Protocol for Creating Learning Environments for Compassionate Care (CLECC): a feasibility study. Version 4.

Abstract

The quality of relationships with staff is key to shaping older people's hospital experiences[1]. While the extent of problems with quality of interactions between older people and nurses on NHS hospital wards is unknown, recent reports indicate that older people frequently fail to experience positive and caring attitudes and behaviours, resulting in a perceived lack of compassion. CLECC (Creating Learning Environments for Compassionate Care) is a practice development programme that aims to promote compassionate care for older people. This study will assess the feasibility of implementing CLECC in acute hospital settings and of evaluating its impact on patient care using an experimental design and associated process and economic evaluations.

Compassion is "a deep awareness of the suffering of another coupled with the wish to relieve it"[2]. Being compassionate requires "relational capacity" in practitioners, i.e. capacity to experience empathy and to engage in a caring relationship[3]. Our research shows that relational capacity can depend on ward conditions with nurses on general hospital wards reflecting lower capacity than critical care nurses, and a greater tendency to avoid relationships with patients and to burn out[4]. Previous research suggests that interventions which foster workplace learning, empathy, peer support and positive culture at ward team level may be more effective than individual interventions but we lack robust research on impact of such interventions on frontline care[5-7]. CLECC is a ward-based practice development programme focused on developing sustainable ward management and team practices that enhance capacity to provide compassionate care[8]. It is based on workplace learning theory with the ward itself conceptualised as learning environment and team as potential community of practice [9-11]. CLECC aims to create and support sustainable work-based opportunities for team dialogue, reflective learning, mutual support and role modelling.

This project is a feasibility study of CLECC implementation and its evaluation. Semi-structured qualitative interviews with staff, patients and carers will be used to assess CLECC's workability and integration into existing work practices. Contextual data will also be gathered at ward level including staffing, sickness rates, agency usage, turnover and shift length. Procedures for a cluster RCT and associated economic evaluation will be piloted to inform a future main trial design, evidence on outcome measures obtained to contribute to the power calculation, risk of contamination between clusters assessed, and participation and attrition rate estimated. Outcomes to be assessed include quality of staff-patient interactions, patient evaluations of care and staff perceptions of empathy. Carer/visitor perceptions of care quality, staff wellbeing, ward climate and perceived workload will also be measured. The study will take part in two phases. Phase 1 will include six wards and follow-up of 36 months. Phase 2 will use process evaluation findings from Phase 1 to enhance CLECC features and introduce to two further wards with up to 12 months of follow-up. Phase 1 pilot procedures will include wards being randomly allocated to participate in CLECC (n=4 wards) or act as control (n=2). Phase 1 baseline assessments will be undertaken 2 months before intervention with follow-up at 8 months, 26 months and 36 months post-randomisation. In an additional phase of the study, 2 further intervention wards will be recruited for baseline assessment, implementation of a modified version of CLECC based on Phase 1 findings and with follow-up assessment for up to 12 months.

An economic evaluation will be conducted from an NHS perspective. Resource usage data associated with delivering the intervention and quality of life data measured using EQ5D will be collected during the study. The study will test the sensitivity of using EQ5D to measure quality of life in the selected patient population. Hence the feasibility of using this measurement in a future definitive economic evaluation will be explored.

Background and rationale

The need to strengthen the delivery of compassionate care in UK health and social care services, in particular to older patients, is consistently identified as a high priority by policy makers [12] . In addition to a series of investigations into high profile failures, substantial and significant variations in the quality of hospital care for older people have been highlighted [13, 14]. Variation exists between hospitals, but also between wards within hospitals and between staff within wards. Training, staffing levels, leadership, motivation and organisational culture are all implicated in failures of care. While these issues are widely reported in the UK, there is evidence to suggest that they are relevant internationally [1, 15].

Our recent systematic review of research reporting older patients' experiences of hospital care highlights the importance of the relational aspects of care to shaping experiences [1]. Older people want nurses and others to use interactions to see the person behind the patient ("see who I am"), to establish a warm and human connection ("connect with me") and to establish understanding and involvement ("involve me") [1]. Being compassionate reflects these ways of working and requires "relational capacity" in practitioners, i.e. capacity to experience empathy and to engage in a caring relationship[3]. Our research also shows that nurses' relational capacity can depend on ward level conditions, and that there is a greater tendency for nurses with low relational capacity to avoid relationships with patients and to burn out, in spite of aspirations to a higher standard of care[4].

Recent evidence indicates that ward climate and ward leadership are key influencing factors on care quality in hospital settings [5, 7, 16]. This leadership and team capacity are key characteristics of the ward-level conditions needed to support nurses' relational work [4] and an important foundation for team activities such as using service user feedback constructively[17]. A recent study on culture change and quality of acute hospital care for older people found that more positive patient and carer assessments of care were correlated with higher staff ratings of team climate in terms of "supporting each other" and "shared philosophy of care"[5]. In addition, "leading by example" (i.e. ward leadership) was a strong indicator of staff in a team sharing a philosophy of care and feeling high levels of team support, a finding that, together with the qualitative data, highlighted the vital role of the ward manager in shaping a positive team climate for care[5].

These findings were mirrored in a second study which highlighted the key role of the ward leader in shaping the local ward climate of care, the importance of staff well-being, and in particular staff experiences of good local work-group climate, co-worker support, job satisfaction, positive organisational climate and support, and supervisor support as antecedents of positive patient experiences[7]. However, in an era of high patient throughput and "target-driven" organisational cultures, there are reduced opportunities for team dialogue and reflective learning. Use of staff without professional qualifications is increasing and nursing staff job satisfaction is low. It is likely therefore that the leadership and team practices such as role modelling, mutual support and dialogue needed to ensure staff wellbeing and thus their relational capacity are not in place in many care settings.

Recent years have seen the development of a number of interventions focused on improving compassionate care, or dignity in care, at hospital ward level [17-21]. They have typically been faciliated by a senior nurse, using reflective learning, action research and/or appreciative inquiry to work with ward-based nursing staff (often using patient stories and/or observations of practice) to strengthen support for existing good practice and to make changes where needed. These interventions are often shaped by a "relationship-centred" philosophy in which achieving the well-being of all groups (patients, staff, family carers) is seen as fundamental to high quality care [22]. They have used democratic and participatory processes involving patients, staff and sometimes family carers to articulate the patient's needs and shape the practice changes made.

The introduction of these interventions has been accompanied by largely qualitative evaluations which have provided important information about the processes of change, and the factors enabling and inhibiting sustainable change. Some of these evaluations have reported concrete practice changes resulting from the intervention [19, 20, 23-25], while others report more variable success [17, 18]. For instance, Dewar used appreciative inquiry and action research to involve older people, staff and relatives in developing compassionate relationship centred care on an acute hospital ward [24, 25]. Methods used included participant observation, interviews, storytelling and group discussions. Dewar's findings indicated the value of appreciative caring conversations between staff, patients and relatives enabling all parties to discover "who people are and what matters to them" and "how people feel about their experiences", with this knowledge enabling them to "work together to shape the way things are done". In the resulting model, Dewar and Nolan detail how older people, staff and relatives can work together to implement compassionate relationship centred care. In specifying "how people can work together to shape the way that things are done here", Dewar identified a number of important conditions for staff to feel able to express emotions, share experiences and ideas with each other, consider others' perspectives, take risks, use "curious questioning" to examine situations and challenge existing practice, all identified as important actions to support the delivery of compassionate care. These conditions included transformational leadership, the level of support received from colleagues and senior staff, a shared set of principles for caring, open dialogue within the team and opportunities where people had permission and space to reflect. These conditions echo the findings from other research as the conditions at team level that can support high quality care. Dewar reports

how these conditions developed and how compassionate caring practices became embedded in the work of the team over the course of the year-long project, providing valuable evidence that change of this kind is possible.

However, Dewar's project took place over the course of a year on an already high-performing ward with a strong leader. The findings informed development work across a wider Leadership in Compassionate Care project implemented in a number of settings, but evaluation of the impact of these strategies elsewhere does not report the influence of the ward climate or programme length on outcomes, so evidence is lacking that such strategies can be universally effective regardless of work team context [26]. In a contrasting study to Dewar's that explored the use of discovery interviews with older hospital patients as a way of improving dignity in care, Bridges and Tziggili (2011) found that ward teams required strong and consistent leadership and intense preparation before they were able to hear and respond to patient stories about care[17]. Both organisations involved in this dignity project experienced significant delays in the progress of the project and limitations in its impact because of a lack of leadership at ward level and a lack of preparedness of the ward teams to engage in responding positively to patient feedback. One ward team with a strong leader was able to successfully engage with the patient stories, but only after some months of team preparation. These findings indicate that, while some wards may be ready to engage in programmes such as Dewar's, others could benefit from a period of groundwork in which leadership and mutually supportive team practices are established.

In summary, research findings to date indicate the potential for change at the level of the ward "micro-climate", and also signal that investing in the potential for ward teams to develop their own leadership and team practices may lay the necessary foundations for service improvement and the support and further growth of existing good practice. In spite of this growing evidence that intervention at a team level has potential, a programme that focuses specifically on relational practices across the team and that aims to develop these practices within a relatively short timescale to promote compassionate care has not previously been developed.

