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

Summary

Background

People aged 75 years and over account for 23% of all hospital admissions, an increase of 66% in the last decade. 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.

Aims

The proposed study aims to:

1. Understand the values-based training needs of HCAs in maintaining the dignity of, and affording respectful care to, older patients in acute NHS settings.
2. Develop a values-based training intervention for HCAs designed to address the needs of older patients for high quality relational care.
3. Assess the feasibility of a cluster randomised controlled trial to compare the performance of the developed training intervention for HCAs against current training in improving the care of older patients in acute NHS settings.

Setting

Selected wards within three acute NHS Trusts in England. Wards will be selected according to the proportion of older people (aged 70+) typically cared for within them.

Study design

The study will be conducted in two sequential but related phases using mixed methods.

Phase 1 (months 1-14): Using mixed methods we will conduct a *scoping exercise* of current education/training/induction for HCAs across NHS Trusts in England together with a more detailed analysis of training needs in three acute NHS Trusts. This exercise will consist of (i) a telephone survey of all acute NHS Trusts in England about provision of current HCA induction and training; (ii) qualitative interviews with HCAs; (iii) qualitative interviews with other staff groups (e.g. nurses and managers who work with HCAs); and (iv) focus group interviews with established community groups of older people. Alongside and informed by this work we will undertake the *development of a values-based training intervention* for HCAs. We have secured agreement to work with four leading retail organisations to gain insights into how to ensure greater focus on the customer/service user. To help HCAs 'see the person inside the patient' we seek to develop a modified form of life story work training.

Phase 2 (months 15-24): We will conduct a feasibility cluster randomised controlled trial. This phase of the study will be asking the question as to whether a definitive cluster randomised controlled trial is viable. 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'.

Background

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 32 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).

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 (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 develop and pilot a training intervention for HCAs, and investigate the feasibility of testing its effectiveness in a full-scale and definitive randomised controlled trial.

Aims

The proposed study aims to:

1. Understand the values-based training needs of HCAs in maintaining the dignity of, and affording respectful care to, older patients in acute NHS settings.

2. Develop a values-based training intervention for HCAs designed to address the needs of older patients for high quality relational care.
3. Assess the feasibility of a cluster randomised controlled trial to compare the performance of the developed training intervention for HCAs against current training in improving the care of older patients in acute NHS settings.

Methods

Study design

The study will be conducted in two sequential but related phases using mixed methods. Phase 1 (scoping and intervention development) will address Aims 1 and 2, and Phase 2 (feasibility cluster randomised trial) will address Aim 3:

Phase 1 (months 1-14): Using mixed methods we will conduct a *scoping exercise* of current education/training/induction for HCAs across NHS Trusts in England together with a more detailed analysis of training needs in three acute NHS Trusts. This exercise will consist of (i) a telephone survey of all acute NHS Trusts in England about provision of current HCA induction and training; (ii) qualitative interviews with HCAs; (iii) qualitative interviews with other staff groups (e.g. nurses and managers who work with HCAs); and (iv) focus group interviews with established community groups of older people (Aim 1). Alongside and informed by this work we will undertake the *development of a values-based training intervention* for HCAs (Aim 2).

Phase 2 (months 15-24): We will conduct a *feasibility cluster randomised controlled trial* of a values-based training intervention for HCAs to inform the design, conduct and viability of a future definitive trial (Aim 3).

Setting

As we wish to develop and ultimately test interventions that are acceptable across different organisations, the study will be founded on a national survey of acute Trusts, and focussed data collection will take place across three case study Trusts selected for their diversity 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.

At each case study Trust we have identified a key senior staff member with responsibility for the work of, and training undertaken by, HCAs within their Trust. We have agreement from each Trust to take part in the proposed study. 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 trial across differences in context and culture.

Phase 1: Scoping & intervention development

Sample

The mixed-methods approach to be used in this phase of the study will require samples of trainers currently providing education for HCAs in acute trusts, HCAs themselves, those working with HCAs, and older people as past or potential 'consumers' of HCA care.

