HTA NAMASTE Protocol

The Namaste Care intervention to improve the quality of dying for people with advanced dementia living in care homes: A realist review and feasibility study for a cluster randomised controlled trial. Phases 1 and 2

Chief Investigator: Professor Katherine Froggatt (Lancaster University)

Co-Investigators:
Dr Catherine Walshe (Lancaster University)
Dr Nancy Preston (Lancaster University)
Dr Guillermo Perez Algorta (Lancaster University)
Professor Claire Goodman (University of Hertfordshire)
Dr Frances Bunn (University of Hertfordshire)
Professor Jo Coast (University of Bristol)
Dr Julie Kinley (St Christopher's Hospice, London)
Professor Paula Williamson (University of Liverpool)
Dr Girvan Burnside (University of Liverpool)
Helen Hind (University of Liverpool)
Dr Anne Davidson Lund (PPI member)
Mr David Scott (PPI member)

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1. Project structure

A three phase feasibility study is being undertaken to examine the feasibility of undertaking a full trial of the Namaste Care intervention to improve the quality of dying for people with advanced dementia living in care homes. The study comprises three phases:

a) ***realist evidence review*** to develop programme theories about how the Namaste care intervention achieves particular outcomes in what circumstances.

b) ***intervention and implementation process refinement*** to create resources and an implementation process acceptable to care staff and families.

c) ***feasibility cluster controlled trial*** (with process and economic evaluation) to establish if the intervention can be implemented in the nursing home context; and if it is feasible to undertake a full trial on the use of the intervention for this population in this setting.

This protocol outlines the Phase 1 and 2 stages of the study. Ethical approval for Phase 3 will be sought from IRAS in 2017.

2. Background and Rationale:

Dementia is a life limiting condition, with a median survival, decreasing with age, of 6.7 to 1.9 years[1]. In advanced dementia, an individual requires full assistance with care, is chair or bedbound, doubly incontinent and no longer able to communicate verbally (FAST scale 6-7)[2]. People with dementia often experience a poor quality of death, preceded by a period of poor quality of life, with over and under treatment occurring[3-5]. There is an increasing urgency for appropriate care that will ensure a good quality of life and dying are achieved[5-6]. Yet uncertainty about when dying will occur still exists for many people[7].

The numbers of people living and dying with dementia are increasing. The total estimated UK cost of dementia was £26.3 billion, with the NHS covering £4.3 billion of the costs and social care £10.3 billion[8]. Costs are attributed to informal care, direct costs of social care (from community care professionals, and in institutional residential settings)[9], and the direct costs of medical care. These institutional and medical costs increase towards the end of life, particularly in the last year of life[10]. Research that generates new knowledge to improve, and sustain over time, individual quality of life and dying and reduce inappropriate use of acute care services is required.

Evidence for therapeutic healthcare interventions for people with advanced dementia is limited. A Cochrane Systematic review (Palliative care (clinical and non-clinical) interventions in advanced dementia) is under way, but has not yet reported its findings. The largest relevant evidence base can be found in systematic reviews of non-pharmacological interventions (mainly complex psycho-social interventions) for those with advanced dementia. These reviews identify equivocal promise in improving quality of life for people with advanced dementia[11]. Reviews of related therapies such as music therapy indicate mixed outcomes for people with dementia, with a Cochrane review identifying equivocal evidence[12]. More recent reviews of these therapeutic interventions identify large positive effects on behavioural, cognitive and physiological outcomes[13], to moderate effects on anxiety with small effects on behavioural symptoms[14] and evidence for short term improvement in mood and reduction in behavioural disturbance[15]. In a Cochrane review of touch therapies, some evidence of an effect was identified, but not specifically for people with advanced dementia[16]. A recent review indicated that massage reduced levels of agitation[17]. Interventions supporting person centered care have been shown to reduce agitation[18] and behavioural disturbance[19]. There is some evidence for individualised interventions, within a bio-psychosocial framework, improving behavioural symptoms[20].

