A conversation analytic study to identify communication practices used by healthcare practitioners caring for people living with dementia who are in hospital, to avoid or resolve episodes of distress and challenging behaviour

Final Version 1.1
8th February 2022

This protocol has regard for the HRA guidance

Short title: An observational study of communication skills to manage distress

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Changes to protocol

Date	Protocol version	Change
08/02/2022	1.1	Protocol amended as requested by REC: i) P17 Information included on what would happen if a participant died during the study or after giving the 1st level consent. "We will exclude patients from the study if they are confirmed by the clinical team to be at the end of life with death expected within one week. In the unlikely event a participant dies after giving first level consent/consultee agreement and before second level consent/consultee agreement, we will wait 8

		weeks before approaching the consultee to seek second level consultee agreement. “ ii) P16 Non-English speakers added to the exclusion criteria. iii) Information included on what would happen if a participant regains consent p17/18 “In the unlikely event that a participant initially assessed as lacking capacity then regains capacity to consent, they would be taken through the consent process and asked to sign a consent form.” iv) p15 reference to nominated consultee removed.

KEY STUDY CONTACTS

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Committees	A study steering committee will be convened Prof Ian James has provisionally agreed to chair.
Study Coordinating Centre	School of Health Sciences; Queen's Medical Centre Nottingham NG7 2HA

SYNOPSIS

Title	A conversation analytic study to identify communication practices used by healthcare practitioners caring for people living with dementia who are in hospital, to avoid or resolve episodes of distress and challenging behaviour
Acronym	VOICE2
Short title	An observational study of communication skills to manage distress
Objectives (Research question)	To identify specific and teachable communication practices that healthcare practitioners use to avoid, de-escalate, or resolve distress and challenging behaviour in hospitalised patients with dementia
Study Design	Non-participant observational study using observations, informal conversations and video and audio recorded data of conversations between healthcare practitioners and patients with dementia.
Setting	Healthcare of the Older Person (geriatric medicine) wards in two acute hospitals
Number of participants	Up to 50 healthcare practitioners Up to 50 people living with dementia Up to 50 other healthcare practitioners or students (this is people who are present during the video or audio recording, but not the focus of the study). Up to 50 family members or friends present during the video or audio recording.
Eligibility criteria	Patient participants: i) Patient on a healthcare of the older person ward ii) Diagnosis of dementia iii) Staff indicate that they are prone to distress and challenging behaviours by virtue of their history and experiences working with them Healthcare practitioners: i) Working on a healthcare of the older person ward.
Description of interventions	Observational study. We will video and audio record interactions between healthcare practitioners and people living with dementia.
Duration of study	Overall, this study will last for 34 months. The patient participants will be included in the study for the duration of their hospital stay. The healthcare practitioner will be included in the study until recruitment finishes, or they leave the ward for other employment.
Methods of analysis	Conversation analysis of video and audio recordings and thematic analysis of ethnographic observations.

ABBREVIATIONS

CA	Conversation analysis
CI	Chief Investigator overall
CRF	Case Report Form
CV	Curriculum Vitae
GCP	Good Clinical Practice
HCP	Healthcare Practitioner
HRA	Health Research Authority
NHS	National Health Service
NUH	Nottingham University Hospitals NHS Trust
LTHT	Leeds Teaching Hospital NHS Trust
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
PLWD	People living with dementia
PPI	Patient and Public Involvement
REC	Research Ethics Committee
R&I	Research and Innovation department
UoN	University of Nottingham

ROLE OF STUDY SPONSOR AND FUNDER

NIHR HS&D 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.

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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 (PLWD) 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 PLWD, 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 PLWD within acute hospital wards. *Every* PLWD 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, challenging 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 PLWD [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 (PCC) can reduce agitation in care homes [11,18,27]. PCC 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]. HCPs are often uncertain what PCC means in practice [29, 35].

The role of communication skills

There is limited empirical research on how best to communicate with PLWD, and the effectiveness of common recommendations [6, 36]. PLWD 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]. PCC 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 PLWD, 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].