Creating Learning Environments for Compassionate Care (CLECC)

CLECC is a unit/ward-based implementation programme focused on developing leadership and team practices that enhance team capacity to provide compassionate care. Its objectives are to:

1. Create an expansive workplace learning environment that supports work-based opportunities for the development of relational practices across the work team;
2. Develop and embed sustainable manager and team relational practices such as dialogue, reflective learning and mutual support.
3. Optimise and sustain leader and team capacity to develop and support the relational capacity of individual team members;
4. Embed compassionate approaches in staff/service-user interaction and practice, and continue to improve compassionate care following the end of programmed activities

CLECC has been designed for use by ward nursing teams in inpatient settings for older people but is potentially transferable for use in other settings. The implementation programme takes place over a 4 month period but it is designed to lead to a longer-term period of service improvement. By envisaging the workplace as a learning environment and the work team as a community of practice, CLECC brings a distinctive approach to promoting compassionate care. It uses insights from workplace learning research [9-11] to develop practices that enhance the capacity of the manager and work team to provide compassionate care within a complex and dynamic organisational context. Fuller and Unwin's research on workplace learning and workforce development in a range of public and private sector industries has shown the importance of identifying and analysing both the organisational and pedagogical features that characterise diverse workplaces as learning environments[10]. They argue that this approach allows workplaces (for instance, hospital wards) to be located on what they term the 'expansive – restrictive' continuum. Those sitting at the expansive end are characterised by a range of features including: the knowledge and skills of the whole workforce (not just the most highly qualified or senior staff) are valued, managers facilitate workforce and individual development, team work is valued, innovation is important, team has shared goals focusing on the continual improvement of services (or products), there is recognition of and support for learning from 'each other', learning new knowledge and skills is highly valued, and the importance of planned time for off-the-job reflective learning is recognised. It follows that an expansive approach to workforce development is more likely to facilitate the integration of personal and organisational development. This has

important implications for the design of learning interventions as it requires workplace learning to be perceived as something which both shapes and is shaped by the work organisation itself rather than a separately existing activity. Such an understanding highlights the importance of interventions which situate and integrate individual and team learning in the everyday life of the workplace (in this case the clinical unit/ward/team setting) as well as providing opportunities for off-the-job provision to foster reflection, consolidate learning and deepen understanding – so enhancing ownership and sustainability of new practices.

CLECC aims to develop and embed sustainable manager and team practices such as dialogue, reflective learning and mutual support. CLECC's implementation period includes several key kinds of activity which are combined to produce an integrated intervention: ward manager action learning sets (monthly for 4 months); team learning activities, including local team climate analysis and values clarification; peer observations of practice and feedback to team by volunteer team members; classroom training (8 hours); daily 5 minute team cluster discussions; and twice weekly team reflective discussions [8]. Many activities draw on the Best Practice for Older People guidelines and associated resources, based on qualitative research about older people's experiences of hospital care, and targeted at developing nurses' relational capacity [1, 27, 28]. Throughout the implementation period, ward managers and their teams develop a team learning plan, which includes a plan for inviting and responding to patient feedback, and puts in place measures for continuing to develop and support manager and team practices that underpin the delivery of compassionate care. CLECC learning activities are led by a senior (UK Band 7) practice development practitioner/nurse (PDN) with strong influencing and interpersonal skills. The PDN delivers the classroom training, "care maker" support (see below), facilitation of cluster and reflective discussions, facilitation of action learning sets and coordination of practice observations. This individual is not part of the hierarchy of the ward team and this enables a distinction between CLECC activities and performance management.

Most learning activities are built into the working day to enable experiential techniques to prompt "real-time" reflective learning and to enable team members to draw on each other's expertise, experiences and support as resources. Wider opportunities are thus available for promoting learning and improving practice at an individual and team level. Learning in the workplace is supplemented by classroom-based experiential learning. This combined approach is theorised to lead to deeper learning and more significant practice change than one that relies on classroom training alone. Research evidence indicates that educational interventions that are strongly theoretically based, multi-faceted, of sufficient intensity and duration, and supplemented by additional supervision and sufficient management support, may deliver the best outcomes [29, 30] . Other research suggests that interventions which foster workplace learning, empathy, peer support and positive culture at unit/ward team level may be more effective than interventions that focus on the development of individual members of staff [5-7].

The focus of the intervention, then, is on creating an 'expansive' environment that supports work-based opportunities for the development of shared goals, dialogue, reflective learning, mutual support and role modelling for all members of the team at an individual and group level [10]. Such an environment should facilitate staff to engage with and learn from service user experiences and their own emotional responses, share positive strategies and support, and optimise and sustain personal and team relational capacity to embed compassionate approaches in staff/service-user interaction and practice. 'Expansive outcomes' are theorised to include high quality interactions between service users and staff, and between care team members, positive care experiences reported by service users and staff reports of high empathy with patients and carers.

Evidence explaining why this research is needed now

This study is the first stage in implementing and evaluating an intervention to promote compassionate care. CLECC's design draws on evidence from process evaluations of similar initiatives about potentially effective mechanisms for change and barriers/facilitators to change. Qualitative research has highlighted the likely features of a successful programme but previous initiatives have not explicitly targeted the potential for intervention at work team level through a focus on the development of sustainable leader and work team relational practices. CLECC has been developed to address these limitations.

To date, no evaluations of initiatives of this kind have enabled a robust assessment of the effectiveness of the programme on patient care. Responding to a general absence of strong evidence

for the effectiveness of service improvements for this client group, and building on promising evidence indicating that a strategy targeted at improving leadership and local ward team climate could improve patient experiences, this study is the first stage in designing a rigorous evaluation that includes quantitative methods to understand what works best in improving care.

The present study provides an important opportunity to assess the feasibility of a programme with unique characteristics designed to address the issues identified in previous process evaluations of other interventions targeted at compassionate care, and to design an evaluation that includes an assessment of its effectiveness. The process and economic evaluations will provide important information about CLECC's workability, its integration into practice and lay the foundations for establishing its value for money. The study will be conducted in two **to four** acute hospitals in neighbouring health districts, and findings from the planned future trial will provide valuable information for education and service commissioners and providers currently operating without an adequate evidence base. The findings will provide the basis for planning a larger, multi-centre trial producing evidence that can be generalized more widely to other NHS acute care providers and, together with the planned standardised intervention package, will be a valuable resource for change and improvement for NHS managers, practitioners and educators.

Aims and objectives

This study will assess the feasibility of implementing a practice development programme aiming to promote compassionate care for older people in acute hospital settings; and assess the feasibility of conducting a cluster RCT with associated process and economic evaluations to measure and explain the effectiveness of CLECC.

The objectives are:

1. To determine the feasibility of implementing CLECC and sustaining the resulting work practices.
2. To inform the design of a definitive evaluation of CLECC's effectiveness.
3. To estimate the costs of the intervention and quality of life.

In order to achieve this, a process evaluation drawing primarily on qualitative data and assessment of implementation will determine CLECC's feasibility and integration into existing work practices. Procedures for a cluster RCT will be piloted to inform main trial design. The economic evaluation will aim to estimate costs of the intervention and to explore the feasibility of a future definitive economic evaluation.

Design

The feasibility of implementing CLECC into practice will be assessed through a process evaluation, using Normalization Process Theory as a framework[31]. Qualitative interviews with nursing staff, managers, patients and carers during implementation and follow-up phases, and a quantitative record of learning activities delivered and attended, will identify and explain the extent to which the planned intervention was implemented into practice, enabling an assessment of its workability and integration into existing work practices. Other contextual data on each ward will also be gathered at baseline and updated at follow-up including ward-level staffing, sickness rates, agency usage, turnover and shift length. These data will enhance the explanations generated from the qualitative data. In addition, data will also be gathered on the feasibility of conducting qualitative interviews with staff, patients and relatives to inform qualitative evaluation to accompany a future definitive trial, with the purpose of explaining trial outcomes.

An experimental design in the definitive evaluation is the most appropriate design to establish effectiveness[32]. In order to prepare for a definitive multi-centre trial, we will assess the feasibility and pilot procedures for a cluster randomised controlled trial of effectiveness. Cluster randomisation of staff and patients in wards appears to be the appropriate approach to maximise rigour [32], but parameters such as intra-cluster correlation in the quantitative outcome measures and the potential for contamination through, for instance, staff transfer between wards, are unknown. In the future trial, we plan that wards will be randomly allocated following baseline data collection to participate in the intervention or act as control. Randomisation would be stratified by hospital and by ward type (medicine for older people or not medicine for older people). Outcome measures would be assessed at baseline (2 months before intervention and before randomisation to groups) and four months after completion of the 4 month CLECC implementation programme (that is, follow-up is 8 months after

randomisation). Further follow-up will take place at 26 months and 36 months post-randomisation enabling a longer-term assessment of sustainability. We plan to observe the quality of interactions between patients and staff, assess patient-reported experiences of care and measure staff-reported empathy. Other potential outcomes include staff wellbeing, ward climate, perceived workload, carer satisfaction and complaints.

Areas of uncertainty in this design that merit a feasibility study include implementation of CLECC into practice, contamination of practices from intervention to control wards, extent of intra-ward clustering of outcomes, selection and use of outcome measures, rates of participation and attrition, and the appropriateness of outcomes, particularly when assessed unblinded. Through piloting these procedures on 6 wards in two English hospitals (3 wards in each hospital), this feasibility study will remove uncertainty in designing and executing a larger, definitive trial. CLECC will be implemented in Phase 1 on four wards, with two wards acting as control. Implementing CLECC on four wards across two hospital sites is likely to provide sufficient diverse contexts within which its feasibility can be assessed, leading to further refinement where needed. The inclusion of a small number of control wards will provide valuable insight into the likely acceptability of randomisation in the main trial and differential compliance with study procedures between intervention and control. Following the analysis of process evaluation results from Phase 1, the CLECC intervention will be modified where findings indicate potential for improving impact and sustainability. This enhanced version of CLECC will be implemented and evaluated as in Phase 1 on 2 wards in a third acute hospital, with follow-up assessment for up to 12 months.

Details of the assessment of feasibility are outlined in Appendix 1 and discussed below. Findings will provide an evidence base from which to make decisions about trial design to be implemented in other centres in a future trial, including the feasibility of ward level randomisation, contributing to sample size calculation and selection of outcome measures.

Additional costs associated with delivering the intervention will be identified. These will include the cost of staff time, replacement and direct delivery as well as any additional time. We also aim to test the sensitivity of using EQ5D as an outcome measure with this group of patients. These assessments and resulting data will inform the design of an economic component in the future trial.

Setting

The study will be conducted in **three** NHS Trusts. The trusts are located in separate areas in the same geographical region which reduces the cost of the research while allowing testing in distinct contexts. It is hoped that a future, larger trial can be carried out including a wider geographical spread of centres.

This study addresses a topic of high priority for trusts **recruited to date**. There is enthusiastic and active director of nursing and other senior and middle management nursing support and this is expected to help ward nursing staff accord the study a high priority. Careful marketing of the study with visible senior manager support at each trust will aid ward and staff recruitment to the evaluation and optimise the participation of staff on the intervention wards in the intervention.

Sample

Wards: Two to three adult medical and/or surgical in-patient wards in each trust with the highest proportion of patients aged 65+ years will be included in the study. The sample will include wards/units specialising in care for older people but not critical care units. Wards will be excluded if departure of ward manager is anticipated in the subsequent 6 months of attempted recruitment.