Interventions with a uni-focus on reducing pain, physical symptoms or specific behavioural disturbances have been found to be effective[4]. It is recognised that for people with advanced dementia there is a need for interventions that complement and enhance pharmacological interventions. This study addresses the lack of evidence available through completed research, to consider the stage specific efficacy of non-pharmacological interventions[21]. There is also a need for practical interventions that staff can learn to deliver which allow them to provide person-centered care.

Palliative and end of life care interventions for people with dementia, which emphasise a person-centered philosophy, and use co-design approaches, are being developed and tested[22]. One such intervention developed by practitioners in the United States, is Namaste Care. The intervention addresses the multiple needs a person with dementia has for attachment, identity, comfort, inclusion and occupation[23]. It utilises individual components of other interventions which have been shown to have most promise[13,16,18].

A number of premises of person centred care inform the Namaste Care intervention[24]. The person with dementia is first and foremost a person, not a patient or resident[25]. Consequently, as a person, they have the same needs as other people for physical comfort and care; emotional, social and spiritual well-being[26]. They are also striving to make sense of the world, however cognitively impaired[27] and will act from their meaning of the world[28]. Care efforts therefore need to focus on building a supportive social psychology or relationships which affirm personhood[29]. The final premise is that supportive environments can not only mitigate against the effects of disease, but have the potential to arrest the social impacts of the progression of the disease[30].

Namaste Care is a complex intervention for people with advanced dementia delivering proactive structured care focused on enhancements to physical settings, comfort assessment and management, and ongoing sensory engagement that incorporates personalised activities to reflect life story and preferences[23]. The intervention aims to integrate enhanced nursing care through individualised activities, that emphasise increased sensory input as a planned, integral part of care work, and the provision of tailored comfort and support to improve the quality of dying and living at the end of life. Staff receive group training about the programme.

Non-randomised research studies have identified that Namaste Care at the end of life reduces the severity of behavioural and physical symptoms and occupational disruptiveness[31-34] and may have an impact on social interaction, delirium and agitation[35]. The potential for cost savings with respect to reduced psychotropic medication use has also been indicated[36]. Qualitative evidence suggests greater family and staff satisfaction with care[35]. However, none of these studies have compared this intervention with other approaches to palliative and end of life care for this population. We do not yet know the optimum way of delivering this complex intervention and whether benefits can be demonstrated in end of life care, for individuals and service delivery.

2. Overall study aim and objectives:

2.1 Overall study Aim:

To establish the feasibility of conducting a cluster controlled trial in a nursing care home context in order to understand the impact on quality of dying of the Namaste Care intervention for people with advanced dementia, when compared to usual end of life care.

2.2 Objectives for Phases 1 and 2

a) To develop a programme theory(ies) of how the Namaste care intervention achieves particular outcomes, and in what circumstances.

b) To refine and develop an evidence based Namaste Care intervention specification and training package

3. Research design

A feasibility study for a multi-centre cluster controlled trial of Namaste Care plus Usual Care (NC+UC) versus Usual Care (UC) is proposed. Three phases are planned:

(1) realist evidence review;
(2) intervention and implementation process refinement;
(3) feasibility cluster randomised controlled trial (with an embedded process and economic evaluation).

The first two phases are presented here for ethical review.

3.1 Phase 1 Realist Evidence Review

The realist review will identify and synthesise evidence from key experts and research and associated literature to develop a theory driven explanation of how the Namaste care intervention might work, in what circumstances and for whom. Information from this review will inform the format of the intervention to be delivered in the nursing care homes and the design of the trial with respect to the assessment and measurement of its implementation, including the way in which different outcome measures are defined and used. A Theory of Change will be written to underpin the study design and process evaluation[37].

Namaste Care is a complex, context sensitive multicomponent intervention. Systematic reviews have suggested that sensory enhancement may have beneficial effects for people living and dying with dementia but the process of care, the different elements of the intervention and how and why it achieves (or not) different resident outcomes are poorly understood.