The VOICE-1 study

We recently completed the VOICE study ('VOICE1'; Communication skills for staff caring for patients with dementia protocol v1.0 18/3/15 REC REF 15/YH/0184; sponsor Nottinghamshire Healthcare NHS Trust sponsor REF Harwood/230315), using CA to identify communication skills that are effective when talking to PLWD. We identified entirely new understandings of successful interactions between HCPs and PLWD [56,57]. These findings were used to develop communication skills training for HCPs, using principles of modern pedagogy. The training evaluated highly in a mixed-methods evaluation, and demonstrated changes in knowledge, confidence and specific areas of communication behaviour and was reported to be useful in clinical practice [5,49]. We delivered VOICE1 training to HCPs nationally at 3 sites as part of dissemination. To enhance implementation and reach we developed a 'train-the-trainer' course and trained clinical educators (speech and language therapists and liaison mental health nurses) from 10 NHS trusts. Five communication skills courses were subsequently delivered, training 54 HCPs, before the COVID-19 pandemic supervened and disrupted roll-out.

Identification of research gaps and why this research is needed now

The number of PLWD 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].

From our literature reviews, we have identified a gap in research on the verbal and non-verbal communication skills needed to prevent or manage challenging behaviours among patients with cognitive disorders. We will address this gap in this research. This study is the first stage of a larger NIHR HS&DR funded study to develop and evaluate a dementia communication skills training course which will give acute hospital healthcare practitioners the communication practices they need to care for PLWD prone to or exhibiting distress. We will use a 'train the trainers' model for the course, training clinical educators in NHS acute hospital trusts to deliver the course. This will ensure sustainability of the course in the long term.

STUDY OBJECTIVES AND PURPOSE

Purpose, aims

The overall aim is to give 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. As a first step, this study will identify a set of 'teachable' communication practices which are effective at avoiding, de-escalating, or resolving distress in patients living with dementia. These communication practices will be used in the second phase of this research (not included in this protocol) as the basis of a dementia communication skills course for healthcare practitioners working in acute hospitals.

Objectives

The objectives are to:

i. Analyse the structure of communication patterns used by HCPs communicating with PLWD who are prone to or in distress.

ii. Describe the context within which distress is occurring.

iii. Identify specific and teachable communication practices that HCPs use to avoid, de-escalate or resolve distress and challenging behaviour in hospitalised patients with dementia

STUDY DESIGN

Study configuration

Multi-centred, descriptive, conversation analytic study supplemented by observations, to analyse the structure of communication patterns used by HCPs to communicate with PLWD who are prone to or in distress whilst in the acute hospital environment and to identify the communication skills that reduce or manage distress in patients.

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 two 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.

The data custodian will be the Chief Investigator.

A Study Steering group of approximately five will include senior academic, clinical, staff training and managerial experience and PPI representation from user groups. It will meet with the research team five 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.

A Data Management Plan, including transcription, anonymisation procedures, confidentiality, security and GDPR compliance has been completed using DMPOnline.ac.uk.

STUDY SETTING

General hospital healthcare of older people's wards on two hospital sites. These wards have been chosen as they have the highest proportion of patients with dementia, and sufficient experience and expertise to have a good likelihood of demonstrating good practice.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration

Recruitment will last six months. The entire study will last 34 months.

Participant Duration

Patients will participate in this study for the duration of their hospital stay, which is likely to range from 1 to 6 weeks. This will include video and audio recording of specific patient-staff interactions, and non-participant ethnographic observations to understand the context of any distress. Observations will vary in length (we anticipate they will last between 2 and 30 minutes, but this could be longer depending on how long the healthcare practitioner stays with the patient participant). We will video- or audio-record patient participants between one and three times over the duration of their hospital stay (PLWD).

The healthcare practitioner will participate in the study for up to six months of data collection. Healthcare practitioner participants may be video- or audio- recorded any number of times during the duration of the study data collection (HCPs).

