Study protocol

End of life care in care homes: supporting the workforce and reducing hospitalisations through an implementation study in care homes

Project Team:

- A/Prof Liz Forbat (CI), University of Stirling
- Prof Alasdair Rutherford, University of Stirling
- Prof Karen Spilsbury, University of Leeds
- Dr Jo Hockley, University of Edinburgh
- Margaret Ogden, PPI
- Maisie McKenzie, PPI
- Irene Soulsby, PPI
- Prof Brendan McCormack, Queen Margaret University
- Prof Barbara Hanratty, University of Newcastle Upon Tyne.

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Full title of project

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Version control table

Version	Date	Changes
V3.1	27-8-2020	-
V3.2	18-9-2020	Modification to study title Modification to data collection procedure for care home resident data. Study registration details added

Abstract

Background and rationale: End of life care in care homes is inadequate, despite high levels of morbidity and mortality.[1,2] Residents can experience uncontrolled symptoms, poor quality deaths and futile/burdensome hospitalisations. Care home staff can feel unprepared and unsupported to look after residents at end of life. Although models exist for improving end of life care in care homes, these are primarily education-focused and do not adequate triage residents to focus on those most at risk of dying without a plan in place,[3,4] and rarely integrate clinical care. Recent work conducted in Australia by the project team tested a novel way of providing specialist palliative care to care home residents. The new approach is 'Palliative Care Needs Rounds' (or 'Needs Rounds') combine triaging, with anticipatory person-centred planning, case-based education and case-conferencing. The approach has been synthesised into a check-list to provide guidance to clinicians running Needs Rounds.[5] Our Australian study showed reduced length of stay in hospital, dying in preferred place, improved symptoms at end of life,[6,7] and normalised death/dying to care home staff.[8] Care home staff felt more confident looking after the residents. Preventing hospital admissions saved $1.7m over a year (nearly £1m).

Aim: To co-design and implement an appropriate scalable UK model of Needs Rounds, which takes account of the different policy/practice context in the UK.

Design and methods: This is a pragmatic implementation study using the PARIHS (Promoting Action on Research Implementation) framework. We will determine what works, for whom, and in what circumstances for the UK Needs Rounds model. The approach uses six case studies, where a case is defined as a specialist palliative care service connecting with 4-6 care homes each. Phase 1 stakeholder interviews (n=40) across the 6 cases, will be used to develop a programme theory. Subsequently we will run a workshop to co-design UK Needs Rounds.

Phase 2 involves implementing, adapting and evaluating UK Needs Rounds in the six cases. Prospective data collection in phase 2 will focus on stakeholder interviews, and quantitative data to allow for comparison with the Australian study on hospitalisations, residents' quality of death,[9] and care home capability of adopting a palliative approach.[10]

Phase 2 will enable description and refinements of case studies' contexts, mechanisms and outcomes to generate a mid-range theory of implementation.

Patient and public involvement (PPI): Three lay people are co-investigators and have contributed to the proposal development and will continue to contribute throughout the whole study, including data analysis, contributing to the co-design workshops, dissemination and blogs.

Timeframe: The project starts 1-Oct-2020, with Phase 1. Phase 2 commences 1-Jun-2021 (month 9). The study runs for 28 months, concluding 31-Jan-2023.

Dissemination, outputs and impact: We will disseminate to policy-makers, care home/palliative care practitioners, care home residents/relatives, and academic audiences. Infographics, blogs, policy briefings, talks at carer groups/conferences will all be used. An implementation package will be developed for practitioners that provides all the tools and resources required to adopt UK Needs Rounds.

Registration: ISRCTN15863801

1. Introduction and rationale

Between 26% and 50% of people admitted to UK nursing homes die within 6 months.[1] Care homes (including nursing homes that provide 24/7 nursing cover and residential care homes which do not have nursing staff) increasingly look after older people with complex multiple morbidities.[11] Care homes will be the most common place of death by 2040.[2] There is therefore an urgent need for evidence-based approaches to support older people at the end of their life, and reduce avoidable and often detrimental admissions to acute care.

Some care home residents (hereafter ‘residents’, recognising that there will be differences between service providers as to the language they use) experience multiple admissions to hospital prior to their death,[12] despite some admissions being preventable.[13] Hospital admissions are costly and may prompt futile or burdensome interventions that can cause distress to residents and family members[14] Many residents will require specialist palliative care to enable care home staff to manage complex symptoms[11] to avoid hospitalisation at end of life. Well managed death and dying is contingent on high quality interdisciplinary care,[15] anticipatory care[16,17] and resident-centred planning.[18]

Care homes can be homely, warm and supportive environments. Supporting these establishments to improve the care they give at end of life can make them even better places for people to spend their final months and weeks of life, especially when compared with clinical settings like hospitals. Care homes are an important location in the nexus of service provision for older people.

Care home education interventions have improved outcomes for staff and residents requiring a palliative approach.[19] Education in advance/anticipatory care planning, as part of palliative care provision has led to increasing rates of completed plans and advance directive, improving consistency of clinical decision with resident preferences.[16,20] Advance care planning interventions led by nurses are also shown to mitigate distress and improve communication with relatives.[21] However, interventions are often inadequate to result in changing clinical behaviour, approaches are inconsistent, and the necessary steps for sustainable change are lacking.[19,22] Realistic Medicine is gaining traction, yet personalising care, tackling unwanted variation and reducing harm/waste remain urgent priorities.[23]

Providing end of life support to care homes is an increasingly busy area of service development. UK service delivery innovations such as ECHO,[4] Gold Standard Framework, Macmillan’s education for carers ‘Foundations in Palliative Care’, Six Steps to Sucess[24], the EU funded PACE work[3] and person-centred dementia care with the Namaste programme[25] offer staff training, but rarely provide facilitation of evidence-based clinical input for people diagnosed as dying. Currently, only the PACE study been tested in an RCT. Hence our Needs Rounds model offers an approach over and above that which already exists. Needs Rounds complement the care home Vanguards, and can learn from their reported barriers to effective implementation[26] while boosting the effectiveness of vanguard care homes by providing an evidence-based structure for, and direct care from, specialist services.

It could be argued that creating a basic organisational structure that promotes palliative care collaboration through monthly multi-disciplinary meetings (both internal and external health and social care professionals) is an important first step on which to build a solid foundation to provide palliative care. Such a foundation helps to break the isolation of care homes and can promote greater sustainability of further initiatives.

No current NIHR studies focus on care home residents and end of life care; only one past NIHR funded project relates to this, which described the uptake of the Liverpool Care Pathway in nursing homes, prior to the pathway’s demise.27 A new NIHR/ESRC study led by Prof Sampson will pilot an approach to delivering person-centred end of life care, but is focused solely on people living with dementia. A recent systematic review identifies a paucity of robust work in this field.28

NHS policy and practice: There's commitment but as yet no robust approach to delivering optimal care to care home residents. NHS England wants to improve care in all settings, and has committed to 'explore improvements' (p13)[29] for residents in care homes, but recognises that there are substantial difficulties in providing adequate care in these settings. The Care Quality Commission (CQC) articulate a requirement for "a clear focus on end of life care and applies in all services where end of life care is delivered. The approach includes […] care homes." (p21).[29] The CQC further state that there is more outstanding care by hospices than any other service, yet their data separate hospice care from nursing/care home care. This underlines a fundamental problem that care homes are not yet considered to be providing effective palliative care, despite the evident morbidity and mortality of residents.

Facilitating improved end of life care in care homes is an explicit driver for NHS England.[30] The 'Ambitions framework' for palliative and end of life care has yet to be fully realised, but includes important elements such as fair access to care and staff/communities able to provide care and talk about death/dying. Clinical commissioning of palliative care clinical and education services across England is variable.[31]

The Scottish Government's Strategic Framework for Action on Palliative and End of Life Care sets out a vision of universal access to palliative care by 2021. This includes individuals, families and carers having timely and focussed conversations with appropriately skilled professionals to plan end of life care, in accordance with their needs and preferences. The vision will be achieved by widening the range of health and care staff providing palliative care, delivering appropriate training, and supporting clinical and health economic evaluations of palliative and end of life care models. Further, Healthcare Improvement Scotland commits to testing and implementing improvements to identify those who can benefit from palliative and end of life care, yet at present there is no delivery model for this in care homes.

Wales has set out a priority action in Health Boards providing access, support and education from specialist palliative care to care homes,[32] but with no dominant model being offered beyond each community clinical nurse specialist linking with one or more care home. Northern Ireland guidelines recommend a designated nurse within the specialist palliative care team for care homes,[33] and although ECHO is a strong model this does not provide the triage and anticipatory planning function of Needs Rounds.