Realist review aims to provide a theory driven account of how in particular settings (**context**), **mechanism**(s) within different complex interventions designed to support people with advanced dementia at the end of life, are effective (or not), leading to particular **outcomes** (C-M-O). This review process recognises that end of life interventions for people with dementia are always jointly produced between the intervention as designed, the different participants, the different settings and how the person dying with or from dementia is acknowledged, understood and managed. Realist review methodology will enable the component theories of the Namaste Care intervention to be deconstructed. Through proposing possible different context-mechanism-outcome configurations to make explicit the based on the evidence, how it is perceived to work and in what circumstances and with what outcomes. Information from this review will inform the format of the intervention to be delivered in the care homes and the assessment and measurement of its implementation, including the way in which different outcome measures are defined and used in the trial.

An iterative two stage approach is proposed that is stakeholder driven and optimises the knowledge and networks of the research team. The approach draws on the work of Pawson[38-39] and is informed by RAMESES guidance on reporting of realist reviews[40].

Stage 1 Defining realist review parameters and develop programme theories
Stage 2 Realist review retrieval, review and synthesis (Figure 1)

3.1.1 Stage 1: Defining realist review parameters and develop programme theories

In Stage 1 the research team, literature, and expert stakeholders will be consulted to identify why certain approaches to end of life care for people with advanced dementia work (or not), in what circumstances and why.

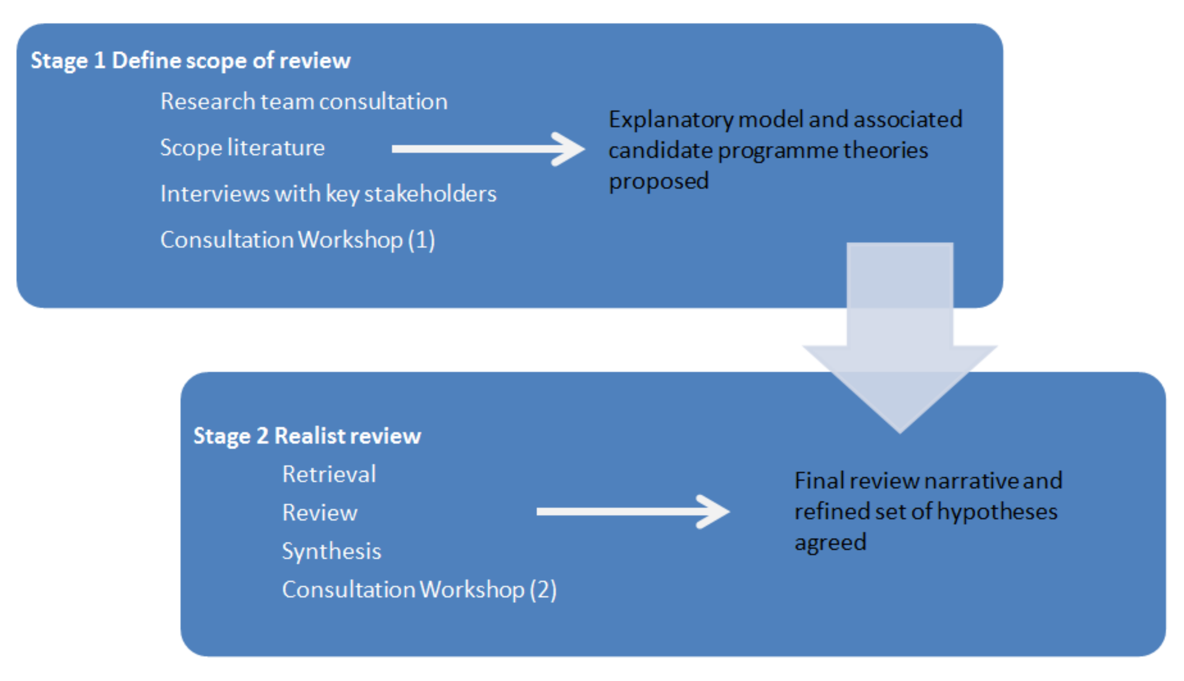

Figure 1: Phase 1 Realist Evidence Review Stages

Aim:
The aim is to establish:

- How the experience of dying with and dying from dementia can be conceptualised (and measured);
- Approaches to comfort and symptom assessment and management for this population;
- Evidence of what supports implementation of end of life care interventions for people with advanced dementia in care homes;
- Guidance for the next stage of the review process.