For the *telephone survey* a named contact responsible for overseeing and delivering training for HCAs will be identified through the Director of Nursing at each of the acute NHS Trusts in England (n=168).

For the *qualitative interviews* we will recruit: (i) HCAs (n=30, n=10 per case study Trust) working on wards where older people constitute the majority of the patients cared for at each of the three case study sites (we will purposefully sample on the basis of length of HCA experience to ensure training interventions are relevant to those with extensive as well as limited experience); (ii) We will sample those who directly manage HCAs (staff nurses and ward managers) and senior managers with responsibility at a Trust level (n=24, n=8 per Trust).

For the *focus groups* (n=3, one per site) we will draw on the membership of existing consultation groups of older people. The following groups have been identified, approached, and have indicated their willingness to be involved in the study:

1. The Age UK Nottingham and Nottinghamshire Older People's Advisory Group (OPAG) is a group of older people who meet regularly on a voluntary basis. The remit of the group includes: helping in the development of appropriate services for older people; commenting on existing services; and listening to and representing the views of older people.
2. Through Age UK Norfolk we have approached Norwich Older People's Forum, Broadland Older People's Partnership, and South Norfolk Older People's Forum. The role of these forums are to ensure the voices of older people are heard in the planning and delivery of services.
3. At the KCL site, investigators have established links with Age UK London, and the Lambeth and Southwark Carers Association. These organisations have expressed their willingness to be involved in studies designed to improve hospital inpatient care of older people.

Recruitment and data collection

Telephone survey of all acute NHS Trusts in England: We will conduct a telephone survey of NHS Trust trainers of HCAs in England to identify and map the dominant approaches deployed. Contact with each of the 168 Acute Trusts in England will be made with each Director of Nursing to establish who takes overall responsibility for HCA training. We will then contact each identified 'trainer' to request their participation in a telephone interview. We anticipate a response rate of >50%. The telephone survey will attempt to establish what 'training as usual' means in practice.

Qualitative interviews of HCAs in three case-study trusts: HCAs will be identified via relevant Trust Directorates. We will present our study at relevant directorate, ward manager, and ward meetings providing HCAs an opportunity to find out about the study. They will be given details of how to get in touch with the research team if they wish to find out more and subsequently take part in a confidential interview. In interviewing HCAs we will explore their views on the extent, frequency, form, relevance, acceptability and value of current training provision particularly in the areas of values-based training and the care of older people. Interviews will take place at a time and location

convenient for the participant. As interviews are likely to take place during the interviewee's work time we will ensure that interviews last no longer than 45 minutes and are conducted at a time that minimises disruption to the interviewee's work. A semi-structured interview schedule will be used to ask interviewees about training undertaken, perceived gaps in training, preferences in terms of form and content of training, and views on optimal length of training packages. Interviews will be audio recorded with the interviewee's permission and transcribed verbatim.

Qualitative interviews of other staff groups: We will sample both those who directly manage HCAs (staff nurses and ward managers) and senior managers with responsibility at a Trust level. For ward-level staff, we will purposively sample from similar wards to those used to sample HCAs. By interviewing nurses and managers we will ensure our understanding of training needs takes into account contextual factors at ward and Trust level. The invitation to participate and the format of the interviews themselves will be the same as for HCAs (see above).

Focus groups involving older people and their carers: Each of the three groups will form the basis of a focus group at each case study site. Each of the established groups are run by and for older people and members have experience (directly or indirectly) of acute hospital care and experience in contributing to health services and health service research. Focus groups of older people will be specifically built around what training older people perceive non-registered healthcare staff need in order to improve their delivery of relational care and to understand the priorities they place on those needs reported by HCAs and other staff groups.