Care home culture: Care home culture inevitably impacts working practices and resident care/experiences.[34] Our study will also be informed by studies which have reported interventions in care homes, and applying their learning. This includes from co-applicants McCormack, and Hockley regarding the need for high quality leadership and facilitation alongside innovation,[35] and consideration of the nursing workforce and culture of education.[36]

Our study is predicated on the need to understand context and adjust implementation in response to care home culture, including local priorities, readiness for change and facilitation champions.[37] Care home culture, and the culture change movement, has become a research focus to identify characteristics which lead to care improvements.[38-41] Care homes which embrace culture change are more likely to provide better resident care.[42]

Measuring care home culture change is challenging,[43] yet the ORCA measure offers useful structure for data capture.[44]

Intervention description: A promising new approach called Palliative Care Needs Rounds (hereafter 'Needs Rounds') has been developed and tested (stepped wedge trial with 1700 care home residents) in Australia by the Chief Investigator.[7] This model offers structured outreach from specialist palliative care services to care homes. Needs Rounds are monthly hour-long triage meetings where specialist palliative care staff and care home staff discuss 6-8 residents who are at greatest risk of dying in the next six months without a plan in place. Needs Rounds use a checklist[5] to trigger identifying suitable residents (including educating staff on identifying dying), discussion of the biopsychosocial concerns (leading to case-based education on symptoms and anticipated symptoms when dying), and necessary actions (e.g. bespoke direct clinical work from specialist palliative care, anticipatory care planning, anticipatory or de-prescribing). Needs Rounds therefore also trigger some direct clinical work with residents e.g. clinical assessments and chairing case conferences.

Needs Rounds therefore are a model of care which provides a structure for specialist palliative care and care homes to discuss residents' needs, and inform personalised and tailored interventions suitable to each individual. Clinical work which is conducted after the Needs Round is always person-centred, and not driven by an *a priori* protocol.

The Needs Rounds intervention in Australia decreased the length of hospitalisations ($p<0.01$; CI −5.05 to −1.41 days), increased residents dying in their preferred place[6] and enabled staff to normalise death and dying[8] by adopting an out-reach model of specialist palliative care. In our definitive study, a stepped wedge trial of 1700 care home residents, we achieved similar levels of reduced acute length of stay ($p=0.048$), and evidenced improvements in residents dying with dignity, compassion and comfort ($p=0.019$) and workforce confidence ($p=0.09$).[7]

The proposed study will adapt the Needs Rounds model using a co-production approach so that it can be used in UK care homes, to replicate the positive outcomes evidenced in Australia.[5,6,8] The UK has a more collaborative health/social care environment and thus the study will need to explore how we can ensure a good fit with the person-centred and shared decision-making approach in the UK.

2. Aims and objectives

New knowledge will be generated regarding how the UK can adopt and adapt the Australian evidence-based model to maximise positive health outcomes. We will generate implementation methods for use across the UK. We will also facilitate new inter-organisational working and relationships.

Simply replicating the Australian stepped wedge trial would not add sufficiently to our knowledge base regarding what works and for whom. A further randomised trial would not be appropriate stewardship of finances, when the most important questions to address are around how to adapt the intervention to the UK setting and determine the enablers and blocks for use in the UK.

The study will produce an approach to care which can be used across the UK care home sector, thus having wider reach and significance beyond the study sites, by offering specialist palliative care input, using pragmatic and effective inter-organisational working.

The aim is to co-design and implement an appropriate scalable UK model of Needs Rounds, which offers specialist palliative care outreach to care homes, in order to improve the lives and deaths of care homes residents.

The implementation objectives are:

1. Co-design a UK version of Needs Rounds, which is responsive to the different (macro, meso and micro) contextual characteristics of the UK care home sector. (Phase 1)
2. Implement the adapted model of care, assess feasibility, acceptability and effectiveness, and ultimately propose how the model of care can be further refined and adopted in the UK context, to reap the benefits demonstrated in the Australian work. (Phase 2)

The intervention objectives are to:

3. Determine the transferability of the core elements of the Needs Rounds intervention in a UK context
4. Delineate the mechanisms of action (individual and group) that enable more effective palliative and end of life care practices to be realised in UK care homes
5. Identify the relationships between (a) the mechanisms of action embedded in Needs Rounds, (b) how these mechanisms function in different care home contexts and (c) the outcomes arising for different stakeholders and parts of the care system.

The process evaluation objectives are to:

6. Document the outcomes of UK Needs Rounds on hospitalisations (including costs), quality of death/dying, and staff capability.
7. Assess and report the perspectives of care home residents/relatives/staff and palliative care staff on using UK Needs Rounds.

3. Research Plan

3.1 Research design

This is a pragmatic critical-realist implementation study[45] using the PARIHS (Promoting Action on Research Implementation in Health Services) framework[46,47] in six case studies. We will use the Kitson and Harvey (2016) iPARIHS Framework to theoretically frame the study. iPARIHS builds on the original PARIHS Framework [48] and addresses many of the criticisms of PARIHS concerning issues such as, missing elements from context, the place of innovation, the work of facilitators and its general utility in practice. iPARIHS represents an integrated approach to implementation practices, recognising that most implementation (such as the one proposed in this study) is a complex social intervention requiring attention to multiple factors simultaneously in order for an innovation to be successful. Innovation in this context is in line with Rogers' [49] idea of 'Diffusion of Innovations' which needs to pay attention to different and multiple voices, different motivations for change as well as the role of leadership and facilitation. iPARIHS pays attention to all these factors through clarity of the role of the facilitator who utilises a variety of skills to work at the level of individual participant as well as internal and external systems. This fluidity between individuals and systems is important in our study given the nature of the intervention and its successful implementation being in part dependent on engagement by individuals in the care home itself and external actors (such as the primary care teams). The facilitator role uses systematic approaches to pay attention to these factors and alter the implementation process accordingly.

The PARIHS Framework: Central to the PARiHS framework, is the development of theory which enables effective implementation of research evidence in everyday practice.[50] Consequently, theory development runs alongside the co-design and implementation components of this study.

Theory can be grand, mid-range, or small. The development of grand theories (such as social determinants of health) is not within the remit of implementation science. However, developing small and mid-range practical theories are key to implementation, and hence forms a core part of this study's design. Small theories, referred to as programme theories within implementation science, explain micro changes and transactions, such as working hypotheses or local theories of change. These programme theories need to be explored and mined to elucidate core concepts, in order to then develop mid-range theories, which have greater explanatory potential to predict and plan for change across different settings.[50]

Theories need to be generated regarding (i) influential components of the UK context, and (ii) the mechanisms of how to implement Needs Rounds in order to deliver desired outcomes. In shorthand, these are referred to as the **c**ontext, **m**echanisms and **o**utcome **c**onfigurations (or, CMOc).

Consequently, in this study we will initially develop small/mid-range theories, and use these to generate a fully specified mid-range theory which accounts for the contextual features, structures, behaviours, and processes necessary to implement UK Needs Rounds.[50]

Study phases

The project will achieve its aim of co-designing and implementing an appropriate scalable UK model of Needs Rounds over two phases:

Phase 1: With key stakeholders, we will conduct concept mining and theoretical modelling to generate programme theories and hypotheses about how Needs Rounds could be used. This theory development will proceed by examining 'what elements of Needs Rounds would work, for whom, in what circumstances and why, in the UK context'. This will take account of core differences between Australia and the UK, such as (i) UK sites having potentially fewer registered nurses and therefore needing attention to the procedures to build greater links with primary care to facilitate the prescribing and administering of medication; (ii) smaller care homes in the UK (52 compared with 90) meaning potentially less frequent Needs Rounds or more in-depth discussion of each resident; (iii) the need to understand current service delivery between care homes and specialist palliative care for our sites (iv) care home engagement in palliative care training opportunities, (v) how UK Needs Rounds fit with improvements in primary care provision in enhanced care in care homes.

Phase 2: The programme theories generated in Phase 1 will be tested and refined by implementing, adapting and evaluating UK Needs Rounds in six case studies. The evaluation of Phase 2 will examine the outcomes predicted from the theories, developing insights into the context, and reasoning/resource mechanisms that lead to the achievement of these outcomes.[51] We will assess acceptability, appropriateness, feasibility, implementation cost, coverage, and sustainability. These assessments will report contexts, mechanisms and outcomes to generate a mid-range theory of implementation which conceptualises the core learning from across all sites.

Definitions:

- A case study is: a specialist palliative care team's input with their local care homes, and their associated health services.
- Key stakeholders are: health care practitioners working within specialist palliative care who deliver the intervention, care home registered nurses/assistants in nursing/managers, care home residents/relatives, and acute care staff involved in emergency presentations (emergency department staff and ambulance staff).

A process evaluation of the public/patient involvement in the study will also be conducted. This will be a qualitative interview study.

