Namaste Trial

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

Protocol version 3.0
12th December 2017

Ethical approval
NRES approval was obtained on the xxxxxxxxx with reference number xxxxxxx

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Sponsorship
Lancaster University is the sponsor of this study.

Registration
The study has been registered with the current controlled trials database under reference number ISRCTN14948133.

Dates
Study start date: 01/Dec/2017
Study end date: 30/Nov/2018

This protocol has regard for the HRA guidance

NHS
National Institute for Health Research

Signature Page

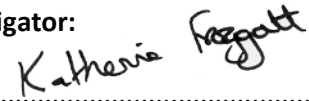
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the Sponsor's (and any other relevant) SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical intervention without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:
Signature: Date: DD/MMM/YYYY
.....

Name (please print):
.....
Position:
.....

Chief Investigator:
Signature:  Date: 25/Oct/2017
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Contents

Abbreviations and Definitions

AE	Adverse Event
CAD-EOLD	Comfort Assessment in Dying – End of Life Care in Dementia - questionnaire
Chief Investigator	Lead person in charge of the overall study
CMAI	Cohen Mansfield Agitation Inventory - questionnaire
CQC	Care Quality Commission - The independent regulator of all health and social care services in England
CRF	Case Report Form
CRN	Clinical Research Network
FAST	Functional Assessment Staging Test
FDA	Functional Data Analysis
GSFCH	Gold Standards Framework in Care Homes – an end of life organisational change approach to promote the delivery of end of life care in care homes
HRA	Health Research Authority – A public body of the Department of Health in the UK, tasked to provide a system of governance for health research in the UK
Informal Carer	People who self-define as a family member or friend who acts as an unpaid carer for a resident
Informed Consent	Is the voluntary agreement of an individual, or his or her authorized representative to take part in research
IS	Interdaily Stability
IV	Intradaily Variability
Nominated Consultee	An independent person who is appointed by the researcher to advise the researcher about the wishes and thoughts of the person who lacks mental capacity in relation to the project and whether they should join the research
NPI-Q	The Neuropsychiatric Inventory - questionnaire
Nursing Home Staff	Managers, Registered Nurses, Care Assistants and Activity Coordinators working in a nursing home
Participants	People who have given consent to take part in the trial. In this trial, there are three participant groups; residents, informal carers and nursing home staff
P-CAT	Person-Centred Assessment Tool - questionnaire
Personal consultee	Someone who knows the person who lacks mental capacity in a personal capacity and who is able to advise the researcher about the wishes and thoughts of the person who lacks mental capacity in relation to the project and whether they should join the research
PPI	Participant and Public Involvement
Principal Investigator	Manager or senior nurse at a given nursing home
Proxy consent/assent	Authorisation for someone to take part in a trial which is given by someone other than the individual taking part in the trial
QUALID	Quality of life in late stage dementia - questionnaire
REC	Research Ethics Committee
Residents	People with advanced dementia who are living in a nursing home
SAE	Serious Adverse Event
SOP	Standard Operating Procedure – written guidance providing instructions on how to conduct the task in question
SWC-EOLD	Satisfaction with care–end of life in dementia - questionnaire

General Information

This protocol describes the Namaste Trial and provides information about procedures for entering participants into it. The protocol should not be used as an aide-memoire or guide for the treatment of other participants; every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to the Principal Investigators in the trial, but nursing homes recruiting participants in the trial for the first time are advised to contact the Namaste Trial Team to confirm they have the most up to date version.

This protocol defines the participant characteristics required for study entry and the schedule of intervention and follow-up. Participant recruitment will be undertaken in compliance with this document and applicable regulatory and governance requirements.

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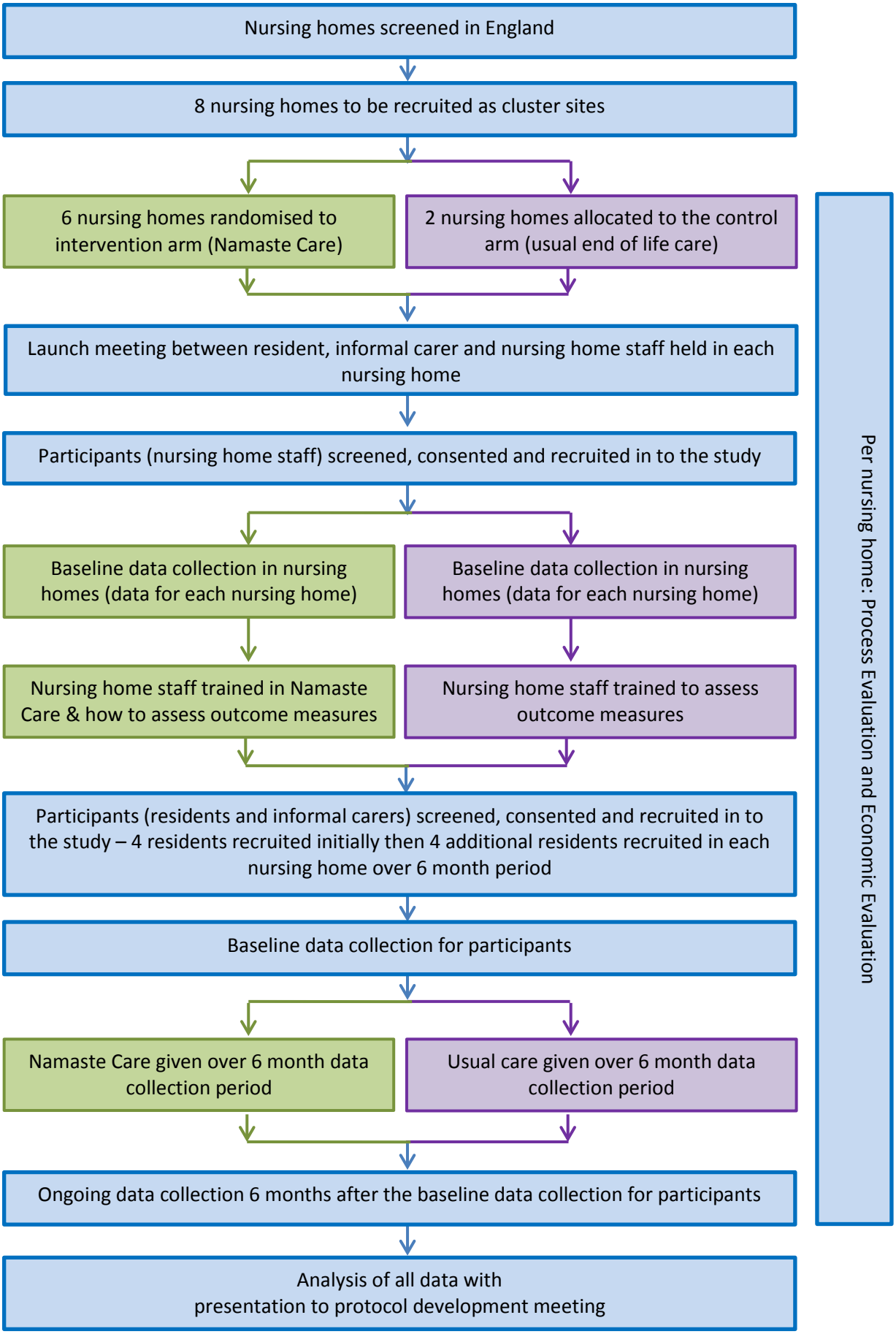
2. Synopsis

Study Title	The Namaste Care intervention to improve the quality of dying for people with advanced dementia living in care homes: A feasibility study for a cluster randomised controlled trial.
Short title	Namaste Trial
Study Design and Methods	Feasibility study, parallel, two-arm, multi-centre cluster controlled randomised trial with embedded process and economic evaluation
Study Participants	Residents: People with advanced dementia (FAST=6-7) Informal carers: Main relative or informal carer of resident with advanced dementia Nursing home staff: managers, registered nurses, care assistants and activity coordinators working in a nursing home caring for people with advanced dementia
Planned Sample Size	A total of 328 participants 64 residents Up to 200 nursing home staff (final number will depend on size of nursing homes recruited) Up to 64 informal carers
Planned Number of Sites	8 nursing homes
Intervention Duration	Up to a maximum of 6 months
Planned trial period	12 months
Primary Objective	To ascertain the feasibility of conducting a full trial of the Namaste Care intervention.
Intervention	Namaste Care programme

3. Trial Flow Chart



4. Introduction

4.1 Background

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]. 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.

4.1.1 Rationale

Evidence for therapeutic healthcare interventions for people with advanced dementia is limited. Reviews of related therapies such as music therapy indicate mixed outcomes for people with dementia, with a Cochrane review identifying equivocal evidence[7]. More recent reviews of these therapeutic interventions identify large positive effects on behavioural, cognitive and physiological outcomes[8], to moderate effects on anxiety with small effects on behavioural symptoms[9] and evidence for short term improvement in mood and reduction in behavioural disturbance[10]. In a Cochrane review of touch therapies, some evidence of an effect was identified, but not specifically for people with advanced dementia[11]. A recent review indicated that massage reduced levels of agitation[12]. Interventions supporting person centred care have been shown to reduce agitation[13] and behavioural disturbance[14]. There is some evidence for individualised interventions, within a bio-psychosocial framework, improving behavioural symptoms[15].