End of the Study

The end of the study will be the last analysis of video or audio recording of an included interaction.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Participants will be recruited from in-patient Healthcare of the Older Person (geriatric medicine) wards. For patients, the initial approach will be from a member of the patient's usual care team, and information about the study will be on display in the relevant clinical areas. For healthcare practitioners, the initial approach will be either from the ward senior clinical team or the investigator or their nominee. Family or friends and other healthcare practitioners or students present at the time of recording will be approached by the investigator or their nominee.

We will consult ward staff to identify possible participants and interactions for recording. We will purposively sample to capture different kinds of interactions, at various times of day, with a range of HCPs. This approach is in preference to focusing on one type of interaction which would limit the range of patients and HCPs who could be included, as well as the range of scenarios encountered.

The investigator or their nominee, e.g., from the research team, Clinical Research Network, 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.

If needed, the usual hospital interpreter and translator services will be available to assist with discussion of the trial, the participant information sheets, and consent forms will be available printed in other languages on request. However, conversation analysis will only be possible for interactions recorded in English.

We are experienced at recruiting (and enabling inclusion of) PLWD to research studies. Video recording or observing episodes of distress or potential distress may be challenging logistically and ethically, but we work clinically in these settings, including on a specialist medical and mental health unit (RH). We have experience in undertaking video and ethnographic studies in sensitive settings (RO'B, SG, CS), including VOICE1 and a documentary (Today is Monday: www.https://vimeo.com/93365033).

Inclusion criteria

Patient participants:

- A patient on a healthcare of the older person ward of any age.
- A diagnosis of dementia recorded in the medical notes
- Reported by staff to be prone to distress (for example, repetitive calling out, physical aggression, verbal aggression, swearing, resistance to care, exit seeking, agitation).

Family member/friend participant:

- Present with the patient at the time of the video recording.

Healthcare practitioner participants:

- Registered healthcare practitioner or assistant to registered healthcare practitioners employed to work on a healthcare of the older person ward.

Student healthcare practitioners:

- Student healthcare practitioners who are present during the interaction.

Exclusion criteria

Patient participants:

- Unwilling to give informed consent or unable to gain consultee agreement.
- Confirmed by clinical team to be at end of life (death expected within one week).
- Do not have an appropriate personal consultee
- Do not speak English in their interactions with clinical staff

Family member/friend participant:

- Unwilling to give informed consent

Healthcare practitioner and student participants

- Unwilling to give informed consent.

Sample size

We will oversample interactions between HCPs and PLWD to generate a large collection of conversation data.

We will video or audio record up to 50 interactions between HCPs and PLWD, across wards and sites. We will therefore recruit up to 50 people living with dementia and 50 healthcare practitioners. Assuming an average interaction length of 8-9 minutes (based on the 9-minute average for VOICE1), this will produce 400-450 minutes of data for analysis.

The unit of analysis in CA is the 'conversational turn' or the specific communication behaviour (e.g., requesting), so a corpus of this size will include thousands of these units of analysis and will include verbal and non-verbal behaviours. Previous research by us and others has shown that a data set of this size is necessary and sufficient to enable the identification of patterns across the data in terms of type of activity being conducted, type of personnel, patient circumstances and different contexts related to ward organisation, e.g., shift changes.

A quantified sample size calculation is not appropriate for this research method.

Informed consent

This study involves video recording interactions between patients with dementia (and when normal for them to be included in the interaction, their relatives and friends), and HCPs (including more than one HCP and students when it is normal for them to be part of the interaction).

We are experienced at assessing, communicating with and recruiting cognitively impaired people and their families and friends to research studies.

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 on the basis of personal consultee agreement, 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.

Informed consent or consultee agreement will be collected for each participant before video or audio recording starts.

The potential patient participant will be given the full version and a short one-page version of the information sheet to support understanding. We will use a variety of communication media to support the patient to understand the study processes, including visual prompts (for example, showing the patient the camera) and photographs if appropriate. The researcher will answer any questions that the participant has concerning study participation.

The capacity of the patient will be initially determined by their usual care team and confirmed when the researcher takes consent/speaks to the patient about the research. 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 complete a consent form. We will also ask their permission to inform a family member about their participation.

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 agreement form. Given the potential sensitivity of collecting video data, we will also seek their agreement. This process may be done remotely (via telephone or video call) where it is not possible to have a face-to-face meeting. This is particularly important as, due to Covid-19, visiting may still be restricted on hospital wards.