Analysis

Data from the telephone survey will be analysed descriptively by the study team, with the aim of discerning any important associations between types of training/induction and Trust level variables such as size, region etc. The qualitative data from Phase 1 interviews and focus groups will be analysed thematically. As the purpose of this phase of the study is to inform the understanding and development of a complex intervention we will use framework analysis (Ritchie and Spencer 1994). This is a method that is particularly useful for applied research designed to meet specific information needs yet remains true to the accounts of the interviewees. The various sources of data for each trust will be integrated using a case study approach, to achieve a comprehensive picture of HCA training the three Trusts concerned, before going on to contrast and compare them. We will also use the national survey data to help to contextualise the case studies. This analysis and synthesis will serve to inform the extent to which the findings from Phase 1 qualitative data pertain to issues that apply more generally across HCAs and their employers.

Intervention development

Drawing on (i) our findings from the scoping exercise and (ii) what is currently known, we will develop a values-based intervention for HCAs working with older people. We know that relational care is a focus for older patient's concerns about hospital care (Maben, Adams et al. 2012). From their review of the qualitative research into older patients' experiences of relational care, Bridges et al made the distinction between the need for reciprocity ('connect with me'), maintaining identity ('see who I am') and sharing decision-making ('include me') (Bridges, Flatley et al. 2010), and as the third of these dimensions was primarily a response to treatment decisions and therefore typically

the domain of medical and nursing staff, our intervention will be built around the first two themes: 'connect with me' and 'see who I am'. The rationale for focusing on these themes is set out below.

'Connect with me': Respectful communication is at the core of dignified care (Tadd, Hillman et al. 2011). In a review of studies of physician-patient communication, physician qualities such as empathy, friendliness, courtesy and listening were associated with positive patient outcomes (Beck, Daughtridge et al. 2002). Hospital patients report that preservation of dignity requires respectful communication and forms of address (Matiti and Trorey 2008) and for older patients in particular, the need for staff to show an interest in them, kindness, timeliness and attention to 'the little things' (Maben, Adams et al. 2012). Minimal work exists around the communication skills of HCAs but there is the potential to draw from other sectors to develop ways of improving these skills. There are isolated but encouraging examples of organisations outside of the public sector working with NHS organisations to develop 'customer focus' such as the work undertaken between Musgrove Park Hospital and John Lewis (Jennings 2012). It is these elements of care that are likely to be key in the new 'family and friends test' initiative that is to be rolled out across acute NHS Trusts in 2013 (Department of Health 2012). Healthcare staff are often uncomfortable with the notion of patients as consumers or customers (Sturgeon 2010) and acute health care staff often hold the view that hospitals are not the best place of care for older patients suggesting that care delivery is often provider led rather than user led (Tadd, Hillman et al. 2011). Important lessons about 'customer focus' and enhancing user satisfaction may be learnt from the private sector (The NHS Confederation 2007). Selective and contextualised input from organisations outside the NHS, where communication with customers is at the core of their business, may help further shift the focus of staff toward the perspectives of service users.

'See who I am': Maintaining identity is a key element in how older people judge their interactions with paid carers (Lloyd, Calnan et al. 2012) and both patients and their relatives comment on the importance of staff 'seeing the person behind the patient' (Goodrich and Cornwell 2008). Life story work is the process of gaining knowledge and information about an individual's life that staff can use to enhance the care they provide and evidence for its effectiveness is predominantly qualitative (McKeown, Clarke et al. 2006). In a Cochrane systematic review (Woods, Spector Aimee et al. 2005), some evidence was found that reminiscence therapy for people with dementia improves mood, cognition and caregiver strain, and staff knowledge of patient backgrounds, but trials are few and often small. When compared to communication skills training, a story sharing intervention for nursing home residents and nurse aides improved mutuality and empathy (Heliker and Nguyen 2010). Life story work is increasingly being used beyond dementia care settings and long-stay care settings (Thompson 2011). In a qualitative study of the introduction of a biographical approach to care in a general hospital setting, strengthening relationships were observed between staff and patients and staff and relatives (Clarke, Hanson et al. 2003). In acute care settings, the challenge is for staff to get to know older patients over a shorter period of time. For patients with dementia, one way of attempting this is the use of the 'This is me' document (Alzheimer's Society).