Interventions with a uni-focus on reducing pain, physical symptoms or specific behavioural disturbances have been found to be effective[3]. 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[16]. There is also a need for practical interventions that staff can learn to deliver which allow them to provide person-centred care.

Palliative and end of life care interventions for people with dementia that emphasise a person-centred philosophy, and use co-design approaches, are being developed and tested[17]. Namaste Care is one such intervention. 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[18-21] and may have an impact on social interaction, delirium and agitation[22]. The potential for cost savings with respect to reduced psychotropic medication use has also been indicated[18, 23]. Qualitative evidence suggests greater family and staff satisfaction with care[22]. 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.

Therefore, we propose:
A feasibility cluster controlled trial in a nursing 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.

5. Trial design

5.1 Trial summary

This is a feasibility study employing a parallel, two-arm, multi-centre cluster controlled randomised trial design with an embedded process evaluation. The trial will recruit people with advanced dementia (n=64) from eight clusters with six nursing homes randomised to the Namaste Care trial arm and two nursing homes randomised to the control arm. The outcome tools will be looked at from the perspective of the nursing home staff, resident and informal carer. The process evaluation will be undertaken to understand issues associated with the acceptability, fidelity and sustainability of the intervention. Organisational data, observational data (researcher structured observation of Namaste Care sessions and care opportunities within control nursing homes), data from the Namaste Care Session log and qualitative data from group /individual interviews with nursing home staff and informal carers will be collected.

5.1.1 Target nursing homes

Nursing homes, with at least 30 beds, providing care for people with advanced dementia using an established palliative care intervention (e.g. Gold Standards Framework for Care Homes (GSFCH), Routes to Success or Six Steps programme) will be eligible. To be considered for the study, the nursing homes need to be able to identify six potentially eligible people with advanced dementia with a view to recruiting four people in to the trial initially and a further four later in the course of the trial. In addition, the nursing home also needs to have a dedicated space available to deliver Namaste Care.

5.1.2 Target population

The target population for participants is nursing home residents with advanced dementia (FAST=6-7)[24]. The target population for informal carers is immediate relatives or friends of those with advanced dementia, whilst the target population for nursing home staff is staff paid to provide care in nursing homes, (this includes, but may not be restricted to, managers, registered nurses, care assistants and activity coordinators).

5.1.3 Health technology

Namaste Care is a complex intervention delivering proactive structured care focused on enhancements to the physical environment, comfort assessment and management, and sensory engagement incorporating personalised activities to reflect an individual's life story and preferences. See section 5.6.1 for more information.

5.2 Objectives

The primary objective of this feasibility study is to ascertain the feasibility of conducting a full trial of the Namaste Care intervention.

The feasibility issues associated with the research design and data collection processes to enable the design of a full trial to determine the efficacy of Namaste Care:

a) To understand how best to sample and recruit nursing homes into a cluster controlled trial of Namaste Care;
b) To determine the most appropriate selection, timing and administration of primary and secondary outcome measures for a full cluster controlled trial of Namaste Care against criteria of bias minimization, burden, and acceptability;
c) To establish recruitment, retention and attrition rates at the level of the nursing home and individual resident, informal carer and nursing home staff;

d) To establish the willingness of a large number of nursing homes representing the range of nursing homes, with respect to provider type, size, resident care needs, to participate in a full trial;
e) To assess the acceptability, fidelity and sustainability of the Namaste Care intervention.

Secondary objectives for the resident include levels of sleep/activity, neuropsychiatric symptoms and pain. Secondary outcomes for the informal carer include satisfaction with care at the end of life and the secondary outcomes for staff are care giving experiences, satisfaction with care in end of life care. Health economic and healthcare resource use will also be assessed.

5.3 Sample size

5.3.1 Sample size calculation

As this is a feasibility study, no formal sample size calculation will be used. A sample size of 8 nursing homes (6 intervention and 2 controls) has been selected as it offers a reasonable test of the intervention to assess the feasibility objectives. There have been a range in the sample sizes used in feasibility studies in nursing homes ranging from 2[25] , 6[26] to 14 (BHiRCH study NIHR RP-PG-06012 -20010).

5.3.2 Sample size

8 nursing homes with 6 nursing homes randomised to deliver Namaste Care and 2 nursing homes randomised to deliver their normal standard of care.
64 residents
Up to 200 nursing home staff
Up to 64 informal carers

Sample size for observations and interviews
Up to 3 observations in each intervention nursing home or up to 2 observations in each control nursing home. The number of observations may increase if more observations are required.
Up to 48 Nursing home staff members interviewed per home (interviews undertaken as group interviews or individual one on one interviews).
Up to 16 informal carers interviewed

5.4 Eligibility and Recruitment

5.4.1 Eligibility

Nursing Home Eligibility
Nursing homes will be eligible for inclusion into the trial if:

- Nursing home is located in England
- Nursing home has at least 30 beds
- Has at least 6 residents who the nursing home staff estimate to be eligible for the trial
- Is currently using a recognised palliative care development intervention (e.g. GSFCH, Routes to Success, Six Steps).
- Has a manager or nominated person willing to be the Principal Investigator for the duration of the project, following appropriate discussions and approvals
- Agrees to identify a suitable space for Namaste Care to be delivered in the facility and provide core Namaste Care resources

- Agrees to release staff for research and Namaste Care training.

A nursing home meeting any of the following criteria will not be eligible to participate in the feasibility trial:

- Rated at the last CQC inspection as Needs Improvement or Inadequate
- Is subject to CQC enforcement notices, admission bans or major CQC compliance breaches
- Have previously introduced Namaste Care into their practice
- Is currently or recently involved in another research study or trial that conflicts with Namaste Care or with data collection during the course of the Namaste Care trial.

Resident Eligibility

A resident meeting all of the following criteria will be eligible to join the feasibility trial:

- A permanent resident within the nursing home (i.e. not present for receipt of respite or day care)
- Has a formal assessment of advanced dementia, (based on the Functional Assessment of Staging of Alzheimer's Disease (FAST) score of 6-7) made by the nursing home manager or another experienced member of staff
- Lacks mental capacity (mental capacity assessed and documented with an appropriate tool)
- Has a key worker member of staff willing to provide proxy outcome data.

A resident meeting any of the following criteria will not be eligible to participate in the feasibility trial:

- Is permanently bedbound and unable to leave their room
- Is currently or has recently been involved in another research study or trial that conflicts with Namaste Care or with data collection during the course of the Namaste Care trial.

Informal Carer eligibility

An informal carer meeting all of the following criteria will be eligible to join the feasibility trial if they:

- Are above the age of 18 who self-define as a relative or friend who acts as an informal carer for a participant with advanced dementia will be eligible for inclusion in the study
- Have the ability to communicate in English.

Nursing home staff eligibility

Nursing home staff: Health and social care staff paid to provide care to individuals with advanced dementia within participating nursing homes will be eligible to participate in the study. This will include nursing home managers, Registered Nurses, care assistants and activity coordinators. Staff in the intervention arm should not have delivered the Namaste Care intervention or cared for residents receiving Namaste Care in nursing homes not involved in this trial.

5.4.2 Recruitment

Nursing home recruitment

Potential nursing homes from England will be invited to participate in the trial according to the eligibility criteria. These nursing homes will be selected from a number of nursing home providers. If more than eight nursing homes are identified as being willing to participate, they will be approached in random order and agreement to take part in the study will be sought until eight nursing homes have agreed to take part.

Recruitment of residents

All residents who meet the eligibility criteria will be considered for the Namaste Trial. The nursing home manager or senior staff member will identify potential residents at their nursing home and follow the process of identification and recruitment shown in Table 1 and Figure 1. The nursing home manager or a senior staff member will subsequently undertake an initial assessment for screening of eligibility for the residents to take part in the trial and record this in the screening log. Part of this initial assessment will include assessing and documenting the residents' mental capacity to consent to participation in the trial. Only residents who lack mental capacity will be eligible to enter the trial. Although the mental capacity of a resident may fluctuate on a daily basis, it is highly unlikely that a resident will regain mental capacity to the extent of consenting to the trial[28]. The resident may, however, regain mental capacity to the point of understanding the intervention during the Namaste Care session or whilst being taken to the Namaste Care space. Consequently, mental capacity will be considered during each session and whilst being taken to the Namaste Care space. If a resident shows signs of not wanting to take part in the Namaste Care session they will be allowed to miss the Namaste Care session and still continue in the trial. Despite the number of Namaste Care sessions missed, residents will continue in the trial.

