training will be most useful and transferable across the system. We will work with the NHS HEE training hubs (e.g. nottstraininghub.nhs.uk) to identify transferable skills and integrate training into their portfolio. We will also identify and engage with other services that our findings could be useful to including the ambulance services (Prof Niro Siriwardena of ARC-EM ambulance service sub-theme is the ambulance services' national research lead). We will set up the VOICE2 train-the-trainers course as a University of Nottingham CPD course. This will ensure it is sustainably delivered in the longer term.

USER AND PUBLIC INVOLVEMENT

SG will be the academic lead for PPI. This study involves people with experience of dementia at every stage of the research cycle. We discussed the study with our dementia, frailty, and palliative care PPI group on several occasions. They considered the research question important and agreed to support the research. We will involve PPI representatives in operationalising recruitment and approach to HCP, people with dementia and family members, including reviewing information and consent/agreement documentation. A PPI member will be on the staff recruitment panel. PPI representatives will be included in the thematic analysis of interviews. PPI representatives will be members of the team co-producing the VOICE2 course. KS will be a member of the main paper writing group and will write the PPI section of the final report with SG. She will also disseminate the study findings at conferences.

We also have two PPI members on the PMG (KS and MW) and two separate PPI members on the Study Steering Committee.

All PPI involvement is paid at NIHR payment guidance rates.

STUDY FINANCES

Funding source

This study is funded by the National Institute of Health Research.

Participant stipends and payments

In total, the HCP questionnaires take about 30 minutes to complete. We will pay a small inconvenience allowance (gift voucher of £10) for completion of outcome questionnaires at

the end of the VOICE2 course and again at the 3 months follow up, as completion rates have been poor in some previous studies [53].

Travel expenses for clinical educators to attend the VOICE2 and 'train the trainers' course and for interviews will be offered where needed.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)_____

Signature:_____

Date: _____

REFERENCES

1. Jackson TA, Harwood RH, et al. Challenges and opportunities in understanding dementia and delirium in the acute hospital. PLoS Med 2017; 14(3): e1002247.

2. Goldberg SE, Harwood RH, et al. The prevalence of mental health problems amongst older adults admitted as an emergency to a general hospital. Age and Ageing 2012; 41: 80-86

3. Sampson EL, et al. Dementia in the acute hospital: prevalence and mortality. Br J Psychiatry. 2009; 195: 61-66.

4. Whittamore K, Harwood RH, et al. The diagnosis, prevalence and outcome of delirium in a cohort of older people on general hospital wards. International Journal of Geriatric Psychiatry 2014; 29: 32-40.

5. Harwood RH, O'Brien R, et al. A staff training intervention to improve communication between people living with dementia and health-care professionals in hospital: the VOICE study. Health Serv Deliv Res 2018; 6 (41).

6. Eggenberger E, et al. Communication skills training in dementia care: a systematic review of effectiveness, training content, and didactic methods in different care settings. Int Psychogeriatrics 2013; 25:345-58.

7. Gladman J, Harwood RH, et al. Care of Older people with Cognitive Impairment in General Hospitals. Final report NIHR Service Delivery and Organisation Programme; 2012.

8. Beaver J. An Exploration of Older People who 'Call Out' repetitively. PhD, University of Nottingham 2020.

9. Surr C, Gates C. What works in delivering dementia education or training to hospital staff? A critical synthesis of the evidence. International Journal Nursing Studies 2017; 75: 172-188.

10. Bridges J, et al. Implementing the Creating Learning Environments for Compassionate Care (CLECC) programme in acute hospital settings: a pilot RCT and feasibility study. Health Serv Deliv Res 2018; 6(33)

11. Livingston G, et al. Systematic review of the clinical and cost-effectiveness of sensory, psychological and behavioural interventions for managing agitation in older adults with dementia. Health Technol Assess 2014; 18(39).

12. Gladman JRF, Harwood RH, et al. Medical crises in older people. Medical Crises in Older People. Programme Grants Appl Res 2015; 3(4)

13. Godfrey M, et al. The Person, Interactions and Environment Programme to improve care of people with dementia in hospital: a multisite study. Health Serv Deliv Res 2018; 6(23).

14. Rycroft-Malone J, et al. Improving skills and care standards in the support workforce for older people: a realist synthesis of workforce development interventions. Health Serv Deliv Res 2016; 4(12)

15. Arthur A, et al. Can Health-care Assistant Training improve the relational care of older people? (CHAT) A development and feasibility study of a complex intervention. Southampton (UK): NIHR Journals Library; 2017.

16. Featherstone K, et al. Refusal and resistance to care by people living with dementia being cared for within acute hospital wards: an ethnographic study. Health Serv Deliv Res 2019; 7 (11).