Form and content of intervention: Although we do not wish to pre-empt our findings from Phase 1, we agree with the conclusions within the Commissioning Brief that empirical studies point towards training which should be focused around values-based and relational care. We therefore intend to use Phase 1 findings to inform and refine a potential two part intervention that addresses the thematic needs to 'connect with me' and 'see who I am'. For the first part of the intervention

('connect with me') we have discussed with training staff from John Lewis and Nick Napper, Lead Learning Advisor at Taunton & Somerset NHS Foundation Trust, about the potential to adapt some of the work John Lewis have undertaken with Musgrove Park Hospital staff (Jennings 2012). We have also secured agreement in principle to work with the following organisations to gain insights into how to ensure greater focus on the customer/service user:

1. Boots Opticians – a company with 600 outlets in the UK and an older customer base.
2. B&Q – the largest home improvement retailer with an established and externally recognised policy for employing older workers.
3. Domestic & General – a provider of protection plans for household appliances whose staff are assessed against the criteria of: empathy, fairness, being caring, expertise, and being dependable.
4. Aldi – a company with 400 supermarkets in the UK where customer care training is delivered in-house and based on DVDs, workbooks and shop floor training and built around the concept of '3 Gs': greet, gratitude and goodbye.

To help HCAs 'see the person inside the patient' there is the potential for the development of a modified form of life story work training that will form the second part of the intervention. We will continue to work with members of the three consultation groups as we develop the intervention. For the intervention to be a viable form of training for HCAs and the potential to be cost effective, we will deliver the intervention as a package that can be used to 'train the trainer'. When developing training and educational interventions, we have experience of using pedagogical design to build learning activities that deliver content by engaging participants, providing timely feedback and sequentially building their knowledge and skills. We would anticipate the training intervention for HCAs to involve role-play, feedback and small group discussions, in line with evidence from a view of communication skills training for physicians that suggests these elements are more likely to be effective than oral presentations alone (Berkhof, van Rijssen et al. 2011). Components of the intervention might include verbal and non-verbal communication skills, dealing with aggressive behaviour, dealing with complaints, and recognising good relational care.
In summary the intervention will be based on the following principles of form and content:

Form:
1. Ward-based in order to embed it within the ward culture and minimise any potential theory/practice gap.
2. Interactive and involving follow-up.
3. Viable training as part of health service delivery beyond the lifetime of this and subsequent studies of the intervention.
4. Readily transferable between acute NHS Trusts.

Content:
1. Targeted at the crucial interface between provider and user where most HCA work with older people takes place.
2. A focus on experience of care rather than clinical outcome.
3. An older person's social history is not lost in efforts to determine clinical history.

Phase 2: Feasibility cluster randomised controlled trial

In line with guidelines on the development and evaluation of complex interventions (Medical Research Council 2008) for the second phase of the study we will conduct a feasibility cluster randomised controlled trial. 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'.

Sample

Within each of the three acute NHS Trusts we will recruit four wards (n=12 wards in total). Within each of the recruited wards we will invite all HCAs to take part in the study. We will aim to recruit a minimum of 48 HCAs per arm with a minimum of 5 HCAs per participating ward. Older patients (aged 70 years or over) receiving inpatient care from the recruited wards from the point of intervention delivery will be approached to take part in the study at discharge. If the patient is not able to provide informed consent we will seek to recruit a close relative who has visited the patient during their stay in hospital. We will aim to recruit a minimum of 48 patients (or their proxy) per arm with a minimum of 5 per participating ward.

Randomisation and interventions

Recruited wards will be randomised to receive either the training intervention developed as part of Phase 1 or 'training as usual'. 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.

HCA training package in relational care: HCAs from wards randomised to the new training package (n=6 wards, 2 wards per Trust) will receive the intervention developed in Phase 1.