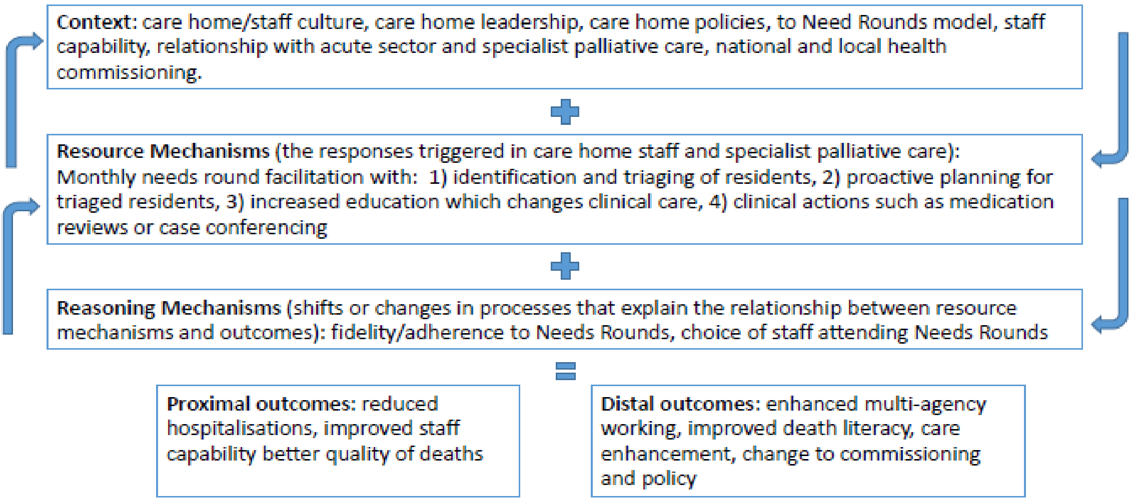
3.2 Methods

The study Flow Chart (Appendix A) illustrates the components and connections of research methods across phases.

Phase 1: We will conduct interviews with key stakeholders to generate initial programme theories to explain how Needs Rounds could be used in the UK. We will then train key personnel (senior specialist palliative care nurses) in running Needs Rounds.

Figure 1 (below) illustrates hypothesised Context Mechanisms and Outcomes (CMOc) generated from the Australian work. Context (e.g. care home policy, or leadership) refers to the conditions within a care setting that shape and feed into mechanisms. Mechanisms trigger action (mechanisms could be both resource-related such as provision of case-based education) or reasoning (e.g. choosing which staff to attend Needs Rounds). This Figure also illustrates the initial focus for data collection in Phase 1 (described in more detail below).

FIGURE 1: indicative programme theories derived from the Australian trial of Needs Rounds



Context: care home/staff culture, care home leadership, care home policies, to Need Rounds model, staff capability, relationship with acute sector and specialist palliative care, national and local health commissioning.

Resource Mechanisms (the responses triggered in care home staff and specialist palliative care): Monthly needs round facilitation with: 1) identification and triaging of residents, 2) proactive planning for triaged residents, 3) increased education which changes clinical care, 4) clinical actions such as medication reviews or case conferencing

Reasoning Mechanisms (shifts or changes in processes that explain the relationship between resource mechanisms and outcomes): fidelity/adherence to Needs Rounds, choice of staff attending Needs Rounds

Proximal outcomes: reduced hospitalisations, improved staff capability better quality of deaths

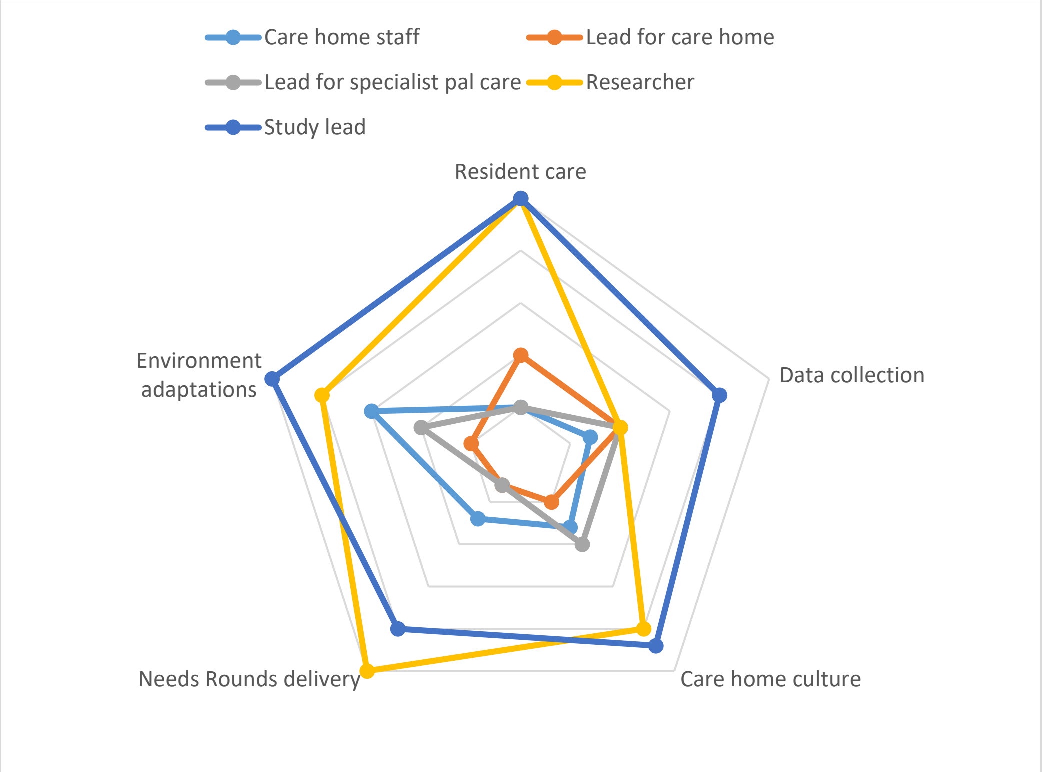
Distal outcomes: enhanced multi-agency working, improved death literacy, care enhancement, change to commissioning and policy

The theories and themes derived from interviews will be presented at a workshops in Phase 1. Workshop participants - key stakeholders in the case - will then co-design case study implementation plans, ensuring that the local plans align with local values, goals and service culture. This co-design phase will attend to core differences between the Australian and UK context. Workshop data will be captured on electronic-flipchart and converted into flow-charts/ infographics and project plans for sites.

The PARIHS framework asserts that implementing a new approach will require facilitation,[52,53] Facilitation can be a role, a process or a structure. Several people have facilitation roles, including care home staff (facilitating daily changes in practice), care home leads for the project (facilitating organising Needs Rounds meetings and ensuring follow-up activities occur), specialist palliative care leads (chairing Needs Rounds and promoting best practice in end of life care), the research team (facilitating data collection) and the project lead (facilitating commitment and enthusiasm for the study). Each facilitator plays a role in improving the care provided to residents, but in different ways and with varying intensity across tasks. Figure 2 below shows the facilitation partners, tasks, influence, and responsibility, with care home residents located at the centre. The facilitators vary in their proximity to certain tasks. For example, the lead for the care home strongly facilitates daily care of the residents and environmental/cultural changes needed, but is less involved in data collection. The lead for specialist palliative care has a strong facilitation role in resident care, but facilitates less in changing care home culture. The facilitation ecology is also influenced by structures such as the culture of the care home, local and national policy context of care provision.

Facilitation requires people to be leaders or champions. During Phase 1 data collection we will determine the best facilitators for each site. As described in Figure 2, facilitation linked with Needs Rounds delivery is likely to be clinicians from the specialist palliative care services (who then chairs Needs Rounds meetings) and staff members from each care home (most likely the service manager/team leader).[54] Facilitators will be identified in each specialist palliative care setting and care home, based on criteria for most effective characteristics for successful implementation.[54] Recognizing the likelihood of high turn-over of staff in care homes, at least two facilitators will be identified in each site.

FIGURE 2: Facilitation ecology



Care home and specialist palliative care facilitators will be prepared for their role through training in Phase 1. This training will be delivered via zoom web-conferencing by the project lead and Nikki Johnston (lead specialist palliative care clinician in the Australian work). Training will involve discussion of the practicalities of running Needs Rounds, subsequent clinical work, case conferences and referrals. Resources created for the Australian work will be re-purposed to assist in this training, including presentations on Needs Rounds, copies of the Checklist and data from Australian participants on implementation.[55]

Phase 2: Implementation of UK Needs Rounds will commence in the six Phase 1 case study sites. Phase 2 will test/evaluate the CMOc and theories to generate a coherent assessment of implementation and adaptations made in Phase 1. Further refinements to implementation will be made as based on the feedback received during Phase 2, and reflected in Figure 1, via recursive feedback loops between different elements of the CMO model. This feedback loop is exemplified in instances whereby change in one part of the system generates changes elsewhere, e.g. as resource mechanisms of case-based education are absorbed, this can shift the culture of the care home about staff learning.

