The CHAT study (feasibility cluster RCT) protocol

Can Healthcare Assistant Training improve the relational care of older people? A development and feasibility study of a complex intervention

Version	2
Date	9.2.2015
Sponsor	University of East Anglia (UEA)
ISRCTN	10385799
NRES #	162616

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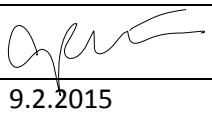
Signature	
Date	9.2.2015

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1 Administrative information

This document is based on the Norwich Clinical Trials Unit (NCTU) Protocol Template Version 2.0. It describes the NIHR Health Services and Delivery Research programme funded CHAT study (12/129/10) which is sponsored by UEA and facilitated by NCTU.

It provides information about procedures for entering participants into the trial, and provides sufficient detail to enable: an understanding of the background, rationale, objectives, trial population, intervention, methods, statistical analyses, ethical considerations, dissemination plans and administration of the trial; replication of key aspects of trial methods and conduct; and appraisal of the trial's scientific and ethical rigour from the time of ethics approval through to dissemination of the results. Every care has been taken in drafting this protocol, but corrections or amendments may be necessary. Any corrections or amendments will be circulated to all principal investigators (PIs) and researchers (RAs) working on the trial. The protocol was reviewed by the Norwich Clinical Trials Unit through their formal protocol review procedure.

1.1 Compliance

The trial will be conducted in compliance with the approved protocol, the Declaration of Helsinki (2008), the principles of Good Clinical Practice (GCP) the UK Data Protection Act, and the National Health Service (NHS) Research Governance Framework for Health and Social Care (RGF). Agreements that include detailed roles and responsibilities will be in place between participating sites and NCTU.

The Study Manager (SM) will inform NCTU by phone or email as soon as they are aware of a possible serious breach of compliance, so that NCTU can fulfil its requirement to notify the trial sponsor. The Chief Investigator (CI) and NCTU Director will assess whether or not the breach is 'serious'. For the purposes of this regulation a 'serious breach' is one that is likely to affect to a significant degree:

- the safety or mental integrity of the HCA and patient participants in the trial, or
- the scientific value of this feasibility trial.

1.2 Sponsor

UEA is the trial sponsor and has delegated responsibility for the overall management of the CHAT feasibility cluster RCT to the Chief Investigator (with support from the SM and NCTU) including the delivery of the trial to time, target and within budget.

1.3 Structured trial summary

Public title:	Can Health Care Assistant Training improve the relational care of older people?
Scientific title:	Can Health Care Assistant Training improve the relational care of older people?: A development and feasibility study of a complex intervention
Acronym:	CHAT
Primary registry and trial identifying number	ISRCTN
Source of monetary or material support	National Institute for Health Research, Health Services and Delivery Research programme grant number 12/129/10
Sponsor	University of East Anglia
Contact for public queries	chat.study@uea.ac.uk
Contact for scientific queries	chat.study@uea.ac.uk
Country of recruitment	England
Disease/condition/study domain	Healthcare of older people
Intervention	HCAs in wards randomised to relational care training will receive two one-day training sessions approximately one week apart. Training will be delivered by HCA trainers based at each of the participating hospitals. Day 1 will introduce and begin to explore aspects of relational care for older patients. At the end of Day 1 HCAs will also be asked to undertake brief unstructured individual study prior to Day 2 and further training support in the form of e-learning will also be available by computer and mobile device. Day 2 will build upon Day 1 and explore further aspects of relational care. HCAs in wards not randomised to relational care training will receive 'training as usual', typically restricted to periods of staff induction or focussed on mandatory training requirements such as manual handling.
Key entry criteria	Ward inclusion criteria: general medical (including stroke) or care of the elderly/older people wards. HCA inclusion criteria: healthcare assistants working either full time or part time within enrolled wards. Patient inclusion criteria: patients aged 70 years or over and discharged from an inpatient stay on an enrolled ward during the four-week baseline period and patients aged 70 years or over and discharged from an inpatient stay on an enrolled ward during the four-week follow-up period. Trainers: Trust based trainers that delivered the training intervention to HCAs Ward exclusion criteria: specialist dementia wards; medical admissions units

	HCA exclusion criteria: healthcare assistants who are employed as bank staff and are not part of the named staff on the ward roster. Patient exclusion criteria: patients transferred to another ward or hospital prior to discharge or considered by the nurse-in-charge not to have mental capacity (according to the Mental Capacity Act 2005) or to be in the final stages of a terminal illness.
Study type	Multicentre feasibility cluster randomised controlled trial.
Study hypothesis	The study will test whether it is feasible to deliver and measure the effect of healthcare assistant training in the relational care of older people within acute hospitals in England using a cluster RCT
Date of first enrolment	Anticipated March 2015
Target sample size	12 wards, 84 HCAs, 200 patients, 3 trainers
Primary outcome	The primary outcome measure will be at the patient level. Patient outcomes will be measured using the Patient Evaluation of Emotional Care during Hospitalisation (PEECH) inventory. Completion may be by patient or proxy.
Secondary outcomes	Secondary outcome measures will be taken at the level of ward and individual HCA. Ward outcomes will be captured using the Quality of Interaction Scale (QUIS) observation tool. Ward interactions will be rated by an observer (the local RA). HCA outcomes will be captured using a self-report questionnaire including: 1) The Toronto Empathy Questionnaire (TEQ) to measure change in empathy. 2) The age group evaluation and description (AGED) inventory to measure change in attitude towards older people. Patient outcomes To assess quality of life the EQ-5D-5L will be used. Additionally, HCAs in the intervention arm and Trust-based trainers who delivered the intervention will be interviewed by local RAs post intervention to examine the acceptability of the intervention to trainees and trainers respectively.

1.4 Time and events table

Stage	Level	Activity	Event timing in relation to randomisation (R) in weeks																				
			R-4	R-3	R-2	R-1	R	R+1	R+2	R+3	R+4	R+5	R+6	R+7	R+8	R+9	R+10	R+11	R+12	R+13	R+14	R+15	R+16
Enrolment	Trainer	Informed consent for interview														x	x	x	x				
	Ward	Inclusion/ exclusion criteria	x																				
	Ward	Ward manager agreement	x																				
	Ward	Random allocation					x																
	HCA	Inclusion/ exclusion criteria by RA	x	x	x	x																	
	HCA	Informed consent for training/ interview	x	x	x	x										x	x	x	x				
	Patient	Inclusion/ exclusion criteria by nurse-in-charge and research nurse	x	x	x	x										x	x	x	x				
Pre-intervention measures	Trainer	Train the trainer						x	x	x	x												
	Ward	Observation	x	x	x	x																	
	HCA	Questionnaire 1	x	x	x	x																	
	Patient	Invitation or telephone interview		x	x	x		x															
	Patient	Reminder				x		x	x	x													
Intervention	HCA	TAU/Training										X	X	X	X								
Post-intervention measures	Trainer	Interview																		x	x	x	x
	Ward	Observation														x	x	x	x				
	HCA	HCA questionnaire (R+9 weeks)														x							
	HCA	HCA questionnaire (R+13 weeks)																		x			
	HCA	Interview																		x	x	x	x
	Patient	Invitation packs or telephone interview															x	x	x	x			
	Patient	Reminder																	x	x	x	x	

1.5 Roles and responsibilities

1.5.1 Role of trial sponsor, those with major delegated activities and funders

Name	Role
UEA	Sponsor – overall responsibility for the conduct of the study
NIHR HS&DR	Funder – responsibility for trial design and funding
Norwich CTU	Supporting role in design, data collection, trial conduct, analysis and dissemination
CI	Responsible for aspects delegated by sponsor
Study Manager	Responsible for day-to-day management of the study

1.5.2 Trial Team

Name	Affiliation	Role and responsibilities
Antony Arthur	UEA	Chief Investigator/PI Norwich
Heather Wharrad	UoN	Principal Investigator, Nottingham
Jill Maben	KCL	Principal Investigator, London
Andrew Walker	UEA	Clinical trials operations manager
Clare Aldus	UEA/NCTU	Researcher/Study Manager
Marcus Barker	UoN	Researcher
Sophie Sarre	UoN	Researcher
Allan Clarke	UEA	Statistician
Anthony Dyer	NCTU	Head of Data Management
Garry Barton	NCTU	Health Economics