HCA training as usual: HCAs from wards randomised to 'training as usual' (n=6 wards, 2 wards per Trust) will receive no additional training in relational care to that already experienced as part of the standard process within the Trust. Findings from Phase 1 will inform us how representative 'training as usual' at case study sites is of NHS Trusts across England.

Randomisation will occur once 70% of HCAs working within wards randomised to the 'HCA training package in relational care' arm have received the training intervention.

Outcomes

As the intervention is seeking to achieve change at the level of the ward, the individual HCA and patients we will test outcomes at each of these levels. Ward and HCA-level outcomes will be measured at baseline prior to randomisation and at two and six weeks following completion of HCA training. Patient-level outcomes will be measured within two weeks of hospital discharge.

Ward level outcomes: The Care Kindness and Compassion Observation Tool (Phair 2012) is used to assess, through an independent observer, three domains of care: (i) general care (e.g. patient centredness, supporting patients who may be disorientated); (ii) patient and visitor engagement (e.g. demonstrating dignity, positive communication); and (iii) patient safety. Whenever one of 21 vital signs of fundamental care are observed, these interactions/activities are rated by the observer as positive, passive, poor.

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 respondent is asked to rate on a five point scale in terms of their frequency of response. To measure change in attitudes towards older people we will use 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. This measure includes 28 semantic differentials relating to a specific age group using a seven point Likert scale. We will also conduct a focus group at each case study site of the HCAs based in wards randomised to the training intervention. This will allow us to explore how well the intervention was received by those undertaking the training and explore potential barriers of implementation fidelity.

Patient level outcomes: 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 are asked to rate the frequency (on a four point scale) to which all hospital staff respond or behave in particular situations. As the Family and Friends Test (Department of Health 2012) is anticipated to be used widely across health settings we will use this as an outcome in order to compare it against normative data.

Measurement of cost and cost-effectiveness: Estimation of cost-effectiveness, within a health-technology assessment, is an iterative process (Sculpher, Drummond et al. 1997). Here we aim to monitor levels of resource-use and quality of life (QoL), to inform the decision as to how costs and benefits should be measured as part of a future, and definitive study. NICE guidance (NICE 2008) recommends that costs are calculated from the perspective of the NHS and personal social services (PSS). We will therefore record levels of resource-use associated with the training intervention and other NHS and PSS resource-items. A modified version of the Client Service Receipt Inventory (CSRI) will be used to monitor resource use post-discharge, including levels of contact patients have with NHS staff, medication use and hospital readmission . This study will also seek to identify how aspects of in-patient care (for example frequency and duration of HCA and patient contact) might be monitored in a subsequent and definitive study. Thus one of the outputs of this work will be to devise methods to monitor items of resource use in a subsequent study (taking account of what can be ascertained from medical records and the extent to which other methods are required). Appropriate unit costs (e.g. Curtis (Curtis 2011)) will be attached to all items of resource-use, to estimate the mean overall cost in each study-arm. When assessing cost-effectiveness, NICE (NICE 2008) recommends use of the EQ-5D (Brooks 1996) which can be used to estimate the QALY (Quality Adjusted Life Year) gain associated with the intervention. However, it is acknowledged that the EQ-5D may not be appropriate in certain population groups (NICE 2008) and it has also been argued that it is too difficult for older people to complete such generic quality of life measures (McHorney 1996). Thus, we will assess the suitability of the EQ-5D in this study context, and the extent to which a future study 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 and compassion, empathy and emotional well-being.