Methods:
The ***research team*** will draw on their collective knowledge and experience in dementia palliative care in care homes to develop initial programme theories or hypotheses to identify why certain approaches to end of life care for people with advanced dementia work (or not).

A ***preliminary review of recent key literature*** on approaches to end of life care for people living and dying with dementia in care homes will be undertaken.

Structured interviews will be undertaken with key expert stakeholders, 5-10 representatives, from palliative care, dementia care and care home provision, policy and research organisations, (e.g. St Christopher's Hospice, National Council for Palliative Care, Lancashire Workforce Development Partnership, care home providers, Alzheimer's Society, My Home Life).

Recruitment: Individuals will be identified through current networks and involvement in published literature. Participants will be approached directly by the research team either via letter or email. Participants will be sent a participant information sheet which will contain details of the purpose of the study and their involvement. Stakeholders will be given 48 hours before further contact is made to see if they are interested in taking part and arranging a convenient time and place to speak to them (interviews may be face to face or via telephone). If the participant is happy to continue with the interview, a consent form will be sent to the participant, completed and returned prior to the interview if by telephone, or completed at the start of a face to face interview. A copy of this will be retained or given to the participant.

Data collection: A topic guide will be used to structure the interviews which will explore what good end of life care looks like for this population and views as to how certain approaches to end of life care for people with advanced dementia work (or not), in what circumstances and why. We will collect basic personal data including gender, occupation and organisation. With the permission of the participant, interviews will be audio recorded and transcribed using an encrypted digital device. Each participant will be assigned an anonymised code which will be used throughout the analysis and presentation of the results (e.g. direct quotation). The document linking participant codes to participant details will be kept separately to data. The data protection act will be adhered to at all times

Analysis: Findings from the scoping of the literature and the stakeholder consultation will be mapped out using the Context-Mechanism-Outcome configuration[38-39] as a template for analysis.

Consultation Workshop (1)

A one day workshop will be held to review the findings from the preliminary scope of the literature and stakeholder interviews, and agree an explanatory model and associated candidate programme theory for testing in phase two.

Participants and recruitment: research team and the key expert stakeholders, 5-10 representatives, from palliative care, dementia care and care home provision and policy organisations as recruited for the Phase 1 expert stakeholder interviews. At the end of the interview, confirmation that the participant will be willing to attend the Consultation Workshops will be sought. Further details of the workshops will be provided such as date, time and venue.

Workshop plan and data collection: Workshop information will be circulated two weeks ahead of the event. At the workshop, following completion of consent forms, findings from work of the research team, preliminary literature review and structured interviews will be reviewed by participants to develop statements around which a narrative can be developed, summarising the links between context, mechanism and outcomes, and the evidence underpinning them. Equal consideration will be paid to negative and positive outcomes. To ensure transparency of approach, and an audit trail, recordings of the group discussion (with permission) will be transcribed and structured field notes recorded on suggestions and decision making processes about which sources of evidence were linked to which strands of theoretical development.

Analysis: Using the template used in the analysis of the qualitative interviews, findings from the workshop will be coded and collated using the Context-Mechanism-Outcome configuration to inform the full realist review process

3.1.2 Stage 2: Realist review - retrieval, review and synthesis

In this stage the literature will be retrieved, reviewed and synthesised prior to final refinement in consultation with stakeholders and the research team using a realist review approach.

Retrieval of literature will entail a systematic search for published and unpublished evidence to test and develop the candidate theory identified in Stage 1. The focus will be on what needs to be in place to achieve key outcomes such as reduction of distress, changes in sleep patterns, symptom management, reduction in use of emergency and out of hours services and avoidance of unplanned hospital admission. The focus will be on end of life care interventions for people living with dementia in long term care that are similar to, or draw on the principles of the Namaste Care approach and will focus on evidence relevant to UK long term care settings and published since 2010 (to reflect the rapid expansion of work and interest in this research area). Inclusion criteria will be expanded in light of emerging data (from Stage 1) to ensure relevant evidence is included. The identification of articles and documents for the review (both published and grey) will begin with a list of documents identified by the project team and other content experts[41]. This will be supplemented by searches of electronic databases (e.g. PubMed, CINAHL, The Cochrane Library) and via lateral searches (e.g. citation searches and review of reference lists). Search terms will be developed collaboratively by the project team.