17. Moniz-Cook E, et al. Challenge Demcare: Management of challenging behaviour in dementia at home and in care homes. Programme Grants Appl Res 2017; 5(15)

18. Ballard C, et al. Improving mental health and reducing antipsychotic use in people with dementia in care homes: the WHELD programme. NIHR Journals Library; 2020. (Programme Grants for Applied Research, No. 8.6)

19. Gwernan-Jones R, et al. Understanding and improving experiences of care in hospital for people living with dementia, their carers and staff: three systematic reviews. Health Serv Deliv Res 2020; 8(43).

20. Bridges J, et al. Older peoples' experiences in acute care settings: Systematic review and synthesis of qualitative studies. International Journal of Nursing Studies 2020; 102.

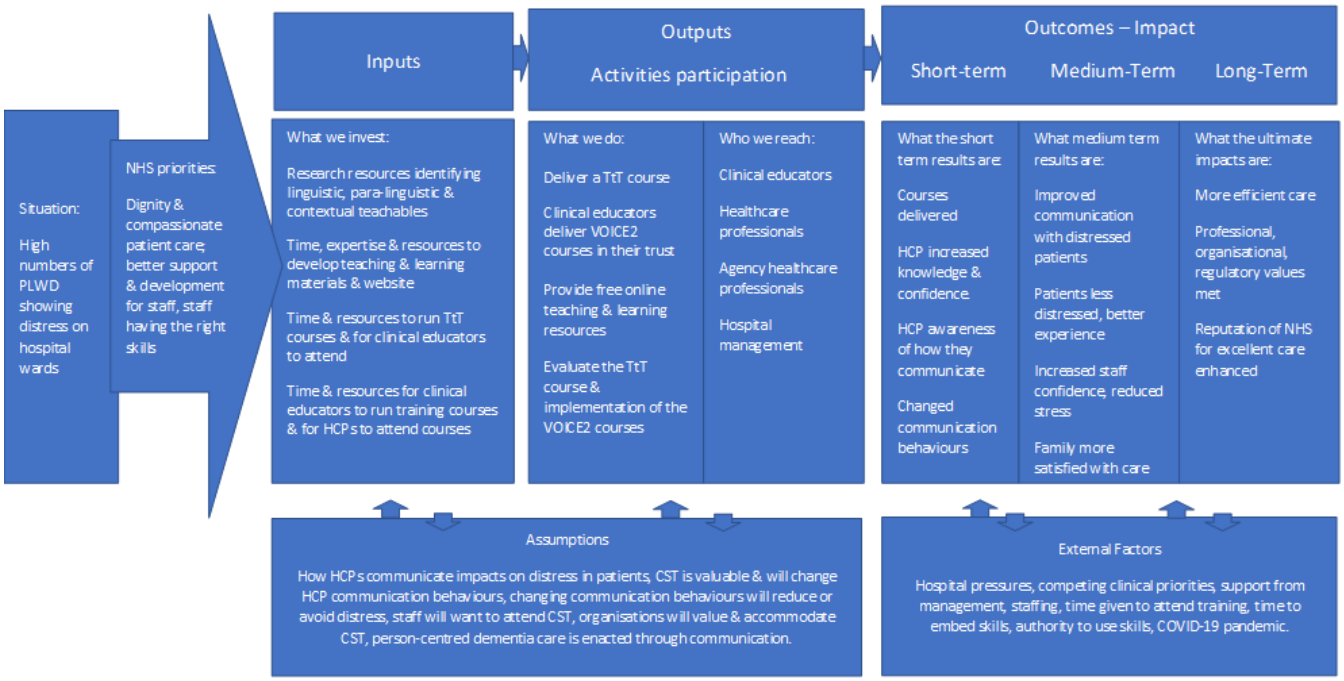
21. Handley M, et al. Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review. BMJ Open 2017; 7: e015257.
22. Spector A, et al. A systematic review of staff training interventions to reduce the behavioural and psychological symptoms of dementia. Ageing Res Rev 2013; 12: 354-64.
23. Fossey J, et al. The disconnect between evidence and practice: a review of person-centred interventions and training manuals for staff working with people with dementia. Int J Geriatric Psychiatry 2014; 29: 797–807.
24. James IA. The use of CBT in dementia care: a rationale for Communication and Interaction Therapy (CAIT) and therapeutic lies. Cogn Behav Ther 2015; 8: e10.
25. Morris L, et al. Communication training for family and professional carers of people living with dementia: a systematic review of effectiveness, acceptability and conceptual basis. Aging Ment Health. 2018; 22: 863-880.
26. Ahmed F, et al. Developing the evidence base for evaluating dementia training in NHS hospitals (DEMTRAIN): a mixed-methods study protocol. BMJ Open 2020; 10: e030739.
27. NICE. Dementia Assessment, management and support for people living with dementia and their carers NICE Guideline 97, 2018. Methods, evidence and recommendations https://www.nice.org.uk/guidance/ng97/evidence
28. Harwood RH. Aggressive patients in acute medical settings. J R Coll Physicians Edinburgh 2017: 47: 176–82.
29. Griffiths A, Harwood RH et al. Preparation to care for confused older patients in general hospitals: A study of UK health professionals. Age and Ageing 2014; 43: 521–527.
30. Beaver J, Goldberg S, et al. Socialised care futility' in the care of older people in hospital who call out repetitively: an ethnographic study. International Journal of Nursing Studies 2020; 107: 103589.
31. Tadd W, et al. Dignity in Practice: Exploration of the care of older adults in NHS Trusts. NIHR SDO report. 2011.
32. Banerjee S. The use of antipsychotic medication for people with dementia: London, Department of Health, 2009.
33. Brooker D. Person-Centred dementia care. Making services better London, Jessica Kingsley, 2006.
34. Clissett P, Harwood RH, et al**.** Challenges of achieving person-centred care in acute hospitals: qualitative study of people with dementia and families. International Journal of Nursing Studies 2013; 50: 1495–1503.
35. Gillespie R, et al. How is patient-centred care understood by the clinical, managerial and lay stakeholders responsible for promoting this agenda? Health Expect 2004; 7:142–8.
36. Small JA, et al. Effectiveness of communication strategies used by caregivers of persons with Alzheimer's disease during activities of daily living. J Speech Lang Hear Res 2003; 46:353-67.
37. James IA. Understanding Behaviour in Dementia That Challenges. Jessica Kingsley, London, 2011.
38. Porock D, Harwood RH, et al. Disruption, control and coping: responses of and to the person with dementia in hospital. Ageing and Society 2014, 1- 27.
39. Goldberg SE, Harwood RH, et al. Caring for cognitively impaired older patients in the general hospital: a qualitative analysis of a specialist Medical and Mental Health Unit and standard care wards. Int J Nurs Stud 2014; 51: 1332-43.
40. Savundranayagam MY, et al. Matched and mismatched appraisals of the effectiveness of communication strategies by family caregivers of persons with Alzheimer's disease. International Journal of Language and Communication Disorders 2014; 49: 49-59.
41. Sidnell J. Conversation Analysis: An introduction. London: Wiley-Blackwell; 2010.
42. Barnes RK. Conversation Analysis of Communication in Medical Care: Description and Beyond. Research on Language and Social Interaction 2019; 52: 300-315.