Analysis

In Phase 2 we will estimate important parameters that are needed to inform the feasibility of definitive trial (and if feasible, then the design of such a trial) (NIHR Evaluation Trials and Studies Coordinating Centre 2012). These include:

1. The acceptability of the training intervention to HCAs, managers and other staff. We anticipate the work in phase one highlighting problems of intervention acceptability in advance of the feasibility trial. However, we will monitor the fidelity of trainers/HCA trainees to the intervention training package as unanticipated problems may arise when the training intervention is being delivered and field tested. Follow-up focus groups of HCAs 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 study. 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. We will do this by recording the number and length of contacts between (i) members of the study team responsible for recruitment and (ii) ward managers, HCAs and patients and how this translates to participation at each of the three levels of analysis – ward, HCA, patient. This will inform the cost of recruitment to a definitive trial.
3. The willingness of ward managers for wards to be randomly allocated. We believe 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 belief may not be shared by ward managers who work at the level where we are proposing to randomise. We will record reasons for not taking part in the study including reluctance to be randomly allocated.
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, we will need participation of ward HCAs to 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, we will use the follow-up focus groups to ask HCAs about the experience of completing the AGED inventory and the TEQ. We will also ask about the experience of the periods when the ward observation tool is being used. Distributions of all measures will be examined for potential floor and ceiling effects.
6. The ability to accurately idenfity costs and cost-drivers for both the HCA training intervention and HCA training as usual. We will assess the completion rate of the EQ-5D to assess its suitability for use in this population.
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. We will monitor movement of staff between wards to assess the risk of contamination between the two arms of the feasibility trail.

Ethical issues and research governance

We will apply for ethical and research governance clearance for each phase separately. In phase one our participants will be NHS staff or members of established community/consultation groups of older people. Therefore we will seek approval from the Research and Development directorates of the three case study sites and ethical approval from the University of East Anglia Faculty of Medicine and Health Sciences Ethics Committee. This will be conducted prior to activating the research grant. In phase two, we will be observing both patients and staff on the participating wards and approaching older people to participate on discharge. This will require NHS Research Ethics Committee approval which we will seek at the three case study sites. The process of applying for phase two ethical and research governance approval will be conducted during phase one.

Project management (see Gantt chart at end of document)

The project will be led from the University of East Anglia by the Chief Investigator (AA). At each of the other two sites there will be a lead investigator (JM and JS). During the study there will be six project management group meetings and six steering meetings. These will be held in London with a project management meeting and steering group meeting held on the same day as the membership of each group will overlap (months 2, 6, 10, 14, 17 and 22). The project management group includes all of the investigators and the three research staff (one from each of the HEIs). Its remit will be to manage and co-ordinate study activities across the three sites and ensure milestones are reached on time. The steering group will additionally involve lay representatives from each of the three locations and study advisors: Tanis Hand (Royal College of Nursing HCA Advisor), Gail Adams (Unison Head of Nursing), Jocelyn Cornwell (King's Fund Point of Care Programme), Nicky Hayes (Consultant Nurse for Older People) and Nick Napper (Learning Advisor at Musgrove Park Hospital). Its remit will be to guide the study to maintain relevance to the wider community of stakeholders, advise on research approach and progress and provide challenge to the research team. In addition at each of the three sites there will be regular meetings (weekly-fortnightly -monthly as required) between lead site investigators (AA, JM and JS); other site specific co-applicants (CN, HW, KC, GB) and research staff employed on the study. This will monitor progress against milestones and ensure effective supervision and feedback as appropriate to the CI. The three site research teams will communicate monthly via Skype and/or conference calls to monitor progress across sites and co-ordinate fieldwork, analysis, intervention development and feasibility protocol. In addition at each site, we will have meetings with investigators, research staff and two members from the local older people's group. These will occur every three months in phase one so that the training intervention remains true to the needs of the users whose care it is intended to enhance (months 3, 6, 9 and 12). During phase one we will hold four intervention development workshops (months 3, 6, 10, and 13). These will include AA, an investigator from the London and Nottingham sites, all three researchers, a member of one of the community consultation groups of older people and an HCA identified at the initial qualitative interviews. The group will be kept deliberately small to maximise its productivity and ensure that the intervention is ready to be delivered at the start of phase two.