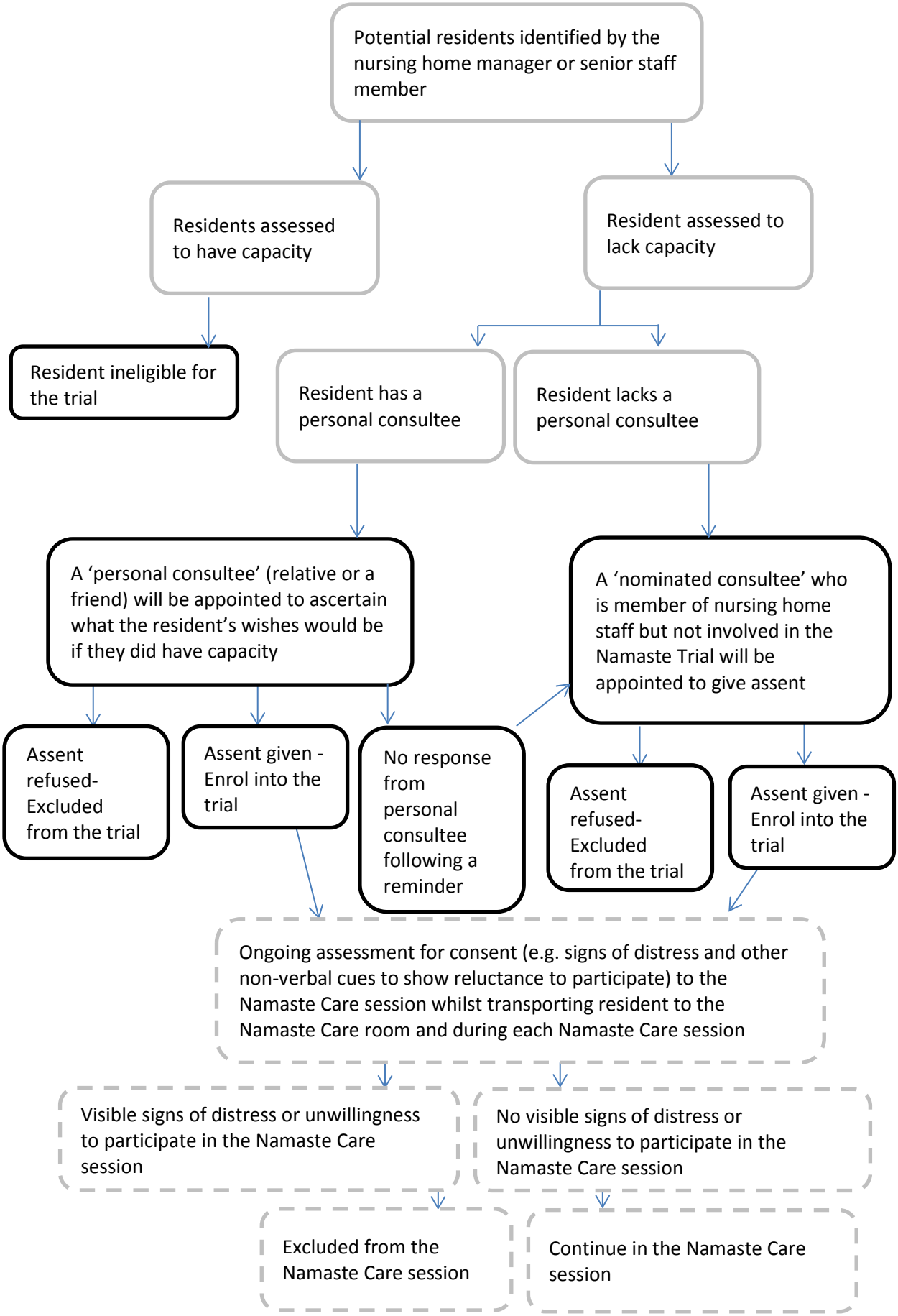
	Step	**Outline of the Task**	**Description of Task**	**By Whom**	**Documents to give or task to complete**
Identification	1	Resident identification and assessment of mental capacity	Conduct an initial assessment of the potentially eligible resident including assessment of mental capacity.	Nursing home manager/senior staff member	Screening log to be completed by nursing home manager/senior staff member
Consent/Assent	2	Resident consent process (through a personal consultee) [see page 4 for a definition of a personal consultee]	Identify personal consultee for the resident. Give out or post the personal consultee information pack. If no personal consultee is available go to Step 4.	Nursing home manager/senior staff member	Give out personal consultee pack (cover letter, information sheet for personal consultees, consultee declaration form, reply slip and pre-paid envelope)
	3	Resident consent process (through a personal consultee)	If assent given by personal consultee then enrol the resident	Researcher	Consultee declaration form (found in the consultee information pack) to be

			into the trial. If assent is refused by personal consultee then exclude resident from the trial.		completed
	4	Resident Consent process (through a nominated consultee) [see page 4 for definition of a nominated consultee]	Identify nominated consultee for the resident. Give out or post the nominated consultee information pack.	Nursing home manager/senior staff member	Give out nominated consultee pack (cover letter, information sheet for nominated consultees, consultee declaration form, reply slip and pre-paid envelope)
	5	Resident Consent process (through a nominated consultee)	If assent given by nominated consultee then enrol the resident into the trial. If assent is refused by nominated consultee then exclude the resident from the trial.	Consultee	Consultee declaration form (found in the consultee information pack) to be completed
Ongoing process consent	6	Ongoing assessment of the resident's desire to take part in each Namaste Care session	Look out for non-verbal cues which may indicate the resident does not want to take part in the current Namaste Care session. If there are signs that the resident does not want to	Namaste Care workers	

			take part in the current Namaste Care session then allow them to leave and return to the next session.		

Table 1. An overview of the steps required for resident recruitment and consent/assent.

Figure 1: Flow Chart of the recruitment and consent process for residents



The process below outlines the procedure to appoint a consultee and gain their advice on the resident's wishes.

Appointment of a personal consultee
As resident's will lack mental capacity to give informed consent, a 'personal consultee' such as Lasting Powers of Attorney – health and personal welfare relative or a close friend will be appointed to ascertain what the resident's wishes would be if they did have mental capacity. Following the mental capacity assessment, the researcher from the Namaste Trial research team will ask a nursing home staff member to identify the resident's informal carer.

A nursing home staff member will be asked to hand out or post out a consultee information pack to the informal carer. This pack will contain a cover letter, consultee information sheet for personal consultees, consultee declaration form, reply slip and pre-paid envelope. The informal carer will be asked to return the reply slip to the researcher or contact the researcher by telephone within two weeks of being given the informal carer pack if they are interested in acting a personal consultee for a relative or friend. . If the informal carer does not return the reply slip within this time, the nursing home staff will be asked to contact the informal carer as a reminder or send out a follow up reminder letter. On return of a reply slip, the researcher will make contact with the informal carer to answer any outstanding questions and ascertain willingness to act as a personal consultee. If the informal carer decides not to provide consent for the resident to participate in the study, their contact details will then be destroyed. If the researcher is present at the time of the informal carer visiting the nursing home, the nursing home staff will ask the informal carer if they would be willing to speak to the researcher about the study. The researcher will then discuss the study with the informal carer and provide the relevant study information.

The informal carer will then be given sufficient time to think about the trial and to talk to the resident and other relatives and/or friends. The consultee information sheet can be used to explain the Namaste Trial to the consultee and to ascertain, where possible, a view on their thoughts about the resident taking part in the trial. If the informal carer is willing to sign the consultee declaration form, they will be asked to return it, by post, directly to the researcher. They will be asked to do this within two weeks of being given the consultee information pack. If the consultee declaration form has not been returned within this time, the nursing home staff will be asked to telephone the informal carer or send out a follow up reminder. If after a further week the form has not been returned the process of appointing a nominated consultee will then be followed. If an informal carer wants to act as a personal consultee for a resident after a nominated consultee has assented for a resident then the process of gaining an opinion from the personal consultee will be followed.

Appointment of a nominated consultee
It is estimated that about 30% of the residents will not have an identifiable personal consultee. If a personal consultee for a resident is not available for any reason, then advice on the residents' participation in the trial will be sought from a 'nominated consultee'. This nominated consultee will be selected in line with the guidelines of identifying a nominated consultee from each nursing home. The Department of Health guidelines suggest the nominated consultee could be someone from the nursing home staff provided the research is not sponsored by the nursing home and the staff member or nursing home does not have an organisational interest in the findings of the study[29]. The nominated consultee will be given a nominated consultee pack by a member of staff from the nursing home. This nominated consultee pack will contain a cover letter, consultee information sheet for nominated consultees, consultee declaration form, reply slip and pre-paid envelope. The nominated consultee will need to complete a reply slip to indicate that they agree for their personal details to be stored securely at Lancaster University and for a researcher to contact them to answer any outstanding questions and ascertain willingness to act as a nominated consultee. If the researcher is present at the nursing home at the same time as the nominated consultee, the nursing

home staff will ask the nominated consultee if they would be willing to speak to the researcher about the study. The researcher will then discuss the study with the nominated consultee and provide the relevant study information.

The nominated consultee will then be given sufficient time to think about the trial and to talk to the resident, and other relatives and/or friends, if available. The consultee information sheet can be used to explain the Namaste Trial to the consultee and to ascertain, where possible, a view on their thoughts about the resident taking part in the trial. If the nominated consultee is willing to sign the consultee declaration form, they will be asked to return it, by post, directly to the researcher. They will be asked to do this within two weeks of being given the consultee information pack. If the consultee declaration form has not been returned within this time, the nursing home staff will be asked to contact the nominated consultee as a reminder or send out a follow up reminder letter. If the nominated consultee advises that the resident should join the study then the resident will be enrolled into the trial. If the nominated consultee advises otherwise then the resident will be excluded from the trial.

After consent is obtained for a resident to enable them to take part in the trial, the resident's GP will be informed that the resident is taking part in the trial.