Staff: all nurses and care assistants (CAs) (health care assistants, assistant practitioner, nursing auxiliaries) working on participating wards during any data collection period will be invited to be interviewed and eligible to complete the nursing questionnaires. Nursing students, bank and agency staff will not be eligible. For the observations, all interactions between patients and staff (of any discipline) working on the ward or visiting the ward will be recorded during the planned periods providing that no objections are raised.

Patients: All adult patients on participating wards will be eligible to take part in the qualitative interviews, to be included in observations of care and to complete the questionnaires. Routine collection of age and cognitive status data will enable assessment of the relative participation rates of different groups. Patients will be excluded if they are unable to communicate their choices about taking part in the research and a consultee (as defined by the Mental Capacity Act) cannot be

consulted. Patients who indicate either verbally or non-verbally that they do not wish to take part will be excluded, as will patients who are unconscious or where there are clinical concerns that may preclude them from being approached. Only people who are able to complete a questionnaire in English with interviewer help (as assessed by the researcher and/or ward staff) will be invited to take part in the patient survey. The decision to focus on including people who understand English is a practical one, in that we anticipate some communication difficulties in relation to old age in a high proportion of the sample, and we are concerned that the likely small sample of people with language differences will not enable us to properly represent the views of people who have language difficulties. Ability to speak English will not determine whether or not patients are invited to have their care observed. Only people who speak English and who have the cognitive and communicative capacity to take part in a research interview and to be interviewed (as assessed by the researcher and/or ward staff) will be invited to take part in the qualitative interviews. An inclusive approach will be taken, that maximises capacity to take part. This approach will include training researchers to be person-centred and patient, allowing sufficient time for successful communication, and making environmental modifications to optimise communication.

Carers/visitors: Primary family carers of patients on participating wards or, where there is no primary family carer, regular visitors (visits 3+ times per week).

For the purposes of the feasibility study, we have set target samples for each dataset. These samples are based on estimates of number of eligible participants during the data collection period, and participation rates in similar studies. The targets will enable us to monitor and assess participation rates. All eligible nursing staff on participating wards will be invited to complete a written survey, and response rates will be documented, together with details of time periods during which questionnaires and distributed and completed, and the relationship of these time periods with distribution and completion of patient and visitor questionnaires. The partial completion of questionnaires will be monitored, as will the proportion of staff who completed a questionnaire at baseline and again at follow-up assessment. For patient questionnaires, we will document the number of eligible patients, the number approached, the number refused (and reasons why), and the number of questionnaires only partly completed. Documenting patient age and evidence of cognitive impairment will enable us to assess participation rates of older patients and patients with cognitive impairment.

Table 1: Target recruitment rates **(total for Phases 1 and 2)**

		QUIS				**Written survey**			
	Qualitative	**Baseline A1**	**Follow-up A2**	**Follow-up A3**	**Follow-up A4**	**Baseline A1**	**Follow-up A2**	**Follow-up A3**	**Follow-up A4**
Nursing staff	**60**	**-**	**-**	**-**	**-**	**130**	**120**	**35**	**35**
Patients	**12**	**173**	**182**	**40**	**40**	**168**	**186**	**0**	**0**
Carers/visitors	**12**	**-**	**-**	**-**	**-**	**89**	**87**	**0**	**0**

Recruitment

The procedures outlined here mirror our currently envisaged procedures for a definitive trial. Opportunity will be taken during the feasibility study to evaluate these procedures and adapt them if necessary. We will gather data on participation rates and potential influencing factors including patient age, cognitive status and ward allocation (see Appendix 1). Pre-screen and screening logs will demonstrate:

- The timeline of the introduction, approach, discussion and consent process
- The number of people assessed for eligibility
- The number of people approached to join the study

- The number of people recruited into the study
- The number of declined offers and the reasons for these decisions
- The achievement of targets.

Recruitment pathways for patients, visitors and staff are summarised in Appendices 2 and 3.

Wards: ward managers and the senior nursing manager to whom they report will be informed about the study and invited to enrol their wards in the study. Multiple opportunities will be taken in each trust to advise trust staff about the study e.g. posters, agenda item at key meetings including one-to-ones and presentations about the study by the research team. Each manager will be approached by a member of the research team two months prior to data collection commencing and given verbal and written information about the study, and opportunities to ask questions and raise concerns. We will not be able to include wards that refuse to take part in the study but will work hard to include wards that are less enthusiastic to take part because, in a future trial, their inclusion will improve the generalizability of the findings. If more wards than required are enrolled we will select wards based on contrasting characteristics with a view to including wards less enthusiastic about participation. There is a need to know if interventions of this kind can also work in contexts in which staff may not recognise the potential benefits of the intervention and/or do not prioritise improving compassionate care.

Staff: Meetings with ward managers on the control and intervention wards and with groups of ward nursing staff, together with letters and posters, will help inform nursing staff about the study. Nursing staff will be invited by letter to a qualitative interview and provided with an information sheet outlining interview procedures and their proposed role in the study. Written consent will be sought for the staff interviews and, as is standard practice, nurses will be given information about not being obliged to take part and their right to withdraw their consent at any time. We will offer a payment (up to £15 in cash or vouchers) to individual staff who complete an interview. All nursing staff will receive questionnaires. Those who do not wish to take part will not return their questionnaires. Questionnaires will be distributed to via managers and / or internal post systems. The survey will be addressed to named staff members and will have a unique identifier to permit linkage to subsequent responses. Response rates will be optimised by briefing ward managers on the purposes of the study and by visits, emails and telephone calls to prompt ward managers to encourage questionnaire completion [5]. We will also offer a prize in the form of vouchers or cash to the ward in each hospital with the highest nursing questionnaire response rate. While staff will be encouraged to take part in the intervention, no individual staff will be obliged to take part in the intervention. We will ensure that all staff working on the ward or visiting the ward are aware of the study and the associated observations, and have an advance opportunity to raise objections to being observed.

Patient observations**:** All eligible patients on the ward at the time the observation is planned will be ascertained. Once eligible patients are identified, an index patient will then be randomly selected from the pool of eligible patients on the ward. This index patient will then be approached and informed (verbally with accompanying written information and with aids where needed) about the planned observations. We will develop aids such as pictorial representations to help explain the study to patients who have difficulty taking in verbal information and communicating their choices. If they indicate verbally or non-verbally that they are happy for the observation to proceed, other eligible patients in the researcher's field of view will be approached, informed (verbally with accompanying written information and with aids where needed) about the planned observations, and if they indicate they are happy for observation to proceed, their care will be included in the observations. We do not plan to seek written consent from patients, as the focus of the observations will be on staff behaviours rather than patients. If the index patient declines to take part, another index patient is randomly selected, and is approached and invited as before. The observation will proceed with data being collected on interactions with all patients who have agreed that the observations can proceed.

Patient questionnaires: All eligible patients over a six week period will be invited to complete a questionnaire while an inpatient. Researchers will visit the ward daily to ascertain with the nurse-in-charge which patients are able to be directly approached by a researcher to complete the questionnaire[5]. Questionnaires will be completed anonymously.

Patient/carer interviews (qualitative): For patients/carers eligible for interview, we plan to obtain written consent to be interviewed, once verbal consent has been given. For qualitative interviews,

researchers will visit the ward daily to ascertain with the nurse-in-charge which patients/carers/visitors are able to be directly approached by a researcher to be interviewed.

Carers/visitors recruited for questionnaires: Posters on the ward will give brief information about the study. Research staff will directly approach eligible individuals over a four week period to give a brief verbal explanation and hand them a questionnaire with accompanying explanatory letter. The questionnaire will be distributed as close to discharge as possible and will be completed anonymously.

Procedures for including adults lacking the capacity to consent to take part in the study are outlined in Appendix 4.

Process evaluation

The process evaluation aims to identify and explain the extent to which the planned intervention is implemented into practice, enabling an assessment of its workability and integration into existing work practices. Normalisation process theory (NPT) will be used to guide the process evaluation, shaping the interview topic guides and informing the framework for analysis[31, 33]. NPT focuses on the dynamic processes that lead to innovations becoming integrated into everyday work, and so is a helpful way to evaluate what actually happens when complex interventions get introduced into practice, and how and why the desired outcomes are achieved (or not). The evaluation will focus on:

1. Exploring how and in what ways the new practice was initially received, how individually and collectively people practically conceptualise and make sense of it (coherence)

2. Assessing the degree of ownership of and participation in the new practice by key individuals and teams (cognitive participation)

3. Identifying the work that individuals and teams do to enact the new practice (collective action)

4. Exploring the perceived impact of the new practice on staff work and on patient outcomes (reflexive monitoring)

One-to-one qualitative interviews will be undertaken during intervention and follow-up phase for both versions of CLECC being implemented with ward managers, nurses and care assistants (1 hour), and older patients and their relatives (30 minutes) from intervention and control wards. Staff will be purposively sampled to ensure representation across ward types and staffing bands. The PDN involved in implementing the intervention at each trust will also be invited to keep detailed field notes and be interviewed following the close of the intervention stage. Previous studies of this kind indicate that categories are likely to be saturated at around 30 interviews but recruitment of staff will continue beyond this if necessary until no new data are emerging. To yield alternative perspectives and to inform the design of future process evaluations, a target sample of 2 patients and 2 relatives per Phase 1 ward will also be interviewed.

A semi-structured format will be used to guide discussion. All interviews will be audio-recorded and fully transcribed. Interviews with nursing staff will take place in a location and at a time of their choosing and patients and carers will be interviewed during their admission (as recall may be affected if interviews take place after discharge) in a quiet room in the hospital that is likely to be free from distraction or interruption. The interview schedule will be designed to reflect the key NPT components of coherence, cognitive participation, collective action and reflexive monitoring.