1.5.3 Trial Management Group

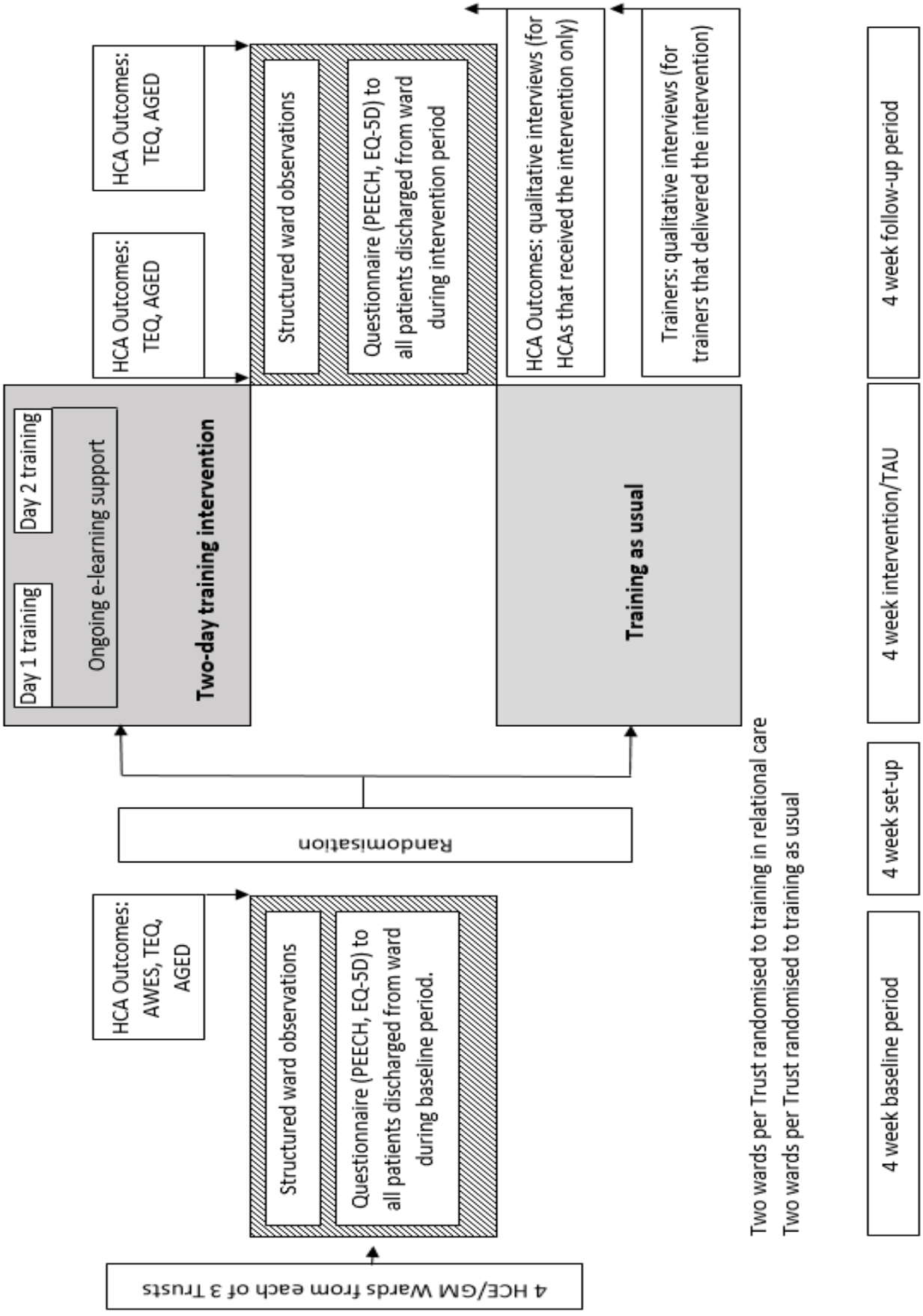
Name	Affiliation	Role and responsibilities
Antony Arthur	UEA	Chief Investigator
Heather Wharrad	UoN	Principal Investigator
Jill Maben	KCL	Principal Investigator
Garry Barton	UEA	Co-investigator
Karen Cox	UoN	Co-investigator
Justine Schneider	UoN	Co-investigator
Caroline Nicholson	KCL	Co-investigator
Clare Aldus	UEA	Study Manager/Researcher
Marcus Barker	UoN	Researcher
Sophie Sarre	UoN	Researcher
Nynke Hardy	NNUH	Trust representative

Name	Affiliation	Role and responsibilities
Nicky Hayes	KCH	Trust representative
Jo Cooper	NUH	Trust representative

1.5.4 Trial Steering Committee

Name	Affiliation	Role and responsibilities
Karen Spilsbury	York University	Independent Chair
Jackie Bridges	University of Southampton	Expert advisor
Tanis hand	RCN	Expert advisor
Gail Adams	UNISON	Expert advisor
Bev Fitzsimons	The King's Fund	Expert advisor
Jo Rycroft-Malone	Bangor University	Expert advisor
Sagila Thiruthanikasalan	Imperial College Healthcare NHS Trust	PPI HCA
Margaret McWilliams	PPIRes Norfolk	PPI Lay person
Janet Gray	PPIRes, Norfolk	PPI Lay person
Statistician	tba	Statistician
Antony Arthur	UEA	Chief Investigator
Heather Wharrad	UoN	PI Nottingham
Jill Maben	KCL	PI Nottingham
Health economist	tba	Health economics

2 Trial diagram



3 Abbreviations

AGED	Age Group Evaluation & Description Inventory
AWES	Assessment of Work Environment Schedule
CHAT	Study acronym: Can Healthcare Assistant Training improve relational care?
CI	Chief Investigator
EQ5D	Euroqol 5-Dimension questionnaire
GCP	Good Clinical Practice
HCA	Healthcare assistant
HS&DR	Health Services and Delivery Research
ISRCTN	International Standard Randomised Controlled Trial Number
KCH	King's College Hospital
KCL	King's College London
NCTU	Norwich Clinical Trials Unit
NIHR	National Institute of Health Research
NNUH	Norfolk and Norwich University Hospital
NUH	Nottingham University Hospital
PEECH	Patient Evaluation of Emotional Care During Hospitalisation
PI	Principal Investigator
PIN	Participant Information Number
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PPIRes	Patient and Public Involvement in Research
QA	Quality Assurance
QC	Quality Control
QMMP	Quality Management and Monitoring Plan
R	Randomisation
RA	Research Associate (University-based researcher)
RCT	Randomised Controlled Trial
R&D	Research and Development
SM	Study Manager
TEQ	Toronto Empathy Questionnaire
TMG	Trial Management Group
TMT	Trial Management Team
TSC	Trial Steering Committee
UEA	University of East Anglia
UoN	University of Nottingham
QUIS	Quality of Interactions Scale

4 Introduction

4.1 Background and rationale

4.1.1 The care of older people in acute settings

There has been increasing recognition of problems in the care of older people, particularly in hospital care. Evidence suggests that older people judge the care they receive in terms of the relational and values-based aspects of care such as kindness, compassion and respectful communication. Healthcare assistants (HCAs) deliver an increasing proportion of direct care to older people, yet their training needs are often overlooked.

Older people account for a large and increasing proportion of those receiving NHS acute care. In 2009/2010, people over the age of 75 years accounted for 23% of all hospital admissions, an increase of 66% from 1999/2000 with the average hospital stay for this age group decreasing from 15.4 to 11.0 days (The Information Centre for Health and Social Care 2010). The quality of care delivered to older people has come under increased scrutiny: a report by the King's Fund cites thirty two initiatives from statutory bodies, charities and campaign groups drawing attention to deficiencies in their care (Cornwell 2012). The King's Fund's Point of Care Programme was a response to a more general concern about 'not getting the basics right' in the delivery of care for older people (Goodrich and Cornwell 2008; Tadd, Hillman et al. 2011).

A fifth of inpatients surveyed by the Healthcare Commission did not feel that they were treated with respect and dignity at all times (Richards and Coulter 2007) and in complaints received about NHS care, the second highest area of concern related to the attitudes of staff (Leatherman and Sutherland 2008). Recently, the CQC review of services in 2012 found that they were 'struggling in areas such as dignity and respect, nutrition, care and welfare' (Care Quality Commission 2012) and the Patients' Association published 13 cases of care failures (The Patients Association 2012). The situation has been acknowledged by the Prime Minister's prioritisation of improving care standards in 2013 (BBC News 2013).

While patient-centred care is an explicit priority, there is a lack of clarity among staff at all levels as to what this actually means and how it can be practically implemented (Gillespie, D. et al. 2004). Emotional support, empathy and respect is the aspect of care considered by patients as most important (Richards and Coulter 2007). For patients, key elements of dignified care include respectful communication, respecting privacy, promoting autonomy, addressing basic needs in a respectful and sensitive manner, and promoting a sense of identity (Tadd, Hillman et al. 2011). Qualitative data from a previous NIHR Health Services and Delivery Research funded study of older patients with acute care needs has highlighted the importance of timeliness of care (particularly around toileting needs) and interest in the person, kindness, compassion and attending to 'the little things' (Maben, Adams et al. 2012).