The literature will be **reviewed** through screening for inclusion on quality criteria. Papers will be screened for inclusion on the basis of the relevance and rigour of the evidence. Inclusion criteria will be refined through a process of discussion between these reviewers and with the wider review team. Relevance is defined as the extent to which evidence can contribute to theory building and/or testing, and rigour is defined as the extent to which the methods used to generate that particular piece of data are credible and trustworthy. Data extractions forms will be developed based on the content of the proposed programme theory.

Synthesis of the data will involve the organisation of data into evidence tables and the identification of cross-cutting themes across the tables, and linking the patterns identified to develop hypotheses, that either support or negate certain C-M-O (context–mechanism-outcome) configurations[42].

Consultation Workshop (2)
Once the preliminary mapping of evidence into relevant evidence tables has been undertaken these will be taken to a second one day consultation workshop to review the findings and to develop and confirm the plausibility of the resultant hypotheses. These will summarise the nature of the links between certain outcomes and C-M-Os, and the characteristics of the evidence underpinning them.

Participants and recruitment: research team and the key expert stakeholders, 5-10 representatives, from palliative care, dementia care and care home provision and policy organisations as recruited for stakeholder interviews recruited for the Phase 1 interviews and Consultation Workshop (1).

Workshop plan and data collection: Workshop information will be circulated two weeks ahead of the event. At the start of the workshop, consent forms will be completed. A structured workshop will be held to review findings from the realist review to either confirm, or reject the initially proposed hypotheses. Recordings of the group discussion will be made (with permission) and then will be transcribed and structured field notes recorded on suggestions and decision making processes collated.

Analysis: Confirmed hypotheses will be used to construct a narrative that summarises the context, mechanism and outcome links and the nature of the evidence present to support it.
This will result in a final review narrative and a refined set of hypotheses that can be tested in the trial phase.

3.2 Phase 2: Intervention programme and implementation process refinement

A consensus approach to consultation with care home staff and family members of people with advanced dementia will be undertaken. Findings from the Realist Review will be presented and consensus methods based on nominal group technique will be used to identify how the Namaste Care programme materials and the resources required to support the implementation process can be refined.

3.2.1 Target population:

NCH staff (includes managers, nurses, care assistants and activity coordinators) from up to 4 NCHs in the North West of England (n=8-12).
Family members of people with advanced dementia (n=4-8).

3.3.2 Inclusion/Exclusion criteria:

NCH Inclusion:

- Using an established palliative care intervention programme (Gold Standards Framework for Care Homes, Routes to Success, Six Steps to Success)
- NCH has experience of using Namaste Care in practice

Staff: Managers, nurses, care assistants and activity coordinators who have worked in an NCH setting for at least 6 months.
Family members of people with dementia: may be currently a family member for a person with dementia, or have held that role in the last three years. Family members will also need to be able to understand and communicate in English.

3.3.3 Method:

A 1 day consensus workshop will be held with care home staff (n=8-12, from up to 4 NCHs), and family members of people with advanced dementia (n=4-8). The term family member refers to family members, close friends or people significant to the person with dementia.

NCH staff recruitment: All NCHs recruited will be based in the North West of England. NCHs from different provider types (private (corporate and owner managed) and not-for-profit) will be sought. An invitation letter to care home managers will be sent inviting participation. The manager will be asked to send a workshop invitation letter and participant information sheet to individual staff (who have worked in the care home for at least six months and experience of the Namaste Care programme) inviting attendance at a consensus workshop. Staff who indicate a willingness to participate and respond by completing the response slip on the expression of Interest letter, or contacting the researcher, will be sent further details of the event, alongside a consent form to be completed and returned at the start of the workshop. If more than the required number of care staff respond, those invited to participate will be purposively chosen to reflect the different roles (manager, nurse, care assistant, activity coordinator in a care home) and different care home sites.