43. Pino M, Parry R et al. Engaging Terminally Ill Patients in End-of-Life Talk: How Experienced Palliative Medicine Doctors Navigate the Dilemma of Promoting Discussions about Dying. PLoS ONE 2016; 11(5): e0156174.
44. Beeke S, et al. Using conversation analysis to assess and treat people with aphasia. Seminars in Speech and Language 2007; 28: 136-147.
45. McCabe R, et al. Engagement of patients with psychosis in the consultation: conversation analysis study. British Medical Journal 2002; 325: 1148-1151.
46. Heritage J, et al. Reducing Patients' Unmet Concerns in Primary Care: the Difference One Word can Make. Journal of General Internal Medicine 2007; 22:1429-33.
47. Reuber M, et al. Using interactional and linguistic analysis to distinguish between epilepsy and psychogenic non-epileptic seizures: A prospective blinded multi-rater study. Epilepsy and Behaviour 2009; 16: 139-144.
48. Skills for Health. Dementia Training Standards Framework. 2018.
49. O'Brien R, Goldberg S, et al. VOICE: a study of a dementia communication skills training course. PLOS One 2018 13(6): e0198567.
50. Kirkpatrick JD, Kirkpatrick WK. Four levels of evaluation. Association for Talent Development: Alexandria; 2015.
51. Griffiths W, Surr CA et al. Validation of the Cohen-Mansfield Agitation Inventory Observational (CMAI-O) tool. International Psychogeriatrics 2020; 32: 75-85.
52. Greenhalgh T, Russell J. Why Do Evaluations of eHealth Programs Fail? An Alternative Set of Guiding Principles. PLoS Med 2010; 7(11): e1000360.
53. Surr CA et al. Components of impactful dementia training for general hospital staff: a collective case study. Aging & Mental Health 2020, 24: 511-521.
54. Godfrey M, et al. The Person, Interactions and Environment Programme to improve care of people with dementia in hospital: a multisite study. Health Serv Deliv Res 2018; 6 (23).
55. Maben J, *et al.* Evaluating a major innovation in hospital design: workforce implications and impact on patient and staff experiences of all single room hospital accommodation. *Health Serv Deliv Res* 2015; 3 (3)
56. Allwood R, Pilnick A, O'Brien R, Beeke S, et al. Should I stay or should I go? How healthcare professionals close encounters with people with dementia in the acute hospital setting. Social Science & Medicine 2017; 191: 212-225.
57. O'Brien R, Beeke S, Pilnick A, et al. When people living with dementia say 'no': negotiating refusal in the acute hospital setting. Social Science & Medicine 2020; 263: 113188.
58. NHS Workforce Statistics 2019. https://digital.nhs.uk/data-and-information
59. Farooqi A, et al. Increasing participation of Black, Asian and minority ethnic (BAME) groups in health and social care research. NIHR Involve 2018 http://learningforinvolvement.org.uk
60. Parry R. Video-based conversation analysis. In: Bourgeault I, et al, editors. Handbook of Qualitative Methods in Health Research. London: Sage, 2010:373-96.
61. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in psychology 2006: 3, 77-101
62. Yardley S, et al. Experiential learning: AMEE Guide No. 63. Medical Teacher 2012: 34:e102–15
63. Kolb DA. Experiential Learning: Experience as the Source of Learning and Development: Prentice-Hall; 1984.
64. Knowles MS. Andragogy in action. San Francisco: Jossey-Bass; 1984.
65. Schön DA. Educating the reflective practitioner. San Francisco: Jossey-Bass; 1987.
66. Cranton P. Teaching for Transformation. New Directions for Adult and Continuing Education 2002; 93:63-72.
67. Pilnick A, et al. Using Conversation Analysis to Inform Role Play and Simulated Interaction in Communications Skills Training for Healthcare Professionals. BMC Med Educ. 2018; 18:267.
68. Parry R. Are interventions to enhance communication performance in allied health professionals effective, and how should they be delivered? Patient Education and Counselling 2008; 73: 186-95.