Expertise and justification of support requested

Expertise

The team bring together diverse and complementary skills and experience that will ensure the successful delivery of the proposed research. AA will lead the study and has expertise in design and conduct of trials of complex interventions, particularly in nursing interventions for older people. GB is a Reader in Health Economics and conducted economic evaluations within a number of randomised trials. JS has an extensive track record of dementia-related research, most recently in relation to HCAs and dementia care, and has a particular interest in knowledge mobilisation and unregistered carers. HW will contribute to the pedagogical aspects of the study and has experience in trials of education interventions. KC is an experienced researcher and research manager of multi-site national projects related to cancer care and clinical research workforce initiatives. She has recently chaired a review of nurse education in Scotland which addressed issues relating to the healthcare workforce and responding to the needs of 21st century healthcare delivery. JM is a registered nurse and social scientist. She has substantial research expertise in the delivery and outcomes of nursing care, healthcare workforce, optimum work environments, caring for older people and quality of nursing care. CN a nurse and social scientist takes up an NIHR Post-doctoral research fellowship on 1 October 2012. She is an expert in collaborative research methods and has developed interventions with staff and patients to improve care quality for frail elders in acute settings.

The study is supported by the Norwich Clincal Trials and Research Unit and for the second year of the study we have costed in proportions of time for staff based within the unit: a Trial Manager, a statistician and a database manager.

Justification of support requested

As the intervention is targeted at staff (HCAs) the main cost will be research costs. The study will run over two years and require a relatively senior researcher at each of the three sites for the duration of the project. To assist the Chief-investigator in co-ordinating the project the researcher at the Norwich Centre will be employed at a slightly more senior level that those at the London and Nottingham sites. Data collection will be undertaken in the same way across each of the three centres but in order for the analysis of phase one to be ready to influence the development of the training intervention we will allocate different elements of the phase one scoping to each of the three researchers depending on the research skills they are likely to bring to the post. We also request funding of 20% of the Chief Investigator time, 7.5% each of JM and JS time (lead investigators for the London and Nottingham sites), 5% for CN and HW and 2.5% for KC. These proportions reflect the availability of investigators time in line with current commitments and the role in which they will play in the study. The four retail organisations are happy to give their time without cost. Funds are requested for suitable equipment and consumables to successfully conduct fieldwork in Phase One. For the successful completion of phase two we are requesting funding for 15% of a Trials Manager for the second year of the project). Funds are requested for a laptop for each of the three sites, travel and accommodation as appropriate to steering and project management group meetings and intervention development workshops (to be held in London with interim project co-ordination meetings to be held by conference call). In line with INVOLVE guidelines and PPIRes study costs for funded studies (PPIRes 2013), we wish to pay members of the older people's community/consultation groups for their time and any expenses that they incur in contributing to steering the project, the development of the intervention, and their contribution to fieldwork. We are requesting funds for one overseas conference and three national conferences to ensure effective

dissemination in the fields of gerontology, health services research, nursing, and the clinical support workforce.

Patient and Public Involvement in the study

PPI Involvement to date

With respect to this application we interpret 'users' as both healthcare assistants (the target of our intervention) and older people (the population the intervention is ultimately designed to improve care for). The lead applicant has had the opportunity to discuss the original idea with a group of new and established healthcare assistants following some training they had undertaken at an acute NHS Trust. They felt that any training intervention should be ward-based and practically relevant to their work. The ideas within this bid have been presented to the Nottingham and Nottinghamshire Older People's Advisory Group. They requested assurance that any ward observation would respect the privacy of hospital patients and their visitors. To further develop our proposal from outline to full application we have used the Patient and Public Involvement in Research (PPIRes) group. PPIRes is a project set up by NHS Norfolk to enable and encourage volunteer members of the public to participate actively with researchers. The proposal went out to members of the volunteer panel of PPIRes. We received constructive feedback from individual members and in response have attempted to cut down on phrases considered as jargon (we have changed the 'plain English' summary and will use some of this feedback to develop the information and consent forms to be used with patients). Members of both groups were keen to support the bid.