A Phase 2 workshop with representatives from all 6 sites will have three functions. First, there will be a ‘sharing learning’ forum to discuss implementation successes and strategies. Second, we will share emergent findings from the qualitative interviews to prompt further discussion to continue co-designing UK Needs Rounds that will generate a single mid-range theory which fits all contexts, in order to harmonise implementation. Third, this workshop will be used to create dissemination materials such as brief ‘talking head’ videos.

For implementation, the case study configurations will expand to include up to 18 more care homes. Consequently, during Phase 2, there will be a ratio of specialist palliative care service to care homes, between 1:4 and 1:6. The number of care homes each specialist palliative care service works with will vary depending on local context (for example size of care homes). Recruitment is described in further detail below.

3.3 Context and setting of targeted sites

Key contextual factors to Needs Rounds in the UK relate to differences between the UK and Australia. Notwithstanding the overall similarities (both countries face similar tensions in service deliveries, such as high turn-over of staff, residents with complex multiple morbidities, reactive provision for end of life care as the norm, no mandatory staff training in palliative care), there are five core elements by which the two countries’ care home contexts differ:

1. The sites involved in the Australian study all employed a registered nurse. UK care homes vary in this regard. This may mean that Needs Rounds in the UK require care homes to improve links with primary care to facilitate the prescribing and administering of medication. It may also mean that the Needs Round ‘case based education’ component of the model will include greater emphasis on core information and skills.
2. Australian care homes tend to be larger than the average size in the UK. This means that the delivery of Needs Rounds is likely to need to be different. Our co-design process will help refine what this would look like, for example more in-depth discussion of each resident, or less frequent Needs Rounds meetings.
3. Local service provision/delivery of palliative care models vary across the UK. We will map this terrain as part of Phase 1 to understand local care.
4. In Australia, care home staff are able to access a national education programme (PEPA – programme of experience in the palliative approach) which enabled care home staff to attend a workshop on palliative care, and some days shadowing staff from specialist palliative care (e.g. in the inpatient unit). In the UK, education is provided via initiatives such as ECHO, and 6-Steps. Further, the Gold Standard Framework for education and accreditation is used in the UK, but not in the region of Australia where Needs Rounds were tested. These differences in education/training provision do not necessarily complicate implementation. Baseline staff scores in their capability of adopting a palliative approach

will be taken, along with follow-up, so we can compare these data with the changes in staff scores in Australia.

5. General practice provides first-line medical care for care homes, but ways of working, quality and impact are highly variable. From 2020 in England, Primary Care Networks are contracted to deliver an enhanced health in care homes service. This national service specification has emerged from the work of the NHS England care home vanguard programme. The seven core elements include enhanced and consistent primary care, multidisciplinary team input and high quality end of life care. We will map local use of this enhanced delivery in Phase 1.

For the implementation study, care homes should provide services for people aged over 65s, situated within the service boundaries of a participating specialist palliative care team. Purposive maximum variability sampling of specialist palliative care services will focus on recruiting a heterogeneous and information-rich sample to reflect, for example: urban/rural, service size, deprivation, cultural demographics, use of ECHO or other specialist palliative care input models, national charity/independent management, funding models, hospital transfer policies. These variables reflect the dominant contextual influences which are likely to impact how Needs Rounds are used in the UK.

3.4 Implementation and implementation strategy

As noted above, Needs Rounds are monthly triage meetings where staff from the care home and specialist palliative care discuss between six and eight residents who are most at risk of dying without an adequate plan in place. The discussion integrates case-based education about symptoms or scenarios most relevant to the residents discussed. Discussion may lead to direct clinical work from the specialist palliative care clinician (e.g. a physical assessment or medication change). These clinical interventions are person-centred and not protocol driven.

Needs Rounds may also lead to identifying the need for a case conference to be held, or referrals to other organisations to be made.

Precise details about which staff attend, their mechanism for identifying residents who should be discussed, the content/focus of case-based education, and referrals to other organisations will all be determined prospectively to suit local context. Workshop discussions in Phase 1 will be the core mechanism by which these decisions will be made.

3.5 Sample and sample size

Target population: Care home residents, in case study sites across the UK. The geographical diversity to sites ensures the resulting model can be implemented across policy/commissioning jurisdictions.

Inclusion criteria

Stakeholders (for interviews in Phase 1&2)

1. Work for the specialist palliative care service or a care home in one of the six cases; or are a resident in one of the care homes; or are a relative of a care home resident in one of the six cases; or work in acute care impacted by hospitalised care home residents
2. Willing to provide informed consent
3. Have capacity to provide their own consent to participate
4. Not engaged in any current safeguarding investigations.

Care homes (Phases 1&2)

1. Located near to the specialist palliative care team
2. Provide care to residents who have high clinical nursing/medical needs
3. Willing to sign a memorandum of understanding with the research team, outlining resident demographics and health service use data, facilitate access to staff for interviews, and engagement in Needs Rounds

4. A range of sizes (focusing primarily on larger care homes, following CQC data indicating lower quality in larger facilities)[56], sole traders and large corporate provider, and with a range of funding models (NHS/social care and self-funded residents).

Residents (who are discussed at Needs Rounds in Phase 2)

1. Resident in a collaborating care home in one of the six case study locations
2. An anticipated life-expectancy of less than 6 months
3. At risk of dying without appropriate planning in place
4. Experiencing inadequately managed bio-psycho-social symptoms
5. Not engaged in any current safeguarding investigations
6. Able to provide their own informed consent

Relatives completing family perceptions of care questionnaire

1. The relative of a resident who was discussed in Needs Rounds
2. Able to provide their own informed consent.

PPI evaluation

1. Co-investigator or a member of one of the case study sites
2. Able to provide their own informed consent

The Australian study informed the sample sizes and data collection time points, which will give adequate opportunity to qualitatively and rigorously examine the relevance of the programme theories and mid-range theory when implementing across heterogeneous contexts. Sample sizes relate to theoretical sufficiency, and are congruent with accepted standards for qualitative data.[57]

For the quantitative sample, we anticipate an average size of the care homes to be 52 beds, and the rate of emergency admission to hospital to be 0.173 per bed within the four month period, for an average of 9 admissions per care home.[58] A sample of 30 care homes would allow us to detect a change in the hospitalisation rate of 0.02 per bed ($\alpha=0.05$, $\beta=0.2$, Δs.d.=0.040). This is sufficient to detect a clinically meaningful change in the primary outcome (reduction of one hospitalisation per four month period in a typical care home) for the quantifiable data in phase 2.

3.6 Recruitment

Participants will be recruited via purposive and criterion sampling and include: care home managers, residents, relatives, nursing and allied health, ambulance, pharmacy, and specialist palliative care managers/clinicians.

Six specialist palliative care teams have agreed to collaborate on this study. These sites were selected for their heterogeneity, including rural/urban and independent/national status, as well as an explicit strong commitment to the study. Sites are as follows: Highland Hospice, Inverness; Strathcarron Hospice, Forth Valley; St Giles' Hospice, Walsall; St Helena, Colchester; Arthur Rank Hospice, Cambridge; Princess Alice Hospice, Surrey.

Recruitment of care homes will be conducted by the specialist palliative care team, with support when required from the research team. Specialist palliative care teams will invite their local care homes to take part and/or draw on the NIHR ENRICH network of care homes with an interest in engaging in research. ENRICH England and Scotland have confirmed their willingness to assist in the study recruitment. We will apply to be an NIHR CRN portfolio study to provide additional support in recruitment. All specialist palliative care teams currently have relationships with some local care homes, and these would be examined initially against inclusion criteria for commencing the study.

Recruitment of interviewees in Phase 1 and 2 will be informed by theoretical sampling – seeking to focus on stakeholders most likely to provide insight into the generation of programme theories and the ultimate mid-range theory. Recruitment of care home staff, residents and relatives will all proceed via the care home manager, asking them to identify and then pass invitation letters to relevant stakeholders. Recruitment of acute care staff will proceed via recommendation by specialist palliative care or care home staff, whereby invitations letters will be emailed to relevant personnel.

Recruitment of PPI evaluation interviewees will be conducted via email requests from the study's Chief Investigator.

3.7 Data collection

Phase 1: Programme theories will be generated from 40 interviewees (individual or small-groups) from six case study sites. Interviewees will be key stakeholders: residents/relatives/clinicians/managers in care homes, clinicians in specialist palliative care and related acute/primary care, and allied health practitioners. Formal respondent checking of transcripts will not be used, since the workshop will provide opportunity to clarify, check accuracy and validate ideas/opinions with participants. Data will be collected initially during face-to-face site set-up visits, and subsequently via telephone.