In all cases, the personal consultee (informal carer) or the nominated consultee will be given the opportunity to speak to the researcher over the phone or face to face about taking on this role. In addition, a member of staff (Research Lead) from each nursing home will be allocated to address any questions or concerns the participants may have.

A personal or nominated consultee can approach the researchers at any time to indicate if they think the person they are representing has changed their mind about participating in the trial, and to withdraw them from participation. Likewise, if the researchers think that during the trial, the wishes of a person who lacks mental capacity may have changed regarding participating in the trial, they will seek advice from the personal or nominated consultee about the residents' continued inclusion.

Informal carer recruitment

Eligible informal carers of residents participating in the trial will be identified by the nursing home manager or a senior staff member. This may or may not be the informal carer who has provided proxy consent for the resident.

It is possible that some residents will not have an informal carer. However, these residents will still be eligible for the trial. The process of informal carer identification and consent is highlighted in Table 2.

	Step	Outline of the Task	Description of Task	By Whom	Documents to give or task to complete
Identification	1	Informal carer identification	Identify potential informal carer to take part in the trial when identifying resident.	Nursing home manager/senior staff member	
Consent	2	Informal carer consent process	Give out/post informal carer pack	Nursing home manager/senior staff member	Give out informal carer pack (cover letter, participant information sheet, consent form, reply slip and pre-paid envelope) and reply slip to be completed and returned to the researcher
	3	Informal carer consent process	On return of a reply slip the researcher will contact the informal carer and if the carer wishes to take part take consent either face to face or over the telephone.	Researcher	Gain written consent

Table 2. An overview of the steps required for informal carer identification and Consent.

Informal carer recruitment and consent

Prior to any information being sent informal carers, a launch meeting for residents, informal carers and nursing home staff will be held at the nursing home at a time convenient to all attendees to introduce the study. Nursing home staff will then be asked to post or hand out a pack which will contain a letter, a participant information sheet, consent form, reply slip and pre-paid envelope to informal carers who meet the eligibility criteria. The informal carer will be asked to return the reply slip to the researcher or contact the researcher by telephone if they wish to take part in the study within two weeks of being given the informal carer pack. If the informal carer does not return the reply slip within this time, the nursing home staff will be asked to contact the informal carer as a reminder or send out a follow up reminder letter. On return of a reply slip, the researcher will make contact with the informal carer to answer any outstanding questions about the study and ascertain if they are willing to take part in the study. The informal carer will be assured that they are free to withdraw from the study at any time without it having any effect on them or on the care of their relative. If the informal carer wishes to proceed, the researcher will then post the baseline questionnaire to the informal carer or will hand out the questionnaire in person if visiting the nursing home. The informal carer will be asked to complete an informed consent form prior to the questionnaire being sent or handed out. A reminder letter will be sent out to the informal carer after two weeks or the researcher will phone the informal carer to check they have received the questionnaire and offer them help to complete it if the informal carer wishes. The option to take part in a telephone or face to face qualitative interview and be observed in the Namaste Care space (intervention arm) or a suitable communal space in the nursing home (control arm) will be included in the informed consent procedure. The informal carer will be contacted by the researcher by email or telephone to see if they still wish to take part in the qualitative interview. This will be around 4-6 months following recruitment of the first resident or earlier if their relative or friend is no longer taking part in the study or being cared for in the nursing home. If the resident dies during the study, the informal carer will only be approached a minimum of 8 weeks after the resident's death.

Nursing home staff recruitment and consent

Researchers will aim to attend a staff meeting in the nursing home to introduce the study to the wider care team. Prior to formal contact with individuals, all nursing home staff who meet the eligibility criteria will be invited to take part in the Namaste Trial by the Chief Investigator, via the nursing home manager. Nursing home staff will be given a letter, participant information sheet, consent form and pre-paid envelope by the nursing home manager. Staff will be asked to return the consent form to the research team either face to face or via the post. The identification and consent process for nursing home staff is shown in Table 3. The information sheet will encourage staff to contact the researcher if they have any questions about the study. A minimum of two members of staff from each nursing home allocated to the intervention arm will be selected to be the Namaste Care Champion. Nursing home staff will be contacted by the researcher around 6 months after the first resident has been recruited to see if they would like to take part in a qualitative group or individual face to face/telephone interview. They may be approached earlier if the nursing home is no longer carrying out the Namaste Care Programme with residents (intervention arm) or there are no longer residents taking part in the study (control arm). New staff members who are eligible but have not previously consented to take part in the trial will be identified and consented using the same procedures.

	Step	Outline of the Task	Description of Task	By Whom	Documents to give or task to complete
Identification	1	Nursing home staff identification	Identify potential nursing home staff to take part in the trial	Nursing home manager/senior staff member	
Consent	2	Nursing home staff consent process	Give nursing home staff "staff information pack"	Nursing home manager/senior staff member	Give out staff Information pack (cover letter Information sheet for staff, consent form, pre-paid envelope)
	3	Nursing home staff consent process	Nursing home staff to return signed consent form to researcher. Encouraged to contact researcher if have any questions before signing the form.	Researcher	Gain written consent

Table 3. An overview of the steps required for nursing home staff identification and consent.

Consent for collection of observational data

Structured observation will only take place in the Namaste Care space (intervention arm) or a pre-selected communal area in the control arm that is most frequented with residents with advanced dementia. The focus of the observation is those participants directly involved in the Namaste Care programme or the 'usual care space' which will probably be the day room in the control arm. Before the observation stage of the project begins, posters will be displayed and information leaflets will be available in the nursing homes to inform residents, staff and visitors about what is planned. The launch meetings between members of the research team nursing home staff and relatives of residents will also have highlighted the observations. Permission to observe residents, their informal carers as well as staff members involved in the Namaste Care programme and usual care in the control nursing homes will be obtained as part of the informed consent procedure for the trial. For those not previously consented, 'opt out' consent will be applied. An 'opt out' form will be included in the information leaflet, and if a resident, visitor or staff member does not wish to be observed they will complete this form and return it to the researcher. The researcher will then avoid conducting observations at a time they are present in the 'observed' area or exclude any data collected about that person[30]. The researcher will ask the nursing home manager or member of staff in charge at the nursing home at the time of their observation visit to provide proxy opt out consent if appropriate for those residents who lack mental capacity who are present in the 'usual care space' (control arm).

5.4.3 Pseudo-anonymisation

Residents taking part in the trial will be assigned an ID number which will be used on all trial documentation. This ID number will have the ID number of the nursing home the participant is associated with followed by either a R for resident, C for Carer or S for Staff and then the ID number for each participant at the nursing home.

5.5.4 Randomisation and stratification

The 8 nursing homes will be randomised to either the intervention arm or the control arm by assigning an ID to each nursing homes and randomly selecting each ID. The random allocation will be carried out by a statistician not otherwise involved in the trial.

5.4.5 Blinding

The nature of the intervention and its delivery means that it will not be possible to blind nursing homes or staff to the allocation status. If possible, to minimise potential for bias, staff involved in the delivery of the Namaste Care intervention will not be involved in the completion of outcome measures. It will not be possible to blind researchers to the allocation of nursing homes, as the intervention requires changes to the nursing home environment which may be visible to any researcher visiting the facility.

5.4.6 Withdrawals/exclusions

The right of participants or personal or nominated consultees to refuse participation, or withdraw from the trial at any time, without providing a reason will be respected and this will not affect the future care provided to them. Due to their advanced dementia, it is highly likely that residents taking part in the trial will be unable to verbally communicate, therefore, careful attention will be paid to non-verbal cues such as facial expressions, body language and willingness to join in the activities to ascertain if residents want to withdraw from the intervention. Data from participants who have withdrawn from the intervention will be used in the final analysis.

5.5 Outcome measures

We consider two contender primary outcomes for a full trial: (1) quality of dying (dementia) (CAD-EOLD) and (2) quality of life (QUALID).

The secondary outcome measures in this trial are the Person-Centred Assessment Tool (PCAT), Actigraphy, NPI-Q, PAIN-AD, SWC-EOLD, EQ-5D-5L, ICECAP-O, ICECAP-SCM, ICECAP-CPM, Health Resource data, Cohen-Mansfield Agitation Inventory, Staff Perceptions of Namaste Care or staff perceptions of the effectiveness of usual care, assessment of the fidelity, acceptability and appropriateness of Namaste Care or of usual care and data log to assess fidelity.

The tools used are listed in Tables 4-7 and is separated based on respondent type i.e. measures for the nursing home (Table 4), resident (Table 5), informal carer (Table 6) and process evaluation (Table 7).