Planned PPI involvement during the study

In Norwich, we will work with PPIRes to identify volunteers to contribute to the steering group, and site-specific project meetings. In London and Nottingham, the organisations we will be working with to contribute in a similar way will be the South London Patient and Carer Consultation group and the Nottingham and Nottinghamshire Older People's Advisory Group. For the intervention development workshops we will seek involvement from one representative of PPI but would see this role as rotational so that the training intervention is relevant across diverse geographical locations. We would anticipate the focus groups in Phase 1 being run by members of the older people community groups, and co-convened by members of the research team. Payment for time and expenses will be as per INVOLVE guidelines.

We will work with Gail Adams from Unison to establish a meaningful way for HCAs to be represented on the steering group.

Dissemination

We will publish our protocol and findings from our study in peer reviewed journals and present at relevant scientific meetings. We will engage with user groups (for example via AgeUK, and the Patients and Relatives Association) at both local and national level to identify suitable mechanisms to report the findings from our work. Members of the research team and the wider steering group work with, or contribute to, highly influential organisations and bodies such as the Nursing and Care Quality Forum (Professor Maben), the King's Fund (Jocelyn Cornwell), the Royal College of Nursing (Tanis Hand) and Unison (Gail Adams). This will ensure that our study will be both policy-relevant and findings will inform policy development.

Health Education for England and the 13 Local Education and Training Boards (LETBs) will be key users of our research. Our three sites are situated within the geographical boundaries of three of the 13 LETBs: East of England, East Midlands and South London. Members of the study team work within departments that are substantial providers of healthcare education commissioned by these LETBs. We will use existing contacts with these relatively new organisations to ensure that our work can have the greatest impact on how the future healthcare workforce is equipped to care for older people.

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). By working with users and providers of acute hospital inpatient services for older people, and drawing on resources from other sectors, we can develop 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. 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 we will be in a position to know if 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.

Other benefits of the proposed study include a national overview of HCA training and training needs, including an understanding of what variation in HCA training exists and the identification of examples of good and poor practice. The proposed study will produce a novel and formally tested values-based training package which might be used in a variety of ways for research and service development. Our work with the retail sector has the potential to inform ways that fruitful collaborations between the health sector and private/non-health organisations can be developed to produce interventions of benefit to the users and providers of healthcare services.

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Project timetable

Month Number:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Month:	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A
Year:	2013				2014												2015							
Phase:	Phase 1														Phase 2									
Steering groups:		X				X				X				X			X					X		
Project management group:		X				X				X				X			X					X		
Skype/conference call co-ordination meetings:	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Development workshops:			X			X				X			X											
Phase 1 Scoping																								
Telephone survey of trusts																								
Survey design																								
Identification of Trust contacts																								
Fieldwork & data entry																								
Analysis																								
Qualitative interviews of HCAs																								
Interview schedule design																								
Identification and recruitment of participants																								
Fieldwork																								
Transcription																								
Analysis																								
Qualitative interviews of staff who work with HCAs																								
Interview schedule design																								
Identification and recruitment of participants																								
Fieldwork																								
Transcription																								
Analysis																								
Focus groups of older people																								
Interview schedule design																								
Identification and recruitment of participants																								
Fieldwork																								
Transcription																								
Analysis																								
Phase 1 Intervention development																								
Gaining insights from partner retail organisations																								
Adaptation of life story instruments																								
Development of training packages																								
Development of online support tools																								
Field testing and refinement prior to feasibility RCT																								
Phase 2 Feasibility RCT																								
Ethical and other regulatory clearance																								
Trial registration																								
Identification of wards and consent of ward managers																								
Recruitment of HCAs																								
Randomisation																								
Baseline measures																								
Training for those randomised to training intervention																								
Recruitment of patients (or proxies)																								
Follow-up measures																								
Analysis																								
Report writing																								