4.1.2 Relational care and the work of health care assistants

The focus of the proposed study is the relational care provided to older people in hospital. Relational aspects of care include dignity, empathy and emotional support as distinct from functional or transactional aspects of care such as access, waiting, food, and noise (Robert, Cornwell et al. 2011). In a review of studies of older people and their relatives' experiences of acute care settings, it was the relational aspects of care that affected whether care experiences were perceived as good or bad (Bridges, Flatley et al. 2010). Three themes that underscored older people's understanding of relational care were identified in this review: older people's need for reciprocity ('connect with me'); maintaining their identity ('see who I am'); and sharing decision-making ('include me'). There is now a substantial body of evidence from which to conclude that older people place great importance on the relational aspects of their care and when this falls short, its absence is felt most acutely. What is needed now is to use this evidence to develop a cost effective values-based pedagogically designed

training intervention for HCAs, and see how and whether this can be tested using robust evaluative methodology.

Perhaps due to the nature of the work they do, nurses have often been targeted as both the problem and solution to concerns about loss of dignity for patients in hospital (Goodrich and Cornwell 2008). However, within the NHS, Band 2 and Band 3 support workers, often referred to as health care assistants (HCAs) have become an increasingly important section of the workforce, particularly in relation to older people with observational data suggesting that the proportion of their time delivering direct and indirect patient care is approximately 60%, nearly twice that of registered nurses (Bach, Kessler et al. 2012). Demographically, HCAs tend to differ from registered nurses, more closely resembling the ethnic diversity of the patient population they serve (Kessler and Heron 2010) and likely to be a more 'static' part of the workforce.

The problems of invisibility, marginalisation and subordination of the 'caring' work of nurses (Maben 2008) are likely to be perpetuated when delegated to HCAs whose work often gets little recognition from other staff groups (Schneider, Scales et al. 2010). Although investments in staffing and work environments are pre-requisites for high-quality care (Aiken, Sermeus et al. 2012; Maben, Adams et al. 2012), historically HCAs position as the 'untrained workforce' has led to an assumption that they are without training needs (Edwards 1997). This problem has been recognised by the Royal College of Nursing, which has established a forum for HCAs and by Skills for Health which is developing competencies for support workers. HCAs and nurses are largely in favour of more formal training for HCAs though a blurring of role boundaries is of concern to both staff groups (Coffey 2004). Between employing organisations there is a lack of consistency in HCA training and how HCAs interface with registered nurses (Maben and Griffiths 2008). HCAs often lack confidence in pursuing what few training opportunities that are available to them (Kessler and Heron 2010; Schneider, Scales et al. 2010). Ethnographic observational data of HCAs working in dementia wards suggest that support in carrying out such a challenging role is drawn from the formation of close-knit groups of HCAs which are sometimes marginalised from the wider ward team (V. Lloyd, Schneider et al. 2011) resulting in HCAs feeling disconnected from the organisation in which they work (Schneider 2010).

Training of HCAs has hitherto been ad hoc, variable, and marked by a tendency to focus on tasks and competencies with little attention paid to values-based training. The importance of using principles of instructional (pedagogical) design (Gagne 1985) to develop educational interventions is rarely considered. This is essential to ensure that training builds on existing knowledge and values, harnesses intrinsic motivation, and actively engages learners. Gagne's approach considers three domains: affective, cognitive and psychomotor, and is particularly suited to the values-based training intervention that will be developed as part of the proposed study. To date, evaluations of training interventions have been typically small scale and lacking in any comparative element (e.g. (Griffin, Arbuthnot et al. 2012)). This study will pilot a training intervention for HCAs, and investigate the feasibility of testing its effectiveness in a full-scale and definitive randomised controlled trial.

4.2 Potential benefits of the proposed study

The proposed study is located within the development and feasibility/piloting stages of the MRC model for the design and evaluation of complex interventions (Medical Research Council 2008). The aim is that by working with users and providers of acute hospital inpatient services for older people, and drawing on resources from other sectors, a training intervention that is theoretically coherent, explicit in its focus on relational care provided by HCAs to older people in acute hospital settings, and transparent in its key components can be tested. The evidence base in this area is lacking in robust evaluation studies yet it is too soon for a definitive trial. By conducting a feasibility cluster randomised controlled trial it will be clear whether a definitive trial is viable. If a trial is viable there will be a highly developed protocol, worked up ready to seek appropriate funding support. The protocol would be directly informed by evidence from our feasibility work using methods robustly tested to ensure that a future definitive trial would be a success.

The proposed study will produce a formally tested values-based training package which might be used in a variety of ways for research and service development.

4.3 Aim and objectives

The proposed study aims to assess the feasibility of a cluster randomised controlled trial to compare the performance of an HCA training package in relational care against current training in improving the care of older patients in acute NHS settings and to explore optimal methods for cost-benefit analysis for a definitive study. Important parameters that are needed to inform the feasibility of a definitive trial (and if feasible, then the design of such a trial) (NIHR Evaluation Trials and Studies Coordinating Centre 2012) will be estimated. These include:

1. The acceptability of the training intervention to HCAs, managers and other staff. The fidelity of trainers/HCA trainees to the intervention training package will be monitored as unanticipated problems may arise when the training intervention is being delivered. Follow-up interviews of HCAs and Trust-based trainers will also allow for a more detailed and reflective examination of how the training package was perceived.

2. The willingness of ward managers, HCAs and older patients to participate in the feasibility cluster RCT. Although preparatory work has been undertaken in securing agreement with Directors of Nursing, at each Trust the viability of a definitive randomised controlled trial will depend on the agreement of ward managers, HCAs and older patients to take part in the study. How identification of potential participants translates to participation at each of the three levels of analysis – ward, HCA, patient will be determined.

3. The willingness of ward managers for wards to be randomly allocated. The lack of evidence that HCA training interventions can improve relational care satisfies the principle of equipoise (and therefore the ethical basis for randomising the intervention). However, that principle may not be accepted by ward managers who work at the level at which randomisation will take place. Reasons for not taking part in the feasibility cluster RCT including reluctance to be randomly allocated will be recorded.

4. The level of non-response and item non-response to outcomes at the level of ward, HCA and patient. For a trial to be feasible, it is necessary that participation of wards and HCAs remain active until outcome measures are completed. The level of loss to follow-up and item non-response will inform feasibility, and if feasible, the number of participating wards, HCAs and patients required.

5. The acceptability and discrimination of outcome measures. In addition to non-response as a measure of acceptability, distributions of questionnaire responses will be examined for potential floor and ceiling effects. Follow-up interviews will be used to ask HCAs about the experience of completing the questionnaires and to validate data with a view to refining questionnaires prior to a definitive trial. HCA experience of the periods when the ward observation tool is being used will also be explored.

6. The ability to accurately identify costs and cost-drivers for both the HCA training intervention and HCA training as usual. Resource-use associated with the training intervention will be recorded. The completion rate of the EQ-5D-5L, to assess its suitability for use in this population, will be assessed.

7. Within- and between-variation in main outcomes across wards and NHS Trusts. This will inform sample size estimates (in terms of number of Trusts, wards, HCAs and patients) needed in a definitive trial to detect a meaningful difference between HCA Training Intervention in relational care and HCA training as usual.

8. The appropriateness of ward as the unit of randomisation. Movement of staff between wards will be monitored to assess the risk of contamination between the two arms of the feasibility trail.

5 Trial design

In line with guidelines on the development and evaluation of complex interventions a feasibility cluster randomised controlled trial will be conducted. This phase of the study will be asking the question as to whether a definitive cluster randomised controlled trial is viable (NIHR Evaluation Trials and Studies Coordinating Centre 2012). Clusters will be wards within the three acute NHS Trusts. The feasibility cluster randomised controlled trial will compare 'HCA training package in relational care' versus 'HCA training as usual'. The design is illustrated in the Trial Diagram (Section2) and flow diagrams depicting ward participant, HCA participant and trainer participant-related study activities (Appendix 1) and patient participant-related study activities (Appendix 2).

6 Methods

6.1 Site selection

The trial sponsor has overall responsibility for site and investigator selection and has delegated this role to the chief investigator.