Patients and carers will be unable to comment on any changes over time and associated factors and so their interviews will focus on describing their personal experiences of interactions with staff during their stay, thus, together with questionnaire responses, providing an insight into staff behaviours and the enactment of compassionate care. We do not anticipate that the interview topics are likely to generate distress but acknowledge that distress may occur all the same. Researchers will be trained to manage such a situation appropriately (see Appendix 5). Researchers will also be trained in what action to take if unsafe practice becomes apparent during data collection (see Appendix 6)

Other contextual data will be gathered on intervention and control wards through the completion of a ward profile questionnaire by the ward manager (or other senior nurse on the team). These ward level

data will include physical layout, specialty, bed occupancy, staffing, sickness rates, agency usage, turnover and shift length.. These data will be gathered at baseline phase and updated at follow-up phase and are intended to complement the qualitative findings in providing data on factors theorised to impact on implementation and to effect change. Records will be kept on the feasibility of gathering these data.

Data will also be gathered on the amount of training delivered through a register of attendance at classroom training and action learning sessions, and a quantitative record of ward cluster discussions, reflective group discussions and cluster discussions. We will also undertake qualitative observation of a sample of training events to complement the interview findings and explain the quantitative data. These data will enable an assessment of the extent to which the intervention was implemented as planned.

Qualitative data will be analysed initially using systematic reading, familiarization and open coding, undertaken independently by at least two research team members and then in collaborative data analysis workshops[34]. At this early stage, we will avoid prematurely "fitting" the data into NPT domains. Coding discussions will lead to the development of a coding frame, to be constructed with reference to NPT, while remaining open to data that do not fit. Disagreements about coding will be resolved by consensus and reference to NPT. Using NPT as a framework for coding and analysis combined with a thematic approach, we will use constant comparison [35] to examine codes and refine emerging themes to develop explanations that enhance understanding of the NPT domains. Narrative data summaries and matrix/charting techniques will be used to facilitate comparison [36, 37]. As the study progresses, the analysis will include all the data produced, with systematic referencing back to our original objectives and the NPT framework. This process mirrors the analysis process developed and used by Pope et al. in an ethnographic study of computer decision support system using NPT[34].

Outcome measure performance

To prepare for a future definitive evaluation, we will assess the performance of a selection of outcome measures during baseline and follow-up assessment periods (see Appendix 1). This will include attrition (and influencing factors), time and assistance needed to complete written questionnaires.

There is no single validated measure for compassionate care and we plan to assess its measurement across three complementary core outcomes: researcher-rated observations of the quality of staff-patient interactions, patient-reported evaluations of emotional care and nurse-reported measures of empathy. These assessments will inform selection of outcome measures in the definitive evaluation, including identification of the most appropriate primary outcome. Data gathered using these measures should also enable baseline and follow-up rates for each measure to be established to inform target effect size and sample size calculations in a future trial.

Core outcome measures

The quality of staff-patient interactions will be measured using QUIS [38], a time sampling tool that gives a measure of both the volume and quality of interactions. While other observational tools have been developed for educational and service improvement purposes, such as dementia care mapping (DCM) and Person Interaction Environment (PIE), their use as a research instrument is problematic. PIE was used in the National Dementia Audit but lacks structure and so is difficult to use quantitatively, and DCM has weak psychometric properties and is resource-intensive to use[39]. QUIS has been used in a number of studies in NHS acute care settings for service improvement and evaluation, including use by the Health Advisory Service in their seminal evaluation "Not because they are old"[40]. Other work has demonstrated that it is sensitive to changes in service quality[38, 41, 42]. Interactions between staff and patients are observed by independent raters and coded as positive social, positive care, neutral, negative protective and negative restrictive. Observations will be divided into 10x2 hour periods (per ward at each assessment period) to ensure representation of a range of patients, times of day, nurses and days of week. Target sample for QUIS observations is 20 patients per ward per assessment period. We predict we will be able to observe more than one relevant patient on some occasions and will be able to test this together with variation in interaction frequency/quality over days of week and times of day. We will also gather data on patients, carers or staff who agree to take part in observations who then withdraw before it commences or during observation. Based on piloting, a mean of 3.5 positive interactions per patient per hour is expected. We plan to treat the number of positive interactions between nursing staff and patients as the primary

outcome for reporting results and sample size calculation, with the number of negative interactions a secondary outcome measure. This feasibility study will enable us to assess this strategy and to identify which of the three core outcome measures is the most appropriate primary outcome measure for the main trial. See Appendix 7 for full QUIS protocol. QUIS data collection that takes place after ward randomisation will be conducted by a team of trained independent observers who are not members of the research team and who are blind to ward allocation. Data collectors will be debriefed to explore the success of these blinding strategies and this assessment will inform future trial design. It may be possible to assess the effect of any failures in blinding on outcome assessment empirically, depending on these results. We will also monitor the impact of observations on staff behaviour by examining differences over time.

Patient-reported evaluations of emotional care will be measured using PEECH and PPE-15. While a number of survey instruments are now available that measure patient experience, most are limited in their capacity to assess patient experiences of the more complex relational aspects of care [43]. Designed to address this gap, the Patient Evaluation of Emotional Care during Hospitalisation (PEECH) survey tool focuses on the nature of interpersonal interactions with hospital staff and patient-reported assessment of the extent to which therapeutic emotional care has occurred [44, 45] Originally developed in Australia, PEECH has since been validated for use in English hospital settings, and can be completed by patients during a hospital stay with or without assistance. PEECH and the Picker Patient Experience Questionnaire (PPE-15) can be used together as a 48 item survey questionnaire to measure the relational aspects of patient experiences (PEECH) in addition to the more transactional and functional aspects of experience (PPE-15)[43]. PEECH is sensitive to changes in service quality and in ward environment[46]. Additional questionnaire items will also be included to test respondents' awareness of CLECC being implemented on the ward or not. It may be possible to assess the effect of any failures in blinding on outcome assessment empirically, depending on these results. Questionnaires will be distributed to all eligible patients over a 4 week period at each assessment period and response rates will be assessed on an ongoing basis. The target sample is 16 patients per ward per assessment period. We will record the length of time survey completion takes. We will offer the option of help with interview completion to increase response rates and monitor the rate at which the assistance is required[47]. Impairments in communication and cognition common in older patients, and the potential for biased responses, especially if patients are not successfully blinded to ward allocation, may limit the utility of patient-reported evaluations as a solitary outcome measure and this study will enable us to explore these issues [39].

Nurses' self-reported empathy will be established using the Jefferson Scale of Empathy (JSE)(Physician/HP version), a 20 item inventory in a 7-point Likert-type format ranging from Strongly Disagree to Strongly Agree with higher scores reflecting a more empathic orientation[48]. While caregiver empathy is recognised to be an important component of compassionate care, JSE is the only scale focusing on this concept that is designed for use in patient care contexts. Developed and validated for use by health care workers, including nurses, the scale is sensitive to changes in individual empathy over time and context[49, 50]. All nursing staff (approximately 42 per ward) currently working on each ward will be invited to complete the written questionnaires at each assessment period. We will record the length of time survey completion takes. It will not be possible to blind nursing staff to the intervention and this limits JSE's capacity as a solitary outcome measure.

Secondary measures

Because it is intended that the intervention optimises the ward team climate to support compassionate care, we will assess the feasibility of evaluating staff local working climate using Climate for Care (CC) and Factors that Enable Climate for Care (FECC) questionnaires, 39-item and 19-item questionnaires with answers on a 5-point Likert scale developed as part of a toolkit from an SDO-funded project measuring culture change and quality of NHS acute hospital care for older people, with the ability to identify distinct nursing team climates [5]. We will also administer the Matron's Assessment of Quality of Care (MAQC) from the same toolkit. Because it is intended that staff's ability to meet older people's needs will be improved we will also assess their perceived workload. This could be positively or negatively affected. Workload might be increased though time spent in interaction and identification of latent need. Workload might decrease because proactive person centred care results in less challenging patient behaviours and more efficient targeting of care interventions on properly assessed needs. We will assess nursing staff perceptions of workload using items from the International Hospital Outcomes Study battery (IHOS)[51, 52] including: (i) enough nurses on staff to provide quality patient care, and (ii) ratings of core care activities which were

deemed necessary but left undone. This survey has been widely validated internationally and subjective ratings from it correlate with objective measures of both staffing and quality. Perceptions of improved quality of care could also lead to higher job satisfaction and reduced burnout so we will measure levels of burnout using the 22 item Maslach Burnout Inventory (MBI)[53]. These instruments will be collated together with the Jefferson Scale of Empathy into a written nursing survey. We will also pilot an online version of the survey. We will gather data on time taken to complete these surveys and feedback from staff. We will assess the feasibility of using ward records to ascertain staff sickness levels and gathering data on the number of written complaints received during each period of data collection.

All eligible carers/visitors on each ward over a six week period will be targeted and invited to complete a Carer Experiences of Care (CEC) questionnaire. The target sample is 6 carers/visitors per ward per assessment period. CEC was developed from SDO-funded project measuring culture change and quality of NHS acute hospital care for older people [5]. The questionnaire is a 19 item structured questionnaire with a 5 point Likert scale. Space will be added for carers to add qualitative comments. Family carers and regular visitors know the patient well but a number of issues have been identified with their ability to evaluate patient care. These issues include the nature and closeness of relationships with the patient, the limited evidence on which assessments can be made e.g. short visiting times, and the influence on responses of previous negative hospital visits, severe carer strain, and their own unmet needs for information[39]. While these issues preclude CEC's consideration at this stage as a potential primary outcome measure, its use in the feasibility study will enable an assessment of the utility of including carer experiences as an additional component of compassionate care. We will also assess the length of time survey completion takes.

Records will be kept on questionnaire response rates, attrition rates and influencing factors. We will develop a bespoke relational database (MS access or equivalent) for the various sources of data in the study. All data will kept anonymously on University of Southampton computers, with paper based records linking study numbers to personal identifiable information (for individual patients and nurses) kept in locked filing cabinets. Data will be imported from various sources (e.g. handheld devices, written questionnaires) with data validation at the point of data entry. A data entry service will be used to input written questionnaire data entry with a standard of double data-entry, 100% verification and full range-checking. Data quality will be monitored as it is entered and all steps taken to ensure completeness in ongoing data collection. We will keep records on issues identified with implementing these procedures to inform their refinement in a future trial.

Economic evaluation

Resource usage associated with delivering the intervention will be calculated from records of CLECC activities that are delivered and the number and banding of staff who attend, the cost of service user involvement in the classroom training sessions and the cost of the practice development nurses who lead CLECC implementation. Along with other items in the patient survey, we will also administer EQ5D, a quality of life questionnaire, to assess its sensitivity as an outcome measure with this patient group and its potential contribution to an economic evaluation in a future trial.