If needed participants or their consultees will be given additional time to consider whether they wish to participate.

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

We will seek a second level of consent to use video material after it has been collected. We will replay the video to participants and their consultees, either in person or via Microsoft Teams, and seek agreement to use it at conferences, in teaching materials, including material held on-line, and for further research. We will exclude patients from the study if they are confirmed by the clinical team

to be at the end of life with death expected within one week. In the unlikely event a participant dies after giving first level consent/consultee agreement and before second level consent/consultee agreement, we will wait 8 weeks before approaching the consultee to seek second level consultee agreement.

One copy of the consent or consultee form 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. Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent or consultee agreement will be obtained using an amended Consent/Consultee agreement form which will be signed by the participant or consultee.

Patient participants are only in this study for the duration of their hospital stay, plus the time it will take to show them the recording and take second level consent. It is unlikely that their capacity will change during this time. 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 the participant in the study. In the unlikely event that a participant initially assessed as lacking capacity then regains capacity to consent, they would then be taken through the consent process and asked to sign a consent form.

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 employment rights.

Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected and uploaded to the University of Nottingham's Microsoft Office 365 Teams/Sharepoint and OneDrive site cannot be erased and may still be used in the final analysis.

STUDY REGIMEN

Pre-study Assessment

A diagnosis of dementia recorded in the medical notes will be established by a member of the patient's usual care We will also establish that there is a potential consultee that we can approach.

We will identify times, activities, and contexts where distress frequently occurs, or which have caused a specific patient distress before, through staff report or in our initial analyses. This will enable us to revisit these activities and contexts in all our data, including the VOICE1 dataset, to identify how distress may have been avoided or managed. Examples of relevant encounters are interactions in which HCPs make attempts to start an action which aims to promote well-being, but which have previously provoked distress (such as taking medications, taking part in therapy or personal care); attempts to stop a damaging behaviour (such as hitting out or repetitive shouting); and interactions dealing with a lack of synchrony of reality (such as exit seeking). Intimate care activities (such as washing or continence care) are common occasions for distress, but video would

not be acceptable, so we will audio record any such episodes, if appropriate and necessary, augmented by field notes.

Video and audio recording of interactions

We have extensive experience of video-based research with PLWD. A researcher will be present on the host wards to set up the equipment to record interactions and will spend time on the wards to be able to capture relevant interactions.

Each patient participant will be video or audio recorded between one and three times. The video or audio recording will be at times or during interactions with healthcare practitioners when the patient participant is likely to become distressed (for example, in the evenings or when visitors leave the ward; whilst being shaved or during a swallowing assessment). For many of these video recordings, we will be capturing how healthcare practitioners communicate with patients to avoid distress. For some of these recordings, the participant may become distressed during the interaction, and we will capture the communication practices the healthcare practitioner uses to de-escalate this distress.

If episodes of distress occur involving a consented patient and a consented healthcare practitioner whilst a researcher is on the ward with a camera set up, we will video-record the episode, so long as it is feasible, safe and does not exacerbate distress.

After the recording has been made, a researcher will arrange to meet the participant or consultee where appropriate, to play them the recording. The meeting could take place in the hospital (if the patient has left hospital), in the participant's or consultee's own home, or by video call. The researcher will ask whether we can use the recording for educational purposes, such as for our training course materials or at scientific meetings, or for future research. The participant or consultee will have the opportunity to ask questions about how the recording will be used. The participant or consultee will be asked to complete a 2nd level consent form detailing exactly how the recordings can be used.

Non-participant observation

We will carry out non-participant observations, and have informal conversations with consented patients, HCPs and family members, around the time of recorded interactions, to support our understanding of the contextual factors affecting communication and wellbeing that will not be captured in their video recordings. For example: prior knowledge or experience of a patient; events or activity on the ward; competing priorities; or recent staff changes. These will be recorded as field notes and later digitised to enable search and comparison.