The feasibility cluster RCT will be conducted in three teaching hospitals within the United Kingdom. As the aim is to develop and ultimately test interventions that are acceptable across different organisations, three acute NHS Trusts in England have been selected for their diversity based on the following dimensions: urban-rural, ethnic mix and London-non-London. These are factors that affect the HCA workforce mobility and ethnic makeup, as well as costs of training.

6.1.1 Study setting

At each Trust a key senior staff member with responsibility for the work of, and training undertaken by, HCAs within their Trust has been identified. Each Trust has agreed to take part in the proposed feasibility cluster RCT. Members of the research team have strong working relationships with these Trusts through previous research projects. The three settings will enable us to look at variation in HCA training need, acceptability of the developed training intervention, and viability of a definitive trial across differences in context and culture.

6.1.2 Principal Investigator's (PI) site responsibilities

The local principal investigator (PI) is responsible for the conduct of the feasibility cluster RCT at her/his site and for the safety of study participants. Specific requirements are to comply with the trial protocol, maintain appropriate qualifications (including current (within 2 years) GCP certification) and familiarity with the intervention, comply with the principles of GCP, maintain the local site file, permit monitoring and audit as necessary at the site, and maintain documented evidence of all staff at the site who have been delegated significant trial related duties including a record of their training.

6.1.3 Resourcing at site

The investigator(s) should be able to demonstrate the potential for recruiting the required number of suitable wards, HCAs and patient participants within the agreed recruitment period. They should also have an adequate number of qualified staff and facilities available for the foreseen duration of the trial to enable them to conduct the trial properly and safely.

HCA Trainers based at each site will be trained to deliver the intervention prior to intervention delivery.

Sites will be expected to complete a delegation of responsibilities log and provide staff contact details.

6.2 Site approval and activation

The CI/study manager (SM) will liaise with PIs over timing of site initiation and training.

The site must conduct the trial in compliance with the protocol. The PI or delegate must document and explain any deviation from the approved protocol, and communicate this to the SM.

6.3 Participants

6.3.1 Eligibility criteria

6.3.1.1 Participant selection

The eligibility criteria for this trial have been carefully considered and are the standards used to ensure that only appropriate wards, HCAs and patients are entered.

Wards, HCAs, patients or trainers not meeting the criteria should not be entered into the trial.

Wards, HCAs, patients or trainers will be considered eligible for enrolment in this trial if they fulfil all the inclusion criteria and none of the exclusion criteria as defined below.

6.3.1.2 Participant inclusion criteria

Ward inclusion criteria: general medical (including stroke) or care of the elderly/older people wards.

Healthcare assistant inclusion criteria: healthcare assistants working either full time or part time within enrolled wards.

Patient inclusion criteria: patients aged 70 years or over and discharged from an inpatient stay on an enrolled ward.

Trainer inclusion criteria: Trust-based trainers who have delivered one or more intervention training session

6.3.1.3 Participant exclusion criteria

Ward exclusion criteria: specialist dementia wards; medical admissions units.

HCA exclusion criteria: healthcare assistants who are employed as bank staff and are not part of the named staff on the ward roster.

Patient exclusion criteria: patients transferred to another ward or hospital prior to discharge or considered by the nurse-in-charge not to have mental capacity (according to the Mental Capacity Act 2005) or to be in the final stages of a terminal illness.

6.3.2 Ward, HCA and patient screening, recruitment and outcome collection procedures

Appendix 3 lists all documents used in screening, recruitment and outcome collection measures.

6.3.2.1Wards:

Within each of the three acute NHS Trusts four wards will be recruited (n=12 wards in total). A Trust-based director of nursing delegated representative will identify four wards meeting ward inclusion criteria.

The numbers of HCAs employed on wards varies according to Trust/ward. Where a number of wards within a Trust are identified as potential participants, wards with larger numbers of HCAs will be preferentially targeted for inclusion.

The intervention will be delivered during periods of low staff absence i.e. outside the winter flu period.

It is recognised that ward inpatients with dementia are a vulnerable group receiving care from HCAs within an NHS setting and that it is ethically important to include these patients in studies such as this. However, wards specialising in dementia tend to care primarily for patients with severe dementia and have been excluded for practical reasons including: the high number of patients on these wards not having capacity to consent or for whom the arrival in the post of the questionnaire may cause confusion or distress; the relative length of patient stay is longer and therefore patient turnover will be lower during the short study period resulting in low questionnaire return; at some Trusts HCAs on specialist dementia wards will receive specialist training sessions not available to HCA staff working on other wards caring for older people.

Medical admissions units have been excluded as duration of patient stay is often very short with patients commonly transferred to other wards prior to discharge. Patients will be asked to evaluate only the care they received on wards included in the study. This will be more difficult for patients if they have received care in more than one setting in the same care episode.

The PI and/or RA will meet with the ward manager of each ward to explain the study and seek agreement for their participation in all trial procedures. On agreement the PI/RA will attend a number of ward-based staff meetings. The PI/RA will explain the study to the staff and provide PISs (Document A) about the structured ward observations. The RA will be available after the meeting to answer further questions. Further PIS copies will be left on the ward for distribution to other staff not present at the meetings. Patients will receive a PIS (Document B) describing the structured observation procedures prior to the start of each observation. Patients will be given time to consider whether they wish to opt out. Posters (Document C) will be displayed on wards to let staff, patients and visitors know that structured observations will be carried out on the ward, the focus of observations is primarily HCAs and that further information is available in the ward reception area. Staff, patients and visitors will be made aware through meetings, PISs and posters that if they wish to, they can opt-out of structured observations prior to or during structured observation periods.

The RA will arrange times to carry out structured observations. Eight 50-minute structured observations will take place on each participating ward during the four week baseline period (R-4 weeks to R-1 week) and the four week follow-up period (R+9 weeks to R+12 weeks). The observations will take place during mornings, mealtimes and visiting times.

Prior to each observation RAs will check whether any staff have asked not to be observed and determine in collaboration with the ward manager, which bay(s) is to be observed. RAs will carry out observations and complete the observation proforma.

6.3.2.2 HCAs:

Within each of the enrolled wards all HCAs will be invited to take part in the feasibility cluster RCT. At a number of ward-based staff meetings during the four week baseline period (R-4 weeks to R-1 week) RAs will provide copies of the PIS (Document D) describing the study, to HCAs present at the meeting. RAs will be available after the meeting to answer questions. Further copies of the PIS will be left on the ward for distribution to other HCAs not present at the meetings. RAs will regularly spend time on the ward from 48 hours post distribution of the first HCA training PIS. RAs will meet with HCAs to identify HCAs who may wish to take part, confirm eligibility and, where appropriate, to take consent (Document E). RAs will complete the recruitment log with name and contact details and assign the HCA an HCA participant identification number (PIN). At consent HCAs will be given the HCA baseline questionnaire (Document F). Immediately after the four week intervention/TAU period

(R+9 weeks) all HCAs will receive an HCA follow up questionnaire (Document G). Four weeks later (R+13 weeks) HCAs will receive a further follow up HCA questionnaire (Document G).

The RA will mark each HCA questionnaire with their PIN and an issue number (to differentiate the three different questionnaires provided to each participant) and give it to the HCA participant with a pre-paid reply envelope. The RA will explain that the questionnaires can be returned by post or can be left in a collection box on the ward. It is important that questionnaires are completed at the specified time point. Therefore, at two and three weeks from provision of each questionnaire the RA may contact the HCA to remind them to return their questionnaires using their preferred method of contact as provided at recruitment.

HCAs who have received the full training intervention and previously expressed an interest in taking part in a post-trial interview will be purposively selected to take part in interviews (based on HCA experience). RAs will provide selected HCAs with a copy of the PIS for interviews (Document H). At least 48 hours later the RA will approach the HCA to determine willingness to take part and, where appropriate, to arrange a date for the interview. The interview will take place at a time and location convenient for the HCA. Immediately prior to the interview the HCA will be formally consented (Document I). Semi-structured interviews will be based on a topic guide (draft presented in Document J) and will take approximately 30-45 minutes.