Measures for the nursing home

Outcome Measures or rationale for data collection	Completed by
Nursing home demographics	Researcher led telephone or face to face interview with NCH manager at baseline
Alberta Context Tool (to assess nursing home readiness for change)	Staff (all staff on duty in the morning and afternoon session on the day of the visit by researcher) at baseline
Person Centred Assessment Tool (control and intervention arm)	Staff (all staff on duty in the morning and afternoon session on the day of the visit by researcher) at baseline* and 6 months or when a nursing home ceases delivery of intervention
To assess nursing homes readiness for Namaste Care (Intervention and Control arm)	Researcher led telephone or face to face interview with NCH manager at baseline
Staff turnover and sickness levels	By researcher from manager at baseline and monthly for 6 months.
Resource use (staff time; equipment and consumables)	By researcher in staff interviews (see Table 7). Nursing home staff on daily log

Table 4. Nursing Home Outcome Measures

* Baseline is before the first resident from the nursing home is recruited in to the trial

Measures for the resident

	Time of data collection				
Outcome Measures or rationale for data collection	**Base line of the individual resident taking part in the study**	**2 Weeks**	**4 Weeks**	**Every 4 weeks for 6 months**	**6 Months or following death**
Resident demographics*	x				
Quality of dying (dementia) (CAD-EOLD)*	x	x	x	x	x
Quality of Life of the person with dementia (QUALID)*	x	x	x	x	x
Neuropsychiatric Inventory- (NPI-Q)*	x	x	x		
Pain (PAIN-AD)*	x	x	x		
EQ-5D-5L*	x	x	x		
ICECAP-SCM*	x	x	x		
ICECAP-O*	x	x	x		
Cohen-Mansfield Agitation Inventory*	x	x	x		
Sleep/Activity (actigraphy)	ongoing for 28 days				
Think Aloud tools (ICECAP-O and ICECAP-SCM)**	x	x	x		x
Resource use (primary and secondary care) ***	x	x	x	x	x

Table 5. Outcome measures completed for each resident and the time points for data collection.
*The outcome measures will be proxy completed by staff and a researcher will help staff complete the tool at baseline.
** This outcome measure will only be completed by selected staff and will be done with a researcher.
*** Completed by researcher through review of care home records

Measures for the informal carer

	Time of data collection			
Outcome Measures or rationale for data collection	**Base line of the individual resident taking part in the study**	**2 Weeks**	**4 Weeks**	**6 Months or following death**
Informal carer demographics	x			
End of Life – Satisfaction with care (SWC-EOLD)	x		x	at least 8 weeks after death
ICECAP-CPM				at least 8 weeks after death
EQ-5D-5L	x			at least 8 weeks after death
Think Aloud tool (ICECAP-CPM)				at least 8 weeks after death
Resource use information (CSRI)			x	

Table 6. Outcome measures completed by the informal carer and the time points for data collection. Note, the Think Aloud tool will only be completed by selected informal carers and will be done with a researcher. If a resident does not have an informal carer these outcome tools will not be completed. *The outcome measures will be proxy completed by staff.

Measures for the process evaluation

Outcome Measures or rationale for data collection	Data collected	Data collected by	Time of data collection
To assess carers' perceptions of Namaste Care (intervention arm) or carers' perceptions of the effectiveness of usual care (control arm)	Semi structured telephone or face to face interview with informal carer	Interviews conducted by the researcher	Approximately 4-6 months after the first resident is recruited at the nursing home. (If a resident dies during the trial then the informal carer will be approached at least 8 weeks after the resident's death)
Staff members' perceptions of Namaste Care (intervention arm) or perceptions of the effectiveness of usual care (control arm)	Semi structured telephone or face to face interviews/group interviews with nursing home staff	Interviews conducted by the researcher	Approximately 6 months after the first resident is recruited at the nursing home
To assess the fidelity, acceptability and appropriateness of Namaste Care (intervention arm) or assess effectiveness of usual care (Control arm)	Structured intermittent observation of Namaste Care sessions or observation of usual care (researcher)	Observations conducted by the researcher	Approximately 2 weeks, 4 weeks and 6 months after the start of the intervention for nursing homes in the intervention arm Approximately 2 weeks and 4 weeks after the first resident is recruited for nursing homes in the control arm
To assess the fidelity, acceptability and appropriateness of the Namaste Care (intervention arm)	Data log template for each Namaste Care session delivered (staff)	Data log completed by the staff delivering the Namaste Care session	Throughout the intervention

Table 7. Data collected for the qualitative element of the study and the different time points.

Below is an overview of the outcome tools listed in Tables 4-7:

Quality of dying (dementia) (CAD-EOLD): the tool of choice when focusing on end of life care is the CAD-EOLD. With 14 items, it addresses the following domains: physical distress, emotional distress, wellbeing, and dying symptoms and is valid with good reliability for all sub-scales[31, 32]. There is a significant correlation with QUALID. This will be measured at baseline, 2 weeks and 4 weeks from

study entry, then every 4 weeks until participant death or end of study. The tool is validated for completion by someone who knows the participant.

Quality of Life in Late Stage Dementia (QUALID): Quality of life is a key outcome for both palliative and dementia care research. The QUALID scale (11 items) comprises both comfort and functioning but also elements of behaviour[33]. This will be measured at baseline, 2 weeks and 4 weeks from study entry, then every 4 weeks until participant death or end of study. The tool is validated for completion by someone who knows the person with dementia. The power calculation incorporates identifying a minimally clinical important reduction of two (improved quality of life) based upon previous individual participant data using QUALID[34]. This work has demonstrated that residents' scores are generally increasing so any decrease in scores would show a meaningful improvement in their quality of life. Much of the work evaluating Namaste Care to date has been qualitative and showed that quality of life was reported as improved, thereby making it a key measure.

Neuropsychiatric Inventory- (NPI-Q): The NPI-Q is frequently used to assess key psychiatric symptoms such as agitation, depression and anxiety. It is a 12-item tool and is a validated tool[35, 36].

Cohen-Mansfield Agitation Inventory (CMAI): The CMAI is tool completed by caregivers which is used to gain information on the frequency and the degree of disruptiveness of a variety of agitated behaviours. This is a 14 item tool covering the areas of physical and verbal agitation[37].

Person-centred Care Assessment Tool (P-CAT): PCAT is a 13 item tool developed to ascertain staff rating of person centred care within a facility[38]. The tool relies on staff within a facility to rate 13 statements around care on a 5 point scale.

Pain (PAIN-AD): PAIN-AD is a tool (5 items) developed to assess pain in people with advanced dementia[39], which rates the person in 5 domains: Breathing, negative vocalization, facial expression, body language and consolability. It relies on knowledge of the person to asses changes in behavioural aspects.

Sleep/activity: The activity/sleep profile of residents participating in the trial will be measured through continuous measurement using an actigraph placed on the wrist of the person for a period of 4weeks. An actigraph will record acceleration variation in three axes at a 50Hz frequency and will store the accumulated value at each epoch during 4 weeks. Actigraphs, such as GENEActiv, have been used in this population, with high levels of acceptability to participants[40, 41].

Three different aspects of sleep/activity will be considered: General sleep activity profiles – sleep/wake ratios, total sleep time, sleep efficiency, wake after sleep onset and total activity will be ascertained; Participant's rhythm fragmentation and synchronization will be estimated via Intradaily Variability (IV) and Interdaily Stability (IS); Dimensions of sleep (length and efficiency) and activity (amount and level) will be measured to see if they differ statistically across groups.

End of life in dementia – Satisfaction with Care (SWC-EOLD): This objective pertains to the individual level for staff and families of participants. They will be asked to complete the brief SWC-EOLD questionnaire (10 items), the measure with excellent and better psychometric properties and feasibility than other such measures[41].

Health economic assessment: EQ-5D-5L, ICECAP-O, ICECAP-SCM, ICECAP-CPM. The use of a number of potential outcome measures will be explored in terms of feasibility and acceptability of proxy completion with the particular population, evaluated through the think aloud technique. The chosen measures are included in the NICE recommended measures for health and social care: EQ-5D-5L (5

items), the ICECAP-O (5 items)[42, 43] and the ICECAP-Supportive Care Measure (ICECAP-SCM) (7 items). The ICECAP-O has previously been used for dementia participants using proxy completion but in a Dutch context[44]. Use of the ICECAP-Close Person Measure for informal carers and the EQ-5D-5L post-bereavement will also be explored in terms of assessing impacts on informal carers.

Think aloud: The think aloud technique involves verbalising thoughts whilst completing questionnaires. The technique has been shown to be valuable to increase face and content validity of the questionnaire[45]. The think aloud will begin with a warm-up exercise to ensure that the person responding understands the nature of 'thinking aloud'. The respondent will then be asked to think aloud whilst completing the relevant measures. A small number of questions will be asked in the form of a short semi-structured interview following the completion of the think aloud exercise. These will probe areas of particular difficulty in completing the measures and more general views about the appropriateness of the measures. The think aloud technique will be used with the ICECAP-O, ICECAP-SCM and ICECAP-CPM tools for a proportion of participants at 2 weeks, 4 weeks and 6 months, to obtain 20-30 think aloud interviews across a range of timepoints.