We will ask interviewees about their local context, such as services' geography, policy, structure, funding and practice elements, generated from the working programme theories from the Australian trial (Figure 1). We will also collect relevant documentation (e.g. service policies). These data will enable us to develop realist theories regarding how implementation would work in practice, what might influence implementation in each case study site, to identify Contextual factors, Mechanisms (including both reasoning and resources) and Outcomes (CMO).

Phase 2: Phone or video-call qualitative interviews with key stakeholders in each case study will be conducted to ask about the process and mechanisms of change and examine the CMOs/theories that were generated in Phase 1. Interviews will collect prospective data on acceptability, appropriateness, feasibility, implementation cost, coverage, and sustainability. The context will be examined alongside how the intervention is delivered in each site (mechanisms including resources and reasoning such as preparedness of sites, agency to affect practice), and how that maps onto adherence to the delivery of the intervention as planned. In the final interviews, stakeholders will be asked to reflect on mechanism to disseminate the findings. Formal respondent checking of transcripts in Phase 2 will not be used but interviews at month 4, 8 and 12 will provide an opportunity for respondents to reflect on views expressed earlier in the study.

Interviews will be audio-recorded and conducted at 4 months (capturing early adoption), 8 months (mid-range) and 12 months (longer term implementation). Our Australian work showed that six-months allows time for clinicians and services to become sufficiently familiar with the Needs Rounds model. The Australian study indicated month-on-month improvements in staff capability over time, and hence this 12 month timeframe allows us to plot the dose effect over time. Interviews in Phase 1 and 2 are likely to last similar lengths of time to our Australian process evaluation interviews, of circa 45-60 minutes,

The main outcome will be determining the characteristics of effectiveness regarding *what works in what circumstances with* Needs Rounds within the UK, derived from through qualitative interviews with key stakeholders (residents, relatives, care home staff, specialist palliative care staff, and acute care staff). Secondarily, we will determine *for whom* Needs Rounds work, focusing on core stakeholder groups: the NHS, residents, care home staff. These include health outcomes which mirror those of the Australian work, to facilitate comparison.

- A bespoke tool will capture **resident data**. This will include basic demographic information (age, ethnicity, first language, number of deaths, Charlson Comorbidity Index). We will also document preferred place of death (and actual place of death if they die during the study), and health service use during the four month data collection periods (name of hospital, duration of admission, speciality/ward of admission, mode of transport to hospital, gender, age, contact with primary care).

  We will also collect information regarding the assessments and interventions which are triggered by Needs Rounds. This might include, for example, physical assessments, blood/urine tests or other clinical investigations. We will record any referrals to other NHS services, changes in pharmacotherapy, commencement of syringe drivers and so forth which are triggered by the resident having been discussed at Needs Rounds. Data will be collected from the care homes by care home staff. Training will be provided to ensure robust data collection and reporting. Following learning from the Australian studies, we recognise the importance of developing and maintaining strong relationships with the local sites to ensure ongoing data collection and reporting.

This data will be captured at a care home level, not individual level data to ensure that data is anonymous and cannot be traced to an individual. Draft data templates are included as Appendix B and C. Data will be collected by members of the care home staff, and hence usual care team. Training will be provided to ensure robustness of data reported.

- **Economic evaluation** will be a cost-benefit analysis[59] drawing on the following data (Table 1 and Table 2)

Cost type	**Cost detail**	**Measurement of costs**
Direct costs	Intervention costs on-site • Staff time • Travel • Consumables and Equipment • Workshop costs	Included within the project budget and therefore directly recorded. Where appropriate additional detail will be collected directly from the care homes.
	Additional NHS staff time attending care home Additional prescriptions	Estimated in the SoECAT, with additional costs recorded by intervention staff as required.
Indirect costs	Wider additional costs incurred by the care home, including: • Changes in their staffing • Changes to facilities (i.e. use of rooms), or overheads as a result of hosting the intervention.	These changes, and their associated costs, will be collected from care homes in a proforma through the interviews
Intangible costs	Inconvenience to staff, residents, family and carers as a result of the intervention.	These will not be measured directly, but will be explored in the qualitative interviews in the main study.

Table 1: *Intervention cost elements*

The **total benefit** from an NHS and Personal Social Services perspective is the change in health and social care service costs that result from the intervention. The costs of hospitalisation will be constructed from resident-level data on length of stay collected by the care homes, and costed using the National Tariffs and hospital -specific PLICS data for both England and Scotland. Total costs for the each of the pre and post periods will be calculated by summing these costs across all residents admitted to hospital from a given site, and the benefit is the difference between pre and post health service-use costs.

Cost type	Cost detail	Measurement of costs
Direct costs	Costs of ambulance journeys	Estimated from the 2019/20 National Tariff Payment System.[1]
	Hospital stay cost	Hospital-specific PLICs data for England[2] and Scotland[3] on stay costs by age and gender to estimate a day rate to use in the hospital costing.
	Primary care usage	Collected from care home sites in a proforma through interviews
Indirect costs	Wider additional costs incurred by the care home, in connection with resident hospital admissions, including staffing, travel, equipment or facilities.	These costs will be collected from care homes in a proforma through the interviews
Intangible costs	Inconvenience to residents and their family/carers arising from hospitalisation	These will not be measured directly, but will be explored in the qualitative interviews in the main study.

Table 2: Health service cost elements

We will not seek linked hospital data as this would require considerable additional resource (time and personnel) and result in reduced data of less robust quality for drawing generalisable conclusions. The reduced volume and robustness of data would occur as a result of requiring individual-level consent to acquire such information, effectively reducing the pool of data to those without cognitive impairment. Since care average prevalence of dementia in care home residents is 69%[60] this presents an unacceptable reduction in sample size.

- **Staff capability** of adopting a palliative approach (CAPA), assessed on a 9-item validated self-report questionnaire.[10] CAPA has a uni-dimensional scale; higher scores indicate greater capacity. Internal consistency reliability is very high with a Cronbach's alpha of 0.95, and split-half reliability coefficient of 0.93.[10] Measures will be taken at baseline from all nursing assistants and registered nurses, and then prospectively each month from those attending Needs Rounds. Final assessment will be taken from all staff following the 12 month trial period. Questionnaires will be filled in by care home staff, either hard copy or online depending on site preferences.
- The **Quality of Death and Dying** Index,[9] (QODDI) completed by care home staff for each decedent resident prospectively throughout the study. This 17 item questionnaire examines four correlated but distinct domains: symptom control, preparation, connectedness and transcendence. The decedent's experience is rated on a 0 to 10 scale, where higher scores indicate a better experience. The Cronbach's alpha for the QODDI total score is 0.89. Following correspondence with the scale's originator confirming psychometric robustness of excluding items, one item on access to euthanasia will be removed, as this is not legal in the UK.

  The QODDI was designed for completion by relatives, however, staff are more consistently likely to have seen the resident in the weeks prior to death, hence staff completion will result in more reliable and valid data. No suitable staff measure exists, and the questionniare worked well in the Australian stepped wedge trial. Questionnaires will be filled in either hard copy or online depending on site preferences.

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[1] https://improvement.nhs.uk/resources/national-tariff/

[2] https://digital.nhs.uk/data-and-information/publications/statistical/mi-acute-patient-level-activity-and-costing/2018-19

[3] https://www.isdscotland.org/Tariff/

- **Family perceptions of care** from relatives of residents who are discussed at Needs Rounds, using the CANHELP lite.[61] We will use the second part of the questionniare which focuses on satisfaction with care. 22-items collect self-report data on family views of care home staff, illness management, communication, relationships with clinicians and relative involvement. The Cronbach's alpha for the total score is 0.88-0.94. Questionnaires will be filled in either hard copy or online depending on family/site preferences, and returned to the research team. A family will only be asked once to complete this measure, even if the resident is discussed at Needs Rounds more than once.
- **Environmental/contextual data** will draw from conceptual work by Estabrook[44] and be qualitative in nature to dynamically explore each care home's culture. Interview topics will cover, for example, leadership, culture, time/space, staff/resident turnover or introduction of new policies/procedures, and prioritisation of the intervention in workload. Data will be collected for each case, from interviews and site documentation. Activity logs will also be generated, to capture time spent by all parties, and additional work generated beyond the Needs Rounds meeting.
- **Needs Rounds discussions** will be recorded by sites. This will allow analysis of breath/depth/content of case-based education provided, and assessment of adaptations made by clinical teams for their local areas. Assessment of fidelity to the agreed approach to Needs Rounds will occur when a singular UK model has been developed and applied across sites. Fidelity will be assessed through analysis of a random sample of 20% of all audio-recorded Needs Rounds to assess adherence to the agreed approach developed in the workshops. A three tier scoring system will be adopted, of 1 (high adherence), 2 (moderate), 3 (low), with operational definitions for these scores developed prospectively as UK Needs Rounds are developed.
- We will collect data on the **experiences and process of PPI** throughout the study. We will conduct interviews with PPI members and the research team, including all co-investigators and representatives from the case study sites (both specialist palliative care and care homes). One-to-one phone/video-conference interviews will be conducted to examine the successes and opportunities of patient/public involvement in this study, to enhance future PPI work. This is likely to be conducted by the study RF, presenting some limitations with objectivity and an independent RF will be used if possible. If sufficient capacity within the Chief Investigator's team allows, then a researcher external to the study team will be engaged to facilitate increased potential for participants to speak openly about deficits or areas to strengthen in the PPI approach.