6.3.2.3 Patients:

Older patients (aged 70 years or over) receiving inpatient care from the enrolled wards in the four week baseline period (R-4 weeks to R-1 week) and the four week follow-up period (R+9 weeks to R+12 weeks) will be identified by the Trust-based research nurses in consultation with ward managers. The research nurse will meet with the nurse-in-charge of the ward on a regular basis. The nurse-in-charge will identify all patients aged 70 or over and likely to be discharged in the next 72 hours to the research nurse. The research nurse will enter data (name, address, telephone numbers, date of birth, and likely or confirmed discharge date) into the screening/recruitment log. The research nurse with the nurse-in-charge will identify which patients do not fulfil entry criteria and reasons will be noted by the research nurse in the screening/recruitment log. The research nurse will approach each of the patients identified as potentially eligible. The research nurse will explain the study, provide the patient with a PIS (Document K), provide a consent form (Document L) and give them an example questionnaire (Document M). The research nurse will ask the patient whether at around two weeks post discharge they would agree to be contacted about their experience of care during their ward stay. The patient will be asked whether their preference would be to receive a paper questionnaire by post or a telephone call during which the questionnaire would be completed. The patient will be alerted to the fact that they may receive a reminder telephone call if no response to the initial approach is received. If the patient does not wish to take part then this will be recorded in the screening/recruitment log and their wishes respected. Only if the patient volunteers the reason(s) for reluctance to participate will the reason be recorded in the recruitment log. Patients agreeing to take part will be formally consented.

At one week post-discharge the Trust-based research nurse will post an invitation/telephone the patient to each patient participant according to their preference. The invitation will comprise a cover letter of invitation (Document N; personalised by the research nurse), questionnaire (Document M; marked with PIN and issue number) and a pre-paid envelope addressed to the research nurse.

If no response has been received from a patient at three weeks post-discharge the Trust-based research nurse will post a reminder/telephone the patient (according to stated preference). For telephone reminders, the research nurse will offer to complete the questionnaire by telephone at that point in time, offer to call back at a time and date to suit the patient or to send a reminder by post. Only one reminder will be given. Postal reminders will comprise a cover letter of reminder (Document O; personalised by the research nurse), questionnaire (Document M) marked with PIN and issue number) and a pre-paid envelope addressed to the research nurse.

All necessary letters, questionnaires, stamps and other stationery will be provided by RAs to Trust-based research nurses in advance.

6.3.2.4 Trainers:

Trust-based trainers (one or two per Trust) who have delivered the training intervention will be asked by RAs to take part in post-study interviews. RAs will provide trainers with a copy of the trainer PIS (Document P) for interviews. At least 48 hours later the RA will approach the trainer to determine willingness to take part and, where appropriate, to arrange a date and venue for the interview. Immediately prior to the interview the trainer will be formally consented (Document Q). Semi-structured interviews will be based on a defined topic guide (draft presented in Document R) and will take approximately 30-45 minutes.

6.4 Interventions

HCAs will receive either training in relational care (intervention) or training as usual (comparator).

6.4.1 Training in relational care

HCA training in relational care: HCAs from wards randomised to the new training course (n=6 wards, 2 wards per Trust) will receive the training intervention. Training comprises two one-day training sessions approximately one week apart. Training will be delivered by HCA trainers trained in delivering the intervention, based at each of the participating hospitals. Training comprises three core themes with each theme being covered on both days. Day 1 will introduce and begin to explore aspects of relational care for older patients. At the end of Day 1 HCAs will also be asked to undertake brief unstructured individual work-based exercises prior to Day 2 and further training support in the form of e-learning will also be available online. Day 2 will build upon Day 1 and explore further aspects of relational care.

Training will seek to: promote empathy with older patients; give time for reflection and shared experience; affirm the importance of the HCA role; ensure that HCAs know the route to access their local support network for any issues that may arise as a result of the training intervention e.g. increased emotional labour.

6.4.2 Training as usual

HCA training as usual: HCAs from wards not randomised to the training intervention (n=6 wards, 2 wards per Trust) will receive 'training as usual'. This is typically restricted to periods of staff induction or focussed on mandatory training requirements such as manual handling. HCAs will receive no additional training in relational care to that already experienced as part of the standard process within their employing NHS Trust.

6.4.3 Accountability

The project will be led from the UEA by the CI. The intervention will be delivered at three sites. At each of the sites there will be a PI. The local PI will be responsible for coordinating delivery of the intervention at each site. This task may be delegated to the site RA.

6.4.4 Compliance and adherence

Attendance at the training sessions will be observed using registration sheets. Unique identifiers will be used to examine utilisation of e-learning resources (e.g. number of times accessed and number of users accessing).

6.4.5 Concomitant training

HCAs in either arm can attend any standard concomitant training as part of treatment as usual.

6.4.6 Participant withdrawal

In consenting to the trial, HCA participants are consenting to take part in trial follow-up and data collection. However, an individual HCA participant may choose to end their trial participation at any time. Although not obliged to give a reason for discontinuing their trial participation, if it is volunteered it will be recorded.

6.5 Outcomes

As the intervention is seeking to achieve change at the level of the ward, the individual HCA and patients, feasibility cluster RCT outcomes will be tested at each of these levels. Interviews with HCAs and trainers will be used to determine acceptability to trainees and trainers respectively.

Wards: Outcomes will be assessed during the four week baseline period (R-4 weeks to R-1 week) and during the four week follow up period (R+9 weeks to R+12 weeks).

HCA: Outcomes will be assessed during the four week baseline period (R-4 weeks to R-1 week) and immediately post intervention/TAU (at R+9 weeks) and again four weeks later (at R+13 weeks). HCAs who have received the intervention will also be invited to take part in post-intervention interviews which will take place after the four week follow up period (R+13 weeks to R+16 weeks).

Patient outcomes: Outcomes will be assessed for the four week baseline period (R-4 weeks to R-1 week) and the four week follow up period (R+9 weeks to R+12 weeks).

Trainer outcomes: Trainers who have delivered the intervention will be invited to take part in post-intervention interviews which will take place after the four week follow up period (R+13 weeks to R+16 weeks).

As this is a feasibility study, other outcomes will be those important in determining the feasibility and design of a definitive trial. Specifically: the acceptability of the training intervention to HCAs, managers and other staff; the willingness of ward managers, HCAs and older patients to participate in the feasibility cluster RCT; the willingness of ward managers for wards to be randomly allocated; the level of non-response and item non-response to outcomes at the level of ward, HCA and patient; the acceptability and discrimination of outcome measures; the ability to accurately identify costs and cost-drivers for both the HCA training intervention and HCA training as usual; within- and between-variation in main outcomes across wards and NHS Trusts.

6.5.1 Primary outcome

Patient level outcome: To assess the emotional well-being of patients, the Patient Evaluation of Emotional Care during Hospitalisation ((PEECH)(Williams and Kristjanson 2009) (Murrells, Robert et al. 2013)) will be used. The PEECH was developed for acute hospital settings and contains 23 items and four subscales of levels of security, knowing, personal value and connection. Patients will be asked to rate the extent (on a four point scale) to which all hospital staff respond or behave in particular situations.

6.5.2 Secondary outcome

Ward level outcomes: To assess quality of interactions within a ward the Quality of Interaction Schedule (QUIS) observation tool will be used by a trained observer (Dean, Proudfoot et al. 1993). QUIS is an observational strategy in which social interactions between residents and care staff are coded as positive social, positive care, neutral, negative protective (keeping safe or removing from harm in a protective way) or negative restrictive (opposing or resisting patients' freedom of action without good reason).

HCA level outcomes: To measure change in empathy, the Toronto Empathy Questionnaire (TEQ) (Spreng, McKinnon et al. 2009) will be used. The TEQ conceptualises empathy as an emotional process and contains 16-items, each a statement about empathetic responses to specific situations which the HCA respondent is asked to rate on a five point scale their agreement. To measure change

in attitudes towards older people the Age Group Evaluation and Description (AGED) inventory (Knox, Gekoski et al. 1995), a measure of the extent to which stereotypes about ageing are held by the respondent will be used. It includes 28 semantic differentials relating to a specific age group using a seven point Likert scale. To measure HCA perception of the support provided to them in their work environment The Assessment of Work Environment Schedule (AWES; (Nolan, Grant et al. 1998); (Nolan, Lundh et al. 1999)) will be used (HCA baseline questionnaire only). Additionally HCA staff in the intervention arm will be asked whether the average duration of their patient contact times has changed since they received the training in relational care. All measures are to be self-completed by the HCA.

Post-intervention semi-structured HCA interviews will follow a topic guide. Topics will cover specifics for the intervention and more general aspects about the trial. The interview will be audio-recorded. The interviews are expected to take around 30 minutes, will be conducted by the RA and will take place at a time and location convenient for the HCA. Only HCAs who have received the training intervention will be interviewed.

Patient-level outcomes: To assess quality of life the EQ-5D-5L (Herdman et al, 2011) will be used.

Trainer outcomes: Post-intervention semi-structured qualitative interviews with trainers will follow a topic guide. Topics will cover specifics for teaching the intervention and more general aspects about student engagement. The interview will be audio-recorded. The interviews are expected to take around 30-45 minutes, will be conducted by the RA and will take place at a time and location convenient for the Trainer. All trainers who delivered the training intervention will be interviewed.