Feasibility of planned analysis

As outlined in Appendix 1, quantitative data gathered will enable the baseline rates for each planned outcome measure to be established, in addition to providing an estimate of intra-cluster correlation in outcome measures and informing the selection of the primary outcome measure. Our primary analysis will be descriptive for the future trial effect size which along with clinical judgement, findings from other studies and rates of attrition will contribute to determining the sample size for the future trial. We will run through the currently envisaged analysis for the main trial in order to get preliminary estimates of effect size and to check the analysis plan.

In considering a cluster RCT design for a future definitive evaluation, we acknowledge that contamination between the wards is a possibility which would undermine trial designs with concurrent CLECC treated and untreated wards in the same hospital. We will monitor and assess the likelihood of contamination in two ways. Firstly, we will check with ward managers to see if any staff have left to work on a control ward. Secondly we will examine the pattern of results to see if contamination is a plausible explanation. The result of any contamination would be to attenuate any differences between wards resulting from the intervention by improving care in control wards. Therefore contamination

might have occurred if there is improvement in both groups with the intervention wards showing a greater difference. Data analysis will inform whether clustering in the future trial should be at ward or hospital level.

PG (deputy PI) and RP (co-applicant) will lead the analysis of outcome data, together with advice from AAS (co-applicant). None of these individuals have been involved in development of the intervention or will be involved in its implementation. In addition, we will test the feasibility of analysis being performed blind to the groups. The Study Steering Committee (SSC), which will include a senior member of Newcastle CTU and other independent members, will aid us in identifying and mitigating other potential sources of bias. The SSC will oversee data analysis and recommend risk mitigation strategies within the protocol, and necessary protocol changes if concerns are raised. These processes will enable us to explore and identify strategies for use in a definitive trial.

Progression to a definitive trial

This study will lay the groundwork for a future definitive trial of the CLECC intervention. In the first instance, the qualitative process evaluation will enable an assessment of CLECC's workability and integration into existing work practices, providing important information to guide its further refinement and implementation. Secondly, findings from the study will enable assessment of the feasibility of a future definitive evaluation against a number of important parameters, as outlined in Appendix 1. These parameters include participation and attrition rates; outcome measure performance, use and baseline rates; potential for bias and contamination; other issues associated with data collection, analysis and management; and ethics and governance issues. Results from the assessment of these parameters will then inform the design and implementation of a definitive evaluation including sample size, level of clustering and selection of outcome measures. It is not possible at this stage to fully quantify the study's success criteria e.g. number of patients/staff to be recruited. We have instead set target recruitment rates which will be reviewed and refined as data are collected and analysed. The success criteria are:

1. Completion of process evaluation into CLECC's workability and integration into existing work practices, sufficient to inform refinement and future implementation, and to inform future process evaluations.

2. Recruitment of sufficient wards (n=**8**) to assess the feasibility of a cluster RCT design to inform the design of a definitive evaluation, including information on participation and attrition rates, blinding strategies, mitigation of contamination, baseline rates and intra-cluster correlations for core outcomes, data collection and analysis procedures (see Appendix 1)

3. Recruitment or refinement of target numbers of staff, patients, carers to enable collection of data estimated to be sufficient to inform the selection and use of primary and other outcome measures in definitive evaluation (see Table 1 and Appendix 1).

Ethical considerations

Our concern in this study is to keep the best interests of participating patients, visitors, and NHS staff at the centre of what we do. We have included a number of measures to help ensure this and have carefully consulted with our PPI group and nursing representatives about our proposals over a two year period. We think what we have proposed is proportionate, does not place undue burden on participants at any part of the process and represents what we think is achievable as a research team working within limited resources, but anxious to extend the amount of high quality research into care for this important group. This is a feasibility study so there is the opportunity to pilot procedures and to develop and change them if we need to.

One key ethical issue is the recruitment of and proposed data collection from patients and family (or other) carers at what can be an already stressful time. The key measures we have developed to address this are: concisely written information accompanied by verbal explanation and the chance to ask questions, including in written and verbal information the clear statement that people are not obliged to take part and their care or treatment will not be affected in any way if they refuse or withdraw, allowing people as much time as they need to make their mind up about taking part, giving people help with completing questionnaires if they need it, keeping questionnaires brief, ensuring

research team members have skills to identify distress caused by recruitment and/or data collection processes and have clear plan of action to follow if this happens.

Another ethical issue is the desire to include people who may lack the capacity to make the decision to take part in the research (see earlier section). We think this is important because this group is often excluded from research and yet evidence suggests that they are most vulnerable to not experiencing compassionate care. It is vital that we use this study to help understand how to develop compassionate care for this group, and to develop meaningful outcome measures to detect differences in a future definitive evaluation. We have clear procedures in place to ensure that the principles of the Mental Capacity Act are adhered to.

A further potential issue is the participation of ward staff as research subjects and the concern that may be raised about their rights to refuse to take part or to withdraw from the study. Our communication strategy should ensure that everyone who should know about the study is informed about it and their right to not take part.

Training for observers and interviewers will emphasise issues relating to the anonymity of staff, visitors and patients. Researchers will respect the anonymity of staff and will not report details of interactions to any third party unless such interactions constitute unsafe practice defined as "incompetence, misconduct or other unsafe practice that a registered practitioner would feel obliged to report to the manager of the individual involved if working in a practice capacity".

Dissemination and projected outputs

This research provides an important foundation to developing an evidence base to inform the NHS on how to improve the standards of compassionate care delivered to older people. The major outputs will be the findings from the process evaluation, particularly the qualitative work on intervention implementation, and the use of these findings to refine the intervention where needed, and develop a training manual and associated toolkit to provide a standardised intervention package. In collaboration with the Wessex AHSN Centre for Implementation Science, and guided by the findings from this study, we will develop a manual and toolkit using a variety of formats (e.g. written guidance, podcasts, narrated powerpoints) and will also link to other relevant resources already developed, to guide NHS teams implementing CLECC and to provide resources to support its implementation. Providing that results indicate that the intervention is feasible, findings from the study will inform the design of a future definitive multi-centre cluster RCT with process and economic evaluations. At the close of the study we will hold a stakeholder workshop for nursing directors from English trusts to share findings and test potential engagement and interest to participate in a definitive trial. We plan to hold the workshop alongside the annual NHS England CNO conference to maximise attendance. It will be facilitated by the CLECC research team and practitioners from this study's NHS sites. We will evaluate the workshop, capturing delegates' interest in the model and their preferred level of involvement in the full trial. This information will then be used to devise a recruitment strategy for the full trial, and a mailing list for future publications, materials, and dissemination activities. We will seek publication of findings in research and practice journals to reach the widest possible audience, and maximise use of open access publications by targeting journals which offer this. We will also take opportunities to present at research / professional conferences and seminars locally, nationally and internationally as they arise. We will work with professional and clinical leads at DH and NHS England, and with Skills for Health and Health Education England to ensure that relevant qualitative findings about, for instance, workplace learning, inform future workforce development strategies. In addition to NIHR full study report, executive summary, journal publications and conference presentations, planned outputs include: (1) standardised CLECC intervention package: multimedia training manual and toolkit to guide implementation of CLECC in NHS organisations; (2) funding application for a definitive evaluation, in collaboration with NHS sites committed to participating; and (3) short report of study findings and link to project website on websites of the following organisations: SCIE Dignity and NHS England Compassion in Practice portals, RCN Older people website/portal, the Dementia UK website, British Geriatrics Society, National Mental Health Development Unit (Let's Respect), My Home Life network for UK care homes.

Study Timetable

Study preparation 12/2014-03/2015
Phase 1
Baseline data collection wards A1 03/2015-04/2015
Randomise wards 01/05/2015
Prepare intervention wards for intervention 05/2015
Intervention (to intervention wards) 06/2015-09/2015
Qualitative interviews 06/2015-03/2016
Follow-up data collection A2 02/2016-03/2016 A3 07/2017-09/2017 A4 04/2018-06/2018
Phase 2
Baseline data collection wards 07/2017-09/2017
Prepare Phase 2 wards for intervention 09/2017
CLECC2 intervention 10/2017-12/2017
Qualitative interviews 10/2017-03/2018
Follow-up data collection 04/2018-06/2018

Data analysis 05/2015-10/2018
Targeted communications, peer review publications and conference presentations 05/2016-12/2018

Appendix 1: Parameters for Feasibility Study

Parameter	Assessment	Comment
Intervention workability and fidelity	Qualitative process evaluation using interviews and observation. Record of amount of training delivered – register of attendance at classroom training, learning sets, ward cluster, reflective group discussions, cluster discussions. Cost estimates.	Assessment of workability and integration of CLECC into working practice to inform CLECC development and future implementation and evaluation.
Target sample	Extent to which target sample specified in protocol is achieved for number of wards, nurse/patient/carer surveys returned, nurses/patients/carers recruited to qualitative interviews, planned number of QUIS observations proceeds.	Inform trial design, recruitment strategy and outcome measure selection in future trial.
Ward participation	Proportion of ward managers invited on behalf of eligible ward nursing team to take part who agree versus those who refuse	Document ward manager rationale for participation/refusal. Inform recruitment strategy/design of future trial.
Ward attrition	Proportion of wards who agree to take part who then complete their participation (baseline, intervention, follow-up) versus those who do not	Document stage of withdrawal and reason. Inform design and implementation of future trial.
Staff/patient/carer participation in qualitative interviews	Proportion of eligible staff/patients/carers invited to qualitative interview who agree to take part, versus number invited who decline to take part	Document reason for not participating. Identify any systematic differences between responders and non-responders. Inform recruitment strategy in future evaluation.
Staff/patient/carer attrition from qualitative interviews	Proportion of eligible staff/patients/carers who agree to take part in qualitative interview for whom interview is completed, versus number who agree but for whom interview is not completed	Document reason for lack of interview completion. Inform design of future evaluation.
Patient/nurse/carer participation in written survey	Number of eligible individuals versus number approached. Proportion of patient/nurse/carer surveys distributed to eligible individuals that are completed and returned, versus those not completed/returned. Level of non-response in surveys. Level of partial completion of surveys.	Document reason for lack of recruitment or participation. Inform trial design/recruitment strategy/choice of outcome measures.
Older patient participation in written survey	Proportion of patient surveys distributed to eligible over 65s that are completed and returned, versus those not completed/returned.	Document reason for not participating. Inform sampling and recruitment strategy and outcome measure selection in future trial.
Patients with dementia/other cognitive impairment: participation in written survey	Proportion of patient surveys distributed to eligible patients known by staff to have a cognitive impairment that are completed and returned, versus those not completed/returned.	Document reason for not participating. Inform sampling and recruitment strategy and outcome measure selection in future trial.