3.8 Outcomes and process evaluation

The main outcome will be determining the characteristics of effectiveness regarding what works in what circumstances with Needs Rounds within the UK, derived from through qualitative interviews with key stakeholders (residents, relatives, care home staff, specialist palliative care staff, and acute care staff). Secondarily, we will determine for whom Needs Rounds work, focusing on core stakeholder groups: the NHS, residents, care home staff.

The primary outcome relating to statistical analysis is cost of hospitalisation for care home residents. Secondary outcomes relating to statistical analysis relate to quality of death and dying, and capability of adopting a palliative approach, number and duration of hospitalisation, mode of transport to hospital, and use of primary care services.

The PPI evaluation seeks to determine areas of strength and learning for future studies. Analysis will be conducted inductively with a standpoint of theoretical freedom, and hence no *a priori* outcomes are indicated.

3.9 Data analysis

Qualitative data: Transcripts of audio data and documentary evidence will be stored and organised using Nvivo. Within and between case analysis will be conducted inductively, drawing on process tracing and constant comparative methods respectively. Differences between the Australian context and the UK will be surfaced to facilitate detailed reporting on the specificity of the UK model to the local context. Deductive analysis will also be used to refine the CMO theories. Thematic analysis will underpin the analytic approach, and follow the five-step process outlined by Braun and Clarke.[62]

Estimating the treatment effect of the intervention on health service outcomes

Baseline data will be collected on the number and duration of hospitalisations over the preceding 4 months. This will be compared to the number and duration of hospitalisations recorded in months 9 to 12 of the intervention. This allows time for the intervention to be established, and ensures that equivalent 4 month periods are being compared to control for seasonality.

The treatment effect will be estimated as paired t-tests of the rate of hospitalisation, and number of hospital days, respectively. We will also conduct multilevel regression modelling of the two outcome measures, controlling for local area deprivation, sector of the care home, and other characteristics to describe the wider factors associated with the changes in the outcomes observed. We will estimate a weighted least squares model of the outcomes, with cases weighted by the number of beds in the care homes, as a further robustness check. The estimates of the treatment effect will be used in the cost effectiveness analysis, incorporating the uncertainty of the estimates in the analysis.

Estimating the cost effectiveness of the intervention on health service outcomes

A cost-benefit analysis of the intervention will be undertaken from a health and social services perspective. The intervention cost will be calculated to include both direct and indirect costs to both NHS and care homes of delivering the intervention. Benefits are calculated as the change in NHS costs incurred following the intervention, including both primary and secondary care. We will estimate these by valuing the reduction in hospital stays and hospital days as a result of the intervention. These will be measured using hospital day rates and ambulance costs. Where possible, we will also collect data on additional health costs such as GP callouts and visits by specialists.

The CBA will be conducted from the perspective of the NHS and Personal Social Services. We will compare the costs of the intervention to the changes in health service costs from reduced hospitalization. When calculating costs and benefits, we take account of i) uncertainty in the estimate of the treatment effect; ii) projected costs over a five-year period; and iii) spatial variation in cost across jurisdictions. Wherever possible the analytical specification will follow that of the NICE Reference Case.[63] While there are also likely to be individual and broader societal benefits arising from the intervention these are challenging to value in financial terms and beyond the scope of this economic evaluation. They will be explored instead in the qualitative portion of the study.

We will model the net benefits of the intervention over a five year period separately for care homes in i) England and ii) Scotland, given the estimate of cost savings per care home bed and the total number of care home beds in each jurisdiction, and applying an annual discount rate. We will model these predictions at the point estimate for the treatment effect, and also for the upper and lower bounds of the 95% confidence interval around the treatment effect, to provide a range of plausible costs savings over five years incorporating the uncertainty in the main study.

We estimate the treatment effect using a pre and post design. One of the limitations of this design is that aggregate time trends can be a confounder. We have attempted to mitigate this by using multiple sites across the country, and by measuring the baseline and post-treatment outcomes at the same time of year. However, in interpreting the results we still need to be mindful that national-level time trends could explain part of the differences observed.

We want to represent the uncertainty of the estimated treatment effect in our cost effectiveness analysis. We will use the 95% confidence intervals from the estimated treatment effect to calculate estimated cost effectiveness ranges i.e. we will report the cost effectiveness at i) the lower bound of the 95% confidence interval; ii) the point estimate of the treatment effect; and iii) the upper bound of the 95% confidence interval. Reporting a cost effectiveness range will allow us to capture the uncertainty in the treatment estimate in our cost effectiveness figures.

Some sub-group analysis is likely to be conducted, for example to examine cases focused on independent specialist palliative care teams, and public versus private care homes.

5.7 COVID-19 contingencies

The study can progress even if localized or national lockdowns are required during the timeframe of the project.

- Needs Rounds can be delivered using video conferencing technology (and has been successfully used in Australia during COVID-19 using appropriate video meeting platforms).
- Care home data collection is conducted by care home staff.
- Interviews can be conducted using video/phones, save for resident interviews which may need to be postponed until care homes can receive visitors.
- Workshops will be conducted online using video-conferencing platforms, and split into part days to manage participant fatigue.
- Steering group and investigator meetings were always planned to be conducted online.
- Clinical work by specialist palliative care clinicians with care home residents may need some adjustments, to fit with the hospice's policy on providing care during COVID. Greater emphasis within Needs Rounds may be required on education for care home staff to support amended delivery of care. Qualitative data will be captured on adjustments required due to local lockdowns as the study progresses.

4. Project management

The study will be sponsored by the University of Stirling. LF, the chief investigator (CI), will maintain oversight of the whole study. LF will lead the project team (including all study co-applicants and the research fellow) which will oversee the study and hold monthly meetings, via zoom video-conferencing. Additional ad hoc discussions may be convened on a needs-led basis throughout, for example during crucial phases of the study. LF will have a formal weekly meeting with the research fellow, who will be based at the University of Stirling.

The CI will be the project manager, working closely with the appointed research fellow and being the named contact for PPI members. The research fellow will be the main point of contact for each of the case study sites and also liaise closely with the PPI members.

Six-monthly reports to the funder (NIHR) will be produced. In the interim the research team will monitor budgets and progress at each collaborating institution. The proposed monitoring will ensure that a high quality study is delivered on time and within budget.

A project steering group (PSG) will be convened and meet a minimum of annually throughout. Membership will comprise expertise in specialist palliative care, care home research, commissioning, health economics, statistics and PPI representatives. The NIHR terms of reference will be used to guide the structure, content and reporting mechanisms of the PSG.

5. Project registration

Registration will be conducted following ethical approval.

6. Ethical considerations

Ethical approval has not yet been granted.

Management approval from care homes will be sought in writing as part of the approvals process. Care homes will act as the data custodians for summary resident data, including health service use. Consequently, there will be no requirement to access to individual-level linked administrative NHS data on hospital episodes.

The study seeks to improve care for people residing in care homes, with a more specific focus on those who would benefit from specialist palliative care. Care home residents are recognised to have high prevalence of dementia and cognitive impairment, at around 70% of residents.[60] Data from 2013 show the rates increasing, thus by 2021 when data collection commences, the 70% figure is likely to be an under-estimate.[64]

Some people with dementia in care homes may have early/mild symptoms and still be able to provide consent. However, a substantial majority are unlikely to be able to. If we only ran Needs Rounds with adults who could provide consent, and if we could only access health service use and other resident data on those who could provide consent this would be (at best) less than a third of residents, and no longer be focused on those most at risk of dying in the next 6 months.
Further, some of the data we wish to collect will be from deceased residents. For example, for baseline data on hospitalisations and health service use, we will want data about each care home's residents' health service use in the four months prior to commencing Needs Rounds. This will include residents who died during that 4 month window, or died subsequently.

Primary care practices used by the care homes will be provided with information about the study.

Researchers will have a current PVG certificate/DBS check, and will undertake the NIHR Good Clinical Practice module. University of Stirling will act as the Sponsor. University and NHS REC ethical permissions will be gained.