Training outcomes: RAs will attend training sessions as observers to determine fidelity.

Measurement of cost and cost-effectiveness: Levels of resource-use and quality of life will be monitored to inform the decision as to how costs and benefits should be measured as part of any future more definitive study.

Resource-use associated with the training intervention will be recorded. HCA staff in the intervention arm will be asked whether the average duration of their patient contact times has changed since they received the training in relational care.

Ward records will be used to ascertain the number of days patients stayed in the ward. Appropriate unit costs (e.g. Curtis (Curtis 2013)) will be attached to all items of resource-use in order to enable the overall costs to be estimated.

Completion rates for the EQ-5D-5L will be used to assess whether it is appropriate for this population group, and the extent to which a future definitive cluster RCT would be better designed as a cost-consequences analysis, where the incremental cost would be presented in relation to a number of outcomes, including the aforementioned measures associated with care, kindness, compassion, empathy and emotional well-being.

6.6 Participant timeline

6.6.1 Early stopping of follow-up

If an HCA participant chooses to end their study participation, they should be invited to continue follow-up in the trial even though they did not complete training. If, however, the HCA participant exercises the view that they no longer wish to be followed up either, this view must be respected and the HCA participant withdrawn entirely from the trial. Data already collected will be kept and included in analyses according to the intention-to-treat principle.

6.6.2 Loss to follow-up

Sites will record numbers of HCA participants lost to follow up. Numbers of patients responding to questionnaires will also be recorded.

6.6.3 Trial closure

The end of the trial will be defined as eight months after delivery of the final training session.

6.7 Sample size

Wards: Four wards will be recruited at each of three Trusts (n=12)

HCAs: All eligible HCAs will be invited to take part. Numbers of HCAs employed on wards varies within and between Trusts. Working on an average of ten HCAs per ward and an estimated recruitment rate of 70% it is anticipated that 84 HCAs will be recruited (42 per arm) to the feasibility cluster RCT across the three Trusts.

Patients: Questionnaires will be sent to all patients who have indicated that they would be interested in taking part in the trial. Numbers of patients discharged during any four week period are difficult to estimate as duration of stay is variable. Therefore, it is not possible to accurately quantify the numbers of older people that will be discharged from wards over the four week baseline period (R-4 weeks to R-1 week) and four week follow-up period (R+9 weeks to R+12 weeks). It is anticipated that across all three Trusts 100 patients will receive questionnaires during the four week baseline period and a further 100 patients will receive questionnaires during the four week follow-up period.

Trainers: All trainers who deliver the training intervention will be asked to take part in follow-up interviews (max=6).

As the study is a feasibility cluster RCT it is not powered to determine superiority of HCA training in relational care or training as usual.

6.8 Retention

Wards: RAs will work closely with the Ward Manager to ensure they are familiar with study procedures including timings for structured observations and training sessions. RAs will be available to answer any queries and to resolve problems.

HCAs: HCAs will be given advance notice of dates of training sessions. RAs will be available to answer queries from HCAs. RAs will make all reasonable adjustments to ensure that all HCAs randomised to receive the intervention are enabled to complete the intervention.

Patients: Trust-based research nurses and RAs will be available to answer any queries.

6.9 Assignment of intervention

6.9.1 Allocation

The allocation of wards to HCA training in relational care or 'treatment as usual' will be generated via computer written code. Randomisation will take place immediately after baseline measurements are completed and four weeks ahead of the start of the intervention to allow appropriate arrangements including HCA cover to be arranged.

6.9.1.1 Sequence generation

Randomisation will be stratified by NHS Trust with block sizes of four to ensure equal clusters in each of the trial arms within each Trust stratum.

6.9.1.2 Allocation implementation

The wards will be allocated to the intervention by a process embedded in the web-based data management system. When wards are randomised an email will be sent to CI and SM and relevant PI and RA.

6.9.2 Blinding

Blinding is not possible for wards, HCAs or trainer participants in this feasibility cluster RCT. However, it is likely that patients will be unaware whether or not they have been cared for within a ward receiving relational care training for HCAs.

6.10 Data collection, management and analysis

6.10.1 Data collection methods

Ward level structured observation data will be entered onto paper proformas by local RAs and data subsequently entered into the online study database by local RAs.

HCA level questionnaires will be self-completed, placed in boxes on the ward for collection by RAs or returned in the provided pre-addressed envelope to local RAs for entry into the online study database. HCA interview data will be audio recorded, transcribed, fully anonymised and subsequently analysed using NVivo10 software.

Patient level questionnaires will be self- or proxy-completed paper forms. Questionnaires will be sent out by and returned to Trust-based research nurses using a pre-paid reply envelope. Questionnaire data from patients will be entered into the online study database by research nurses. Patients will be made aware that questionnaires will be returned to the research nurse. If patients return unsolicited personal information in the return, the research nurse will apply a redaction process if appropriate. Research nurses and RAs will receive training on data collection and RAs will be trained in the use of the online database.

Trainer interview data will be audio recorded, transcribed, fully anonymised and subsequently analysed using NVivo10 software.

6.10.2 Non-adherence, non-completion and non-retention

Wards: In each ward eight 50-minute structured observations will be conducted in the four-week baseline period and again in the four-week follow-up period. HCAs based on the ward will be the primary target of structured observations. However, due to the nature of ward activity, other staff groups are also likely to be observed. Staff and patients will be made aware that structured observations will be taking place on the ward by provision of posters and PISs. Staff on wards will be made aware that they can opt out of structured observations. Where staff members or patients express a reluctance to be observed as part of the study the RA will respect that wish and will observe in a different bay/part of the ward. Should this cause difficulties the RA will ask the ward manager to identify an alternative time or date for the structured observation. Staff wishing to opt out will let RAs or the ward manager know that they do not wish to be observed. Frequency of events preventing or disrupting planned structured observations will be recorded.

HCAs: Adherence of HCAs to the intervention will be measured using a register of attendance on each of the training days and remote monitoring of utilisation of e-resources. Questionnaire completion rates and HCA withdrawal rates will be monitored. Interview attendance rate will be recorded.

Patients: Numbers of patients identified as eligible and approached will be recorded. Numbers of patients agreeing to receive questionnaires after discharge will be recorded. Patients will be invited to return non-completed questionnaires if they do not wish to participate. Non-completed returned questionnaire rates will be recorded. Whether only invitations to complete the questionnaire post-discharge or invitations and reminders were sent to individual patients will be recorded on the recruitment log sheet.

Trainers: Interview attendance rate will be recorded.

The consent form will explain that if a ward, HCA or trainer participant wishes to withdraw from the study the data acquired prior to that point will be retained. Reason for withdrawal will be recorded, if given. Loss to follow up will be recorded.

6.10.3 Data management

Identification, screening and enrolment logs, linking participant identifiable data to the pseudo anonymised Participant Identification Number, will be held locally by the research sites (HCA and trainer data) and in Trust research offices (patient data). Data will be stored in locked cupboards within access controlled offices.

Within each trial site all ward, HCA, patients and trainer participants will be allocated unique ward HCA, patient and trainer identification number respectively. These will collectively be referred to as the PIN (participant identification number). The PIN will be clearly marked on all HCA and patient questionnaires, ward observation proformas and interview transcripts. Paper questionnaires sent to HCAs will also be clearly marked with the issue number i.e. pre- or post-intervention/TAU.

Data will be entered under the respective PIN onto a central database stored on the servers based at UEA. No personal identifiable data will be entered into the database. The database will be password protected and only accessible to members of the CHAT study team. The server is in a secure room, which is protected by CCTV, where access is restricted to members of the UEA Information Systems team by security door access. The study database will be built using Microsoft SQL Server tools and direct access will be restricted to NCTU data management staff. Data entry will be via web pages created using Microsoft.NET technology. All internet traffic will be encrypted using the standard SSL (Secure Sockets Layer) methodology. The data entry system will validate data on entry to ensure it is of the expected type (e.g. integers, dates etc.) and range of values. Periodically and at database lock the data will be further validated for errors and inconsistencies. The database is linked to an audit tool where all data additions, modifications and deletions are recorded with date/time and the user ID of the person making the change. The database is designed to comply with the ICH Guideline for Good Clinical Practice (GCP), within the Standard Operating Procedures for Data Management in NCTU and also where appropriate with UEA IT procedures.

The database and coding values have been developed by the Head of Data Management in conjunction with the study statistician and other NCTU members. The database software provides a number of features to help maintain data quality, including; maintaining an audit trail, allowing custom validations on all data, allowing users to raise data query requests, and search facilities to identify validation failure/ missing data. Further details can be found in the CHAT study Trial Data Management Plan. After completion of the trial the database will be retained on the servers of UEA for five years for on-going analysis of secondary outcomes.