Parameter	Assessment	Comment
Patient/carer assistance required to complete survey	Proportion of patients/carers who wish to complete a survey who require researcher or other help to complete the survey.	Document nature of help, who helped, how long survey took to complete. Inform future trial/outcome measure selection.
Patient/nurse/carer survey: time take to complete	Written record of time taken to complete on each survey copy.	Resource implications for future trial. Inform outcome measure selection in future trial.
Patient participation in QUIS observations	Proportion of eligible patients invited to take part in observations who agree observation can go ahead, versus patients who do not wish observation to go ahead.	Document reason for not participating. Inform outcome measure selection and recruitment in future trial.
Consultee agreement for patient without capacity to participate in QUIS observations	Proportion of consultees of eligible patients without decision-making capacity who agree for QUIS observations to go ahead, versus proportion who do not agree.	Document who consultee is and reason for refusal. Inform recruitment strategy in future trial.
Patient withdrawal from QUIS observations	Proportion of observations commenced, that are then discontinued on patient's request, staff request on patient's behalf or researcher's assessment of patient distress.	Document length of observation and reason for discontinuation. Inform outcome measure selection in future trial.
Staff participation in QUIS observations.	Proportion of planned observations that go ahead with staff implicit agreement, versus those that do not proceed because staff raise objection.	Document who raised objection and nature of objection. Inform outcome measure selection in future trial.
Staff cooperation with QUIS observations.	Proportion of observations commenced, that are then discontinued on request of member of staff.	Document length of observation and reason for discontinuation. Inform outcome measure selection in future trial.
Relative/carer participation in QUIS observations	Proportion of eligible relatives/carers invited to take part in observations who agree observation can go ahead, versus relatives/carers who do not wish observation to go ahead.	Document reason for not participating. Inform outcome measure selection in future trial.
Relative/carer withdrawal from QUIS observations	Proportion of observations commenced, that are then discontinued on request of relative/carer	Document length of observation and reason for discontinuation. Inform outcome measure selection in future trial.
Baseline and follow-up rates for QUIS, PEECH, PPE-15, JSE	Estimates of treatment effect and variance.	To inform outcome measure selection and calculate ICC, level of clustering, target effect size and sample size in future trial.

Parameter	Assessment	Comment
QUIS feasibility	Number of patients who can feasibly be observed simultaneously; actual numbers of interactions recorded over a given observation period; variation in interaction frequency / quality over days of week and times of day. Explore if staff responses to being observed change over time/other evidence that observations impact on behaviour.	To inform outcome measure selection, observation scheduling and time sampling in future trial.
Patient/carer survey: impact of ward allocation on responses	Explore after survey if individual respondents aware of ward allocation, and, if so, perceptions of impact on responses.	To identify bias to inform design and implementation of future trial.
QUIS observations: impact of ward allocation on ratings	Explore before and after observations if individual observers aware of ward allocation and, if so, perceptions of impact on responses.	To identify bias to inform design and implementation of future trial.
Recruitment: selection bias	Compare rates and characteristics of patients/carers invited to take part, and those recruited, between intervention and control wards.	To identify bias to inform design and implementation of future trial.
Data collection: comparison of levels of staff cooperation with data collection between intervention and control wards	Compare ward level rates of staff refusal to enable QUIS observations, responses to nursing surveys, help with identifying patient and carer recruits.	To identify bias to inform design and implementation of future trial.
Contamination from intervention to control wards	Staff movements from intervention wards to other wards in same hospital. Staff perceptions of contamination from intervention wards to other wards in same hospital. [Staffing records, ward manager interview]	To identify contamination to inform design and implementation of future trial.
Data management issues	Document implementation issues associated with data collection and other data management systems and processes.	To inform implementation of future trial.
Data analysis issues	Document issues identified during pilot of data analysis procedures for future trial: data quality issues, time for analysis, database issues, etc.	To inform outcome measure selection, data analysis plan and implementation of future trial.
Ethics and governance issues	Document ethical difficulties that arise and the response, lack of adherence to agreed ethics and governance procedures and rationale.	To inform design and implementation of future trial.
Adherence to protocol	Document instances of non-compliance with protocol and rationale. Document changes made to study protocol and rationale.	To inform design and implementation of future trial.

Appendix 2: Communication and recruitment pathway for patients and visitors

1. Display “ward information poster” in locations throughout the ward that are visible to patients and visitors.

Observations

2. Once the index patient has been randomly selected and nurse-in-charge agrees with their inclusion (see QUIS Appendix for further guidance), and other patients in observation field have been identified, all relevant patients will be approached.
3. Follow guidance for patients who lack capacity to make decisions where this is relevant.
4. Verbally explain about the study to each patient and any visitors present, providing copies of “Patient and visitor observations information sheet”.
5. If a patient or visitor declines to take part, observation will go ahead but no data will be gathered on that patient or visitor. If all patients in observation field decline, then another index patient is selected.
6. If one or more patients agree to take part, display “Ward information poster on observations” in clinical area where observation is planned.
7. At close of observation, verbally thank patients and visitors involved, and record in patient’s medical notes, and in researcher log about patients and visitors who agreed to take part or refused to take part.

Questionnaires

8. Distribute questionnaires and envelopes by hand to individual patients and visitors who express a verbal interest in completing one, following a brief verbal explanation and reference to the written information if this is helpful.
9. Give patients or visitors help with completing questionnaires if they need it.
10. Receive completed questionnaires by hand or collect from CLECC questionnaire return box.

Interviews

11. Following agreement from nurse-in-charge, approach eligible patients or visitors to verbally explain about the study, providing copy of “Patient and visitor interviews information sheet”.
12. Arrange to return to discuss further.
13. If they wish to take part, ask them to sign a consent form.

Appendix 3: Communication and recruitment pathway for staff

1. Distribute summary staff information sheet to all nursing staff.
2. Send summary information sheet to department/team managers of other staff groups likely to be visiting study wards.
3. Visit staff meetings/handovers to talk about study and answer questions.
4. Display “Information poster for nursing staff areas” in staff areas, using the version offering prize draw entry and coffee vouchers if sponsorship is in place.
5. Give “Staff observations information sheet” and/or “Staff interviews information sheet” to staff who would like to see more written information about the planned data collection.

Observations

6. Remind ward staff of observation during shift handover.
7. Display “Ward information poster on observations” in clinical area where observation is planned.
8. Before observation begins, remind staff allocated to that area that observation will be taking place and answer any questions.
9. If a member of staff objects, continue observation but do not record data about that staff member’s part in observations.
10. At close of observation, verbally thank staff involved and record in researcher log about staff agreeing or refusing to take part.

Questionnaires

11. With ward manager’s help and advice, distribute questionnaires and envelopes to individual members of staff, using ward system for distributing mail to staff.
12. Receive questionnaires by hand or collect from CLECC questionnaire return box.

Interviews

13. With ward manager’s help and advice, distribute “Staff interviews information sheet”, using ward system for distributing mail to staff.
14. Arrange to discuss study with staff who express an interest in being interviewed.
15. If they wish to take part, ask them to sign a consent form.
16. If insufficient people volunteer using above methods, then visit handover and ward meetings to remind the staff group about the study. This must not be targeted at individuals.
17. If insufficient people volunteer using the above methods, then after two weeks, the “Staff interviews information sheet” will be redistributed.

Appendix 4: Including adults lacking the capacity to consent[1]

Many past projects in acute hospital settings have excluded people unable to consent for themselves, or people where this is not clear. As a result, we understand little about the experiences of acute care of people who have a cognitive impairment. It is probable that individuals with a cognitive impairment are more vulnerable to assaults to their dignity, and the research team feels strongly that local and wider learning from this study needs to be inclusive of the views and experiences of people with a cognitive impairment. In addition, most people with a cognitive impairment like dementia want to be treated in the same way as others and as they were when they did not have dementia and want the opportunity to participate and be included.

This study will adhere to the five key principles of the Mental Capacity Act:

- Every adult has the right to make his or her own decisions and must be assumed to have capacity to make them unless it is proved otherwise.
- A person must be given all practicable help before anyone treats them as not being able to make their own decisions.
- Just because an individual makes what might be seen as an unwise decision, they should not be treated as lacking capacity to make that decision.
- Anything done or any decision made on behalf of a person who lacks capacity must be done in their best interests.
- Anything done for or on behalf of a person who lacks capacity should be the least restrictive of their basic rights and freedoms.

Members of the research team with skills, knowledge and experience in assessing capacity to decide to take part in research will recruit patients into the study and part of this process will include an assessment of capacity. This will usually be a research nurse. They will assess capacity by meeting and talking with the patient, reviewing medical notes and, if necessary, discussing the patient's capacity with others who know the patient e.g. key family member, other members of the clinical team. They will consider:

- "Does the person have a general understanding of what decision they need to make and why they need to make it?
- Does the person have a general understanding of the likely consequences of making, or not making, this decision?
- Is the person able to understand, retain, use and weigh up the information relevant to this decision?
- Can the person communicate their decision (by talking, using sign language or any other means)? Would the services of a professional (such as a speech and language therapist) be helpful?"