Compliance

This study is observational, and involves video and audio recording naturally occurring interactions, compliance is not relevant. Flexibility is required in delivering this research, which will be monitored by the Project Management Group. If significant changes are required these will be discussed with the Steering Committee, Sponsor and Funder and an appropriate ethics amendment submitted.

Criteria for terminating the study

This is an observational study and there are no formal criteria for terminating the study. Recruitment and data collection at individual study sites may be stopped if there are substantial problems with the rate of recruitment and data collection or other major issues with study conduct.

ANALYSES

Analysis will proceed simultaneously with data collection. We will map the structure of different communication encounters and specific communication practices that are more or less effective. Data analysis will be led by CA-trained researchers, supported by the senior conversation analysts (who will be actively involved in analysis). We will investigate how the structure of encounters affects how patients respond, in terms of the common organisation of interactional encounters, where distress occurs and the presence of recurrent and systematic linguistic and embodied features.

Video or audio recordings will be transcribed verbatim by a University of Nottingham approved transcriber working under a confidentiality agreement. The researchers will enhance the verbatim transcripts of sections of analytic interest using the specialist CA notation system for recording micro level features of speech and non-verbal interaction (e.g., emphasis, pauses, overlapping talk, touch and gaze). Where relevant we will also transcribe aspects of body movement (e.g., turning towards/away).

Transana software will facilitate data management.

Observational and field note data will be analysed thematically, using NVivo software, following the procedures of Braun and Clark.

We will follow the accepted 3-stage approach for analysis which we have used previously: careful observation of the dataset; identification and collection of relevant phenomena; and detailed description of the practice. We will identify instances where distress occurs and where prior actions may have averted it. Episodes will then be retrieved that cover the variety of ways that distress is responded to, managed, or averted by HCPs, along with PLWD responses to these. PLWD's responses to the approaches will be compared to identify patterns. For example, some strategies may typically be met with minimal responses, while others might typically result in more extended engagement. Where the data show patterns in the context or activities where distress arises (e.g., during examinations, or administering medication) we will examine these activities across the corpus, in order to identify practices HCPs may be using to avoid distress arising.

Analysis will draw on relevant evidence generated by other studies, as a means of increasing validity and generalisability of findings. Procedures to verify and augment findings will include analysis sessions with experienced researchers, dementia clinicians and PPI representatives, using raw or

disguised data according to consents. The overall aim is to distil and generalise a profile of successful and appropriate approaches to avoiding or managing distress.

Findings will be used to identify 'teachables', that is specific features of talk and non-verbal communication that can be learned and changed in practice. These teachables will be set in the context of broader person-centred care. Since the specific teachable features will have been identified in practice, they will be grounded in the realities of the setting and demonstrably successful there. They will provide HCPs with concrete and specific approaches, rather than the broader person-centred care concept.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

Risk and benefits to participants

Little or no risk or benefit to participants is anticipated. In our experience, patients soon forget that a camera is present. Recording will be terminated if there is any suggestion that recording is exacerbating distress, or if the researcher is in any physical danger.

Healthcare participants may be self-conscious being recorded but may also feel a sense of professional pride. In our experience, most want to contribute to researching ways to improve care.

Patients or their consultees may feel that a recording compromises the patient's dignity.
If a recording has already been uploaded to university computer systems, we will seek to be able to analyse the data but will not show recordings outside the immediate research team unless consent to do so has been explicitly obtained (as part of the '2-stage consent' procedure).

Ethics committee and regulatory approvals

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) 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 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, the Mental Capacity Act, 2005, 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, and Good Clinical Practice (GCP), 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 Consent Form or Consultee Agreement Form before the person can participate in the study. Where consultee agreement is taken remotely, we will record this on a 'remote consultee agreement form.'

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

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to the potential participant 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 their employment rights (HCPs). No study-specific interventions will be done before informed consent or consultee agreement has been obtained.

We will include vulnerable adults, most or all of whom will lack mental capacity to consent to participate. The research questions could not be answered by studying people with mental capacity. The procedures set out in Sections 30-34 of the Mental Capacity Act (2005) will be followed. Consultee agreement to participate will be obtained in lieu of consent.