After completion of the trial the identification, screening and enrolment logs will be stored securely by the sites for a minimum of five years.

6.10.4 Statistical methods

6.10.4.1 Statistical methods – outcomes

This section describes the analysis of outcomes at each level. Although the methods are described here, the emphasis will be on the estimation and potential differences via confidence intervals rather than formal hypothesis testing.

Ward -level analysis

The outcomes for wards will be analysed as a total average rating as well as the individual sub-types. Analysis will be based on the change from baseline to outcome. Due to the small number of wards this analysis will be descriptive.

HCA-level analysis

The outcomes of TEQ and AGED will be assessed using a linear mixed effect model with fixed effect being the intervention and the random effect will be ward in order to account for the potential of dependence of patient-level responses from patients within the same ward. Additionally, the baseline value of the outcome will also be included as a fixed effect in a sensitivity analysis. These models will allow the estimation of the parameters required for the planning of future trials, including the HCA-level variation and between-ward variation.

Due to the small number of clusters the results of the random effect model will also be compared to those using a generalised estimating equation (GEE) model. Additionally, sensitivity will be analysed as a total average rating as well as the individual sub-types. Analysis will be based on the change from baseline to outcome. Due to the small number of wards this analysis will be descriptive. Due to the small number of clusters the results of the random effect model will also be compared to those using a generalised estimating equation (GEE) model. Additionally, the sensitivity of the assumption of a normally distributed outcome will be assessed using the non-parametric bootstrap.

Patient-level analysis

All analysis will be based on the intention-to-treat principle including all randomised patients. The total PEECH score will be analysed using a linear mixed effect model with fixed effect being the intervention and the random effect will be ward in order to account the potential of dependence of patient-level responses from patients within the same ward. The four subscales will be analysed using the same model. These models will allow the estimation of the parameters required for the planning of future trials, including the patient-level variation and between-ward variation.

Due to the small number of clusters the results of the random effect model will also be compared to those using a generalised estimating equation (GEE) model. Additionally, the sensitivity of the assumption of a normally distributed outcome will be assessed using the non-parametric bootstrap.

If appropriate sensitivity of the results to missing data will be checked via multiple imputation. If appropriate adjustment for baseline factors will be made.

Analysis of interview data

HCAs who received the intervention and trainers who delivered the intervention will be invited to take part in follow-up interviews. Interview data will be analysed according to prescribed topics using proprietary software (NVivo10) to identify emergent themes with respect to acceptability and design of the training intervention.

Item response

For each outcome measure, either the HCA or patient level, the non-response of each measure will be summarised.

Ceiling and floor effect

The distribution of each outcome measure will be assessed and any floor or ceiling effects investigated. If there are floor of ceiling effect it would indicate that the measure was not appropriate for use in a future definitive trial in this population.

6.11.1 Data monitoring committee

There will be no independent data monitoring committee given the feasibility nature of the trial.

6.11.2 Interim analyses

There is no plan for interim analysis.

6.11.3 Data monitoring for harm

This trial is not a clinical trial of an investigational medicinal product. The intervention comprises training for HCAs undertaken within their own Trust by HCA trainers. No adverse events attributable to training are anticipated, however, any untoward outcomes that are noted will be reported to the CI/SM immediately and where appropriate escalated to senior ward staff so that ward staff can comply with their own trust complaints or clinical incident reporting system if required. Adverse events for HCAs may be identified through complaints to the researcher or ward manager. Adverse events for others will be identified and managed using normal complaints and NHS incident reporting procedures for patients and wards respectively. Any reportable incident observed as a result of structured observations will be reported to the CI/SM immediately and where appropriate escalated to senior ward staff so that ward staff can comply with their own trust complaints or clinical incident reporting system if required. Adverse incidents will be captured in the study report but will not be attributed to a named Trust or ward.

6.11.4 Quality assurance and quality control

6.11.4.1 Risk assessment

The Quality Assurance (QA) and Quality Control (QC) considerations for the CHAT feasibility cluster RCT are based on a formal risk assessment that identifies and describes the risks associated with the trial and includes proposals of how to mitigate them through appropriate QA and QC processes.

Risks are defined in terms of their impact on: the rights and safety of HCAs and patients; project concept including trial design, reliability of results and institutional risk; project management; and other considerations.

QA is defined as all the planned and systematic actions established to ensure the trial is performed and data generated, documented and/or recorded and reported in compliance with the principles of GCP and applicable regulatory requirements.

QC is defined as the operational techniques and activities performed within the QA system to verify that the requirements for quality of the trial related activities are fulfilled.

6.11.4.2 Local monitoring

RAs will review questionnaire and observation data for errors and missing key data points. The trial database will also be programmed to generate reports on errors and error rates. Essential trial issues, events and outputs, including defined key data points, will be detailed in the CHAT study Data Management Plan.

6.11.4.3 Direct access to participant records

Participating PIs must agree to allow trial related monitoring, including audits by providing access to recruitment and delegation logs and other trial related documentation as required. Wards, HCA, patient and trainer information sheets will advise ward managers, HCAs and patients respectively that this is part of the monitoring process for the trial.

6.11.4.4 Trial oversight

Trial oversight is intended to preserve the integrity of the trial by independently verifying a variety of processes and prompting corrective action where necessary. The processes reviewed relate to ward, HCA and patient enrolment, consent, eligibility, and allocation to trial groups; adherence to trial interventions and policies to protect participants, including reporting of harms; completeness, accuracy and timeliness of data collection; and will verify adherence to applicable policies detailed in the Compliance section of the protocol. Independent trial oversight complies with NIHR trial oversight policy.

6.11.4.4.1 Trial Management Team

The Trial Management Team (TMT) comprising CI/PI, CTU staff and RAs from each site will assist with developing the design, co-ordination and day to day operational issues in the management of the trial, including budget management. Meetings will be held at approximately monthly intervals or more frequently if required.

6.11.4.4.2 Trial Management Group

A Trial Management Group (TMG) comprising CI/PI, co-investigators, site coordinators and RAs from each site will assist with developing the design, co-ordination and strategic management of the trial. Meetings will be held at approximately four-monthly intervals or more frequently if required.

6.11.4.4.3 Trial Steering Committee

The Trial Steering Committee (TSC) is the group responsible for oversight of the trial in order to safeguard the interests of all trial participants. The TSC provides advice to the CI, the funder and sponsor on all aspects of the trial through its independent Chair. The committee meets the 75% independence requirement of NIHR and includes three PPI members one of whom is an HCA. The membership, frequency of meetings, activity (including trial conduct and data review) and authority is as agreed with NIHR. Meetings will be held at approximately four-monthly intervals or more frequently if required.

6.11.4.4.4 Trial sponsor

The sponsor of the trial is the University of East Anglia. Day to day activities for management of the trial are delegated to the CI and NCTU.

7 Ethics and dissemination

7.1 Research ethics approval

Before initiation of the trial at any clinical site, the protocol, all informed consent forms and any material to be given to ward managers, HCAs, patients or trainers will be submitted to the relevant research ethics committee for approval. Any subsequent amendments to these documents will be submitted for further approval. Before initiation of the trial at each additional clinical site, the same/amended documents will be submitted for local Research and Development (R&D) approval.

The rights of wards, HCAs, patients or trainers to refuse to participate in the trial without giving a reason must be respected. After the wards, HCAs, patients or trainers have agreed to enter the trial, the CI remains free to withdraw the intervention, if s/he feels it to be in the best interest of the ward or patients. For example, if sufficient HCA bank cover cannot be recruited for part of the intervention therefore a risk to patient safety is presented. However, the reasons for doing so must be recorded.

After randomisation the ward and HCA should remain within the trial for the purpose of follow up and data analysis according to allocation. However, HCAs remain free to change their mind at any time about study participation and follow-up without giving a reason and without affecting their rights.

7.2 Other approvals

The protocol will be submitted to the relevant R&D department of each participating site. A copy of the local R&D approval (or other relevant approval as above) and other participant materials (e.g. letters of invitation, PIS, consent forms, questionnaires, topic guides etc.) must be forwarded to the co-ordinating centre prior to commencement of the trial.

The protocol has received formal approval and methodological, statistical, clinical and operational input from the NCTU Protocol Review Committee.

7.3 Protocol amendments

Substantial protocol amendments will be co-ordinated by the CHAT SM after approval by the TSC. Investigators and other relevant parties will be notified of amendments in a timely manner so as to ensure appropriate regulatory and ethical principles are met. A summary of protocol amendments will be maintained within the protocol.