If the research team member determines that the person does not have the capacity to make a decision about taking part in the research, then they will identify an appropriate person to consult with in order to make a decision about including the potential participant in the research. A personal consultee will be sought in the first instance, that is, someone who cares for the potential participant or interested in their welfare. If a personal consultee cannot be identified, then a professional who is not connected to the research will be nominated and consulted. The consultee or legal representative will be nominated if they are able to represent the person's presumed will and give an opinion about what they think the person decide if they had the capacity to make their own decision. The research team member will provide the consultee with information about the study and ask them:

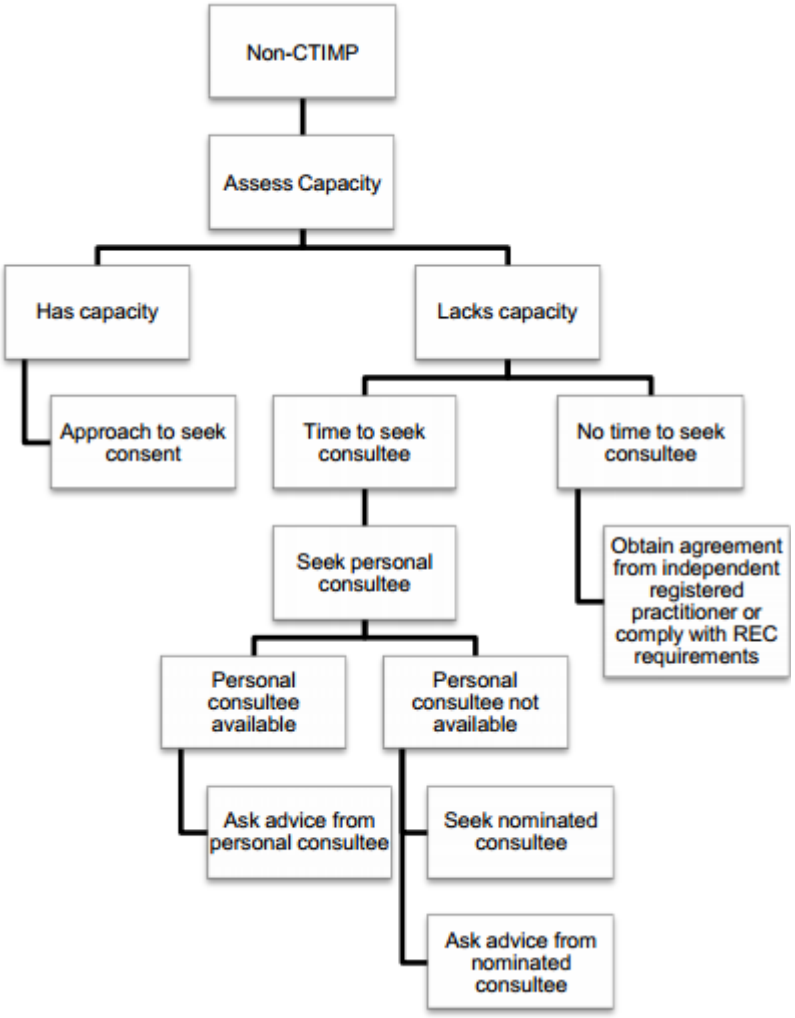
[1] Material in this appendix is drawn from learning materials and resources in on-line GCP training module "Informed Consent Involving Adults Lacking Capacity".

- for advice about whether the person who lacks capacity should take part in the project, and
- what they think the person's feelings and wishes would be, if they had capacity to decide whether to take part."

The consultee will be informed about all aspects of the study which are relevant to their decision and given as much time as they need to consider their decision. Consultee information sheets will be used which also include a clarification of their legal obligations under the Mental Capacity Act.

Once the consultee has given their advice to the research team the process and outcome of finding an appropriate consultee will be documented in the participant's patient notes. This will include details of the advice the consultee gave including their reasons for coming to the conclusions they have. When making the decision about including the potential participant in the research, the research team member will take into account the consultee's advice and any previous wishes or feelings expressed about taking part in research of this kind.

Figure 1: NRES decision tree: adults lacking capacity to consent to research



Even if the decision is made to include someone who lacks capacity, if they subsequently indicate verbally or otherwise that they are unhappy with taking part or with any aspect of data collection taking place, in spite of appropriate explanation and reassurance by a member of the research team, then data collection will be halted. Data gathered up to that point will be retained and used in the

study. Capacity to make decisions can fluctuate and, if a participant loses capacity during the study, then the above procedures will be followed to identify a suitable consultee.

Process Consent

Measures outlined here are based on guidance from Department of Constitutional Affairs on the 2005 Mental Capacity Act and Dewing's guidance on methods of process consent with persons who have dementia. The approach and method developed by Dewing have been approved by various research ethics committees in universities and health care provider organizations such as NHS Trusts across the UK, Republic of Ireland and Australia in recent years. The chief investigator has worked closely in the past with Professor Dewing to ensure that the methods outlined here meet the guidelines concerning process consent with people who have dementia. This proposal extends the same principles to approaching and dealing with individuals who have other impairments, particularly those with a brain injury like a stroke.

Briefly, process consent is based on the fact that (1) many people with dementia (or other cognitive impairments) retain a residual capacity for making choices and communicating assent or dissent even after the legal threshold for capacity has diminished and been assessed as lacking. (2) people with dementia (or other cognitive impairments) can improve their capacity in certain situations and environments (3) most people with dementia (or other cognitive impairments) want to be treated in the same way as others and as they were when they did not have dementia and want the opportunity to participate and be included. In this way process consent is adhering to the key principles of the assumption that capacity exists and acting in the best interests of the person and restricting their fundamental human freedoms as minimally as possible.

Process consent recognizes that once the legal threshold has been crossed that informed cognitively based consent is no longer possible and instead works on the basis of the person with dementia (or other cognitive impairment) making choices based on other criteria. Process consent draws on how the person makes and communicates their choices and preferences in everyday situations and uses this as a basis for negotiating consent/assent and for knowing when the person is not consenting and is dissenting. Thus the key criteria for excluding anyone with a dementia is an inability to make known and communicate their choices and preferences either verbally or non-verbally. Process consent enables others such as clinical staff and relatives to contribute and thus ensures that the choices of the person are clearly understood.

Using these guidelines will ensure that legal requirements are met, in addition to a person-centred focus for the researcher's judgement and behaviour, so that acts and omissions by the researcher serve to promote or maintain patient well-being as a primary focus.

All members of the research team will receive training in the 2005 Mental Capacity Act. These individuals will also receive additional training in using process consent, applying the Mental Capacity Act in relation to research and dealing with the likely challenges that will be faced. This approach will ensure that these researchers have the necessary skills to use the guidance of the Mental Capacity Act to determine an individual’s capacity to consent. It will also help ensure that patients have the benefit of specialist skills as the project is explained to them, and as their potential part in it is discussed and negotiated. These discussions may need to take place on more than one occasion, depending on the individual’s capacity. These researchers will also have specialist supervision made available to them, to enable them to raise difficulties or issues of concern with dealing with this client group.

The following steps will take place once a capacity issue has been identified, a consultee consulted and the decision made to include the individual concerned in the research. Before they meet with the patient, the researcher will, as a minimum have established, through discussions with staff who know the patient, or with significant others, patient cues that indicate a state of well-being. This is to ensure that the patient is in a state of well-being when initially approached and in subsequent interactions. Secondly, the researcher will establish capacity to consent. This will involve considering:

- the individual's usual level of well-being/ill-being

- triggers that decrease level of well-being

- how person usually consents or not to range of daily living activities

- existing assessments or opinions on capacity from clinical staff who know the individual and from consultees/family members

In addition the researcher will:

- Make every effort to communicate with the person to explain what is happening

- Make every effort to try to help the person make the decision or make a choice in question

- See if there is a way to explain or present information about the decision in a way that makes it easier to understand. If the person has a choice, ask if they have information about all the options. Simplified or dementia sensitive written and pictorial information will be used.

- If applicable, see if the decision can be delayed to take time to help the person make the decision, or to give them time to regain the capacity to make the decision for themselves

- Find out if the person understands what decision they need to make and why they need to make it

- See if the person understands information about the decision and if they can retain it, use it and weigh it to make the decision

Means of conveying information about the project will vary depending on the individual's cognitive abilities and preferences for taking in information. The level of qualification of the researchers will enable them to draw on a range of resources here including adapted written information or pictorial information.

If an individual is judged to lack the capacity to consent to the research, their objections, wishes and feelings about the project will still be respected. The individual patient's interests will take primacy over any need to undertake the research, and any objections that the individual patient makes or indicates will be interpreted as a desire to withdraw from the study – even where the consultee had assessed that the person would wish to take part.

Finally, ongoing process consent will be renegotiated and documented at each encounter between the research team and the patient. This may also be necessary on more than one occasion during a single encounter with some patients, if for instance, levels of awareness fluctuate or the patient is distracted.

All researchers will have received training in the Mental Capacity Act (2005). If, during the process of introducing the research, getting consent, or undertaking data collection with any person, a researcher suspects that the potential/actual participant does not have the capacity to consent, they will cease the activity in which they are engaged, offering an appropriate explanation to the person. The steps above will then be followed.

Appendix 5: Guidance on managing distress during an interview

There may be occasion when interviewees become upset and distressed during the course of an interview. It is important that the interviewer is prepared to manage such a situation appropriately.

The points listed below may help the interviewer to manage such a situation.

• Turn off the recorder.

• Respond appropriately according to the circumstances or level of distress.

• Offer to restart when and if the interviewee is ready.

• Offer to finish or stop the interview.

• If the interviewee lives alone, ask the interviewee if they would like the interviewer to contact a relative or friend to be with them.

• The interviewer should offer appropriate contacts taken from the locally agreed contacts list. The contacts list will be prepared prior to starting any interviews and will be taken by the interviewer to each interview. This will contain local contact details of groups, organisations and key personnel who can offer different types of support.

• Leave the interviewee only when it is felt that the situation appears calmer.

• If there is on-going concern about the interviewee's distress, it would be appropriate to let the interviewee's doctor or nurse know, after obtaining their permission.

• Make follow-up call within 24 hours to check if interviewee's concerns remain. Reiterate the suggested contact source if necessary.

• Document situation which should be attached to the consent forms and held centrally

Appendix 6: Guidance on critical incident reporting

Prior to their involvement in data collection, all members of the research team involved in gathering and handling research data will receive training in identifying and responding appropriately to unexpected events during observations such as patient anxiety, dangerous practice, patient safety breaches. The training will include the presentation of a number of scenarios representative of those that may occur during data collection, and the discussion of appropriate responses in these situations. This training will ensure a consistent approach to incidents that occur or that are suspected, ensuring local policies and procedures are followed, and that patient interests are paramount in decisions taken. Participant information sheets will also clearly set out the procedures to be followed, to ensure that patients/visitors and staff are aware of the researcher's obligations and the implications of this.