7. Patient and Public Involvement

Our PPI approach is informed by the National Standards and INVOLVE guidelines. The aim of our PPI engagement and involvement is to ensure the study is focused on improving services for residents and families. Both consultation and collaboration will be used as appropriate throughout the study. The study has PPI representatives as full members to ensure that study leadership is informed by people with lived experience of relatives/friends receiving end of life care in care homes. Plain language is always used for communication with PPI members, and training provided prospectively as required throughout.
A PPI protocol will be devised prior to the start of the study, outlining expectations for all investigators, research fellows and PPI members.
The three PPI representatives, Ms Ogden, Ms McKenzie and Ms Soulsby, bring expertise through experience of relatives and close friends residing in care homes. Our PPI network crosses the UK, to ensure that we gain insight from people with a range of backgrounds and experiences.

PPI members will provide advice on all aspects of the study. They will also contribute to activities such as developing ethics documentation, assisting with refining recruitment processes (particularly with reference to recruiting family members to Phase 1), and data collection for both phases. Our PPI team members have chosen to contribute to data analysis, the Phase 2 workshop, writing blogs on their involvement in the study, tweeting about the study, and giving talks to local carers groups. As the project develops other opportunities for engagement and leadership will be discussed and PPI members can take on roles which interest them.

We will evaluate our PPI work throughout, and produce a summative document at the end of the study. This will include an audit of PPI resources/costs.
No specific on-boarding will be conducted with the PPI members, since they have been engaged in the study development for over a year.

8. Project / research expertise

This is a senior and multi-disciplinary team with expertise from psychology (LF), nursing (BMcC, JH, KS, NJ), statistics and economics (AR), and personal experience of care homes (MO, MM, IS). We have methodological expertise in implementation (BMcC, JH), qualitative methods (LF, BMcC, JH), and case study methodology (LF). Together, we provide all the expertise required to deliver this project.

- **Dr Forbat** is the CI. She is a research psychologist and family systems psychotherapist. She led the Australian Needs Rounds trial and has expertise in specialist palliative care, ageing, interventions, qualitative research and case study methodology. She won an award for her user involvement work from the National Cancer Research Institute (2011). She will lead this study, drawing on her track record of delivering high quality studies on time and on budget.
- **Prof McCormack** is an internationally recognised leader in implementation science, ageing, nursing and care homes. He is one of the founders of the PARHiS implementation science framework and has applied the methodology to dozens of implementation studies. His writing and research focuses on person-centred practice, gerontological nursing, and practice development. He is Editor Emeritus of the “International Journal of Older People Nursing”, holds an honorary appointment as consultant nurse in NHS Forth Valley (one of our case study locations), and is on the Board of Age Scotland.
- **Prof Spilsbury** has developed a programme of clinically and policy relevant research in the areas of the workforce, care for older people and care homes. She leads a portfolio of research with care homes: including the RCN Foundation funded project addressing support for nurses in care homes; the first UK study of the relationship between staffing and quality in care homes; and is Academic Director of NICHE-Leeds - a partnership between the care sector and academia to enhance quality of care, quality of life and quality of work in care homes. She has widely disseminated her work to promote impact and benefits for health and care. She was Associate Editor for the International Journal of Nursing Studies and a former NIHR HSDR Commissioning Board member.
- **Dr Hockley** is an expert in palliative care, nursing and care homes. She has considerable expertise in facilitation’s role in implementation, and has been involved in both the PACE European study on improving care in nursing homes and the Namaste person-centred approach to care in nursing homes.
- **Prof Rutherford** is a health economist and social statistician specialising in working with administrative data on hospitalisation, care and the third sector. He led the Scottish Civil Society Data Partnership, and has been a co-investigator in the Scottish Administrative Data Research Centre; the Centre for Population Change; and the Scottish Longitudinal Study of Ageing (HAGIS). He is a member of the Scottish Informatics and Linkage Collaboration Strategic Management Board; and is a board member of Age Scotland.
- **Prof Hanratty** is GP with expertise in primary care, palliative care and care homes. She holds and NIHR grant using a critical realist methodology, and will ensure Needs Rounds evolve to suit the primary care clinical context of the UK.
- **Ms Ogden** won the 2019 award for her PPI role ‘Putting Patients and Carers First (palliative care) from South London Clinical Research Network. She has relatives who have lived in care homes, and experience of acute hospital provision of specialist palliative care. She will link with Age UK and Carers UK to garner further PPI input into the study. She attended International Research Summer School in 2011 (palliative care) at Lancaster University. She was also a member of NCRI Clinical Studies Group on palliative care and sub-group on pain management. She has completed projects on sedation, breathlessness, social determinants at end of life (place of death), childhood bereavement and transitions into palliative care. She has also conducted a piece of work on evaluating PPI for the Cicely Saunders Institute of Palliative care.
- **Ms McKenzie** worked in the NHS and has expertise in psychological first aid. She cared for her father-in-law and is passionate about bringing her personal and professional experience to improving nursing home care.
- **Ms Soulsby** has links with the Newcastle carers network, and is a PPI representative for projects in Scotland and England. She has taken part in a James Lind Alliance Priority Setting Partnership (PRIORITY II) as a Steering Group member and has also been a member of the Steering Group for RAINDROP (**R**esource **A**llocation **in** **N**HS **D**entistry: **R**ecognition **o**f societal **P**reference). She is a PPI representative on Trial Steering Groups and Trial Management Groups, and a Patient Research Ambassador for the North East and North Cumbria. She is an

expert by experience with several neighbours experiencing care and an elderly friend receiving dementia care. Her father and aunt both received palliative care. Ms Soulsby will use her enthusiasm for the work to ensure everyone gets the best possible care, being treated with dignity, compassion and respect.

- **Specialist palliative care teams:** We have named a co-applicant from each of the specialist palliative care teams implementing UK Needs Rounds, who have acted as our strategic leads for each site providing authorisation for the study to proceed. After securing funding, each specialist palliative care team will then identify suitable practitioners who will deliver Needs Rounds in those sites. Some sites will redeploy current staff, other sites may recruit new staff to deliver Needs Rounds; these practical decisions have not yet been taken and hence the members are staff are not named in the application.
- **Partner:** Nikki Johnston is a nurse practitioner and was the lead clinician in the Australian study. She has extensive experience in providing specialist palliative care in nursing/care homes in Australia, and won the Australian ‘HESTA’ 2019 nursing ‘team excellence’ award for the Needs Rounds project, and also won the inaugural Australian Health Minister’s Award for ‘Nursing Trailblazers’ in 2019.

9. Project / research timetable (key milestones are in red)

	Oct 20	Nov 20	Dec 20	Jan 21	Feb 21	Mar 21	Apr 21	May 21	Jun 21	July 21	Aug 21	Sep 21	**Oct 21**	Nov 21	Dec 21	Jan 22	Feb 22	Mar 22	Apr 22	May 22	Jun 22	Jul 22	Aug 22	Sep 22	**Oct 22**	Nov 22	Dec 22	Jan 23
Month	**1**	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Governance/staffing																												
Appoint research fellow	🟦																											
Ethics approvals	🟦	🟦	🟦	🟦																								
PPI key tasks	🟥	🟥	🟥	🟥	🟦	🟥	🟥	🟥	🟦	🟥	🟦	🟦	🟥	🟦	🟦	🟦	🟥	🟦	🟦	🟦	🟥	🟥	🟦	🟦	🟥	🟥	🟥	🟥
Steering group meetings		🟦						🟦						🟦						🟦						🟦		
Empirical data tasks																												
Stakeholder interviews					🟦	🟦																						
Analysis						🟦	🟦		🟦					🟦				🟦				🟦	🟦	🟦	🟦	🟦	🟦	
Co-design workshop							🟥		🟥											🟥								
Identify and train facilitators								🟥																				
Implementation										🟥	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦							
Prospective interviews													🟦				🟦				🟦				🟦			
Prospective data collection on residents										🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦							
Cost analysis completed																								🟥				
UK Needs Rounds model finalised																											🟦	🟦
PPI evaluation data collection																							🟦	🟦	🟦			
Analysis													🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟥	🟥
Dissemination																												
Social media and 3rd sector updates		🟦					🟦			🟦			🟦			🟦			🟦			🟦			🟦		🟦	🟦
Site newsletters/updates		🟦			🟦			🟦			🟦			🟦			🟦			🟦			🟦			🟦	🟦	🟦
Conference: EAPC																											🟦	🟦
Develop and submit journal articles																											🟦	🟦
Policy-maker dissemination		🟦								🟦																	🟥	🟥
Translation tools																											🟥	🟥