Family member recruitment: Family carers will be recruited through the NCHs and an invitation letter and participant information sheet will be sent to all family carers identified by the care home manager as having had relatives who are or have received the Namaste Care intervention in the nursing care home and meet the inclusion criteria. Following receipt of a response slip, or having contacted the researcher, family members will receive details of the event, alongside a consent form to be completed and returned at the start of the workshop. If more than the required number of family members respond, those invited to participate will be selected by randomly ‘drawing names from a hat’.

The consensus workshop has the following aims:

- To learn about the findings of the realist review and factors that shape the intervention delivery;
- To refine and prioritise the implementation process for the delivery of the Namaste Care programme on the basis of the realist review findings;
- To inform the format of the Namaste Care programme and implementation resources.

Two weeks ahead of the workshop, materials will be circulated to participants with specific guidance on what documents are supplied and the process to be followed. A lay version of the review findings from Phase 1 will be presented, alongside current materials available to support the implementation of the Namaste Care intervention.

Consensus methods will be used to identify how the intervention programme and resources required to support the implementation process can be refined. A modified nominal group technique using the following steps will be followed in the workshop: Introduction and explanation; Silent generation of ideas; Sharing ideas—Round robin; Group discussion/clarifying and Ranking[43].

During this process workshop participants will be asked to consider:

- components of implementation that need to be considered, to support the delivery of the Namaste care intervention into care home practice and relative importance of different elements;
- adaptations required to the content of Namaste care resources and implementation guidance in terms of language, style, appropriateness to the care context and presentation format.

Data collection will comprise notes taken during the meeting and documents (e.g. flip chart sheets) generated by participants in the meeting. These will be summarised and circulated to all participants for agreement on the decisions arising from the event. The findings of the consensus workshop will be used to inform the refinement of the intervention materials and implementation guidance to support its use in the subsequent feasibility trial. Personal demographic data will be sought on all participants at the consensus workshop using a structured template.

Analysis: Drawing on nominal group technique analytical methods[44,] analysis will consider both the strength of rankings and their frequency alongside a thematic analysis of reasoning for preferences.

4. *Ethical and governance approval*

The study will be undertaken following the Helsinki recommendations for research set out originally in 1964, but amended in 2013. Ethical approval is being sought from the host university for Phase 1 (rapid review) and Phase 2 (intervention refinement). Neither phase involves patients.

4.1 Consent

Informed written consent will be obtained from all participants in Phases 1 and 2. In both Phases 1 and 2, all participants will be sent an expression of interest letter and in interested in participating, will be sent a participant information sheet.

For the qualitative interviews, if by telephone, the consent form will need to be returned prior to the start of the interview data, in a freepost envelope. If a face to face interview, the consent form can be completed at the start of the interview.

For participants in the consultation and consensus workshops, consent forms will be signed at the start of each workshop.

The right of participants to refuse participation, or withdraw, without providing a reason will be respected. Participants will be able to withdraw from the interviews or workshops at the time. They can indicate they wish to withdraw their interview up to two weeks following the interview. Once a workshop is completed it will not be possible to withdraw an individual's data, because of the group nature of the collection process and subsequent analysis.

4.2 Confidentiality and Anonymity:

The confidentiality of participants involved in qualitative interviews will be partially maintained. Personal data will be kept separate from qualitative interview transcripts. For participants in consultation and consensus workshops, neither confidentiality and anonymity can be maintained during workshop groups but will be following data collection. Transcribers of interviews will be authorised providers of such services to Lancaster University, and will have signed a confidentiality agreement as part of the contracting process. It will be indicated on the PIS that transcription may be undertaken by an individual external to Lancaster University, but that they will have signed a confidentiality agreement.

Participants participating in qualitative interviews and workshops will have their anonymity maintained through the following processes. Each participant will be assigned an anonymised code which will be used throughout the analysis and presentation of the results (e.g. direct quotation). Anonymity will be maintained as individuals will not be identified in any reports or academic papers coming from the work.

4.3 Emotional Distress

For family carers attending the Phase 2 Consensus workshop, it is possible that participation in the workshop and discussion of care for a person with dementia might evoke memories and emotions of difficult personal experiences. If this should happen, a member of the research team will support the person on the day. Sources of further support are identified on the participant information sheet and will distributed again on the day to all participants, if requested.

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