Resource use measures for economic assessment: nursing homes, person/family, societal perspectives: Although it is anticipated that in a full trial the primary interest will be the analysis from the nursing homes perspective, other perspectives are also important in dementia care, and the potential impact of conducting the evaluation alongside the full trial from three perspectives will be considered: nursing homes; residents and family (including informal carers); society. Relevant resource use is expected to fall under the following categories: a) nursing home costs, including staff time; b) primary care costs, including staff time and medication; c) secondary care costs, including hospital admission; d) close person costs, including out-of-pocket expenses; e) productivity costs for informal carers. A number of sources of data will be explored for collection of resource use data. A detailed bottom-up costing will be used to generate costs associated with provision of the Namaste intervention itself. Information about resource use associated with the intervention will be collected through session logs containing data on staff time, session location, activities and associated consumables. The extent to which the resources used in Namaste care are additional to the nursing home's usual provision will be noted. More general nursing home costs will be collected for both intervention and control sites. This will include information about the overall costs of care within the nursing home, adjusted for the differential needs of those within the nursing home. Information about the resources used in care provision for participants enrolled in the study in control sites will be collected through the rotas and staff allocations held within each facility; the adequacy of the information contained in these, and their accessibility across different nursing homes will be assessed, to enable recommendations to be made for a full trial. Medical data kept routinely within the nursing home for each participant in their care home records will be used to identify hospital visits and admissions, outpatient appointments and GP attendances. Variability in the detail in notes kept across different nursing homes will be explored, so that recommendations can be made as to any supplementation of routine collected information that might be required in nursing homes for a full trial. An adapted version of the Client Service Receipt Inventory (CSRI) will be used to collect resource use information from close persons at four weeks following baseline. This will focus on the costs faced by the close person and any contributions to their care paid by the patient.

To further check the appropriateness of the 4 week endpoint for a future full trial, at month 22, the status of participants who had not died by the end of the trial will be checked with the nursing homes, to establish when participants died subsequent to the trial finishing.

*Process evaluation: p*rocess evaluations are advocated in clinical trials[46, 47] to explore the implementation process and assist in the cost analysis of outcome results; particularly important in multi-centre studies. As such a robust process evaluation will be undertaken to ensure data which directly addresses the feasibility objectives and addresses the acceptability, fidelity and sustainability

of the intervention are captured. This evaluation will identify factors which influence the implementation of the Namaste Care intervention in the context of a cluster controlled trial to enable the planning of a full trial. In designing the process evaluation, we have drawn from a framework for designing process evaluations for cluster randomised trials of complex interventions[48], and descriptors of components of process evaluations[49]. The process evaluation will also provide key information to add to the theory of change model in relation to how and why Namaste Care might work as a complex intervention[24].

Data collection on context and nursing home recruitment: To understand the context of the trial delivery within intervention and control nursing homes

Descriptive data will be collected on participating nursing homes from nursing home managers. On study commencement for each nursing home descriptive data on ownership and funding model, size, staffing, case mix, staff turnover, staff sickness/absence and geographical location will be collected during a telephone /face to face interview with the nursing home manager. During this interview the organisation's readiness for change will also be explored. Staff turnover, staff sickness/absence data will be collected for the 6 months of the data collection period.

A survey of nursing home staff will also be undertaken to identify the readiness for change within the nursing home and the extent to which the care within the facility is experienced by staff as being person-centred. The Alberta Context Tool[30] and P-CAT, will be administered to all available care staff at the study baseline visit and the manager working in each nursing home (intervention and control). This will provide contextual data for the findings of the feasibility trial. Where possible context data will also be collected on nursing homes approached to participate but who declined to determine differences between recruited and non-recruited homes. We will collect data on nursing homes approached, agreed to participate and who actually participated. This will enable full reporting to fulfil CONSORT requirements for reporting cluster trials[62].

Data collection on delivery of Namaste Care within intervention nursing homes: To understand how Namaste Care is delivered within nursing homes, and identify any differences in Namaste Care delivery between nursing homes

Descriptive data will be collected to understand how Namaste Care is adopted into the nursing home and integrated into daily practice. A Namaste Care log will be completed by nursing home staff which will capture for each session in which Namaste Care is delivered; a) Who delivered Namaste Care at each session, b) Which residents received Namaste Care at that session, c) A checklist to identify which components of Namaste Care were available, d) A checklist to identify which components were delivered to which residents.

In addition, intermittent observations will be conducted by research staff of Namaste Care sessions at 2 weeks, 4 weeks and 6 months into the study, to collect data on intervention fidelity and challenges or issues raised. A mixture of morning and afternoon Namaste Care sessions will be randomly selected. The researcher will observe for 20 minutes at the beginning, middle and end of the session. A structured log reflecting the core components of the intervention along with field notes will be used to collect observational data. The observation sessions will also be audio recorded to ensure all verbal data is captured[30].

Data on delivery of other interventions within control nursing homes: to capture any care or activities which appear to have some similar elements to those in the Namaste Care Intervention.

This will enable an understanding of delivery of any components similar to Namaste Care (or parts thereof) in control nursing homes providing usual care and aid interpretation of results of the interventions effectiveness.

Data on usual care within control homes will collected in a number of ways:

Structured intermittent observation of activities will be carried out by research staff within communal spaces in the nursing home using a similar version of the log used in intervention nursing homes. The same sampling procedures will be used as in the intervention arm apart from there is an additional observation at 6 months in the intervention arm to document practice in the nursing home 6 months after the implementation of Namaste Care.

Qualitative group interviews with managers and staff within control nursing homes will be carried out around 6 months post baseline of the first resident recruited. This interview maybe carried out earlier if there are no longer residents taking part in the study or the nursing home wishes to leave the study. If group interviews are not possible due to staff availability, staff members will be offered the opportunity to take part in an individual telephone or face to face interview with the researcher.

Individual qualitative telephone or face to face semi-structured interviews will be conducted with a sample of informal carers in control nursing homes around 4-6 months following recruitment of the first resident or earlier if their relative or friend is no longer taking part in the study or being cared for in the nursing home. If the resident dies during the study, the informal carer will only be approached at least 8 weeks after the resident's death. These detailed data, which will also capture elements of resource use, will also be used in the economic analysis to explore the extent to which important aspects of resource use are being fully captured within the quantitative assessments.

Data collection on perceptions of Namaste Care and its sustainability: To understand perceptions of the Namaste Care intervention. This will explore issues such as what people find meaningful about Namaste Care, how they understood Namaste Care, how engaged they felt with Namaste Care, how Namaste Care integrated with existing practices, what facilitated or hindered Namaste Care.

Qualitative group interviews with managers and staff within intervention nursing homes will be carried out around 6 months post baseline of the first resident recruited or earlier if the nursing home is no longer carrying out the Namaste Care Programme with residents. These interviews will provide data that will feed into information on sustainability, implementation and the impact of Namaste Care. If group interviews are not possible due to staff availability, staff members will be offered the opportunity to take part in an individual telephone or face to face interview with the researcher.

Individual qualitative telephone or face to face interviews will be conducted with a sample of informal carers in intervention nursing homes around 4-6 months following recruitment of the first resident or earlier if their family member or friend is no longer taking part in the study or being cared for in the nursing home. If the resident dies during the study, the informal carer will only be approached at least 8 weeks after the resident's death.

5.6 Trial Procedure

5.6.1 Namaste Care

People with advanced dementia often find it difficult to communicate and interact with other people. This means that they are no longer engaging in the ongoing group activities of the nursing home. People with advanced dementia living in nursing homes sometimes spend long hours alone in their rooms, and staff can find it hard to engage them with the day-to-day activities in the home. Namaste Care seeks to give comfort and pleasure to people with advanced dementia through engagement, meaningful and creative activities as well as sensory stimulation, especially through the use of touch and movement[50].

Namaste Care does not require expensive equipment but requires a designated space in a nursing home, where everything can be left in place, ideally a separate room, but it can be space within another room, or a room which is also used for other purposes at other times. The environment must be made 'special' and should enable a feeling of calm i.e. welcoming and homely, with natural or slightly dimmed lighting, perhaps attractive scents, such as lavender from an aromatherapy diffuser, and with soft music playing. The Namaste Care programme is based on best practice dementia care and best practice end-of-life care. Whilst none of the core elements are new, what is different is that Namaste brings them together in a single care programme. Namaste Care is based around sensory experience: music, massage, colour, taste and scents. Namaste Care promotes person-centred care with adaptations made to the programme to reflect the resident's 'life story'.

The core team are the 'Namaste Care Champions' who run the programme daily and lead it within the nursing home and they are present whenever a Namaste Care session is running. They are staff already working within the nursing home and have received training in the Namaste Care programme. Namaste Care also depends upon the involvement and commitment of every member of the nursing home team, and where possible relatives, friends and volunteers. Namaste Care is a group programme with around 4-8 residents in each session. It is proposed that the programme is conducted up to seven days a week, two hours in the morning and two hours in the afternoon. Other residents may 'drop in' and visit the Namaste session and other members of the nursing home staff as well as family visitors/friends are also welcome in the Namaste room.

Fidelity to the intervention will be assessed by the research team through the observation of selected Namaste Care Sessions in each nursing home and completion of a proforma at each Namaste Care session during the trial by the 'Namaste Care Champions'.

5.6.2 Training to deliver Namaste Care

A one day workshop will be conducted in each participating nursing home to train staff and interested relatives and volunteers on delivering the Namaste Care intervention and collecting research data. The training on the Namaste Care intervention will cover the following areas: What is Namaste Care, getting your nursing home ready for Namaste Care, preparation for Namaste Care, the Namaste Care session. The time allocated to collecting research data will cover the importance of data collection in research, how to complete the outcome tools. and use of the actigraphy watch for those in the intervention sites

5.6.3 Usual care

Usual care is the term used to describe the control arm of this trial. It is the end of life care provided in the nursing home for people with dementia that addresses the key components of good practice: advance care planning and symptom management for people with dementia[51]. No further

education, training or support on end of life care will be provided by the study team to the nursing homes in the control arm of the trial.