While undertaking observations of care or interviews, the delivery of an unacceptable standard of clinical practice may become apparent or be strongly suspected by one or more members of the research team. Such incidents will be classified as either sub-optimal or unsafe practice.

Sub-optimal practice
Observers may witness events or interactions which they do not consider represent 'best practice', but which do not pose a direct and immediate risk to patients or others. This includes observations that are rated as "negative" using the QUIS tool. In such circumstances researchers will use a 'manager test' in order to determine how to proceed.

The manager test: If the researcher were working clinically as a registered practitioner in the clinical setting and observed the incident in question (incompetence, misconduct or other unsafe practice), is it of such severity that they would they feel obliged to report the incident to the manager of the individual involved? If yes, this is defined as unsafe practice, and the guidelines below would be followed. If no, no further action would be taken.

Unsafe practice
This is defined for the purposes of this study as incompetence, misconduct or other unsafe practice that a registered practitioner would feel obliged to report to the manager of the individual involved if working in a practice capacity. (Note this is a higher test than whether a professional would simply discuss the incident with that person directly). This will include any behaviour that is clearly illegal or dangerous, placing individuals at direct risk of harm.

Unsafe practice is likely to be a very rare occurrence. If it does occur, the research team member will take the following actions:

If unsafe practice is observed/suspected during an observation of care or research interview:
1. Halt the observation or interview.
2. Explain to the patient/visitor/staff member that the practice must be reported due to its potentially serious nature and it may not be possible to maintain anonymity.
3. Outline the process for doing this (use local Trust reporting system).
4. Terminate the observation session and follow the guidelines below.

Guidelines for taking further action:

• The patient/visitor/staff member is given the required time and support and empathic approach to the issue.
• The patient/visitor/staff member is given a thorough explanation of the course of action required to ensure the event is fully investigated and acted upon.
• The patient/visitor/staff member is treated with respect and dignity at all times.
• The researcher maintains responsibility for keeping the patient/visitor/staff member informed and involved where appropriate, until the incident is reported to senior trust personnel.
• The patient/visitor/staff member is offered support and guidance in line with research governance.
• The researcher collates the necessary information from the patient/visitor/staff member to report to the most appropriate senior personnel in order to take further action.

Although this response would breach the assumption of confidentiality, it is considered that the potential benefit to others should outweigh the desirability of maintaining anonymity.

Appendix 7: Protocol for use of Quality of Interaction Schedule

The Quality of Interaction Schedule (QUIS) is a time sampling tool that gives a measure of both the volume and quality of interactions[38]. Interactions with patients are coded as positive social, positive care, neutral, negative protective and negative restrictive. QUIS has been used in a number of studies in acute care settings and is sensitive to changes in service quality [38, 40, 42]. This protocol outlines its intended use in the CLECC feasibility study. This will enable an assessment of the feasibility of this protocol.

Observations will be undertaken **1**-12 weeks *before* the CLECC implementation period, and 4 months**, 22 months and 32 months** *after* its end. This observation-based measure will be administered by an individual trained in its use. Training will include: assessing patient capacity to make decisions about taking part in research, providing clear information to patients with cognitive and/or communication impairment, obtaining informed consent from patients, using measures and recording measurements, identifying and responding appropriately to unexpected events during observations such as patient anxiety, dangerous practice, patient safety breaches. Observations of all interactions with eligible patients will cover 2 hour periods from 8am to 10pm on weekdays. The 2 hour time period is chosen based on experience to manage observer fatigue. Two periods of observation will be undertaken per day with a 2 hour rest period between. Our previous experiences with QUIS indicate that very high inter-rater reliability is achievable with the tool. Training the research team in the reliable use of the tool will clearly be crucial here and data collection will not commence until high reliability is achieved. We also plan to test inter-rate reliability at three time points following the commencement of data collection and to take corrective action if reliability rates fall.

Observation schedule

At each assessment period in each hospital (before and after) observation will be undertaken on pairs of control and intervention wards over a period of 2 weeks (10 hours per week per ward) on 5 week days with 2X 2 hour sessions of observation per day (4 hours total observation per day across two wards). Observers will have a rest period of 2 hours before commencing another observation session. Ward staff, patients and visitors will need to be aware in advance that the observations will be taking place but not the specific time of observations planned for that day or the ward areas of patients to be observed.

The periods to be observed will be chosen at random according to the following schedule:

Days 1-5: First observation start time is selected randomly (8am to 10pm) using a preprogramed excel spread sheet using random number function. This is the index start time (i). The ward (C or I) for this observation will also be identified randomly. The second observation period for that day will commence 4 hours after the randomly selected time. IF the second observation would be scheduled to end after 22.00 THEN the second observation is undertaken earlier in the day, @ 8+ (4-(20-i).

Day 6-10: The observation schedule for week 1 is repeated with wards with allocation to I & C reversed so that I&C wards are observed on matched time periods.

Observation procedures

Prior to commencing the observation period a research team member will identify eligible patients. One patient will be selected from the list of eligible patients *at random* as the index patient. This will be achieved by matching the alphabetically ordered list against a random number table. The observer will then check with the nurse in charge if there is any specific reason that this patient should not be observed – reasons for excluding a patient would be terminal care or any exceptional ethical objection to observation. If the patient is excluded the patient will be removed from the list and the selection repeated.

The observer will identify a discrete location where interactions for the index patient can be observed, identify other eligible patients who could be observed simultaneously from that position and introduce themselves to *all* the patients in the observation field. Their non-participant status will be explained. Patient objections will be respected and another observation site chosen/index patient selected if the

index patient refuses to take part. As far as is practical all staff members will be informed about the nature of the research and given assurances of confidentiality within the bounds of the law and provided that there is no immediate threat to patient safety. Staff will not be informed which patients are being observed, although it may be possible for them to tell if, for instance, a patient involved in an observation is located in a single room.

In our experience with QUIS, the level of interactions does tend to be low and so observing more than one patient is feasible. We will flag index patient data to enable us to compare index patient data with other patient data, to enable us to identify bias and to adjust the protocol if needed.

Once observation commences all interactions between staff and patients will be recorded on a tablet computer. The presence of others in the room (e.g. visitors) will also be recorded. Observed interactions will be time stamped with a start and end time.

An interaction will be deemed to have begun:

a) when a member of staff enters the immediate proximity of the patient and directs their attention to them, either through speaking, demonstrably listening or making physical contact with them OR
b) when a member of staff communicates with the patient verbally by directing comment, instruction or a question directly to the patient either as an individual or as part of a group of patients.

An interaction will be deemed to have ended when the member of staff is no longer directing attention to or making contact with the patient, whether they remain in the vicinity of the patient or not.

For each interaction the following will be recorded: One of five QUIS categories (listed here a-e):

a. Positive social

Interaction principally involving 'good, constructive, beneficial' conversation and companionship:

- Greetings directed to individuals
- General chat and conversation, on its own or during other social and physical care activities
- Offering choices (e.g. food, drink, nail colour)
- Serving food while saying what it is, asking if subject likes it, who made it, etc.
- Offering more food/asking if finished, only if carer waits for a response
- Verbal explanation, encouragement and comfort during other care tasks (lifting, moving, walking bathing, etc.) that is more than necessary to carry out the task

b. *Positive care*

Interactions during the appropriate delivery of physical care:

- Toileting, bathing, medication, feeding, etc. These may involve brief verbal explanations and encouragement but only that necessary to carry out the task. No general conversation.
- Keeping safe or removal from danger with explanation and reassurance

c. *Neutral*

Brief, indifferent interactions not meeting the definitions of the other categories:

- Putting plates down without verbal or non-verbal contact
- Undirected 'good morning/hello/goodbye'

d. *Negative protective*

Providing care, keeping safe or removing from danger, but in a restrictive manner, without explanation or reassurance:

- 'Don't eat that, it's been on the floor'
- 'Don't hit X'
- Being told to wait for medication/treatment
- Being fed too quickly

e. *Negative restrictive*

Interactions that oppose or resist residents' [patients'] freedom of action without good reason, or which ignore resident [patient] as a person:

- Being moved without warning or explanation
- Told to do something (e.g. button dress) without discussion, explanation or help offered
- Being told can't have something (e.g. cup of tea) without good reason/explanation
- Being told not allowed to swear/show anger
- Being sworn at or physically assaulted

Interactional content will also be recorded:

Physical care:

- medication administration
- nutritional care
- hygiene & toileting
- nursing / medical procedures (e.g. dressings)
- transfer
- mobilising
- other

Communication:

- One way – staff member to patient with no dialogue established
- Two way – patient initiated (there is at least one contribution by patient and the staff member)
- Two way – staff initiated (there is at least one contribution by patient and the staff member)

Staff groups (registered nurse, health care assistant, other, unknown) will be recorded.

All interactions with all patients will be recorded. Where several people interact with one patient simultaneously a summary interaction will be recorded ending when the last staff member withdraws attention. The variety of staff groups involved will be recorded but not the number.

Other information to be recorded includes:

Patient – age, gender, dementia diagnosis, in bed/chair, agitation level, asking for help

Bed layout, how many patients on ward, how many staff on duty

Significant events during observation – e.g. patient deterioration, patient fall, patient leaves ward, intervention from observer, observation stopped and reason.

Other relevant events – patient falls asleep, visitors arrive, curtains get drawn.

Does observer think this is intervention/control ward.

Where interactions occur simultaneously with several patients the interaction that commenced first will be recorded in detail. If detail of the other interactions cannot be recorded at the same time an entry will be made for the interaction with detail recorded as 'missing'.

When the curtains are drawn around a patient, the observer will remain seated outside of the curtains and will use what is heard (words, sounds, tone of voice) to rate the interaction.

If patients request assistance from the observer, in the first instance, the observer will remind the patient of their status and request the patient await attention. If the situation is urgent or the patient is insistent or distressed then the observer will interrupt observation to inform the relevant nurse and record any subsequent interaction as 'observer initiated'. Should behaviour from staff that is illegal or dangerous be observed the observer will immediately inform the nurse in charge. If a patient becomes distressed as a result of the observation, the researcher will explain about the study again if appropriate and seek agreement to continue observing. If at any time, a patient involved in the observation shows distress apparently related to the observation or indicates verbally or non-verbally that they do not wish the observation to continue, then the observation will be terminated.

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