7.4 Consent or assent

During the consent process it will be made clear that wards, HCAs or patients can decline to participate in all or any aspect of the trial, at any time and for any reason.

A copy of approved consent forms is available from the NCTU team.

7.5 Confidentiality

Within each trial site all wards, HCAs, patients and trainers will be allocated a unique ward identification number, HCA identification number, patient identification number or trainer identification number. Trust-based research nurses will securely maintain the log which enables linkage of the PIN numbers to the patient's details. RAs will securely maintain the log which enables linkage of the PIN numbers to the ward HCA and trainer details. Any data reported will be fully anonymised for Trust, ward, HCA, patient and trainer.

7.6 Declaration of interests

The investigators named on the protocol have no financial or other competing interests that impact on their responsibilities towards the scientific value or potential publishing activities associated with the trial.

7.7 Indemnity

The UEA indemnity scheme will apply to the potential liability of the sponsor for harm to HCA and patient participants arising from the management and conduct of the research.

7.8 Finance

The CHAT study is fully funded by National Institute for Health Research Health Services and Delivery Programme Grant number 12/129/10.

7.9 Archiving

The investigators agree to archive and/or arrange for secure storage of CHAT study trial materials and records for a minimum of five years after the close of the trial unless otherwise advised by the NCTU.

7.10 Access to data and samples

Requests for access to trial data will be considered, and approved in writing where appropriate, after formal application to the TMG and TSC

7.11 Publication policy

Publication will be carried out in accordance with the CHAT study publication and dissemination guidelines.

7.11.1 Trial results

The protocol and findings from our feasibility study will be published in peer reviewed journals and presented at relevant scientific meetings.

7.11.2 Authorship

Ownership of the data arising from the study resides with the trial team. The authorship policy will be in accordance with the CHAT study dissemination guidance and in line with guidelines of the International Committee of Medical Journal Editors (ICMJE recommendations for the conduct 2013 update).

8 Protocol amendments

This is version 1 of the CHAT study (feasibility cluster RCT) protocol: no protocol amendments have been made.

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Appendix 1. Ward, HCA and participant study activities

RA meets with ward managers to explain study and seek agreement for their participation in all trial procedures

PI/RA arranges with ward manager to attend ward-based meetings

PI/RA attend ward meetings to explain the trial including both ward observations and HCA training activities. RA to distribute PISs for structured observations (Document A) and HCA study activities (Document D; additional copies of each to be left on the ward). RA to be available after the meeting to answer any questions.

RA displays ward observation poster (Document C)

RA agrees times and dates for observations with ward manager (including mornings, mealtimes and visiting times for each ward).

RA attends ward:

- provides patients in bay with PIS (Document B)
- checks with ward manager whether any staff decline to participate
- identifies ward bay for observations
- checks patient willingness to participate
- performs structured observations

From 48 hours after receipt of the HCA PIS the RA regularly spends time on ward, meeting with HCAs to:

- identify HCAs who may wish to take part
- where appropriate, complete consent procedures (Document E)
- record details in recruitment log and assign PIN
- enter PIN onto HCA baseline questionnaire (Document F; this questionnaire contains TEQ, AGED and AWES inventories)
- give baseline questionnaire with prepaid return envelope to HCA
- indicate that the questionnaire can be returned by post or left in the collection box on the ward

RANDOMISATION

RA removes ward observation poster (Document C)

RA informs ward managers of their randomisation status.

For intervention wards, the RA coordinates HCA attendance at training in conjunction with ward manager.

INTERVENTION/TAU PERIOD RA attends training session to monitor fidelity. Attendance at training will be recorded

Baseline ward structured observation procedures repeated

At commencement of the 4 week post intervention period RAs will provide all consented HCAs with a follow-up HCA questionnaire (Document G; this questionnaire comprises TEQ and AGED inventories) with a pre-paid return envelope.

At completion of the 4-week follow-up period (R+13 weeks) RAs will provide all consented HCAs with a follow-up HCA questionnaire (Document G) and pre-paid return envelope.

At R+13 weeks RAs will invite trainers that delivered the intervention to take part in interviews. RA will provide trainers with a PIS for HCA interviews (Document P).

At R+13 weeks RAs will randomly sample HCAs that took part in the intervention and which previously expressed interest in taking part in interviews. RAs will provide selected HCAs with a PIS for HCA interviews (Document H).

A minimum of 48 hours after trainers have received the interview PIS, RAs will contact them to arrange a convenient time and place for the interview

A minimum of 48 hours after HCAs have received the interview PIS, RAs will contact HCAs to arrange a convenient time and place for the interview

At the pre-arranged time the RA will consent the trainers (Document Q) and conduct a qualitative interview (Document R).

At the pre-arranged time the RA will consent (Document I) the HCA and conduct a qualitative interview (Document J).

Note: yellow sections denote ward-based activity; blue sections denote HCA-based activities; orange sections denote trainer-based activity

Appendix 2. Patient participant-related study activities

A Trust-based research nurse meets with ward manager/nurse-in-charge on a number of occasions each week over the four week baseline (R-4 weeks to R-1week) period.

Nurse-in-charge identifies all patients aged 70 years or over who are expected to be discharged within the next 72 hours

Research nurse checks/enters name, address, telephone number, DoB and likely or confirmed discharge date into screening/recruitment log

Nurse-in-charge with research nurse identifies which patients do not fulfil all entry criteria and records the reason(s) in the screening/recruitment log.

Research nurse meets with potential patient participant to:

- Explain the study and to provide the PIS (Document G) and an example questionnaire (Document M);
- Ask them whether at around two-weeks post-discharge they may agree to be contacted about their experience of care during their ward stay
- Ask them whether their preference would be to complete a paper questionnaire or telephone questionnaire (if they express a wish to receive the questionnaire by email this can also be arranged)
- Alert them to the fact they may receive a reminder telephone call
- Take informed consent (Document L) and the patient's contact telephone number

If the patient does not wish to take part in the study then this wish will be respected. Only if given will reasons for reluctance to take part be recorded

RA provides materials for invitation to research nurses.
Invitations will comprise an A4 envelope containing a letter of invitation (Document N; personalised by the research nurse), PIS, patient questionnaire (with PIN) and pre-paid return envelope addressed to the research nurse.
Reminders will comprise an A4 envelope containing a letter of reminder (Document O; personalised by the research nurse), PIS, patient questionnaire (with PIN) and pre-paid return envelope addressed to the research nurse.

Research nurse either:
Makes telephone call to discharged patient to complete questionnaire by telephone (at two weeks post discharge); or:
Sends questionnaire to patients (at discharge plus one week)

At four weeks post discharge the research nurse will remind non-responding patients by telephone or post according to their stated preference. Patient participants reminded by telephone, who indicate that they would like to take part will be given the opportunity to take part there and then or to make an appointment for a further telephone call from the research nurse at a mutually convenient date and time or to receive a paper-based questionnaire.

Patient personal data will be recorded in paper-based screening recruitment logs which will be stored securely in Trust research offices. Telephone responses will be recorded directly into the study database by the research nurse. Paper-based questionnaire responses will be transcribed into the study database by the research nurse.

RANDOMISATION AND PRE-INTERVENTION DELIVERY ARRANGEMENTS PERIOD (4 WEEKS)

INTERVENTION/TAU PERIOD (4 WEEKS)

Baseline steps repeated during the follow-up period (R+9 weeks to R+12 weeks)

Appendix 3. List of associated study documents

Document name	Document reference
Protocol (feasibility RCT)	Protocol
Ward observations PIS for ward staff (feasibility RCT)	Document A
Ward observations PIS for patients (feasibility RCT)	Document B
Ward observations poster (feasibility RCT)	Document C
HCA trial PIS (feasibility RCT)	Document D
HCA trial consent form (feasibility RCT)	Document E
HCA baseline questionnaire (feasibility RCT)	Document F
HCA follow-on questionnaire (feasibility RCT)	Document G
HCA interview PIS (feasibility RCT)	Document H
HCA interview consent form (feasibility RCT)	Document I
HCA interview topic guide (feasibility RCT)	Document J
Patient PIS (feasibility RCT)	Document K
Patient consent form (feasibility RCT)	Document L
Patient questionnaire (feasibility RCT)	Document M
Patient letter of invitation (feasibility RCT)	Document N
Patient letter of reminder (feasibility RCT)	Document O
Trust-based trainer PIS (feasibility RCT)	Document P
Trust-based trainer consent form (feasibility RCT)	Document Q
Trust-based trainer interview topic guide (feasibility RCT)	Document R