5.6.4 End point for the trial

We have chosen 4 weeks as a primary end point because we want to include as many participants in the analysis as possible, and recognise that in this frail and ill participant group intervention effects need to be rapid to be meaningful. Attrition due to death (ADD) is a limiting factor in the successful completion of studies including participants with advanced disease[52]. Hence recommendations are to use early endpoints[51]. In previous work evaluating Namaste Care, early deaths (<2 months) were not uncommon[19].

Benefits from the intervention have been reported within days[19], so by recording an early assessment at 2 weeks and 4 weeks some record of temporal change will be made. Missing data and attrition are also likely to be an issue and by having an early measure of 2 weeks this can be used to impute missing data.

5.7 Adverse event management

5.7.1 AE and SAE management

For this research population there is a relatively high risk of death, hospitalisation or progression of disease for participants during the course of the study but which are not anticipated to be related to the receipt of the intervention. This level and type of risk will be treated as an acceptable risk for the purposes of the study and will not constitute adverse events (AE) or serious adverse events (SAE) unless concern is raised by anyone associated with the study that these events could be directly related to participation in this study.

As a feasibility study, any events reported to any personnel involved in the trial (including health professional, informal carer or research team members) which could potentially be considered as (serious) adverse events will be noted on a specially constructed trial event recording form, which will be completed by or returned to the trial manager and/or CI. The trial manager or CI will investigate the event with the reporting person and other involved individuals and will:

a) Consider removing the participant from the study if advised of an event, which could be categorised as an AE or SAE.
c) Advise referring clinical and associated study personnel (e.g. CTCU) if the participant is removed from the study.
d) Record AEs and SAEs reported from any origin on a specially constructed proforma.
e) Collate all safety report issues in the Trial Master File and report to the trial management team at Lancaster University. Each meeting held by the trial management team at Lancaster University will consider all events recorded, not just those initially categorised as AEs or SAEs.

Although all deaths and hospitalisations are considered as SAE's in a clinical trial, only deaths and hospitalisations related to the Namaste Care intervention will be considered as an SAE due to participant group being studied and their health status. SAEs include any untoward occurrence that:

- results in death
- is life threatening eg anaphylaxis to any activity undertaken during the Namaste Care session including wearing the actigraphy watch
- requires hospitalisation.

All SAE's will be entered onto the SAE reporting form and sent to the Namaste Trial research team office within 24 hours of the Principal Investigator becoming aware of them. The SOP on SAE's will provide guidance on assessing the relatedness of SAE's to the Namaste Care intervention. The SAE form will be signed off by the Registered Nurse on duty at the nursing home before being sent to the Namaste Trial research team and the sponsor (Lancaster University). If a Registered Nurse is not available, the SAE form will be sent to the Namaste Trial research team without the signature of Registered Nurse and a Registered Nurse will be asked to sign the form at the earliest opportunity. Once received, causality and expectedness will be assessed and confirmed by the Chief Investigator. A SOP on AE's and SAE's will be given to all nursing home staff involved in the study to help them identify AE's and SAE's provide guidance on the reporting process.

SAE's that are considered to be unexpected and related to the trial will be notified to the Research Ethics Committee (REC) within 15 days. All such events will be reported to the Trial Steering Committee at their next meeting. As death is expected in this group of participants, death will not be considered as SAE unless if it is related to the Namaste Care intervention e.g. anaphylaxis due to the essential oil used. Moreover, in previous work evaluating Namaste Care early deaths (<2 months) were not uncommon[19].

5.8 End of trial

The end of the trial will be the date of the database lock. At the time of database lock, data entry privileges are withdrawn from the trial database

6. Data Management and Analysis

6.1 Data Management

Data management is provided by the Clinical Trials Research Centre (CTRC), University of Liverpool. Data stored at CTRC will be checked for missing or unusual values (range checks) and checked for consistency within participants over time. Any suspect data will be returned to the site in the form of data queries. Data query forms will be produced at the CTRC from the trial database and sent either electronically or through the post to a named individual (as listed on the site delegation log). Sites will respond the queries providing an explanation/resolution to the discrepancies and return the data query forms to CTRC. The forms will then be filed along with the appropriate case report forms (CRFs) and the appropriate corrections made on the database.

6.2 Data Collection

Consent in the intervention nursing homes will be to receive the intervention and data collection; in the control nursing homes it will be for data collection only. Where possible, to minimise potential for bias, staff involved in the delivery of the Namaste Care intervention will not be involved in the completion of outcome measures. Where possible, the same staff member will be asked to complete the measures at each data collection point to ensure consistency. Where, possible additional secondary outcome measures related to daytime activity will be conducted by a member of the nursing home staff not delivering the Namaste Care intervention. Both control and intervention sites will be given training in research recruitment and the outcome measures that may reduce some bias. It will not be possible to blind researchers to the allocation of nursing homes, as the intervention requires changes to the nursing home environment which may be visible to any researcher visiting the facility. As a feasibility study, data will be collected throughout to inform the feasibility objectives in parallel with collection of outcomes data.

6.3 Data Analysis

6.3.1 Statistical analysis of quantitative data

Descriptive statistics based on the full trial indicators will be performed to see if it is feasible to undertake a full trial. Analysis of the outcome data will focus on recruitment, response and completion rates, and missing data. Reasons for non-consent and missing outcome data will be reported. Estimates of standard deviation and proxy agreement will be determined, and construct validity estimated intracluster correlation coefficent will be made for definitive trial design.

6.3.2 Actigraphy

The sleep/activity data from the actigraph will be analysed for the following

- Summary statistics will be used to analyse sleep analysis data provided by the actigraph software, such as sleep/wake ratios, total sleep time, sleep efficiency, wake after sleep onset and total activity.
- Participant's rhythm fragmentation and synchronization will be estimated via Intradaily Variability (IV) and Interdaily Stability (IS). IV quantifies the frequency and extent of transitions between periods of rest and activity on an hourly basis. IS quantifies rhythm's synchronization to Zeitgeber's 24 hs day-night cycle. Also, average activity during the least active 5-h period (L5), and average during the most active 10-h period (M10) will be computed[53, 54].
- A third approach, based on Functional Data Analysis (FDA) will be used. This approach converts subject's raw actigraphy data to a functional form (i.e., continuous curve over time) and, analyze sets of functions to see if they differ statistically across groups. In particular, this method informs about where and with what level the difference between groups (e.g. control vs. Namaste Care) occur along the time, providing valuable reference for treatment effects. A non-parametric permutation F test to detect the difference between groups will be used[55, 56].
- IV, IS and FDA analyses will be conducted using R packages "nparACT: Non-Parametric Measures of Actigraphy Data" and "Actigraphy"[57].

6.3.3 Analysis of health economic data

Economic assessments will combine qualitative assessments of feasibility of use for the outcome measures gained through the use of think aloud techniques and more quantitative assessments of agreement between proxies, and assessments of construct validity for the measures[58]. Response and completion rates will also be assessed. Think aloud interviews will be fully transcribed. Up to five raters will independently utilise these transcripts to identify errors in completion associated with comprehension, retrieval, judgement or response. Constant comparative analytical methods will be used to provide a more in-depth assessment of both the questionnaire completion and respondents' perceptions of the measures.

Sources of resource use data will be assessed in terms of their completeness and the extent of missing data. Where there are multiple sources for the same item of resource use, differences in estimated resource use will be explored. Unit cost information will be generated using bottom-up costing for the Namaste intervention itself, ensuring that a cost for the intervention will be available in a full trial. Other sources of unit cost information will be identified and collated for use in the main

trial, and will be applied to the collected resource use data to enable the conduct of preliminary economic analyses. It is likely that most items of resources use will be obtained from the PSSRU Unit Costs of Health & Social Care[59]. All data will be costed using unit cost data in pounds sterling, and from a single year, as close as possible to the end of the feasibility study.

6.3.4 Analysis of qualitative data

Framework analysis will be used in the analysis of qualitative data, with data collection, management and analysis rigorously conducted to enable reporting against COREQ guidelines. Group/ individual interviews and observation sessions will be digitally audio-recorded and fully transcribed. NVivo™ will be used to facilitate data management and analysis as this supports framework analysis techniques.

Framework analysis involves a systematic process of sifting, charting, and sorting material according to key issues and themes following five key stages: familiarisation, identifying a thematic framework, indexing, charting, and mapping and interpretation. Familiarisation will lead to a thematic framework drawing upon a priori issues, emergent issues raised by respondents, and analytical themes arising from the patterning of particular views or experiences. Indexing refers to the process whereby the thematic framework or index is systematically applied to the data in its textual form, and changes made to it to reflect data collected. These textual elements will be created into 'sets' for each nursing home. Charts will be developed for each major thematic grouping to facilitate analysis[60, 61]. These thematic groupings will be the vehicle for analysis identifying facilitators and barriers to the Namaste Care intervention.

6.4 Progress to a full trial

This study will lay the foundation for a future trial of the Namaste Care intervention. The process evaluation will establish the acceptability and practicality of integrating the Namaste Care intervention into the usual working practices of nursing homes. This information will be used to further refine the intervention for future implementation. The feasibility of a future definitive trial will be established from the findings of this study in a number of important domains: intervention acceptability and practicality of use in practice; recruitment and attrition of nursing homes and people with dementia; staff and family carer participation in written surveys and, interviews and group interviews along with time to complete, and ability to identify sufficient nursing homes willing to participate in a future trial. These full trial indicators are summarised in Table 8 with the data source(s) for the analysis of the identified indicators.