69. Parry R 2020. Real Talk, University of Loughborough. https://www.realtalktraining.co.uk/.
70. Beeke S, et al. Better Conversations with Aphasia: an e-learning resource. 2013 At: https://extend.ucl.ac.uk/
71. Stokoe E. Simulated interaction and communication skills training: 'Conversation Analytic Role-play Method'. In: Antaki C. Applied Conversation Analysis: Changing Institutional Practices. Basingstoke: Palgrave Macmillan, 2011.
72. Mayrhofer A et al. The feasibility of a train-the-trainer approach to end-of-life care training in care homes: an evaluation. BMC Palliative Care 2016; 15:11
73. Yin RK. Case study evaluations: a decade of progress? New Directions for Evaluation 1997: 69-78.
74. Yazan, B., 2015. Three approaches to case study methods in education. In: Yin, Merriam, and Stake. The qualitative report, 20(2), 134-152.
75. O'Connor ML & McFadden SH. Development and psychometric validation of the dementia attitudes scale. International Journal of Alzheimer's Disease 2010; 4: 1–10.
76. Elvish R, et al. 'Getting to Know Me': the development and evaluation of a training programme for enhancing skills in the care of people with dementia in general hospital settings. Aging Ment Health 2014; 18: 481–8.
77. Taylor N et al. Development and initial validation of the Influences on Patient Safety Behaviours Questionnaire. Implement Sci. 2013; 8: 81.
78. Rosen J, et al. The Pittsburgh Agitation Scale: a user-friendly instrument for rating agitation in dementia patients. The American Journal of Geriatric Psychiatry 1994; 2: 52-59.
79. Surr CA, et al. Dementia Care Mapping to reduce agitation in care home residents with dementia: the EPIC cluster RCT. Health Technol Assess 2020; 24 (16).
80. Maslach C et al. Maslach Burnout Inventory manual (3rd ed), Consulting Psychologists Press, 1996.
81. Public Health England. Logic Models. https://www.gov.uk/government/publications/evaluation-in-health-and-well-being-overview/introduction-to-logic-models
82. Gale NK, et al. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology 2013, 13, 1-8.
83. Ritchie J, et al (Ed). Qualitative research practice: A guide for social science students and researchers. Sage 2013.
84. O'Cathain A, et al. Three techniques for integrating data in mixed methods studies. BMJ 2010; 341: c4587
85. Buchholz MB. Patterns of empathy as embodied practice in clinical conversation. Front. Psychol., April 2014. https://doi.org/10.3389/fpsyg.2014.00349

Appendix 1 Logic Model

LOGIC MODEL



* CST Clinical Skills Training; TtT Train the Trainer; HCP Healthcare practitioner