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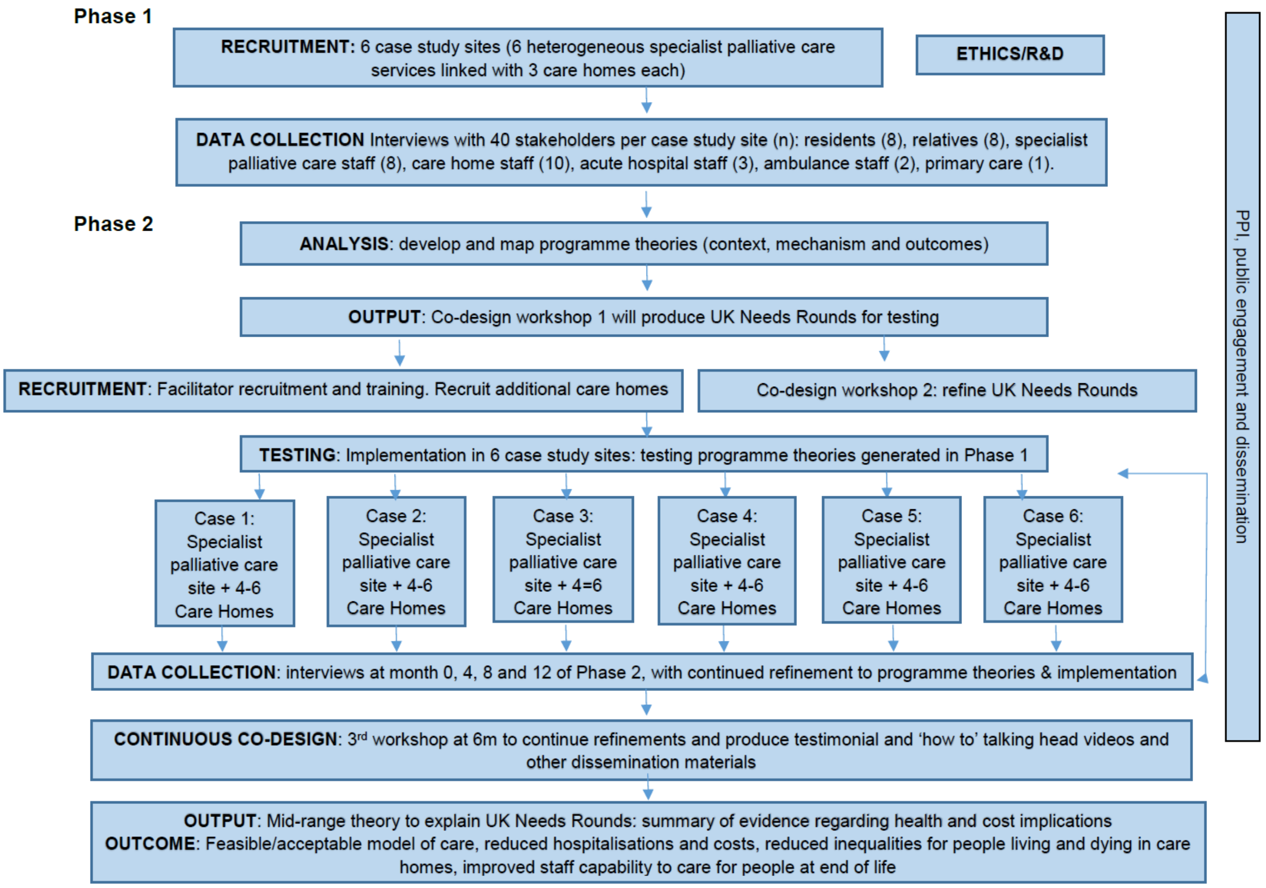
Appendix A: Study flowchart



Phase 1

RECRUITMENT: 6 case study sites (6 heterogeneous specialist palliative care services linked with 3 care homes each)

ETHICS/R&D

DATA COLLECTION Interviews with 40 stakeholders per case study site (n): residents (8), relatives (8), specialist palliative care staff (8), care home staff (10), acute hospital staff (3), ambulance staff (2), primary care (1).

Phase 2

ANALYSIS: develop and map programme theories (context, mechanism and outcomes)

OUTPUT: Co-design workshop 1 will produce UK Needs Rounds for testing

RECRUITMENT: Facilitator recruitment and training. Recruit additional care homes

Co-design workshop 2: refine UK Needs Rounds

TESTING: Implementation in 6 case study sites: testing programme theories generated in Phase 1

Case 1: Specialist palliative care site + 4-6 Care Homes

Case 2: Specialist palliative care site + 4-6 Care Homes

Case 3: Specialist palliative care site + 4=6 Care Homes

Case 4: Specialist palliative care site + 4-6 Care Homes

Case 5: Specialist palliative care site + 4-6 Care Homes

Case 6: Specialist palliative care site + 4-6 Care Homes

DATA COLLECTION: interviews at month 0, 4, 8 and 12 of Phase 2, with continued refinement to programme theories & implementation

CONTINUOUS CO-DESIGN: 3rd workshop at 6m to continue refinements and produce testimonial and 'how to' talking head videos and other dissemination materials

OUTPUT: Mid-range theory to explain UK Needs Rounds: summary of evidence regarding health and cost implications
OUTCOME: Feasible/acceptable model of care, reduced hospitalisations and costs, reduced inequalities for people living and dying in care homes, improved staff capability to care for people at end of life

Appendix B: Draft care home resident data reporting template

Example provided, to illustrate summary data

	Use this column to put your numbers in
Care Home ID:	012
What month is it?	July 2021
Number of beds	60
Number of residents	62 (2 deaths)
Number of residents who did not participate/opt outs	0
Sex	
Women	40
Men	22
Age	
<60	1
61-69	10
70-79	44
80-89	6
90+	1
First Language	
English	40
European	10
Asian (Indian subcont)	5
Asian (Other)	5
Other/DK	2
Ethnicity	
White British	25
Any other mixed/multiple ethnic background	25
Asian (Indian subcont)	5
Asian (other)	5
African	
African/Caribbean	1
Any other ethnic group	1
Preferred Place of Death	
Care Home	40
Hospital	5
Hospice	5

Other	1
Don't know	9
Number of deaths	2
Place of death	
Care Home	2
Hospital	
Hospice	
Other	
Don’t know	
Charlson score	
0	
1	
2	
3	
4	
5	
6	1
7	
8	
9	
10	
11	2
12	3
13	1
14	22
15	
16	12
17	5
18	
19	10
20	
21	6
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	

35	
36	
37	
Lasting Power of Attorney/ Guardianship Order/ Emergency management order	
Yes	20
No	40
Don't know	2
Advance care plan/statement of choices	
Yes	20
No	40
Don't know	2
Hospitalisations	
Number of residents hospitalised	6
Total number of hospitalisations	7
Hospitalisation 1 • Length of stay (<1 day, 1,2,3,4,5,6,7,8…)	2
• Charlson score of resident (score between 1-37)	14
• Age of resident (in years)	85
• Gender of resident (M, F, DK)	F
• Admitting department (cardiology, ED, orthopaedics, surgery)	Cardiology
• Name of hospital	Colchester hospital
Hospitalisation 2 • Length of stay (<1 day, 1,2,3,4,5,6,7,8…)	4
• Charlson score of resident (score between 1-37)	16
• Age of resident (in years)	82
• Gender of resident (M, F, DK)	F

- Admitting department (cardiology, ED, orthopaedics, surgery)	General surgery
- Name of hospital	Colchester Hospital
Hospitalisation 3 - Length of stay (<1 day, 1,2,3,4,5,6,7,8…)	<1 day
- Charlson score of resident (score between 1-37)	19
- Age of resident (in years)	85
- Gender of resident (M, F, DK)	M
- Admitting department (cardiology, ED, orthopaedics, surgery)	ED
- Name of hospital	Ipswich General
Hospitalisation 4 -7 (etc etc)	--
Transport to hospital	
Ambulance (999)	6
Ambulance (non emergency)	
Private car	1
Other (tell us how many and how they got there)	
Primary Care (contacts with staff at the GP practice)	
Total number of primary care contacts	24
Saw a GP	6
Saw a nurse at the GP	12
Saw a pharmacist at the GP	1
Paramedic	4
Pharmacist	
Don't know	
Reasons for contact with GPs	
Reason 1	Constipation x3
Reason 2	Blood tests x5
Reason 3	Confusion x12
Reason 4	Review meds x4
Reason 5	
Reason ….	

Appendix C: Needs Rounds data reporting template

Example provided, to illustrate summary data

	Use this column to put your numbers in
Care Home ID:	035
What Month is it?	December 2021
How many residents were discussed at Needs Rounds this month?	8
How many case conferences were needed?	2
Assessments triggered by Needs Rounds	
Bloods	1
Urine	2
Pain assessment	4
Clinical assessment	1
Syringe driver set-up	0
New prescriptions	
Opiates	4
Aperients	2
benzodiazepines	0
anti-emetics	1
antipsychotics	0
anticonvulsants	0
De-prescribing	
Name: Statins	2
Name	
Name	
Name	
Number of syringe Drivers started	
	1
External referrals made	
None (put an x if none made this month)	X
Name: (e.g. physio)	
Name: (e.g. dementia friends)	