Indicator	Data source	Achieved if:
Recruitment rate	Screening logs	6 residents per nursing home recruited
Attrition rate	Researcher records	No more than 2 residents per nursing home cease receiving the intervention because of practical or preference issues.
Number of Namaste Care Sessions delivered in a week by the nursing home staff	Nursing home staff completed Namaste Care session logs and interviews (nursing home staff)	*To be discussed at the end of the trial*
Average length of Namaste Care Session	Nursing home staff completed Namaste Care session logs	1 hour
Potential primary outcome data completion	Complete CAD-EOLD and QUALID questionnaires)	80% of residents participating in the study have CAD-EOLD and QUALID questionnaires completed for them.
Namaste Care intervention acceptability to staff and family	Interviews (informal carer) group interview (nursing home staff) nursing home staff completed Namaste Care session logs	Intervention described as acceptable in terms of components of care provided, timing and frequency of delivery
Namaste Care intervention suitable for UK nursing home environments	Interviews (informal carer group interview (nursing home staff) Observation of care delivery	Intervention described as being suitable for this context
Identification of a sufficient pool of potential nursing homes, that reflect nursing home diversity, who would be willing to participate in a full trial	ENRICH network data; CQC database; partner sites engagement with local nursing home networks.	Identified a pool of nursing homes willing to participate in a future trial, that exceeds proposed sample required for a future trial. (See potential sample size calculation below).

Table 8. Full trial indicators and the data source(s) that will be used to analyse the indicators.

There are two contenders for the primary outcome measure in a full trial: quality of dying (CAD-EOLD) and quality of life (QUALID), which will be decided following the feasibility trial. The identification of the primary outcome measure for the full trial will be made at the end of the trial using the following criteria: completion rate, amount of missing data, feedback from staff on completion, relationships of concepts measured in the tools to the qualitative feedback on NAMASTE intervention from staff and family interviews. Interrelationships between the two contender primary outcome measures and the results from actigraphy will also be examined to see which has the strongest association.

The number of Namaste Care sessions delivered in week by the nursing home staff (dose) will also be considered as a full trial indicator, however, the minimum number of sessions a week required for progression to a full trial will be discussed at the end of the study and a minimum number of sessions will be decided based on the data from sessions logs and interviews with staff. The precise minimum

number of sessions required cannot be determined as this point due to the lack of data from published literature on fidelity or efficacy of the Namaste Care intervention.

Final decisions about choice of economic outcome measure(s) for the full trial will rest on a synthesis of the economic data in conjunction with the policy environment at the time that the full trial begins.

7. Ethical and Regulatory Considerations

The study will be submitted to, and approved by relevant RECs. Ethical approval will be sought for via Health Research Authority (HRA) at an ethics committee that has Mental Capacity Act 2005 expertise, as resident participants will lack mental capacity to give formal consent. For each nursing home site management and local governance processes will be followed. Formal permission from the nursing home owner, as well as the manager, will be sought.

7.2 Good Clinical Practice and Regulatory Considerations

The trial will be undertaken following the principles and guidelines of Good Clinical Practice (GCP), Declaration of Helsinki recommendations for research set out originally in 1964, but amended in 2013, relevant UK legislation and this Protocol. Researchers conducting this trial will be GCP-trained.

7.2 Poor Practice

A procedure will be written for researchers to identify a clear process for reporting concerns about the quality of care in a nursing home. This will be shared with the nursing home manager of each facility.

8. Administrative Aspects, Monitoring and Publication

8.1 Trial management and supervision

The **Trial Management Group**, comprises the Chief Investigator, Phase 1 lead, Phase 2 lead, Phase 3 (Trial) lead, Process evaluation lead, Health Economic lead, CTU lead and PPI leads, ensuring each university is represented. This group is responsible for i) protocol completion, ii) obtaining ethical approval for Phases 1 and 2 iii) obtaining ethical approval for Phase 3 plus nursing home approval process; iv) appointing and facilitating the Trial Steering Committee; v) working with the dissemination partners. The group will meet for a 'kick off' meeting face to face at the start of the project. Thereafter there will be monthly teleconferences and twice yearly face to face meetings.

The **Trial Steering Committee (TSC),** with an independent chair will provide overall supervision of the trial including trial progress and participant safety. Membership will be drawn from experts in health services research, nursing home research, and PPI. They will meet prior to the start of the trial phase and then twice during the second year of the project. Their role is to provide oversight for the trial, monitor recruitment rates, review reports of trial progress from the sites, monitor completion of case report forms, approve any protocol amendments, and oversee reporting of the trial results. They will provide an independent consideration of whether a future trial is justified, on the basis of the findings of the feasibility study with respect to recruitment and attrition rates. The TSC will have the role of a traditional Data Monitoring Committee as this a feasibility study with a low risk intervention. A TSC charter based on the guidelines published by the NIHR will be used to identify the remit of the TSC committee.

An **International Advisory Group (IAG)** has been established to provide external expert advice on the overall progress of the study. The IAG will meet (by teleconference) prior to the start of the trial

phase and then twice during the second year of the project. Membership is drawn from international leads in this intervention, research methods and research setting, alongside 2 PPI representatives (to be appointed). The following members have agreed to be involved: Dr Sharon Kaasalainen, McMaster University, Canada; Dr Robert Meadows, Surrey University; Professor. Deborah Parker, Western Sydney University; Joyce Simard; Dr Jenny van der Steen, VU University Amsterdam; Dr Ladislav Volicier, University of South Florida; Professor Dawn Brooker, University of Worcester, Dr Sonia Dalkin, Northumbria University and Amanda Hobson (PPI).

8.2 Handling and storage of data and documents

All information collected during the course of the study will be kept strictly confidential at the Liverpool Clinical Trials Research Centre and participating universities. Once completed, questionnaires and Namaste Care session logs will be collected from the nursing homes by the research team. A copy of the questionnaires/logs will be made and the original copies will be sent to the Clinical Trials Research Centre in Liverpool via the postal service who will enter the data on a Namaste Trial specific database. The copies of the questionnaires/logs and original field notes from the observation sessions will be stored securely (locked room, in a locked filing cabinet with limited access) at Lancaster University. The lead person in the nursing home will also be asked to store the study folder in a locked office to be accessed only by the lead person. Audio recordings of the interviews and observation sessions will be transferred as soon as possible to a secure password protected University server and then deleted from the recorder. Recordings maybe transferred to a University approved transcriber through a secure electronic upload and transcribers working on the study will be asked to sign and follow Lancaster University's confidentiality agreement. The audio files sent to the transcriber will be encrypted before being transferred via a secure electronic upload. Interview transcripts will be anonymised during transcription. All aspects of the Data Protection Act will be complied with, as laid out in the project Data Management Plan.

8.3 Archiving

The study questionnaires and essential documents and data will be retained and archived for 10 years after completion of the study. They will be stored securely and adequately protected from fire, flood and pest for a period of 10 years.

8.4 Amendments

The NRES Research Ethics Committee (REC) that gave a favourable opinion will be notified of any substantial amendments and approval will be sought from both, the REC and the study sponsor before changes are implemented. A table containing the amendments will be kept under the Section 9 – Protocol Amendments.

8.5 Study Reports

The Chief Investigator will submit an end of study report outlining the project findings and conclusions to the NIHR HTA after the end of the study.

8.6 Project timetable and milestones

This HTA funded project is a two year study with the first 12 months (1st December 2016 – 1st December 2017) being used for predominantly for preliminary work for the trial. The proposed timetable of the trial is detailed in Table 9 below.

Month	Milestone
Month 0: Dec 2017	Protocol for Phase 3 Feasibility trial written Ethics and governance approval for Phase 3 Feasibility trial obtained
Month 3: Feb 2018	Nursing homes recruited Baseline data collection completed in intervention and control nursing homes Research and Namaste Care intervention briefing delivered to nursing homes
Month 6: May 2018	Second TSC meeting held
Month 9: Aug 2018	Trial data collection completed Health Economics data collection completed Process evaluation data collection completed Data cleaned and database locked
Month 12: Nov 2018	Data analysis completed Final TSC meeting held Protocol development meeting held Protocol for full trial written (if appropriate) Final report written and submitted to the HTA

Table 9. Overview of the project timeline.

8.7 Funding

This study is funded by the National Institute for Health Research Health Technology Assessment (15/10/11).

8.8 Insurance and indemnity arrangements

Lancaster University (sponsor) legal liability cover will apply.

8.9 Dissemination

The following dissemination channels will be used: a project website (www.namastetrial.org.uk), a leaflet summarising the study, summaries of findings, publications/articles for general as well as scientific media and social media such as Twitter (@namasteresearch).

9. Protocol Amendments:

Version and Date	Date of amendment	Date of Approval	Summary of Major Changes
V1.0		25Oct2017	NA
V2.0		30Oct2017	Minor changes to the progression to a future trial
V3.0	12Dec2017	12Dec2017	Changes made to highlight that researchers will contact participants to discuss the study before consent

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