We have previously developed protocols with service users for collecting, storing, and managing data which have been acceptable to ethics committees and the HRA. We will complete a Data Management Plan before we start data collection.

Researchers may observe unacceptable behaviour by staff towards patients. The team includes senior clinicians who will manage an appropriate response to concerns raised, in accordance with clinical management and safeguarding policies (RH, RO'B, LB, SH, SN, AR).

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

RECORDS, DATA MANAGEMENT

Case Report Forms

Each participant will be assigned a study identity code number, for use on study forms, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mm/yy).

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, date of birth, local hospital number or NHS number, and Participant Study Number, to permit identification of all participants enrolled in the study, in case additional follow-up is required.

Study forms shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

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, initialed, and dated.

The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the study forms.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and video and audio records. A study form may also completely serve as its own source data. Only study staff 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 any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure web server. Access will be restricted by user identifiers and passwords (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 clinical study participants and NHS 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 in respect of claims made by research subjects.

Study conduct

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; 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, timeliness of visits); 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.

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.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10%) will be checked on a regular basis for verification of all entries made. In addition, the subsequent capture of the data on the study database will be checked. Where corrections are required, these will carry a full audit trail and justification.

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

Record retention and archiving

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These 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.

The 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 audio recordings, video recordings, 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 as appropriate in making this decision.

Statement of confidentiality

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

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

If clinically necessary, medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

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. This study will create a profile of effective staff communication practices for healthcare practitioners to use when the PLWD is prone to or in distress. The knowledge from this study will be used as the basis of a dementia communication skills training course.

Our research outputs will be disseminated to hospital leaders, clinical educators, HCP, PLWD and their carers, academic experts in dementia, training and linguistics and CA 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 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.

Where we have consent or consultee agreement to do so, we will use extracts from the video recordings in training materials and conference presentations. Use of real-life examples enhances the understanding and learning of healthcare practitioners. We will follow a two-stage consent process (see section Ethical and Regulatory Aspects, p17) and explicitly ask participants for consent to use the video recordings in different contexts.

USER AND PUBLIC INVOLVEMENT

This study involves PLWD and their carers at every stage of the research cycle. At the beginning of the study, a PPI strategy will be developed and agreed at the programme management group. We will include experienced PPI (KS) with a track record of innovative thinking on the VOICE1 research project and other PPI contributors.

We have discussed the study with our UoN Dementia and Frail Older People's PPI group. They considered the research question important. After asking questions related to consent and processes for filming, the group considered it ethical to video patients in distress provided appropriate agreement was given. KS has worked with the wider research team to develop this application, contributing to application development meetings and additional meetings with SG and ROB.

SG, KS and the research fellow (RF) will write and lead the PPI strategy, supported by the research administrator. SG started the UoN's Dementia and Frail Older People's PPI group in 2012 and has managed the group since then. The group meets nine times a year and receives regular training, most recently on qualitative analysis. Our PPI co-applicant (KS) had extensive experience of caring for parents with dementia and as a PPI co-applicant (including VOICE1). The RF will have 10% of their workload allocated to PPI activities.

SG will be the academic lead for PPI, working with KS. KS will be on the interview panel appointing the VOICE2 researchers. KS and one or more other PPI members will be part of the data analysis team, and attend regular data analysis sessions with ROB, AP, SB and the RF. The PPI members will contribute their lived experience to the interpretation of the data. KS has experience of CA data analysis sessions from her work on VOICE1. We will present the CA findings to the PPI group to gain their views on how we have interpreted the data and to support identification of appropriate 'teachables.'

Throughout the study, KS will be an active member of the PMG. We will invite two further PPI representatives to the Study advisory group and the PMG.

STUDY FINANCES

Funding source

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

Participant stipends and payments

Participants will not be paid to participate in the study. Where necessary, we will pay the travel expenses of participants or their consultees to travel to the University to view viewo or audio recordings and to give second level consent.

SIGNATURE PAGES

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Signatories to Protocol:

Chief Investigator: (name)_____

Signature:_____

Date: _____

Co- investigator: (name) _____

Signature:_____

Date: _____

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